REGISTRATION REPORT
Part A

Risk Management

Product code:	**A19786A (AVOXA)**
Active Substance:	**Pinoxaden 33,3 g/L**
	Pyroxsulam 8,33 g/L
Safener:	**Cloquintocet-mexyl 8.33 g/L**

COUNTRY: Germany

Central Zone
Zonal Rapporteur Member State: Germany

NATIONAL ASSESSMENT

Applicant:	**Syngenta Agro GmbH**
Submission Date:	**28/03/2014**
Date:	**23/02/2018**

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PART A – Risk Management

This document describes the acceptable use conditions required for the registration of AVOXA (A19786A) containing pinoxaden and pyroxsulam in Germany. This evaluation is required subsequent to the inclusion of pinoxaden and pyroxsulam on Annex 1.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-8 and Part C and where appropriate the addendum for Germany. The information, data and assessments provided in Registration Report, Parts B includes assessment of further data or information as required at national registration by the EU review. It also includes assessment of data and information relating to AVOXA where that data has not been considered in the EU review. Otherwise assessments for the safe use of AVOXA have been made using endpoints agreed in the EU review of pinoxaden and pyroxsulam.

This document describes the specific conditions of use and labelling required for Germany for the registration of AVOXA.

Appendix 1 should include the authorisation of the final product in Germany. Due to technical reasons, the authorisation of the final product in Germany is inserted under Appendix 4.

Appendix 2: The submitted draft product label has been checked by the competent authority. The applicant is requested to amend the product label in accordance with the decisions made by the competent authority. The final version of the label has to fulfil the requirements according to Article 65 of Regulation (EC) No 1107/2009 and Commission Regulation (EU) No 547/2011.

Appendix 3: Letter(s) of access is/are classified as confidential and, thus, are not attached to this document.

Appendix 4 of this document provides a copy of the final product authorisation from Germany.

1 Details of the application

1.1 Application background

This application was submitted by Syngenta Agro GmbH on 28/03/2014. During evaluation product code A19786A has been changed to product name AVOXA by applicant.

The application was for approval of A19786A which is an emulsifiable concentrate (EC) containing 33.3 g/L pinoxaden, 8.33 g/L pyroxsulam and 8.33 g/L of the herbicide safener cloquintocet-mexyl for use in winter wheat, winter rye and winter triticale for the control of annual grass and broadleaf weeds in spring.

1.2 Annex I inclusion

Pinoxaden

Pinoxaden is a new active substance which has been reviewed for EU inclusion under Commission Regulation (EC) 1107/2009 (repealing Council Directive 91/414/EEC).). Following consideration at the Standing Committee on the Food Chain and Animal Health (SCoFCAH) a positive opinion was given on 29 January 2016 to approve under Regulation (EC) 1107/2009 with entry into force date of 1 July 2016 (Commission Implementing Regulation (EU) No 2016/370).

The Annex I Inclusion Directive for pinoxaden (2016/370/EU**)** provides specific provisions under Part B which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation.

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on pinoxaden, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed on 29 January 2016 shall be taken into account.

In this overall assessment Member States shall pay particular attention to the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions.

The Member States concerned shall carry out monitoring programmes to verify potential groundwater contamination from the metabolite M2 in vulnerable zones, where appropriate.

The applicant shall submit confirmatory information as regards:

(a) a validated method of analysis of metabolites M11, M52, M54, M55 and M56 in ground water;

(b) the relevance of the metabolites M3, M11, M52, M54, M55 and M56, and the corresponding groundwater risk assessment, if pinoxaden is classified under Regulation (EC) No 1272/2008 as H361d (suspected of damaging the unborn child).

The applicant shall submit to the Commission, the Member States and the Authority the relevant information set out in point (a) by 30 June 2018 and the information set out in point (b) within six months from the notification of the classification decision under Regulation (EC) No 1272/2008 of the European Parliament and of the Council (2) concerning pinoxaden.

Pyroxsulam

Pyroxsulam is a new active substance which has been reviewed for EU inclusion under Commission Regulation (EC) 1107/2009 (repealing Council Directive 91/414/EEC). Following consideration at the Standing Committee on the Food Chain and Animal Health (SCoFCAH) a positive opinion was given on 3rd October 2013 to approve under Regulation (EC) 1107/2009 with entry into force date of 1 May 2014 (Commission Implementing Regulation (EU) No 1176/2013).

The **EFSA Journal 2013; 11(4):3182** is considered the relevant source of information for this active substance as well as the Draft Assessment Report prepared by the RMS (UK) which has been forwarded to EFSA. The representative formulated product for the evaluation was GF-1274 a solo WG formulation containing 7.5 % w/w pyroxsulam.

A letter of access from Dow AgroSciences to the data provided to address these concerns is provided within the current submission.

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on pyroxsulam, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 October 2013 shall be taken into account.

In this overall assessment Member States shall pay particular attention to:

(a) the risk to groundwater, when the active substance is applied in regions with vulnerable soil or climatic conditions;

(b) the risk to aquatic organisms.

Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards:

(1) the toxicological relevance of impurity number 3 (as referred to in the review report);

(2) the acute toxicity of the metabolite PSA;

(3) the toxicological relevance of metabolite 6-Cl-7-OH-XDE-742. The applicant shall submit to the Commission, Member States and the Authority that information by 30 April 2016.

Cloquintocet-Mexyl

Cloquintocet-mexyl is a safener and not included on Annex I of Council Directive 91/414/EEC or mentioned in the Commission Implementing Regulation (EU) No. 540/2011 of 25 May 2011.

Cloquintocet-mexyl has been evaluated and approved under national registrations across the EU in formulations and mixtures containing the active substances Clodinafop, Pinoxaden and Pyroxsulam. Cloquintocet-mexyl has also been considered in this formulation dossier for A19786A.

A review programme for safeners is planned under Regulation (EC) 1107/2009.

1.3 Regulatory approach

To obtain approval the product A19786A must meet the conditions of Annex I inclusion and be supported by dossiers satisfying the requirements of Annex II and Annex III, with an assessment to Uniform Principles, using Annex I agreed end-points.

This application was submitted in order to allow the first approval of this product/use in Germany in accordance with the above.

1.4 Data protection claims

Where protection for data is being claimed for information supporting the registration of A19786A, it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B, sections 1 - 8 and Part C.

1.5 Letters of Access

The applicant provided a LoA regarding data for the active substance pyroxsulam. The remaining data requirements were addressed by own data.

2 Details of the authorisation

2.1 Product identity

Product Name	A19786A
Authorization Number (for re-registration)	008178-00/00
Function	Herbicide
Applicant	Syngenta Agro GmbH
Composition	33.3 g/L pinoxaden 8.33 g/L pyroxsulam 8.33 g/L cloquintocet-mexyl (as safener)
Formulation type	Emulsifiable concentrate [Code: EC]
Packaging	1-20 L canisters HDPE, 5-20 L canister, fluorinated HDPE

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC

Not proposed.

2.2.2 Classification and labelling under Regulation (EC) No 1272/2008

The following labelling is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard classes and categories:	
Skin Sens. 1, Eye Irrit. 2, Repr. 2, Aquatic acute 1, Aquatic chronic 1	
Hazard pictograms:	
GHS07	exclamation mark
GHS08	health hazard
GHS09	environment
Signal word:	
Warning	
Hazard statements:	
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H361d	Suspected of damaging the unborn child.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
Precautionary statemtents:	
P101	If medical advice is needed, have product container or label at hand.
P102	Keep out of reach of children.
P201	Obtain special instructions before use.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352	IF ON SKIN: Wash with plenty of water/...
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308+P313	IF exposed or concerned: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash before reuse.
P391	Collect spillage.
P405	Store locked up.
P501	Dispose of contents/container to ...
Special rule for labelling of PPP:	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	
EUH 208 - Contains cloquintocet-mexyl (CAS No. 99607-70-2), pinoxaden (CAS No. 243973-20-8), and pyroxsulam (CAS No. 422556-08-9). May produce an allergic reaction.	

2.2.3 Standard phrases under Regulation (EC) No 547/2011

None

2.2.4 Other phrases notified under Regulation (EC) No 547/2011

2.2.4.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Human health protection	
SB001	Avoid any unnecessary contact with the product. Misuse can lead to health damage.
SB005	If medical advice is needed, have product container or label at hand.
SB010	Keep out of children's reach.
SB111	Concerning the requirements for personal protective gear for handling the plant protection product the material safety data sheet and the instructions for use of the plant protection product as well as the guideline "Personal protective gear for handling plant protection prod-ucts" of the Federal Office of Consumer Protection and Food Safety (www.bvl.bund.de) must be observed.
SB166	Do not eat, drink or smoke when using this product.
SF245-01	Treated areas/crops may not be entered until the spray coating has dried.
SS110	Wear standard protective gloves (plant protection) when handling the undiluted product.
SS206	Working clothes (if no specific protective suit is required) and sturdy footwear (e.g. rubber boots) must be worn when applying/handling plant protection products.
SS2101	Wear a protective suit against pesticides and sturdy shoes (e.g. rubber boots) when handling the undiluted product.
SS530	Wear face protection when handling the undiluted product.
SS610	Wear a rubber apron when handling the undiluted product.
Integrated pest management (IPM)/sustainable use	
WMA	Mode of action (HRAC-group): A
WMB	Mode of action (HRAC-group): B
WH951	The risk of resistance has to be indicated on the package and in the instructions for use. Particularly measures for an appropriate risk management have to be declared.
NN3002	The product is classified as harmful for populations of relevant beneficial predatory mites and spiders.
Ecosystem protection	
NW 262	The product is toxic for algae.
NW 264	The product is toxic for fish and aquatic invertebrates.
NW 265	The product is toxic for higher aquatic plants.

NW 468	Fluids left over from application and their remains, products and their remains, empty containers and packaging, and cleansing and rinsing fluids must not be dumped in water. This also applies to indirect entry via the urban or agrarian drainage system and to rain-water and sewage canals.

The authorization of the PPP is linked to the following conditions (voluntary labelling):

Integrated pest management (IPM)/sustainable use	
NN1001	The product is classified as non-harmful for populations of relevant beneficial insects.
NB6641	The product is classified as non-hazardous to bees, even when the maximum application rate, or concentration if no application rate is stipulated, as stated for authorisation is applied. (B4)

2.2.4.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions (mandatory labelling):
See 2.4 (Product uses)

Integrated pest management (IPM)/sustainable use	
WH9161 for uses 001, 002	The instructions for use must include a summary of weeds which can be controlled well, less well and insufficiently by the product, as well as a list of species and/or varieties showing which crops are tolerant of the intended application rate and which are not.
WP734 for uses 001, 002	Damage is possible to the crop.
WP740 for uses 001, 002	Take care of adjacent crops, since damage is possible.
Ecosystem protection	
NW605-1 for uses 001, 002	When applying the product on areas adjacent to surface waters - except only occasionally but including periodically water bearing surface waters - the product must be applied with equipment which is registered in the index of 'Loss Reducing Equipment' of 14 October 1993 ('Bundesanzeiger' [Federal Gazette] No 205, p. 9780) as amended. Depending on the drift reduction classes for the equipment stated below, the following buffer zones must be kept from surface waters. In addition to the minimum buffer zone from surface waters stipulated by state law, the ban on application in or in the immediate vicinity of waters must be observed at all times for drift reduction classes marked with "*".Drift reduction by 90% * 75 % 5 m 50% 5 m
NW606 for uses 001, 002	The only case in which the product may be applied without loss reducing equipment is when at least the buffer zone stated below is kept from surface waters - except only occasionally but including periodically water bearing surface waters. Violations may be punished by fines of up to 50 000 Euro. Buffer zone of 5 m

NT109 for uses 001, 002	A buffer zone of at least 5 m must be kept from adjacent areas (except agriculturally or horticulturally used areas, roads, paths and public places). In addition, in an adjoining strip of at least 20 m, the product must be applied using loss reducing equipment which is registered in the index of 'Loss Reducing Equipment' of 14 October 1993 (Federal Gazette No 205, p. 9780) as amended, and be registered in at least drift reducing class 90 %. Neither loss reducing equipment nor a buffer zone of at least 5 m are required if the product is applied with portable plant protection equipment or if adjacent areas (field boundaries, hedges, groups of woody plants) are less than 3 m wide. A buffer zone of at least 5 m is also unnecessary if the product is applied in an area which has been declared by the Biologische Bundesanstalt in the "Index of regional proportions of ecotones" of 7 February 2002 (Federal Gazette no. 70 a of 13 April 2002), as amended, as agrarian landscape with a sufficient proportion of natural and semi-natural structures, or if evidence can be shown that adjacent areas (e.g. field boundaries, hedges, groups of woody plants) were planted on agriculturally or horticulturally used areas.

2.3 Product uses

GAP rev. (No. 3), date: 2018-02-23

PPP (product name/code): **AVOXA (A19786A)**
Active substance 1: **pinoxaden**
Active substance 2: **pyroxsulam**
Safener: **cloquintocet-mexyl**

Formulation type: **EC**
Conc. of a.s.1: **33.3 g/L**
Conc. of a.s. 2: **8.33 g/L**
Conc. of safener: **8.33 g/L**

Applicant: **Syngenta Agro GmbH**
Zone(s):central/EU

Professional use: ☒
Non-professional use: ☐

Verified by MS: yes

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation (crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)**	**Application**				**Application rate**			**PHI (days)**	**Remarks:**
					Method / Kind	**Timing / Growth stage of crop & season**	**Max. number of applications a) per use b) per crop/ season**	**Min. interval between applications (days)**	**kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season**	**g, kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season**	**Water L/ha min/max**		**e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures**
001	DE	winter soft wheat (TRZAW)	F	*Alopecurus myosuroides* (ALOMY),	spraying	after emergence, spring,	a) 1	-	a) 1.8 L/ha	a) pinoxaden 59.94 g /ha pyroxsulam	200-400	F *	14.99 g/ha safener cloquintocet-mexyl,

		winter rye (SECCW) winter triticale (TTLWI)		*Bromus* ssp. (BROSS), *Galium aparine* (GALAP)		BBCH 10–32	b) 1		b) 1.8 L/ha	14.99 g/ha b) pinoxaden 59.94 g /ha pyroxsulam 14.99 g/ha			WH9161 WP734 WP740
002	DE	winter soft wheat (TRZAW), winter triticale (TTLWI), winter rye (SECCW	F	*Apera spica-venti* (APESV), *Lolium species* (LOLSS), annual dicotyle-donous weeds (TTTDS)	spraying	after emergence, spring, BBCH 10-32	a) 1 b) 1	-	a) 1.35 L/ha b) 1.35 L/ha	a) pinoxaden 44.95 g /ha pyroxsulam 11.25 g/ha a) pinoxaden 44.95 g /ha pyroxsulam 11.25 g/ha	200 - 400	F *	11.25 g/ha safener cloquintocet-mexyl, WH9161 WP734 WP740

F* The PHI is covered by the conditions of use and/or the vegetation period remaining between the application of the plant protection product and the use of the product (e. g. harvest) or the setting of a PHI in days is not required resp.

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references

2 Use official codes/nomenclatures of EU Member States

3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)

4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.

6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.

7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application

8 The maximum number of application possible under practical conditions of use must be provided.

9 Minimum interval (in days) between applications of the same product

10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.

11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).

12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.

13 PHI - minimum pre-harvest interval

14 Remarks may include: Extent of use/economic importance/restrictions

3 Risk management

3.1 Reasoned statement of the overall conclusions taken in accordance with the Uniform Principles

3.1.1 Physical and chemical properties (Part B, Section 1, Points 2 and 4)

Overall Summary:
The product A19786A is an emulsifiable concentrate. All studies have been performed in accordance with the current requirements, the critical GAP and the results are deemed to be acceptable. The appearance of the product is that of light brown liquid, with a weak odour. It is not explosive, has no oxidising properties. It has a self-ignition temperature of 415°C. In aqueous solution, it has a pH value around 4.2. The stability data indicate a shelf life of at least two years at ambient temperature.
The technical characteristics of A19786A are acceptable for an emulsifiable concentrate formulation.

Implications for labelling: *none.*

Compliance with FAO specifications:
There are no FAO specifications for pinoxaden and pyroxsulam.

Compliance with FAO guidelines:
The product A19786A complies with the general requirements according to the FAO/WHO Manual (2016).

Compatibility of mixtures:
No tank mixtures are intended.

Nature and characteristics of the packaging:
Information with regard to type, dimensions, capacity, size of opening, type of closure, strength, leakproofness, resistance to normal transport & handling, resistance to & compatibility with the contents of the packaging, have been submitted, evaluated and is considered to be acceptable.

Nature and characteristics of the protective clothing and equipment:
Information regarding the required protective clothing and equipment for the safe handling of A19786A has been provided and is considered to be acceptable.

3.1.2 Methods of analysis (Part B, Section 2, Point 5)

3.1.2.1 Analytical method for the formulation (Part B, Section 2, Point 5.2)

Adequate analytical methods for the determination of the active substances pinoxaden and pyroxsulam in the formulation are available. Concerning the relevant impurity toluene, the applicant is informed that according to Regulation (EU) No 2016/340 a maximum content of 1 g/kg was set for pinoxaden technical and a validated analytical method for the determination of toluene in the formulation is missing. In principle, CIPAC method MT 198 could be used for analysis. However, the applicability of the CIPAC method should be demonstrated by the applicant.

3.1.2.2 Analytical methods for residues (Part B, Section 2, Points 5.3 – 5.8)

Analytical methods used to meet the requirements of the Annex to Regulation (EU) No 544/2011, Part A, point 4.2 can be also applied for the product.
Adequate LC-MS/MS methods are available to monitor residues of pinoxaden in food of plant origin, soil, water and air. Analytical methods for analysis of pinoxaden in animal matrices are not needed, because no MRLs are set for food of animal origin.
For pyroxsulam, adequate LC-MS/MS methods are available to monitor residues in food of plant and animal origin, soil, water and air by LC-MS/MS.
Methods for body fluids and tissues are not required, because pinoxaden and pyroxsulam are not considered to be toxic or very toxic (T / T+) nor are they classified according to GHS as follows: Acute toxicity (cat. 1 - 3), CMR (cat. 1) or STOT (cat. 1).
However, the following minor data gap has been identified according to the requirements of SANCO/825/00 rev. 8.1:

- An independent laboratory validation of the method by Amic (2012) is missing for fatty plant commodities

This data gap can be addressed in the context of the next renewal of the approval of pinoxaden according to Reg. (EC) No 1107/2009 or in the context of the assessment of existing MRLs according to Reg. (EC) No 396/2005.

For the safener cloquintocet-mexyl sufficiently sensitive and selective analytical methods are not available for all analytes included in the residue definitions. Cloquintocet-mexyl residues can be monitored in food of plants by GC-MS and LC-MS/MS. An LC-MS/MS method for water is only accepted for confirmation. Methods for animal matrices are not required, because no MRLs are proposed. Methods for soil, surface water and air are not required, because no residues are expected. Methods for body fluids and tissues are not required, since cloquintocet-mexyl is not considered to be toxic or very toxic (T / T+) nor is it classified according to GHS as follows: Acute toxicity (cat. 1 - 3), CMR (cat. 1) or STOT (cat. 1).
The following data gaps were noticed:

- A confirmatory method for determination of cloquintocet-mexyl in fatty plant commodities is missing.
- A primary method for determination of cloquintocet-mexyl in drinking water is missing.

These data gaps are considered being of minor relevance because residue analytical methods for safeners are not yet required. A review program for safeners is planned under Regulation (EC) 1107/2009 (articles 25 and 26). Therefore, the applicant will be informed about the data gaps.

3.1.3 Mammalian Toxicology

3.1.3.1 Acute Toxicity

Acute toxicity studies for A19786A were not evaluated as part of the EU review of the pinoxaden and pyroxsulam. Therefore, all relevant data were provided and are considered adequate.
A19786A, containing 33.3 g/L pinoxaden, 8.33 g/L pyroxsulam and 8.33 g/L cloquintocet-mexyl (as safener) has a low toxicity in respect to oral, dermal and inhalativ toxicity. It has sensitizing properties to skin (H317) It is not irritating to skin but to eyes (H319).

3.1.3.2 Operator Exposure

Operator exposure was assessed against the AOEL agreed in the EU review (pinoxaden 0.1 mg/kg bw/d, pyroxsulam 0.7 mg/kg bw/d, cloquintocet-mexyl 0.05 mg/kg bw/d). No data on dermal absorption for A19786A are available. Therefore default values are used. The detailed evaluation is provided in Part B.
According to the model calculations, it can be concluded that the risk for the operator using A19786A in cereals is acceptable when the product is used as intended. No specific PPE is necessary. Further reduction of exposure is to be expected due to necessary PPE allocated according to dangerous substances regulations.
The calculation of combined exposure to all active substances in A19786A is not expected to present a risk for operators.

3.1.3.3 Bystander Exposure

The bystander and/or resident exposure estimations indicated that the acceptable operator exposure level (AOEL) for pinoxaden, pyroxsulam and cloquintocet-mexyl will not be exceeded under conditions of intended uses.

3.1.3.4 Worker Exposure

The worker exposure was estimated using the model “German model”. Even without any PPE the estimated consumption of AOEL was below 19 % for all active substances.

Implications for labelling resulting from operator, worker, bystander assessments:

See 2.2

3.1.3.5 Groundwater Metabolites

As described in Part B.8 the pyroxsulam metabolites PSA and 6-Cl-7-OH as well as the pinoxaden metabolites M3, M11, M52, M54, M55 and M56 are of no toxicological relevance in the groundwater.
Remark:
According to Implementing Regulation (EU) 2016/370 of 15 March 2016 the applicant shall submit confirmatory information as regards the relevance of the pinoxaden-metabolites and the corresponding groundwater risk assessment, if pinoxaden is classified under Regulation (EC) No 1272/2008 as H361d (suspected of damaging the unborn child). The applicant shall submit to the Commission, the Member States and the Authority the relevant information within six months from the notification of the classification decision under Regulation (EC) No 1272/2008.

3.1.4 Residues and Consumer Exposure

3.1.4.1 Residues

Fundamental residue data on pinoxaden and pyroxsulam like metabolism are already evaluated previously and is described in detail in the respective DARs.
An exceedance of the current MRLs of 1 mg/kg for pinoxaden and 0.01*mg/kg pyroxsulam in grains of rye, wheat and triticale as laid down in Reg. (EU) 396/2005 is not expected. Furthermore, an exceedance of the MRL of 0.05 mg/kg for the safener cloquintocet-mexyl in cereal grains as established in the national RHmV is not expected.

3.1.4.2 Consumer exposure

An estimation of dietary intake using EFSA PRIMo results in a maximum consumption of the respective ADIs/ARfDs below 100 %.

Substance	ADI/ARfD	Model / Diet	ADI/ARfD Consumption
Pinoxaden	ADI: 0.1 mg/kg bw/d	TMDI, EFSA PRIMo, DK children	10 %
	ARfD: 0.1 mg/kg bw	IESTI, EFSA PRIMo rev.2, UK toddler	< 1 %
Pyroxsulam	ADI: 0.9 mg/kg bw/d	TMDI, EFSA PRIMo, FR toddler	0.1 %
	ARfD: not allocated		
Cloquintocet-mexyl	ADI: 0.04 mg/kg bw/d	IEDI, EFSA PRIMo, UK toddler	5.4 %
	ARfD: 1 mg/kg bw	IESTI, EFSA PRIMo rev.2, UK toddler	< 1 %

The chronic and the short-term intake of pinoxaden, pyroxsulam and cloquintocet-mexyl residues are unlikely to present a public health concern. The product is a mixture of two active substances and a safener, but only for the active substance pinoxaden and the safener cloquintocet-mexyl an acute reference dose have been allocated. The cumulative short-term intake of pinoxaden and cloquintocet-mexyl residues in grains of rye, wheat and triticale is unlikely to present a public health concern. Concerning the cumulative risk arising from the acute exposure to animal commodities the contribution of pinoxaden and cloquintocet-mexyl residues is insignificant.

3.1.5 Environmental fate and behaviour (Part B, Section 5, Point 9)

3.1.5.1 Predicted Environmental Concentration in Soil (PEC_{soil}) (Part B, Section 5, Points 9.4 and 9.5)

PEC_{soil} was calculated for the active substance Pinoxaden considering a soil depth of 2.5 cm. Due to the fast degradation of the active substance Pinoxaden in soil the accumulation potential of Pinoxaden was

not considered.

PEC_{soil} was calculated for the active substance Pyroxsulam considering a soil depth of 2.5 cm. Due to the fast degradation of Pyroxsulam and its soil metabolites (except Pyridine sulfonamide) in soil, their accumulation potential was not considered. However, due to the slow soil degradation of soil metabolite Pyridine sulfonamide, the accumulation potential of Pyridine sulfonamide was considered.

For details please refer to Part B, Section 5 (core assessment and National Addendum-Germany), Chapter 5.5.

3.1.5.2 Predicted Environmental Concentration in Ground Water (PEC_{GW}) (Part B, Section 5, Point 9.6)

Model simulations conducted with FOCUS PELMO 5.5.3 and results of a lysimeter study (Pinoxaden) show that the active substances Pinoxaden and Pyroxsulam are not expected to penetrate into groundwater at concentrations ≥ 0.1µg/L for the intended use of AVOXA/ A19786A in Germany. For the metabolite M2 of Pinoxaden as well as for the metabolites 5-OH, 7-OH, 6-Cl-7-OH, 5,7-di-OH and Pyridine Sulfonamide of Pyroxsulam, concentrations of ≥ 0.1µg/L in groundwater can be excluded.

For the metabolites M3, M11, M52, M54, M55 and M56 of Pinoxaden as well as for the metabolites PSA and 6-Cl-7-OH of Pyroxsulam, the model simulations show that concentrations of ≥ 0.1µg/L in groundwater cannot be excluded. An assessment of relevance has been performed for these metabolites, demonstrating that the metabolites have no biological activity as compared to the parent compound.

For details please refer to Part B (core assessment and National Addendum-Germany), Section 5, Chapter 5.7 and Part B, Section 8 (core assessment).

3.1.5.3 Predicted Environmental Concentration in Surface Water (PEC_{SW}) (Part B, Section 5, Points 9.7 and 9.8)

For the intended uses of the plant protection product AVOXA/ A19786A in Germany, PEC_{sw} was calculated for the active substances Pinoxaden and Pyroxsulam considering separately the following two routes of entry (i) spray drift and volatilisation with subsequent deposition, and (ii) runoff, drainage.

Surface water exposure via spray drift and volatilisation with subsequent deposition is estimated with the model EVA 3 using drift data by Rautmann and Ganzelmeier. Surface water exposure via surface runoff and drainage is estimated using the model EXPOSIT 3.0.

The vapour pressure at 20 °C of the active substances Pinoxaden and Pyroxsulam is < 10^{-5} Pa. Hence, the active substances Pinoxaden and Pyroxsulam are regarded as non-volatile and exposure of adjacent surface waters to the active substances due to volatilisation with subsequent deposition was not considered in the model simulations.

For details please refer to Part B (core assessment and National Addendum-Germany), Section 5, Chapter 5.6.

Implications for labelling resulting from environmental fate assessment

See chapter 2.2

3.1.6 Ecotoxicology (Part B, Section 6, Point 10)

The risk assessment for the metabolites of Pinoxaden and Pyroxsulam has already been performed for EU approval (see EFSA Journal 2013;11(8):3269 and 2013;11(4):3182) as well as in the core assessment.

3.1.6.1 Effects on Terrestrial Vertebrates (Part B, Section 6, Points 10.1 and 10.3)

Birds

The results of the assessment indicate an acceptable risk for wildlife birds for the intended use of AVOXA/ A19786A.

Terrestrial vertebrates (other than birds)

The results of the assessment indicate an acceptable risk for wildlife mammals for the intended use of AVOXA/ A19786A.

3.1.6.2 Effects on Aquatic Species (Part B, Section 6, Point 10.2)

The product AVOXA/ A19786A (*O. mykiss*, LC50 = 8.879 mg/L mm; *D. magna* EC50 = 3.78 mg/L mm; *L. gibba*, E_rC_{50} = 0.122 mg/L (mm)**)** and the active substances (pinoxaden: *D. magna*, EC_{50} (96 h) = 0.40 mg/L; *S. costatum*, NOErC = 0.52 mg/L mm; *L. gibba*, NOErC = 0.23 mg/L mm; pyroxsulam: *P. subcapitata* NOE_rC: 0.055 mg/L mm; *L. gibba*, EC_{50} = 0.00257 mg/L mm) are toxic to the aquatic environment. Therefore, additional labelling with risk phrases (NW262, NW264, NW265) and safety phrases (NW468) is assigned, particularly to enforce prevention of any point source entry into surface waters; see also chapter 2.2.

In agreement with the German modelling scheme TER values are calculated for all relevant exposure routes; i.e. spray drift, run-off and drainage entry. The calculation is based on the following relevant endpoint: E_rC_{50} = 122 µg/L (AVOXA/ A19786A *L. gibba*) and EC_{50} = 2.57 µg/L (pyroxsulam *L. gibba*).

The results of the risk assessment indicate an acceptable risk for aquatic organisms due to spray drift according to the intended use of AVOXA/ A19786A, provided that the following risk mitigation measures are applied:
NW605-1/NW606 (5 m buffer zone or 90% drift reduction).

The results indicate an acceptable risk for exposure of aquatic organisms due to run-off or drainage for the intended use of AVOXA/ A19786A if applied according to the recommended use pattern.

3.1.6.3 Effects on Bees and Other Arthropod Species (Part B, Section 6, Points 10.4 and 10.5)

Bees

Effects on bees of A19786A were not evaluated as part of the EU review of pinoxaden or pyroxsulam. Therefore all relevant data and assessments are provided here and are considered adequate.

Toxicity

Table 3.1.6.3-1 presents the results of laboratory bee toxicity studies with the formulation. Further details regarding the tests with the formulation are provided in Part B Section 6 chapter 10.4.2. For the sake of completeness the table also presents results of laboratory bee toxicity studies with the active substance.

Table 3.1.6.3-1: Results of laboratory bee toxicity studies

Test substance	Exposure route	LD_{50}	Reference
A19786A	oral 48 h	> 591 µg product/bee	Kling A., 2013 Report Number: S12-03713
	contact 48 h	> 406 µg product/bee	
pinoxaden tech.	oral 48 h	> 200 µg a.s./bee *	EFSA Scientific Report, 2013; 11(6): 3269 Conclusion on the peer review of the pesticide risk assessment of the active substance pinoxaden
	contact 48 h	> 100 µg a.s./bee *	
pyroxsulam tech.	oral 48 h	> 107.4 µg a.s./bee *	EFSA Scientific Report, 2013; 11(4): 3182 Conclusion on the peer review of the pesticide risk assessment of the active substance pyroxsulam
	contact 48 h	> 100 µg a.s./bee *	

* EU agreed endpoint

Exposure

The recommended use pattern for A19786A includes application in cereals at a maximum application rate of up to 1.8 L product/ha. This maximum single application rate is equivalent to 1904 g product/ha.
Bees may be exposed to A19786A by direct spraying while bees are foraging on flowers and weeds, through contact with fresh or dried residues or by oral uptake of contaminated pollen, nectar and honey dew.

Hazard quotients

Table 3.1.6.3-2 presents the Hazard quotients for oral and contact exposure according to EPPO (2010) Environmental risk assessment scheme for plant protection products (Chapter 10: Honeybees (PP 3/10(3)). Bulletin OEPP/EPPO Bulletin 40: 323-331). The HQ-values were calculated as follows:

$$\text{Hazard Quotient} = \text{max. application rate [g product/ha]} / LD_{50} \text{ [µg product/bee]}$$

Table 3.1.6.3- 2: Hazard quotients for honeybees

Test substance	Max. single application rate [g product/ha]	Exposure route	LD_{50} [µg product/bee]	Hazard quotient (HQ)	HQ trigger
A19786A	1904	oral	> 591 µg	< 3.2	50
		contact	> 406 µg	< 4.7	

Risk assessment

Due to the results of laboratory tests A19786A is considered to be practically non-toxic to bees. All hazard quotients are clearly below the trigger of 50, indicating that the intended use poses a low risk to bees in the field. Bee brood testing is not required since the test item is not an IGR.

Overall conclusion

It is concluded that A19786A will not adversely affect bees or bee colonies when used as recommended. Label NB6641 is assigned to the product.

Other non-target arthropods

The results of the assessment indicate an acceptable risk for non-target arthropods in off-field and in-field habitats for the intended use of AVOXA/ A19786A.
For details please refer to Part B (core assessment and National Addendum-Germany), Section 6, Chapter

3.1.6.4 Effects on Earthworms and Other Soil Marco-organisms (Part B, Section 6, Point 10.6)

The results of the assessment indicate an acceptable risk for earthworms and other soil macro-organisms for the intended use of AVOXA/ A19786A.
For details please refer to the core assessment Part B, section 6, Chapter 6.8.

3.1.6.5 Effects on organic matter breakdown (Part B, Section 6, Point 10.6)

Since no risk was identified for soil fauna, soil micro-organisms and non-target arthropods from the intended use of AVOXA/ A19786A, data on the effects on organic matter breakdown (litterbag) is not required.

For details please refer to Part B (core assessment and National Addendum-Germany), Section 6, Chapters 6.7, 6.8, and 6.9.

3.1.6.6 Effects on Soil Non-target Micro-organisms (Part B, Section 6, Point 10.7)

The results of the assessment indicate an acceptable risk for soil microorganisms for the intended use of AVOXA/ A19786A.

3.1.6.7 Assessment of Potential for Effects on Other Non-target Organisms (Flora and Fauna) (Part B, Section 6, Point 10.8)

Non-Target Plants

The results of the risk assessment indicate an acceptable risk for Non-Target Plants due to spray drift according to the intended use of AVOXA/ A19786A, provided that the following risk mitigation measures are applied:
NT109 (5 m buffer zone and 90% drift reduction).
The calculation is based on the following relevant endpoint: ER_{50} biomass (geomean) of 14.88 mL A19786A/ha derived for *Avena sativa* in vegetative vigour tests.

For details please refer to Part B (core assessment and National Addendum-Germany), Section 6, Chapter 6.10.

Implications for labelling resulting from ecotoxicological assessment:

See chapter 2.2

3.1.7 Efficacy (Part B, Section 7, Point 8)

Information on the active ingredients (Uptake and mode of action)
Pinoxaden is a representative of the phenylpyrazolin class of chemistry. Pinoxaden is a post emergent herbicide and is taken up by the leaves, almost exclusively. The active ingredient is rapidly degraded in soil and poorly taken up by the roots, thus providing very little soil activity. After foliar absorption, pinoxaden is translocated to the meristematic tissue, where it exerts its action on the lipid synthesis in dividing cells. The mode of action is the inhibition of the enzyme Acetyl Co-A Carboxylase (ACCase), a

key enzyme in fatty acid biosynthesis. Pinoxaden inhibits both the chloroplastic and cytosolic ACCase enzyme in monocotyledonous weeds. ACCase activity in dicotyledonous species is stated as not affected. Crop tolerance within monocotyledonous species is based on different metabolic kinetics. Tolerant crops like wheat, triticale and rye can metabolize the herbicide faster than susceptible monocotyledonous weeds. This tolerance however, is typically insufficient to provide an agronomically adequate margin of crop safety. Co-application of the safener (cloquintocet-mexyl) induces metabolic enzymes specifically in the crop species resulting in degradation of the herbicide to non-phytotoxic compounds before damage can occur to the crop. The safener does not affect metabolism in monocotyledonous weeds. Site of action (HRAC-group): A
Label WMA is assigned to the product.
Pyroxsulam belongs to the chemical group of triazolopyrimidines. Activity is primarily foliar/systemic, although some residuality is a feature of pyroxsulam and some other ALS inhibitor herbicides. Pyroxsulam is taken up by roots or by foliage and redistributes throughout the plant. Pyroxsulam is a systemic, phloem and xylem mobile herbicide. The compound is translocated in plants to meristematic tissue. Pyroxsulam inhibits amino-lactate synthase (ALS-inhibitor), there-by blocking the formation of branch chain amino acids in plants. Pyroxsulam affects the formation of protein and the plants die. Symptoms include stunting and chlorosis, followed by necrosis and then plant death. Selectivity in wheat, rye and triticale is achieved through detoxification via cytochrome P450 mono-oxygenases, a process which is accelerated by the addition of a herbicide safener acting on the cytochrome complex; for example, cloquintocet mexyl. Site of action (HRAC-group): B
Label WMB is assigned to the product.
Cloquintocet-mexyl is a safener. Cloquintocet-mexyl is used as a safener in conjunction with the herbicide for post-emergence use. It acts as an agonist of cytochrome P450 and accelerates the detoxification in responsive plants (e.g. cereals, rice, maize) of all compounds that are metabolically vulnerable to cytochrome P450s. Site of action (HRAC-group): no classification

Minimum effective dose tests

Data have been provided mainly from the maritime EPPO zone and additionally from the north-eastern zone. However, no trials have been conducted in the south-eastern EPPO zone.
The use includes the target species *Alopecurus myosuroides* (ALOMY), *Bromus* spp. (BROSS), *Apera spica-venti* (APESV), *Lolium* sp. (LOLSS), annual dicotyledonous weeds (TTTDS) by using 1.8 L/ha. However, the minimum effective dose data do not demonstrate that - except for *Alopecurus myosuroides, Bromus* spp. and *Galium aparine* the intended dose of 1.8 L/ha is necessary for a sufficient weed control. The results show that most of the relevant weed species will be sufficiently controlled by the reduced dose of 1.35 L/ha. It is suggested to split the formerly intended use into two uses with different field rates and target weeds:

1. The first use should include the target species *Alopecurus myosuroides* (ALOMY), *Bromus* spp. (BROSS) and *Galium aparine* (GALAP) and the max. field rate of 1.8 L/ha.
2. The second use should include *Apera spica-venti* (APESV), but also *Lolium* sp. (LOLSS) and annual dicotyledonous weeds (TTTDS) and the max. field rate 1.35 L/ha.

Efficacy tests

Data have been provided mainly from the maritime EPPO zone and additionally from the north-eastern zone for the dose of 1.8 L/ha A19786A. However, no trials have been conducted in the south-eastern EPPO zone.
For both EPPO zones covered by these efficacy trials the dose of 1.8 L/ha of A19786A is sufficiently effective against several relevant weed species, especially grasses. However, as discussed above (for more detail please refer to Part B Section 7 of the core dossier under IIIA1 6.1.2 “minimum effective

dose") the requested dose depends on the weed species and most of them will be controlled with lower doses.
For Germany the application rate of water is adapted to the standard of 200-400 L/ha.
Label requirement WH9161 is assigned to the use.

Effects on yield and quality
Under weed-free conditions the herbicide A19786A reduced the yield of winter wheat by 1% and 2% (single and double dose), respectively 2% and 3% for winter triticale and 1% and 2% for winter rye. Concerning hectolitre and thousand grain weight effects of the herbicide ranged from +1% to -3%. By trend the effects at the double dose were slightly stronger compared to the single dose. No differences between the test and standard herbicide have been observed.
Consequently, the herbicide A19786A has no negative effect on yield and yield parameters. The trials have been conducted only in the maritime EPPO zone.

Phytotoxicity to host crop
In most of the selectivity trials the use of the herbicide A19786A did not result in any crop damage. However, in some cases phytotoxic effects of more than 20% occurred. Although there were no negative yield effects it is decided to put a warning on the label "crop damage is possible".
Label WP734 is assigned to the use.

Adverse effects on beneficial organisms (other than bees)
A19786A is classified as not harmful for the parasitoid wasp *Aphidius rhopalosiphi*, but as harmful for relevant predatory mites and spiders at the proposed maximum application rate of 1.8 L/ha.
Labels NN1001 and NN3002 are assigned to the product.

Impact on succeeding crops
Based on the PEC- and TER calculation there is a theoretical risk for succeeding crops by pyroxsulam whereas the risk of pinoxaden can be considered as low. An evaluation based on the herbicide A19786A instead of both active substances has not been submitted by the applicant. The most sensitive crops are spring crops like sugar beet, soya, sunflower and peas. Since these crops are sown much later than 120 DAT (TER > 3.9) the risk can be considered as low. These findings have been supported by field experiments where no unacceptable crop damage occurred in normal crop rotation.

Impact on other plants including adjacent crops
Based on the data submitted by the applicant there is a risk for adjacent crop by the herbicide A19786A. By using conventional nozzles a buffer zone of 5 m is recommended respectively 1 m for 50% drift reduction. A warning information should be given in the label.

Possible development of resistance or cross-resistance
The resistance risk inherent to A19786A can be assumed to be comparable to that of other herbicides of HRAC group A and B, i.e. medium-high. The increasing occurrence of dicotyledonous biotypes with ALS resistance in Europe emphasizes an increasing risk of resistance evolution for ALS active substances. In addition, most of the grass target species can be regarded as high risk species and ACCase and ALS inhibitors are frequently used in other main crop species in central Europe. The general resistance risk of A19786A is therefore assessed as high.
The label warning WH951 is assigned to the product.

3.2 Conclusions

With respect to the physical, chemical and technical properties of the formulation an authorisation can be granted.

Concerning analytical methods for the formulation an authorisation can be granted.

Regarding analytical methods for residues, an authorisation can be granted.

With respect to toxicology, residues and consumer protection an authorisation can be granted.

Concerning fate and ecotoxicology assessment, an authorisation can be granted.

With respect to efficacy/IPM and sustainable use incl. protection of honeybees and beneficial arthropods an authorisation can be granted.

An authorisation can be granted.

3.3 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation

No further information is required.

Appendix 1 – Copy of the product authorisation (see Appendix 4)

Appendix 2 – Copy of the product label

The submitted draft product label has been checked by the competent authority. The applicant is requested to amend the product label in accordance with the decisions made by the competent authority. The final version of the label has to fulfil the requirements according to Article 65 of Regulation (EC) No 1107/2009 and Commission Regulation (EU) No 547/2011.

Appendix 3 – Letter of Access

Letter(s) of access is/are classified as confidential and, thus, are not attached to this document.

Appendix 4 – Copy of the product authorisation

Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit
Dienstsitz Braunschweig • Postfach 15 64 • 38005 Braunschweig

Dr. Niklas Bald-Blume
Referent

TELEFON +49 (0)531 299-3439
TELEFAX +49 (0)531 299-3002
E-MAIL niklas.bald-blume@bvl.bund.de

Syngenta Agro GmbH
Am Technologiepark 1 -5
63477 Maintal

IHR ZEICHEN
IHRE NACHRICHT VOM

AKTENZEICHEN 200.22100.008178-00/00.102472
(bitte bei Antwort angeben)

DATUM 01. März 2018

ZV1 008178-00/00

AVOXA

Zulassungsverfahren für Pflanzenschutzmittel

Bescheid

Das oben genannte Pflanzenschutzmittel

mit den Wirkstoffen:	33,3 g/l	Pinoxaden
	8,33 g/l	Pyroxsulam
mit dem Safener:	8,33 g/l	Cloquintocet (als Mexyl (1-Methyl-hexylester) 8 g/l)
Zulassungsnummer:	008178-00	
Versuchsbezeichnungen:	SYD-11740-H-0-EC	
Antrag vom:	28. März 2014	

wird auf der Grundlage von Art. 29 der Verordnung (EG) Nr. 1107/2009 des Europäischen Parlaments und des Rates vom 21. Oktober 2009 über das Inverkehrbringen von Pflanzenschutzmitteln und zur Aufhebung der Richtlinien 79/117/EWG und 91/414/EWG des Rates (ABl. L 309 vom 24.11.2009, S. 1), wie folgt zugelassen:

Zulassungsende

Die Zulassung endet am 30. April 2025.

Festgesetzte Anwendungsgebiete bzw. Anwendungen

Es werden folgende Anwendungsgebiete bzw. Anwendungen festgesetzt (siehe Anlage 1):

Anwendungs-nummer	Schadorganismus/ Zweckbestimmung	Pflanzen/-erzeugnisse/ Objekte	Verwendungszweck
008178-00/00-001	Acker-Fuchs-schwanz, Trespe-Ar-ten, Kletten-Labkraut	Winterweichweizen, Wintertriticale, Winter-roggen	
008178-00/00-002	Gemeiner Windhalm, Weidelgras-Arten, Einjährige zweikeim-blättrige Unkräuter	Winterweichweizen, Wintertriticale, Winter-roggen	

Festgesetzte Anwendungsbestimmungen

Es werden folgende Anwendungsbestimmungen gemäß § 36 Abs. 1 S. 1 des Gesetzes zum Schutz der Kulturpflanzen (Pflanzenschutzgesetz - PflSchG) vom 6. Februar 2012 (BGBl. I S. 148, 1281), zuletzt geändert durch Artikel 4 Absatz 84 des Gesetzes vom 18. Juli 2016 (BGBl. I S. 1666), festgesetzt:

(NW468)
Anwendungsflüssigkeiten und deren Reste, Mittel und dessen Reste, entleerte Behältnisse oder Packungen sowie Reinigungs- und Spülflüssigkeiten nicht in Gewässer gelangen lassen. Dies gilt auch für indirekte Einträge über die Kanalisation, Hof- und Straßenabläufe sowie Regen- und Abwasserkanäle.
Begründung:
Die im o.g. Pflanzenschutzmittel enthaltenen Wirkstoffe Pinoxaden und Pyroxsulam weisen aufgrund ihrer Toxizität ein hohes Gefährdungspotenzial für aquatische Organismen auf. Jeder Eintrag von Rückständen in Oberflächengewässer, der den Eintrag als Folge der bestimmungsgemäßen und sachgerechten Anwendung des Mittels entsprechend der guten fachlichen Praxis übersteigt, würde daher zu einer Gefährdung des Naturhaushaltes aufgrund von nicht akzeptablen Auswirkungen auf Gewässerorganismen führen. Da ein erheblicher Anteil der in Oberflächengewässern nachzuweisenden Pflanzenschutzmittelfrachten auf Einträge aus kommunalen Kläranlagen zurückzuführen ist, muss dieser Gefährdung durch die bußgeldbewehrte Anwendungsbestimmung durchsetzbar begegnet werden.

Siehe anwendungsbezogene Anwendungsbestimmungen in Anlage 1, jeweils unter Nr. 3.

Verpackungen

Gemäß § 36 Abs. 1 S. 2 Nr. 1 PflSchG sind für das Pflanzenschutzmittel die nachfolgend näher beschriebenen Verpackungen für den beruflichen Anwender zugelassen:

Verpackungs-art	Verpackungs-material	Anzahl		Inhalt		
		von	bis	von	bis	Einheit
Kanister	HDPE	1		1,00	20,00	l
Kanister	HDPE, fluoriert	1		5,00	20,00	l

Die Verpackungen für den beruflichen Anwender sind wie folgt zu kennzeichnen:
Anwendung nur durch berufliche Anwender zulässig.

Auflagen

Die Zulassung wird mit folgenden Auflagen gemäß § 36 Abs. 3 S. 1 PflSchG verbunden:

Kennzeichnungsauflagen:

(NN3002)
Das Mittel wird als schädigend für Populationen relevanter Raubmilben und Spinnen eingestuft.

(NW262)
Das Mittel ist giftig für Algen.

(NW264)
Das Mittel ist giftig für Fische und Fischnährtiere.

(NW265)
Das Mittel ist giftig für höhere Wasserpflanzen.

(SB001)
Jeden unnötigen Kontakt mit dem Mittel vermeiden. Missbrauch kann zu Gesundheitsschäden führen.

(SB005)
Ist ärztlicher Rat erforderlich, Verpackung oder Etikett des Produktes bereithalten.

(SB010)
Für Kinder unzugänglich aufbewahren.

(SB111)
Für die Anforderungen an die persönliche Schutzausrüstung beim Umgang mit dem Pflanzenschutzmittel sind die Angaben im Sicherheitsdatenblatt und in der Gebrauchsanweisung des Pflanzenschutzmittels sowie die BVL-Richtlinie "Persönliche Schutzausrüstung beim Umgang mit Pflanzenschutzmitteln" des Bundesamtes für Verbraucherschutz und Lebensmittelsicherheit (www.bvl.bund.de) zu beachten.

(SB166)
Beim Umgang mit dem Produkt nicht essen, trinken oder rauchen.

(SF245-01)
Behandelte Flächen/Kulturen erst nach dem Abtrocknen des Spritzbelages wieder betreten.

(SS110)
Universal-Schutzhandschuhe (Pflanzenschutz) tragen beim Umgang mit dem unverdünnten Mittel.

(SS206)
Arbeitskleidung (wenn keine spezifische Schutzkleidung erforderlich ist) und festes Schuhwerk (z.B. Gummistiefel) tragen bei der Ausbringung/Handhabung von Pflanzenschutzmitteln.

(SS2101)
Schutzanzug gegen Pflanzenschutzmittel und festes Schuhwerk (z.B. Gummistiefel) tragen beim Umgang mit dem unverdünnten Mittel.

(SS530)
Gesichtsschutz tragen beim Umgang mit dem unverdünnten Mittel.

(SS610)
Gummischürze tragen beim Umgang mit dem unverdünnten Mittel.

(WMA)
Wirkungsmechanismus (HRAC-Gruppe): A

(WMB)
Wirkungsmechanismus (HRAC-Gruppe): B

Siehe anwendungsbezogene Kennzeichnungsauflagen in Anlage 1, jeweils unter Nr. 2.

Sonstige Auflagen:

(WH951)
Auf der Verpackung und in der Gebrauchsanleitung ist auf das Resistenzrisiko hinzuweisen. Insbesondere sind Maßnahmen für ein geeignetes Resistenzmanagement anzugeben.

(WH952)
Auf der Verpackung und in der Gebrauchsanleitung ist die Angabe zur Kennzeichnung des Wirkungsmechanismus als zusätzliche Information direkt jedem entsprechenden Wirkstoff-namen zuzuordnen.

Vorbehalt

Dieser Bescheid wird mit dem Vorbehalt der nachträglichen Aufnahme, Änderung oder Ergänzung von Anwendungsbestimmungen und Auflagen verbunden.

Angaben zur Einstufung und Kennzeichnung gemäß Verordnung (EG) Nr. 1272/2008

Signalwort:

(S1) Achtung

Gefahrenpiktogramme:

(GHS07) Ausrufezeichen

(GHS08) Gesundheitsgefahr

(GHS09) Umwelt

Gefahrenhinweise (H-Sätze):

(H317)
Kann allergische Hautreaktionen verursachen.

(H319)
Verursacht schwere Augenreizung.

(H361d)
Kann vermutlich das Kind im Mutterleib schädigen.

(H400)
Sehr giftig für Wasserorganismen.

(H410)
Sehr giftig für Wasserorganismen mit langfristiger Wirkung.

(EUH 208-0045)
Enthält Cloquintocet-mexyl. Kann allergische Reaktionen hervorrufen.

(EUH 208-0077)
Enthält Pyroxsulam. Kann allergische Reaktionen hervorrufen.

(EUH 208-0186)
Enthält Pinoxaden. Kann allergische Reaktionen hervorrufen.

(EUH 401)
Zur Vermeidung von Risiken für Mensch und Umwelt die Gebrauchsanleitung einhalten.

Sicherheitshinweise (P-Sätze):
(P101)
Ist ärztlicher Rat erforderlich, Verpackung oder Kennzeichnungsetikett bereithalten.

(P102)
Darf nicht in die Hände von Kindern gelangen.

(P201)
Vor Gebrauch besondere Anweisungen einholen.

(P280)
Schutzhandschuhe/Schutzkleidung/Augenschutz/Gesichtsschutz tragen.

(P302+P352)
BEI BERÜHRUNG MIT DER HAUT: Mit viel Wasser/... waschen.

(P305+P351+P338)
BEI KONTAKT MIT DEN AUGEN: Einige Minuten lang behutsam mit Wasser spülen. Eventuell vorhandene Kontaktlinsen nach Möglichkeit entfernen. Weiter spülen.

(P308+P313)
BEI Exposition oder falls betroffen: Ärztlichen Rat einholen/ärztliche Hilfe hinzuziehen.

(P362+P364)
Kontaminierte Kleidung ausziehen und vor erneutem Tragen waschen.

(P391)
Verschüttete Mengen aufnehmen.

(P405)
Unter Verschluss aufbewahren.

(P501)
Inhalt/Behälter ... zuführen.

Abgelehnte Anwendungsgebiete bzw. Anwendungen

Für folgende Anwendungsgebiete bzw. Anwendungen lehne ich Ihren Antrag ab (siehe Anlage 2):
- keine -

Hinweise

Auf dem Etikett und in der Gebrauchsanleitung kann angegeben werden:
(NB6641)
Das Mittel wird bis zu der höchsten durch die Zulassung festgelegten Aufwandmenge oder Anwendungskonzentration, falls eine Aufwandmenge nicht vorgesehen ist, als nicht bienengefährlich eingestuft (B4).

(NN1001)
Das Mittel wird als nicht schädigend für Populationen relevanter Nutzinsekten eingestuft.

Weitere Hinweise und Bemerkungen
Zu KIIIA1 5.2.4:
Mit der Verordnung (EU) Nr. 2016/340 wurde ein Maximalgehalt für die relevante Verunreinigung Toluol in dem technischen Wirkstoff Pinoxaden festgesetzt. Daher ist eine geeignete Analy- semethode zur Bestimmung von Toluol in der Formulierung einzureichen.

Vorsorglich weise ich darauf hin, dass bisher mitgeteilte Forderungen bestehen bleiben, soweit sie noch nicht erfüllt sind.

Unterbleibt eine Beanstandung der vorgelegten Gebrauchsanleitung, so ist daraus nicht zu schließen, dass sie als ordnungsgemäß angesehen wird. Die Verantwortung des Zulassungsinhabers für die Übereinstimmung mit dem Zulassungsbescheid bleibt bestehen.

Hinsichtlich der Gebühren erhalten Sie einen gesonderten Bescheid.

Rechtsbehelfsbelehrung

Gegen diesen Bescheid kann innerhalb eines Monats nach Bekanntgabe Widerspruch erhoben werden. Der Widerspruch ist bei dem Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Messeweg 11/12, 38104 Braunschweig, schriftlich oder zur Niederschrift einzulegen.

Mit freundlichen Grüßen
im Auftrag

gez. Dr. Martin Streloke
Abteilungsleiter

Dieses Schreiben wurde maschinell erstellt und ist daher ohne Unterschrift gültig.

Anlage

Anlage 1 zugelassene Anwendung: 008178-00/00-001

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Acker-Fuchsschwanz, Trespe-Arten, Kletten-Labkraut

Pflanzen/-erzeugnisse/Objekte: Winterweichweizen, Wintertriticale, Winterroggen

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	10 bis 32
Anwendungszeitpunkt:	Nach dem Auflaufen, Frühjahr
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	1
- für die Kultur bzw. je Jahr:	1
Anwendungstechnik:	spritzen
Aufwand:	
-	1,8 l/ha in 200 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

(WH9161)
In die Gebrauchsanleitung ist eine Zusammenstellung der Unkräuter aufzunehmen, die durch die Anwendung des Mittels gut, weniger gut und nicht ausreichend bekämpft werden, sowie eine Arten- und/oder Sortenliste der Kulturpflanzen, für die der vorgesehene Mittelaufwand verträglich oder unverträglich ist.

(WP734)
Schäden an der Kulturpflanze möglich.

(WP740)
Vorsicht bei benachbart wachsenden Kulturpflanzen, da Schäden möglich.

2.3 Wartezeiten

(F)	Freiland: Getreide (Gerste, Hafer, Roggen, Triticale, Weizen) Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NT109)
Bei der Anwendung des Mittels muss ein Abstand von mindestens 5 m zu angrenzenden Flächen (ausgenommen landwirtschaftlich oder gärtnerisch genutzte Flächen, Straßen, Wege und Plätze) eingehalten werden. Zusätzlich muss die Anwendung in einer darauf folgenden Breite von mindestens 20 m mit einem verlustmindernden Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung, mindestens in die Abdriftminderungsklasse 90 % eingetragen ist. Bei der Anwendung des Mittels ist weder der Einsatz verlustmindernder Technik noch die Einhaltung eines Abstandes von mindestens 5 m erforderlich, wenn die Anwendung mit tragbaren Pflanzenschutzgeräten erfolgt oder angrenzende Flächen (z. B. Feldraine, Hecken, Gehölzinseln) weniger als 3 m breit sind. Bei der Anwendung des Mittels ist ferner die Einhaltung eines Abstandes von mindestens 5 m nicht erforderlich, wenn die Anwendung des Mittels in einem Gebiet erfolgt, das von der Biologischen Bundesanstalt im "Verzeichnis der regionalisierten Kleinstrukturanteile" vom 7. Februar 2002 (Bundesanzeiger Nr. 70a vom 13. April 2002) in der jeweils geltenden Fassung, als Agrarlandschaft mit einem ausreichenden Anteil an Kleinstrukturen ausgewiesen worden ist oder angrenzende Flächen (z. B. Feldraine, Hecken, Gehölzinseln) nachweislich auf landwirtschaftlich oder gärtnerisch genutzten Flächen angelegt worden sind.
Begründung:
Das Pflanzenschutzmittel AVOXA / A19786A weist ein hohes Gefährdungspotenzial für terrestrische Nichtzielpflanzen auf. Bewertungsbestimmend ist hier die Geomittel-ER50 von 14.88 g/ha für Avena sativa im Vegetative-vigour-Test. Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die o.g. Anwendungsbestimmung erforderlich, um einen ausreichenden Schutz von terrestrischen Nichtzielpflanzen in Saumbiotopen vor Auswirkungen des Mittels AVOXA / A19786A zu gewährleisten. Weitere Informationen hierzu sind dem Draft Registration Report, Part B, nationales Addendum bzw. dem Core Assessment zu entnehmen.

(NW605-1)
Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände

zu Oberflächengewässern einzuhalten. Für die mit "*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten.
reduzierte Abstände: 50% 5 m, 75% 5 m, 90% *
Begründung:
Das Pflanzenschutzmittel AVOXA / A19786A weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere höhere Wasserpflanzen auf. Bewertungsbestimmend ist hier die ErC50 für Lemna gibba von 122 µg/L. Ausgehend von den geltenden Modellen zur Abdrift und einem modifizierten Sicherheitsfaktor von 30 ist nach dem Stand der wissenschaftlichen Erkenntnis die Anwendungsbestimmung NW 605-1/606 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Mittels AVOXA / A19786A in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Draft Registration Report, Part B, nationales Addendum zu entnehmen.

(NW606)
Ein Verzicht auf den Einsatz verlustmindernder Technik ist nur möglich, wenn bei der Anwendung des Mittels mindestens unten genannter Abstand zu Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - eingehalten wird. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.
5 m
Begründung:
Siehe unter NW605-1.

Anlage 1 zugelassene Anwendung: 008178-00/00-002

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung:	Gemeiner Windhalm, Weidelgras-Arten, Einjährige zweikeimblättrige Unkräuter
Pflanzen/-erzeugnisse/Objekte:	Winterweichweizen, Wintertriticale, Winterroggen
Verwendungszweck:	

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	10 bis 32
Anwendungszeitpunkt:	Nach dem Auflaufen, Frühjahr
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	1
- für die Kultur bzw. je Jahr:	1
Anwendungstechnik:	spritzen
Aufwand:	
-	1,35 l/ha in 200 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

(WH9161)
In die Gebrauchsanleitung ist eine Zusammenstellung der Unkräuter aufzunehmen, die durch die Anwendung des Mittels gut, weniger gut und nicht ausreichend bekämpft werden, sowie eine Arten- und/oder Sortenliste der Kulturpflanzen, für die der vorgesehene Mittelaufwand verträglich oder unverträglich ist.

(WP734)
Schäden an der Kulturpflanze möglich.

(WP740)
Vorsicht bei benachbart wachsenden Kulturpflanzen, da Schäden möglich.

2.3 Wartezeiten

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(F)	Freiland: Winterweichweizen Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.
(F)	Freiland: Wintertriticale Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

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Bei der Anwendung des Mittels muss ein Abstand von mindestens 5 m zu angrenzenden Flächen (ausgenommen landwirtschaftlich oder gärtnerisch genutzte Flächen, Straßen, Wege und Plätze) eingehalten werden. Zusätzlich muss die Anwendung in einer darauf folgenden Breite von mindestens 20 m mit einem verlustmindernden Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung, mindestens in die Abdriftminderungsklasse 90 % eingetragen ist. Bei der Anwendung des Mittels ist weder der Einsatz verlustmindernder Technik noch die Einhaltung eines Abstandes von mindestens 5 m erforderlich, wenn die Anwendung mit tragbaren Pflanzenschutzgeräten erfolgt oder angrenzende Flächen (z. B. Feldraine, Hecken, Gehölzinseln) weniger als 3 m breit sind. Bei der Anwendung des Mittels ist ferner die Einhaltung eines Abstandes von mindestens 5 m nicht erforderlich, wenn die Anwendung des Mittels in einem Gebiet erfolgt, das von der Biologischen Bundesanstalt im "Verzeichnis der regionalisierten Kleinstrukturanteile" vom 7. Februar 2002 (Bundesanzeiger Nr. 70a vom 13. April 2002) in der jeweils geltenden Fassung, als Agrarlandschaft mit einem ausreichenden Anteil an Kleinstrukturen ausgewiesen worden ist oder angrenzende Flächen (z. B. Feldraine, Hecken, Gehölzinseln) nachweislich auf landwirtschaftlich oder gärtnerisch genutzten Flächen angelegt worden sind.
Begründung:
Das Pflanzenschutzmittel AVOXA / A19786A weist ein hohes Gefährdungspotenzial für terrestrische Nichtzielpflanzen auf. Bewertungsbestimmend ist hier die Geomittel-ER50 von 14.88 g/ha für Avena sativa im Vegetative-vigour-Test. Ausgehend von den geltenden Model-

len zur Abdrift und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die o.g. Anwendungsbestimmung erforderlich, um einen ausreichenden Schutz von terrestrischen Nichtzielpflanzen in Saumbiotopen vor Auswirkungen des Mittels AVOXA / A19786A zu gewährleisten. Weitere Informationen hierzu sind dem Draft Registration Report, Part B, nationales Addendum bzw. dem Core Assessment zu entnehmen.

(NW605-1)
Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände zu Oberflächengewässern einzuhalten. Für die mit "*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten.
reduzierte Abstände: 50% 5 m, 75% 5 m, 90% *
Begründung:
Das Pflanzenschutzmittel AVOXA / A19786A weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere höhere Wasserpflanzen auf. Bewertungsbestimmend ist hier die ErC50 für Lemna gibba von 122 µg/L. Ausgehend von den geltenden Modellen zur Abdrift und einem modifizierten Sicherheitsfaktor von 30 ist nach dem Stand der wissenschaftlichen Erkenntnis die Anwendungsbestimmung NW 605-1/606 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Mittels AVOXA / A19786A in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Draft Registration Report, Part B, nationales Addendum zu entnehmen.

(NW606)
Ein Verzicht auf den Einsatz verlustmindernder Technik ist nur möglich, wenn bei der Anwendung des Mittels mindestens unten genannter Abstand zu Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - eingehalten wird. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.
5 m
Begründung:
Siehe unter NW605-1.

REGISTRATION REPORT
Part B

Section 1: Identity, physical and chemical properties, other information

Detailed summary of the risk assessment

Product name:	**AVOXA**
Product code:	**A19786A**
Active Substance:	**Pinoxaden 33.3g/L**
	Pyroxsulam 8.33g/L
Safener:	**Cloquintocet-mexyl 8.33 g/L**

Central Zone
Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant:	**Syngenta**
Submission Date:	**28/03/2014**
Date:	**23/02/2018**

Table of Contents

Introduction

This document summarises the information related to the identity, the physical and chemical properties, the data on application, further information and the classification for the product A19786A containing the active substances pinoxaden and pyroxsulam which were approved according to Regulation (EC) No 1107/2009. Cloquintocet-mexyl is a safener which is not yet reviewed according to Article 26 of Regulation (EC) No 1107/2009.

This product was not the representative formulation. The product has not been previously evaluated according to Uniform Principles.

The following table provides the EU endpoints to be used in the evaluation.

Agreed EU End-points

End-Point	**Pinoxaden** (Reg. (EU) No 2016/370)	**Pyroxsulam** (Reg. (EU) No 1176/2013)
Purity of active substance	min 970 g/kg	min 965 g/kg
Relevant impurities:	Toluene: max 1 g/kg	–

Appendix 1 of this document contains the list of references included in this document for support of the evaluation.

Information on the detailed composition of A19786A can be found in the confidential dossier of this submission (Registration Report - Part C).

IIIA 1 IDENTITY OF THE PLANT PROTECTION PRODUCT

IIIA 1.1 Applicant

Syngenta Crop Protection AG

CH 4002 – Basel

Switzerland

Contact person:	[redacted]
Tel.No.:	[redacted]
Fax No:	[redacted]
e-mail:	[redacted]

IIIA 1.2 Manufacturer of the Preparation, Manufacturer and Purity of the Active Substance(s)

IIIA 1.2.1 Manufacturer(s) of the preparation

Confidential information - data provided separately (Part C).

IIIA 1.2.2 Manufacturer(s) of the active substance(s)

Confidential information - data provided separately (Part C).

IIIA 1.2.3 Statement of purity (and detailed information on impurities) of the active substance(s)

Pinoxaden: min 970 g/kg
Relevant impurity: Toluene: max 1 g/kg

Pyroxsulam: min 965 g/kg

Further information/justification is provided in Part C.

IIIA 1.3 Trade Names and Manufacturer's Code Numbers for the Preparation

Trade name: A19786A

Company code number: A19786A

IIIA 1.4 Detailed Quantitative and Qualitative Information on the Composition of the Preparation

IIIA 1.4.1 Content of active substance and formulants

The formulation was not the representative formulation.

Pure active substance:

content of pure pinoxaden:	33.3 g/L
content of pure pyroxsulam:	8.33 g/L
limits pinoxaden:	30.0 - 36.6 g/L
limits pyroxsulam:	7.08 - 9.58 g/L

Pure safener:

content of pure cloquintocet-mexyl:	8.33 g/L
limits cloquintocet-mexyl:	7.08 - 9.58 g/L

Technical active substance:

content of technical pinoxaden at minimum purity (97.0 %):	34.3 g/L	(3.24 % w/w)
content of technical pyroxsulam at minimum purity (96.5 %):	8.63 g/L	(0.82 % w/w)

Technical safener:

content of technical cloquintocet-mexyl at minimum purity (93 %):	8.96 g/L	(0.85 % w/w)

None of the active substances in the formulation are present in the form of a salt, ester, anion or cation.

Further information on the active substances and on the certified limits of formulants is considered confidential and is provided separately (Part C).

IIIA 1.4.2 Certified limits of each component

This is not an EC data requirement/ not required by regulation (EU) 2011/545.

IIIA 1.4.3 Common names and code numbers for the active substance(s)

Data Point	Type	Name/Code Number	
1.4.3.1	ISO common name	Pinoxaden	Pyroxsulam
1.4.3.2	CAS No.	243973-20-8	422556-08-9
1.4.3.2	EINECS No.	–	–
1.4.3.2	CIPAC No.	776	793
1.4.3.2	ELINCS	–	–
1.4.3.3	Salt, ester anion or cation present	–	–

IIIA 1.4.4 Co-formulant details: identity, structure, codes, trade name, specification and function.

CONFIDENTIAL information - data provided separately (Part C).

IIIA 1.4.5 Formulation process

IIIA 1.4.5.1 Description of formulation process

This is not an EC data requirement/ not required regulation (EU) 2011/545.

IIIA 1.4.5.2 Discussion of the formation of impurities of toxicological concern

Pinoxaden, pyroxsulam and cloquintocet-mexyl do not contain any impurities of toxicological or ecotoxicological concern.

IIIA 1.5 Type of Preparation and Code

Type : Emulsifiable concentrate Code : EC

IIIA 1.6 Function

The product will be used as herbicide.

IIIA 1.7 Other/Special Studies

There are no additional European requirements for formulated products, however the following data summary is available for the safener cloquintocet-mexyl:

Report:	IIIA 1.7/01, de la Fuente K. (2003)

Title:	Cloquintocet-mexyl (co-formulant in A-12303) Document I, Part 1 Identity, physical and chemical properties, further information and proposed classification.
Document No:	Syngenta File No. NOA407855/0468
GLP	No

Summary and evaluation:

Cloquintocet-mexyl is a white to light brown powder with a melting point of 69.4 °C. A vapour pressure of $5.31 \cdot 10^{-6}$ Pa was determined at 25 °C and the Henry's law constant, which largely determines the tendency of a chemical to volatilise from water solution to air was calculated to be $3.0 \cdot 10^{-3}$ Pa · m^3 / mol, that means cloquintocet-mexyl does not volatilise from water. The pKa-value of cloquintocet-mexyl is 3.55, that means in aqueous solutions the neutral form is predominantly present at pH > 3.55. The solubility in pure water was found to be 590 µg / L at 25 °C. The log Pow of 5.2 at 25 °C indicates that the possibility of bioaccumulation needs to be investigated.

Cloquintocet-mexyl is hydrolytically more stable in an acid than in a basic environment. It degrades at 20 °C with half-lives of 4.4 years, 134 days and 6.6 hours at pH 5, 7 and 9, respectively. Over the whole pH range only one hydrolysis product, the free acid of cloquintocet-mexyl, was found. Moderately fast photodegradation was observed upon irradiation of a buffered solution (pH 5.36) with xenon arc light at 25 °C the photodecomposition led to several products of higher polarity than cloquintocet-mexyl which could not be identified.

Flammability, autoflammability, oxidizing and explosive properties do not create critical problems in the production environment or during transport and storage.

IIIA 2 PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF THE PLANT PROTECTION PRODUCT

All studies have been performed in accordance with the current requirements, the critical GAP and the results are deemed to be acceptable.

All tests were conducted using material from batch: SMU3AP001 containing a mean of 3.1 % w/w, Pinoxaden and 0.77 % w/w Pyroxsulam

Table 1: Summary of the physical, chemical and technical properties of the plant protection product

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Colour, odour and physical state (IIIA 2.1)	Visual assessment and organoleptic determination	Batch SMU3AP001	The preparation is a light brown liquid with a weak odour.	N	Fumeaux, J., 2013, A19786A_10041	Acceptable
Explosive properties (IIIA 2.2.1)	Theoretical assessment	-	Based on the composition the formulation does not posses explosive properties. An experimental determination has not been conducted.	Y	Jackson, W. A., 2013, A19786A_10042	Acceptable.
Oxidizing properties (IIIA 2.2.2)	Theoretical assessment	-	Based on the composition the formulation does not posses oxidising properties. An experimental determination has not been conducted.	Y	Jackson, W. A., 2013, A19786A_10042	Acceptable.
Flash point (IIIA 2.3.1)	EEC A 9 Pensky-Martens closed-cup	Batch SMU3AP001	150 ± 8 °C Not classified in terms of its flash point	Y	Jackson, W. A., 2013, A19786A_10042	Acceptable.
Flammability (IIIA 2.3.2)	-	-	Not required for liquid formulations	-	-	Acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Auto-flammability (IIIA 2.3.3)	EEC A 15	Batch SMU3AP001	Auto-ignition at 410°C .	Y	Jackson, W. A., 2013, A19786A_10042	Acceptable.
Acidity or alkalinity and pH (IIIA 2.4.1)	CIPAC MT 191	Batch SMU3AP001	Acidity: 0.18 % (calculated as H_2SO_4)	Y	Fumeaux, J., 2013a, A19786A_10040	Acceptable.
pH of a 1% aqueous dilution, emulsion or dispersion (IIIA 2.4.2)	CIPAC MT 75.3	Batch SMU3AP001	deionised water, 25 °C: 4.2	Y	Fumeaux, J., 2013a, A19786A_10040	Acceptable.
			Before and after storage at 0 °C for 7 days: deionised water, 25 °C: 4.3	N	Fumeaux, J., 2013, A19786A_10041	
Kinematic viscosity (IIIA 2.5.1)	-	-	not relevant	-	-	Acceptable.
Dynamic viscosity (IIIA 2.5.2)	OECD 114	Batch SMU3AP001	25.5 mPa s at 20 °C, shear rate range = 250 – 170 s^{-1}: 11.5 mPa s at 40 °C, shear rate range = 250 – 170 s^{-1}: Test item is a Newtonian liquid.	Y	Fumeaux, J., 2013a, A19786A_10040	Acceptable.
Surface tension (IIIA 2.5.3)	EEC A 5	Batch SMU3AP001	36.5 mN/m (2.4 % w/v) 38.9 mN/m (0.3 % w/v) 41.0 mN/m (0.1 % w/v)	Y	Fumeaux, J., 2013a, A19786A_10040	Acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
			32.9 % (undiluted) At 20 °C in CIPAC D.			
Relative density (IIIA 2.6.1)	OECD 109	Batch SMU3AP001	d_4^{20} = 1.058	Y	De Benedictis, S., 2013, A19786A_10039	Acceptable.
Bulk or tap density (IIIA 2.6.2)	-	-	Not relevant for liquid formulations	-	-	Acceptable.
Storage Stability after 14 days at 54° C (IIIA 2.7.1)	CIPAC MT 46.3	Batch SMU3AP001	Storage material: HDPE The content of the active substance does not decrease > 5 %. Content of pinoxaden: before storage: 32.8 g/L after storage: 31.8 g/L Content of pyroxsulam: before storage: 8.15 g/L after storage: 8.05 g/L Content of cloquintocet-mexyl: before storage: 8.68 g/L after storage: 8.53 g/L The changes of the physical and chemical properties are negligible, see table below	N	Fumeaux, J., 2013b, A19786A_10045	Acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
			Storage material: f-HDPE Content of pinoxaden: before storage: 32.8 g/L after storage: 32.8 g/L Content of pyroxsulam: before storage: 8.15 g/L after storage: 8.24 g/L Content of cloquintocet-mexyl: before storage: 8.68 g/L after storage: 8.77 g/L The changes of the physical and chemical properties are negligible, see table below.	N	Fumeaux, J., 2013c, A19786A_10044	
Stability after storage for other periods and/or temperatures (IIIA 2.7.2)	-	-	Not relevant as the formulation is stable at 54 °C	-	-	Acceptable.
Minimum content after heat stability testing (IIIA 2.7.3)	-	-	Not necessary, since the decrease of the active substance did not exceed 5 %.	-	-	Acceptable.
Effect of low temperatures on stability (IIIA 2.7.4)	CIPAC MT 39.3	Batch SMU3AP001	No separated material, homogeneous liquid. The product shows good low temperature stability, the effects are	N	Fumeaux, J., 2013, A19786A_10041	Acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
			negligible.			
Ambient temperature shelf life (IIIA 2.7.5)	-	-	Storage material: HDPE The content of the active substance does not decrease > 5 %. Content of pinoxaden: before storage: 32.8 g/L after storage: 32.2 g/L Content of pyroxsulam: before storage: 8.15 g/L after storage: 8.24 g/L Content of cloquintocet-mexyl: before storage: 8.68 g/L after storage: 8.67 g/L The changes of the physical and chemical properties are negligible, see table below.	-	Wochner, F., 2015, A19786A_10517	Acceptable, study was submitted on request.
			Storage material: f-HDPE The content of the active substance does not decrease > 5 %. Content of pinoxaden: before storage: 32.1 g/L after storage: 33.0 g/L Content of pyroxsulam: before storage: 8.15 g/L		Wochner, F., 2015, A19786A_10519	

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
			after storage: 8.19 g/L Content of cloquintocet-mexyl: before storage: 8.68 g/L after storage: 8.65 g/L The changes of the physical and chemical properties are negligible, see table below.			
Shelf life in months (if less than 2 years) (IIIA 2.7.6)	-	-	Please refer to 2.7.5	-	-	Acceptable.
Wettability (IIIA 2.8.1)	-	-	Not required for liquid formulations	-	-	Acceptable.
Persistence of foaming (IIIA 2.8.2)	CIPAC MT 47.2	Batch SMU3AP001	CIPAC water D, 2.4 %: Before storage 10s: 32 mL 1 min: 16 mL 3 min: 10 mL 12 min: 6 mL CIPAC water D, 0.3 %: Before Storage 10s: 24 mL 1 min: 10 mL 3 min: 6 mL 12 min: 2 mL	N	Fumeaux, J., 2013, A19786A_10041	Acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Suspensibility (IIIA 2.8.3.1)	-	-	Not applicable (preparation forms an emulsion)	-	-	Acceptable.
Spontaneity of dispersion (IIIA 2.8.3.2)	-	-	Not applicable (preparation forms an emulsion)	-	-	Acceptable.
Dilution stability (IIIA 2.8.4)	-	-	Not applicable (preparation is not water soluble)	-	-	Acceptable.
Dry sieve test (IIIA 2.8.5.1)	-	-	Not required for liquid formulations	-	-	Acceptable.
Wet sieve test (IIIA 2.8.5.2)	-	-	Not applicable (preparation forms an emulsion)	-	-	Acceptable.
Particle size distribution (IIIA 2.8.6.1)	-	-	Not applicable (preparation forms an emulsion)	-	-	Acceptable.
Nominal size range of granules (IIIA 2.8.6.2)	-	-	Not relevant (liquid)	-	-	Acceptable.
Dust content (IIIA 2.8.6.3)	-	-	Not relevant (liquid)	-	-	Acceptable.
Particle size of dust (IIIA 2.8.6.4)	-	-	Not relevant (liquid)	-	-	Acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Friability and attrition (IIIA 2.8.6.5)	-	-	Not relevant (liquid)	-	-	Acceptable.
Emulsifiability (IIIA 2.8.7.1) Emulsion stability (IIIA 2.8.7.2) Re-emulsifiability (IIIA 2.8.7.3)	CIPAC MT 36.3	Batch SMU3AP001	No oil was observed in Water A and D before and after storage. **CIPAC water A, 2.4 %:** Before storage 0 h: spontan emulsifiable 0.5 h: 2 mL cream 2 h: 2.5 mL cream 24 h: 4 mL cream 24 h: complete re-emulsifiable 24.5 h: 2.5 mL cream After 7 days at 0 °C 0 h: spontan emulsifiable 0.5 h: 2 mL cream 2 h: 3 mL cream 24 h: 4 mL cream 24 h: complete re-emulsifiable 24.5 h: 3 mL cream **CIPAC water D, 2.4 %:** Before storage 0 h: spontan emulsifiable 0.5 h: 2 mL cream 2 h: 2.5 mL cream 24 h: 3.5 mL cream 24 h: complete re-emulsifiable	N	Fumeaux, J., 2013, A19786A_10041	Acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
			24.5 h: 2 mL cream After 7 days at 0 °C 0 h: spontan emulsifiable 0.5 h: 2 mL cream 2 h: 2.5 mL cream 24 h: 3.5 mL cream 24 h: complete re-emulsifiable 24.5 h: 2.5 mL cream **CIPAC water A and D, 0.3 %:** Before storage 0 h: spontan emulsifiable 0.5 h: <1 mL cream 2 h: 1 mL cream 24 h: <1 mL cream 24 h: complete re-emulsifiable 24.5 h: <1 mL cream After 7 days at 0 °C 0 h: spontan emulsifiable 0.5 h: <1 mL cream 2 h: <1 mL cream 24 h: <1 mL cream 24 h: complete re-emulsifiable 24.5 h: <1 mL cream			

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Stability of dilute emulsions (IIIA 2.8.7.4)	CIPAC MT 20	Pinoxaden 3.10 % w/w; Pyroxsulam 0.77 % w/w EC (A19786A)	Concentration: 2.4 % Stability after 1h in CIPAC water D: 2 ml cream separation at the bottom Stability after 1h in HPLC water: 2 ml cream separation at the bottom Concentration: 0.3 % Stability after 1h in CIPAC water D: < 1 ml cream separation at the bottom Stability after 1h in HPLC water: < 1 ml cream separation at the bottom	N	Fumeaux, J., 2013, A19786A_10041	Acceptable.
Flowability (IIIA 2.8.8.1)			Not relevant (liquid)			Acceptable.
Pourability (including rinsed residue) (IIIA 2.8.8.2)			Not relevant (Emulsifiable Concentrate)			Acceptable.
Dustability following accelerated storage (IIIA 2.8.8.3)			Not relevant (liquid)			Acceptable.
Physical compatibility of tank mixes (IIIA 2.9.1)			This dossier does not include recommendations for the specific mandatory tank mixing of the preparation with any other product.			Acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Chemical compatibility of tank mixes (IIIA 2.9.2)			This dossier does not include recommendations for the specific mandatory tank mixing of the preparation with any other product.			Acceptable.
Distribution to seed (IIIA 2.10.1)			Not relevant (not a seed treatment product)			Acceptable.
Adhesion to seeds (IIIA 2.10.2)			Not relevant (not a seed treatment product)			Acceptable.
Miscibility (IIIA 2.11)			Not required by regulation (EU) 2011/545.			Acceptable.
Dielectric breakdown (IIIA 2.12)			Not required by regulation (EU) 2011/545.			Acceptable.
Corrosion characteristics (IIIA 2.13)			Not required by regulation (EU) 2011/545.			Acceptable.
Container material (IIIA 2.14)			Not required by regulation (EU) 2011/545.			Acceptable.
Other/special studies (IIIA 2.15)			Not required by regulation (EU) 2011/545.			Acceptable.

Table 2-1: Storage stability data before and after storage for two weeks at 54 °C in HDPE packaging

Content of active substances before and after storage

Active Substance	Storage Conditions	Content of control sample	Content of test sample
Pinoxaden	Initial	32.8 g/l	-
Pinoxaden	2 weeks below - 10 ºC	33.2 g/l	-
Pinoxaden	2 weeks 54 ºC	-	31.8 g/l
Pyroxsulam	Initial	8.15 g/l	-
Pyroxsulam	2 weeks below - 10 ºC	8.24 g/l	-
Pyroxsulam	2 weeks 54 ºC	-	8.05 g/l

Physical and technical properties before and after storage

Test Description	Method	Initial Results	Results after 2 weeks at 54 °C
Color	Visual	Light brown	Light brown
Odour	Organoleptic	Weak	Weak
Physical state	Visual	Liquid	Liquid
Appearance	Visual	Clear	Clear
pH Value concentration: 1% deionised water	CIPAC MT 75.3	4.2	4.2
Relative Density Temp.: 20 ºC	OECD 109	1.058 g/cm^3	1.057 g/cm^3
Persistent Foaming CIPAC Water D Waiting Period 1min.: Concentration: 2.4 % Concentration: 0.3 %	CIPAC MT 47.2	 16 ml 10 ml	 18 ml 10 ml
Emulsifiability, Emulsion, Stability, Re-emulsifiability Concentration: 2.4 % CIPAC Water A Temp: 30 ºC	CIPAC MT 36.3		
Spontaneity of emulsion		Spontaneous	Spontaneous
Emulsion stability after: 0.5 h		2 ml cream at the bottom, no oil	2 ml cream at the bottom, no oil
2 h		2.5 ml cream at the bottom, no oil	2.5 ml cream at the bottom, no oil
24 h		4 ml cream at the bottom, no oil	4 ml cream at the bottom, no oil
Re-emulsification		Complete	Complete
Emulsion stability 0.5 h after re-emulsification		2.5 ml cream at the bottom, no oil	2 ml cream at the bottom, no oil

Test Description		Method	Initial Results	Results after 2 weeks at 54 °C
Emulsifiability, Emulsion, Stability, Re-emulsifiability Concentration: 2.4 % CIPAC Water D Temp: 30 ºC		CIPAC MT 36.3		
Spontaneity of emulsion			Spontaneous	Spontaneous
Emulsion stability after:	0.5 h		2 ml cream at the bottom, no oil	2 ml cream at the bottom, no oil
	2 h		2.5 ml cream at the bottom, no oil	2.5 ml cream at the bottom, no oil
	24 h		3.5 ml cream at the bottom, no oil	3.5 ml cream at the bottom, no oil
Re-emulsification			Complete	Complete
Emulsion stability 0.5 h after re-emulsification			2 ml cream at the bottom, no oil	2 ml cream at the bottom, no oil
Emulsifiability, Emulsion, Stability, Re-emulsifiability Concentration: 0.3 % CIPAC Water A Temp: 30 ºC		CIPAC MT 36.3		
Spontaneity of emulsion			Spontaneous	Spontaneous
Emulsion stability after:	0.5 h		<1 ml cream at the bottom, no oil	<1 ml cream at the bottom, no oil
	2 h		1 ml cream at the bottom, no oil	<1 ml cream at the bottom, no oil
	24 h		1 ml cream at the bottom, no oil	<1 ml cream at the bottom, no oil
Re-emulsification			Complete	Complete
Emulsion stability 0.5 h after re-emulsification			<1 ml cream at the bottom, no oil	<1 ml cream at the bottom, no oil
Emulsifiability, Emulsion, Stability, Re-emulsifiability Concentration: 0.3 % CIPAC Water D Temp: 30 ºC		CIPAC MT 36.3		
Spontaneity of emulsion			Spontaneous	Spontaneous
Emulsion stability after:	0.5 h		<1 ml cream at the bottom, no oil	<1 ml cream at the bottom, no oil
	2 h		<1 ml cream at the bottom, no oil	<1 ml cream at the bottom, no oil
	24 h		<1 ml cream at the bottom, no oil	<1 ml cream at the bottom, no oil
Re-emulsification			Complete	Complete
Emulsion stability 0.5 h after re-emulsification			<1 ml cream at the bottom, no oil	<1 ml cream at the bottom, no oil

Test Description	Method	Initial Results	Results after 2 weeks at 54 °C
Emulsifiability, Emulsion, Stability, Re-emulsifiability 0.3 % in CIPAC water A Emulsion stability after 0.5 hours 0.3 % in CIPAC water D Emulsion stability after 0.5 hours	CIPAC 170 (mod)	Chemical Assay Pinoxaden 33 % Pyroxsulam 83 % Pinoxaden 83 % Pyroxsulam 88 %	Chemical Assay Pinoxaden 44% Pyroxsulam 83 % Pinoxaden 68 % Pyroxsulam 91 %

Packaging Evaluation after storage

Evaluation Criteria	Results after 2 weeks at 54 °C
Color change of the packaging	None
Odor (noticeable before opening the packaging)	None
Panelling of the test container	None
Ballooning of the test container	None
Pimples on the test container	None
Cracks in the test container	No one
Tightness of the test container	Tight
Reclosability of closure	Reclosable
Tightness of closure	Tight
Weight change (gross weight)	0.03 % weight gain
Permeation through the container walls	None

Table 2-2: Storage stability data before and after storage for two weeks at 54 °C in f-HDPE packaging

Content of active substances before and after storage

Active Substance	Storage Conditions	Content of control sample	Content of test sample
Pinoxaden	Inital	32.8 g/l	-
Pinoxaden	2 weeks below - 10 ºC	33.5 g/l	-
Pinoxaden	2 weeks 54 ºC	-	32.8 g/l
Pyroxsulam	Inital	8.15 g/l	-
Pyroxsulam	2 weeks below - 10 ºC	8.37 g/l	-
Pyroxsulam	2 weeks 54 ºC	-	8.24 g/l

Physical and technical properties before and after storage

Test Description	Method	Initial Results	Results after 2 weeks at 54 °C
Color	Visual	Light brown	Light brown
Odour	Organoleptic	Weak	Weak
Physical state	Visual	Liquid	Liquid
Appearance	Visual	Clear	Clear

Test Description	Method	Initial Results	Results after 2 weeks at 54 °C
pH Value concentration: 1% deionised water	CIPAC MT 75.3	4.2	4.2
Relative Density Temp.: 20 ºC	OECD 109	1.058 g/cm^3	1.057 g/cm^3
Persistent Foaming CIPAC Water D Waiting Period 1min.: Concentration: 2.4 % Concentration: 0.3 %	CIPAC MT 47.2	 16 ml 10 ml	 24 ml 12 ml
Emulsifiability, Emulsion, Stability, Re-emulsifiability Concentration: 2.4 % CIPAC Water A Temp: 30 ºC Spontaneity of emulsion Emulsion stability after: 0.5 h 2 h 24 h Re-emulsification Emulsion stability 0.5 h after re-emulsification	CIPAC MT 36.3	 Spontaneous 2 ml cream at the bottom, no oil 2.5 ml cream at the bottom, no oil 4 ml cream at the bottom, no oil Complete 2.5 ml cream at the bottom, no oil	 Spontaneous 2 ml cream at the bottom, no oil 2.5 ml cream at the bottom, no oil 4 ml cream at the bottom, no oil Complete 2 ml cream at the bottom, no oil
Emulsifiability, Emulsion, Stability, Re-emulsifiability Concentration: 2.4 % CIPAC Water D Temp: 30 ºC Spontaneity of emulsion Emulsion stability after: 0.5 h 2 h 24 h Re-emulsification Emulsion stability 0.5 h after re-emulsification	CIPAC MT 36.3	 Spontaneous 2 ml cream at the bottom, no oil 2.5 ml cream at the bottom, no oil 3.5 ml cream at the bottom, no oil Complete 2 ml cream at the bottom, no oil	 Spontaneous 1 ml cream at the bottom, no oil 2 ml cream at the bottom, no oil 3 ml cream at the bottom, no oil Complete 1.5 ml cream at the bottom, no oil

Test Description	Method	Initial Results	Results after 2 weeks at 54 °C
Emulsifiability, Emulsion, Stability, Re-emulsifiability Concentration: 0.3 % CIPAC Water A Temp: 30 ºC	CIPAC MT 36.3		
Spontaneity of emulsion		Spontaneous	Spontaneous
Emulsion stability after: 0.5 h		<1 ml cream at the bottom, no oil	<1 ml cream at the bottom, no oil
2 h		1 ml cream at the bottom, no oil	<1 ml cream at the bottom, no oil
24 h		1 ml cream at the bottom, no oil	<1 ml cream at the bottom, no oil
Re-emulsification		Complete	Complete
Emulsion stability 0.5 h after re-emulsification		<1 ml cream at the bottom, no oil	<1 ml cream at the bottom, no oil
Emulsifiability, Emulsion, Stability, Re-emulsifiability Concentration: 0.3 % CIPAC Water D Temp: 30 ºC	CIPAC MT 36.3		
Spontaneity of emulsion		Spontaneous	Spontaneous
Emulsion stability after: 0.5 h		<1 ml cream at the bottom, no oil	<1 ml cream at the bottom, no oil
2 h		<1 ml cream at the bottom, no oil	<1 ml cream at the bottom, no oil
24 h		<1 ml cream at the bottom, no oil	<1 ml cream at the bottom, no oil
Re-emulsification		Complete	Complete
Emulsion stability 0.5 h after re-emulsification		<1 ml cream at the bottom, no oil	<1 ml cream at the bottom, no oil
Emulsifiability, Emulsion, Stability, Re-emulsifiability 0.3 % in CIPAC water A Emulsion stability after 0.5 hours 0.3 % in CIPAC water D Emulsion stability after 0.5 hours	CIPAC 170 (mod)	Chemical Assay Pinoxaden 33 Pyroxsulam 83 % Pinoxaden 83 % Pyroxsulam 88 %	Chemical Assay Pinoxaden 70 Pyroxsulam 91 % Pinoxaden 66 % Pyroxsulam 88 %

Packaging Evaluation after storage

Evaluation Criteria	Results after 2 weeks at 54 °C
Color change of the packaging	None
Odor (noticeable before opening the packaging)	None
Panelling of the test container	None
Ballooning of the test container	None
Pimples on the test container	None
Cracks in the test container	No one
Tightness of the test container	Tight
Reclosability of closure	Reclosable

Tightness of closure	Tight
Weight change (gross weight)	0.01 % weight gain
Permeation through the container walls	None

Table 2-3: Storage stability data before and after storage for two years at 20 °C in HDPE packaging

Content of active substances before and after storage

Active Substance	Storage Conditions	Content of control sample	Content of test sample
Pinoxaden	Initial	32.8 g/l	-
Pinoxaden	2 years below - 10 ºC	32.8 g/l	-
Pinoxaden	2 years 20 ºC	-	32.2 g/l
Pyroxsulam	Initial	8.15 g/l	-
Pyroxsulam	2 years below - 10 ºC	8.27 g/l	-
Pyroxsulam	2 years 20ºC	-	8.24 g/l

Physical and technical properties before and after storage

Test Description	Method	Initial Results	Results after 2 years at 20 °C
Color	Visual	Light brown	Light brown
Odour	Organoleptic	Weak	Weak
Physical state	Visual	Liquid	Liquid
Appearance	Visual	Clear	Clear
pH Value concentration: 1% deionised water	CIPAC MT 75.3	4.2	4.1
Relative Density Temp.: 20 ºC	OECD 109	1.058 g/cm^3	1.057 g/cm^3
Persistent Foaming CIPAC Water D Waiting Period 1min.: Concentration: 2.4 % Concentration: 0.3 %	CIPAC MT 47.2	 16 ml 10 ml	 16 ml 8 ml
Emulsifiability, Emulsion, Stability, Re-emulsifiability Concentration: 2.4 % CIPAC Water A Temp: 30 ºC	CIPAC MT 36.3		
Spontaneity of emulsion		Spontaneous	Spontaneous
Emulsion stability after: 0.5 h		2 ml cream at the bottom, no oil	2 ml cream at the bottom, no oil
2 h		2.5 ml cream at the bottom, no oil	2 ml cream at the bottom, no oil
24 h		4 ml cream at the bottom, no oil	3 ml cream at the bottom, no oil
Re-emulsification		Complete	Complete
Emulsion stability 0.5 h after re-emulsification		2.5 ml cream at the bottom, no oil	2 ml cream at the bottom, no oil

Test Description	Method	Initial Results	Results after 2 years at 20 °C
Emulsifiability, Emulsion, Stability, Re-emulsifiability Concentration: 2.4 % CIPAC Water D Temp: 30 ºC	CIPAC MT 36.3		
Spontaneity of emulsion		Spontaneous	Spontaneous
Emulsion stability after: 0.5 h		2 ml cream at the bottom, no oil	1 ml cream at the bottom, no oil
2 h		2.5 ml cream at the bottom, no oil	2 ml cream at the bottom, no oil
24 h		3.5 ml cream at the bottom, no oil	3 ml cream at the bottom, no oil
Re-emulsification		Complete	Complete
Emulsion stability 0.5 h after re-emulsification		2 ml cream at the bottom, no oil	2 ml cream at the bottom, no oil
Emulsifiability, Emulsion, Stability, Re-emulsifiability Concentration: 0.3 % CIPAC Water A Temp: 30 ºC	CIPAC MT 36.3		
Spontaneity of emulsion		Spontaneous	Spontaneous
Emulsion stability after: 0.5 h		<1 ml cream at the bottom, no oil	<1 ml cream at the bottom, no oil
2 h		1 ml cream at the bottom, no oil	<1 ml cream at the bottom, no oil
24 h		1 ml cream at the bottom, no oil	<1 ml cream at the bottom, no oil
Re-emulsification		Complete	Complete
Emulsion stability 0.5 h after re-emulsification		<1 ml cream at the bottom, no oil	<1 ml cream at the bottom, no oil
Emulsifiability, Emulsion, Stability, Re-emulsifiability Concentration: 0.3 % CIPAC Water D Temp: 30 ºC	CIPAC MT 36.3		
Spontaneity of emulsion		Spontaneous	Spontaneous
Emulsion stability after: 0.5 h		<1 ml cream at the bottom, no oil	<1 ml cream at the bottom, no oil
2 h		<1 ml cream at the bottom, no oil	<1 ml cream at the bottom, no oil
24 h		<1 ml cream at the bottom, no oil	<1 ml cream at the bottom, no oil
Re-emulsification		Complete	Complete
Emulsion stability 0.5 h after re-emulsification		<1 ml cream at the bottom, no oil	<1 ml cream at the bottom, no oil

Packaging Evaluation after storage

Evaluation Criteria	Results after 2 years at 20 °C
Color change of the packaging	None
Odor (noticeable before opening the packaging)	None
Panelling of the test container	None

Ballooning of the test container	None
Pimples on the test container	None
Cracks in the test container	No one
Tightness of the test container	Tight
Reclosability of closure	Reclosable
Tightness of closure	Tight
Weight change (gross weight)	0.03 % weight gain
Permeation through the container walls	None

Table 2-3: Storage stability data before and after storage for two years at 20 °C in f-HDPE packaging

Content of active substances before and after storage

Active Substance	Storage Conditions	Content of control sample	Content of test sample
Pinoxaden	Initial	32.8 g/l	-
Pinoxaden	2 years below - 10 ºC	33.0 g/l	-
Pinoxaden	2 years 20 ºC	-	32.1 g/l
Pyroxsulam	Initial	8.15 g/l	-
Pyroxsulam	2 years below - 10 ºC	8.30 g/l	-
Pyroxsulam	2 years 20ºC	-	8.65 g/l

Physical and technical properties before and after storage

Test Description	Method	Initial Results	Results after 2 years at 20 °C
Color	Visual	Light brown	Light brown
Odour	Organoleptic	Weak	Weak
Physical state	Visual	Liquid	Liquid
Appearance	Visual	Clear	Clear
pH Value concentration: 1% deionised water	CIPAC MT 75.3	4.2	4.1
Relative Density Temp.: 20 ºC	OECD 109	1.058 g/cm^3	1.057 g/cm^3
Persistent Foaming CIPAC Water D Waiting Period 1min.: Concentration: 2.4 % Concentration: 0.3 %	CIPAC MT 47.2	 16 ml 10 ml	 12 ml 10 ml

Test Description	Method	Initial Results	Results after 2 years at 20 °C
Emulsifiability, Emulsion, Stability, Re-emulsifiability Concentration: 2.4 % CIPAC Water A Temp: 30 ºC	CIPAC MT 36.3		
Spontaneity of emulsion		Spontaneous	Spontaneous
Emulsion stability after: 0.5 h		2 ml cream at the bottom, no oil	2 ml cream at the bottom, no oil
2 h		2.5 ml cream at the bottom, no oil	2 ml cream at the bottom, no oil
24 h		4 ml cream at the bottom, no oil	3 ml cream at the bottom, no oil
Re-emulsification		Complete	Complete
Emulsion stability 0.5 h after re-emulsification		2.5 ml cream at the bottom, no oil	2 ml cream at the bottom, no oil
Emulsifiability, Emulsion, Stability, Re-emulsifiability Concentration: 2.4 % CIPAC Water D Temp: 30 ºC	CIPAC MT 36.3		
Spontaneity of emulsion		Spontaneous	Spontaneous
Emulsion stability after: 0.5 h		2 ml cream at the bottom, no oil	2 ml cream at the bottom, no oil
2 h		2.5 ml cream at the bottom, no oil	2 ml cream at the bottom, no oil
24 h		3.5 ml cream at the bottom, no oil	3 ml cream at the bottom, no oil
Re-emulsification		Complete	Complete
Emulsion stability 0.5 h after re-emulsification		2 ml cream at the bottom, no oil	2 ml cream at the bottom, no oil
Emulsifiability, Emulsion, Stability, Re-emulsifiability Concentration: 0.3 % CIPAC Water A Temp: 30 ºC	CIPAC MT 36.3		
Spontaneity of emulsion		Spontaneous	Spontaneous
Emulsion stability after: 0.5 h		<1 ml cream at the bottom, no oil	<1 ml cream at the bottom, no oil
2 h		1 ml cream at the bottom, no oil	<1 ml cream at the bottom, no oil
24 h		1 ml cream at the bottom, no oil	<1 ml cream at the bottom, no oil
Re-emulsification		Complete	Complete
Emulsion stability 0.5 h after re-emulsification		<1 ml cream at the bottom, no oil	<1 ml cream at the bottom, no oil

Test Description	Method	Initial Results	Results after 2 years at 20 °C
Emulsifiability, Emulsion, Stability, Re-emulsifiability Concentration: 0.3 % CIPAC Water D Temp: 30 ºC	CIPAC MT 36.3		
Spontaneity of emulsion		Spontaneous	Spontaneous
Emulsion stability after: 0.5 h		<1 ml cream at the bottom, no oil	<1 ml cream at the bottom, no oil
2 h		<1 ml cream at the bottom, no oil	<1 ml cream at the bottom, no oil
24 h		<1 ml cream at the bottom, no oil	<1 ml cream at the bottom, no oil
Re-emulsification		Complete	Complete
Emulsion stability 0.5 h after re-emulsification		<1 ml cream at the bottom, no oil	<1 ml cream at the bottom, no oil

Packaging Evaluation after storage

Evaluation Criteria	Results after 2 years at 20 °C
Color change of the packaging	None
Odor (noticeable before opening the packaging)	None
Panelling of the test container	None
Ballooning of the test container	None
Pimples on the test container	None
Cracks in the test container	No one
Tightness of the test container	Tight
Reclosability of closure	Reclosable
Tightness of closure	Tight
Weight change (gross weight)	0.03 % weight gain
Permeation through the container walls	None

IIIA 2.16 Summary and Evaluation of Data Presented Under Points 2.1 to 2.15

The product A19786A is an emulsifiable concentrate. All studies have been performed in accordance with the current requirements, the critical GAP and the results are deemed to be acceptable. The appearance of the product is that of light brown liquid, with a weak odour. It is not explosive, has no oxidising properties. It has a self-ignition temperature of 415°C. In aqueous solution, it has a pH value around 4.2. The stability data indicate a shelf life of at least two years at ambient temperature.

The technical characteristics of A19786A are acceptable for an emulsifiable concentrate formulation.

Experimental testing of the product's physico-chemical and technical characteristics:

See Appendix 3

Implications for labelling:

No labelling necessary due to physical or chemical properties described above.

IIIA 3 DATA ON APPLICATION OF THE PLANT PROTECTION PRODUCT

IIIA 3.1 Field of Use

A19786A is an emulsifiable concentrate (EC) containing 33.3 g/L pinoxaden, 8.33 g/L pyroxsulam and 8.33 g/L of the herbicide safener cloquintocet-mexyl for use in winter wheat, winter rye and winter triticale for the control of annual grass and broadleaf weeds in spring.

IIIA 3.2 Nature of the Effects on Harmful Organisms

Pinoxaden is a representative of the phenylpyrazolin class of chemistry. Pinoxaden is a post emergent herbicide and is taken up by the leaves, almost exclusively. The active ingredient is rapidly degraded in soil and poorly taken up by the roots, thus providing very little soil activity. After foliar absorption, pinoxaden is translocated to the meristematic tissue, where it exerts its action on the lipid synthesis in dividing cells. The mode of action is the inhibition of the enzyme Acetyl Co-A Carboxylase (ACCase), a key enzyme in fatty acid biosynthesis. Pinoxaden inhibits both the chloroplastic and cytosolic ACCase enzyme in monocotyledonous weeds. ACCase activity in dicotyledonous species is stated as not affected. Crop tolerance within monocotyledonous species is based on different metabolic kinetics. Tolerant crops like wheat, triticale and rye can metabolize the herbicide faster than susceptible monocotyledonous weeds. This tolerance however, is typically insufficient to provide an agronomically adequate margin of crop safety. Co-application of the safener (cloquintocet-mexyl) induces metabolic enzymes specifically in the crop species resulting in degradation of the herbicide to non-phytotoxic compounds before damage can occur to the crop. The safener does not affect metabolism in monocotyledonous weeds. Site of action (HRAC-group): A

Pyroxsulam belongs to the chemical group of triazolopyrimidines. Activity is primarily foliar/systemic, although some residuality is a feature of pyroxsulam and some other ALS inhibitor herbicides. Pyroxsulam is taken up by roots or by foliage and redistributes throughout the plant. Pyroxsulam is a systemic, phloem and xylem mobile herbicide. The compound is translocated in plants to meristematic tissue. Pyroxsulam inhibits amino-lactate synthase (ALS-inhibitor), there-by blocking the formation of branch chain amino acids in plants. Pyroxsulam affects the formation of protein and the plants die. Symptoms include stunting and chlorosis, followed by necrosis and then plant death. Selectivity in wheat, rye and triticale is achieved through detoxification via cytochrome P450 mono-oxygenases, a process which is accelerated by the addition of a herbicide safener acting on the cytochrome complex; for example, cloquintocet mexyl. Site of action (HRAC-group): B

Label WMB is assigned to the product.

Cloquintocet-mexyl is a safener. Cloquintocet-mexyl is used as a safener in conjunction with the herbicide for post-emergence use. It acts as an agonist of cytochrome P450 and accelerates the detoxification in responsive plants (e.g. cereals, rice, maize) of all compounds that are metabolically vulnerable to cytochrome P450s. Site of action (HRAC-group): no classification

IIIA 3.3 Details of Intended Use

IIIA 3.3.1 Details of existing and intended uses

Please refer to Appendix 2 - Critical Uses - and Part B Section 7.

IIIA 3.3.2 Details of harmful organisms against which protection is afforded

Please refer to Appendix 2 - Critical Uses - and Part B Section 7.

IIIA 3.3.3 Effects achieved

Please refer to Part B Section 7.

IIIA 3.4 Proposed Application Rates (Active Substance and Preparation)

Please refer to Appendix 2 - Critical Uses - and Part B Section 7.

IIIA 3.5 Concentration of the Active Substance in the Material Used

Please refer to Appendix 2 - Critical Uses - and Part B Section 7.

IIIA 3.6 Method of Application, Type of Equipment Used and Volume of Diluent

Please refer to Appendix 2 - Critical Uses - and Part B Section 7.

IIIA 3.7 Number and Timings of Applications, Timing, Growth Stages (of Crop and Harmful Organism) and Duration of Protection

IIIA 3.7.1 Maximum number of applications and their timings

Please refer to Appendix 2 - Critical Uses - and Part B Section 7.

IIIA 3.7.2 Growth stages of crops or plants to be protected

Please refer to Appendix 2 - Critical Uses - and Part B Section 7.

IIIA 3.7.3 Development stages of the harmful organism concerned

Please refer to Appendix 2 - Critical Uses - and Part B Section 7.

IIIA 3.7.4 Duration of protection afforded by each application

Please refer to Part B Section 7.

IIIA 3.7.5 Duration of protection afforded by the maximum number of applications

Please refer to Part B Section 7.

IIIA 3.8 Necessary Waiting Periods or Other Precautions to Avoid Phytotoxic Effects on Succeeding Crops

IIIA 3.8.1 Minimum waiting periods or other precautions between last application and sowing or planting succeeding crops

Please refer to Part B Section 7.

IIIA 3.8.2 Limitations on choice of succeeding crops

Please refer to Part B Section 7.

IIIA 3.8.3 Description of damage to rotational crops

Please refer to Part B Section 7.

IIIA 3.9 Proposed Instructions for Use as Printed on Labels

Please refer to Registration Report – Part A, Appendix 2 for the relevant country.

IIIA 3.10 Other/Special Studies

This is not an EC data requirement/ not required by Directive 91/414/EEC.

IIIA 4 FURTHER INFORMATION ON THE PLANT PROTECTION PRODUCT

IIIA 4.1 Packaging and Compatibility with the Preparation

Packaging Summary

Information with regard to type, dimensions, capacity, size of opening, type of closure, strength, leakproofness, resistance to normal transport & handling, resistance to & compatibility with the contents of the packaging, have been submitted, evaluated and is considered to be acceptable.

IIIA 4.1.1 Description and specification of the packaging

Packaging proposed for A19786A is 1, 5, 10 and 20 L HDPE cannnisters.

1 litre bottle:	material:	HDPE
	shape/size:	cylindrical / approx. 89 mm diameter x 230 mm
	opening:	45 mm inner diameter
	closure:	Screw thread cap
	seal:	Induction heat seal or compression wad and tamper evident ring.
5 litre bottle:	material:	HDPE or f-HDPE
	Length x Width x Height	190 mm x 135 mm x 315 mm
	opening:	63 mm inner diameter
	closure:	Screw thread cap
	seal:	Induction heat seal or compression wad and tamper evident ring.
10 litre bottle:	material:	HDPE or f-HDPE
	Length x Width x Height	240 mm x 180 mm x 375 mm
	opening:	63 mm inner diameter
	closure:	Screw thread cap
	seal:	Induction heat seal or compression wad and tamper evident ring.
20 litre bottle:	material:	HDPE or f-HDPE
	Length x Width x Height	295 mm x 245 mm x 400 mm

opening: DIN 60

closure: Screw thread cap

seal: Induction heat seal or compression wad and tamper evident ring.

IIIA 4.1.2 Suitability of the packaging and closures

The packaging for formulation complies with all current UN and ADR requirements for use with this product.

IIIA 4.1.3 Resistance of the packaging material to its contents

Report:	Fumeaux, J., 2013b
Title:	A19786A Storage Stability and Shelf Life Statement (2 weeks 54 ºC) in Packaging made of HDPE;
Document No:	Syngenta File No. A19786A_10045
Guidelines:	Regulation (EU) No 545/2011.Annex III 2.7.1, EEC 94/37, Manual on Development and Use of FAO Specifications for Plant Protection Products (Jan. 1999)
GLP	No

Package: HDPE

Weight loss after 24 month: 0.02 %.

Report:	Fumeaux, J., 2013c
Title:	A19786A Storage Stability and Shelf Life Statement (2 weeks 54 ºC) in Packaging made of f-HDPE
Document No:	Syngenta File No. A19786A_10044
Guidelines:	Regulation (EU) No 545/2011.Annex III 2.7.1, EEC 94/37, Manual on Development and Use of FAO Specifications for Plant Protection Products (Jan. 1999)
GLP	No

Package: HDPE fluorinated

Weight loss after 24 month: 0.01 %.

As part of the storage stability study, packs were examined to ensure that no significant interaction with the formulation, affecting the stability of the packaging material, had taken place during storage. The studies have been carried out according to CIPAC MT 46.3.

It can therefore be concluded that the packaging will be resistant to its contents for up to 2 years under normal storage conditions.

IIIA 4.2 Procedures for Cleaning Application Equipment

IIIA 4.2.1 Procedures for cleaning application equipment and protective clothing

Cleaning procedures for application equipment

Immediately after use, clean the spray equipment thoroughly. Drain the system completely and rinse spray tank, boom and nozzles two to three times with clean water until the foam and all traces of product have been removed.

Cleaning procedures for protective clothing

Rinsing with water and detergent.

IIIA 4.2.2 Effectiveness of the cleaning procedures

A study on the effectiveness of cleaning procedures performed on A19786A, was not assessed in the EU review of pinoxaden or pyroxsulam

Report:	Fumeaux, J., 2013d
Title:	A19786A The Effectiveness of the Tank Cleaning Procedure
Document No:	Syngenta File No. A19786A_10038
Guidelines:	<none>
GLP	No, not subject to GLP regulations

Tests have been carried out to determine the effectiveness of the tank cleaning procedure for A19786A pinoxaden/pyroxsulam EC (33.3/8.33). After applying the cleaning procedure, 0.01 % residue was found in the refilled spray tank and therefore the cleaning procedure is effective.

IIIA 4.3 Re-entry Periods to Protect Man, Livestock and the Environment

IIIA 4.3.1 Pre-harvest interval (in days) for each relevant crop

See section 4.

IIIA 4.3.2 Re-entry period (in days) for livestock, to areas to be grazed

See section 4.

IIIA 4.3.3 Re-entry period (in hours or days) for man to crops, buildings or spaces treated

See section 4.

IIIA 4.3.4 Withholding period (in days) for animal feeding stuffs

See section 4.

IIIA 4.3.5 Waiting period (in days) between application and handling of treated products

See section 4.

IIIA 4.3.6 Waiting period (in days) between last application and sowing or planting succeeding crops

See section 4.

IIIA 4.3.7 Information on specific conditions under which the preparation may or may not be used

See section 4.

IIIA 4.4 Statement of the Risks Arising and the Recommended Methods and Precautions and Handling Procedures to Minimise Those Risks

The safety data sheet complies with actual EEC regulations and is based on the present state of knowledge.

IIIA 4.4.1 Warehouse storage

Requirements for storage areas and containers:

No special storage conditions required.

Keep containers tightly closed in a dry, cool and well-ventilated place.

Keep out of the reach of children.

Keep away from food, drink and animal feeding stuffs.

Advice on safe handling:

No special protective measures against fire required.

Avoid contact with skin and eyes.

When using, do not eat, drink or smoke.

For personal protection refer to Annex Point IIIA 4.4.5.

IIIA 4.4.2 User level storage

Refer to Annex Point IIIA 4.4.1.

IIIA 4.4.3 Transport

Land transport

ADR/ RID:

UN-Number:	3082
Class:	9
Labels:	9
Packaging group	III
Proper shipping name :	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (PYROXSULAM)

Sea transport

IMDG:

UN-Number:	3082
Class:	9
Labels:	9
Packaging group:	III
Proper shipping name :	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (PYROXSULAM)
Marine pollutant :	Marine pollutant

Air transport

IATA-DGR

UN-Number:	3082
Class:	9
Labels:	9
Packaging group:	III
Proper shipping name :	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (PYROXSULAM)

IIIA 4.4.4 Fire

Suitable extinguishing media:

Extinguishing media - small fires: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Extinguishing media - large fires: Use alcohol-resistant foam or water spray.

Extinguishing media which shall not be used for safety reasons:

Do not use a solid water stream as it may scatter and spread fire.

Specific hazards during fire fighting:

As the product contains combustible organic components, fire will produce dense black smoke containing hazardous products of combustion. Exposure to decomposition products may be a hazard to health.

Special protective equipment for firefighters:

Wear full protective clothing and self-contained breathing apparatus.

Further information:

Do not allow run-off from fire fighting to enter drains or water courses. Cool closed containers exposed to fire with water spray.

IIIA 4.4.5 Nature of protective clothing proposed

Components with workplace control parameters

Components	Exposure limit(s)	Value type	Source
Pinoxaden	0.1 mg/m^3	Ceiling limit value	SYNGENTA
Pyroxsulam	5 mg/m^3	Time weighted average	SYNGENTA
Cloquintocet-mexyl	10 mg/m^3	8 h TWA	SYNGENTA

ENGINEERING MEASURES:

Containment and/or segregation is the most reliable technical protection measure if exposure cannot be eliminated. The extent of these protection measures depends on the actual risks in use. If airborne mists or vapours are generated, use local exhaust ventilation controls. Assess exposure and use any additional measures to keep airborne levels below any relevant exposure limit.

Where necessary, seek additional occupational hygiene advice.

PERSONAL PROTECTIVE EQUIPMENT

Protective measures:

The use of technical measures should always have priority over the use of personal protective equipment. When selecting personal protective equipment, seek appropriate professional advice. Personal protective equipment should be certified to appropriate standards.

Respiratory protection:

No personal respiratory protective equipment normally required. A particulate filter respirator may be necessary until effective technical measures are installed.

Hand protection:

Chemical resistant gloves should be used. Gloves should be certified to an appropriate standard. Gloves should have a minimum breakthrough time that is appropriate to the duration of exposure. The breakthrough time of gloves varies according to the thickness, material and manufacturer. Gloves should be discarded and replaced if there is any indication of degradation or chemical breakthrough.

Suitable material - Nitrile rubber.

Eye protection:

If eye contact is possible, use tight-fitting chemical safety goggles.

Skin and body protection:

Assess the exposure and select chemical resistant clothing based on the potential for contact and the permeation / penetration characteristics of the clothing material. Wash with soap and water after removing protective clothing. Decontaminate clothing before re-use, or use disposable equipment (suits, aprons, sleeves, boots, etc.) Wear as appropriate:impervious protective suit

IIIA 4.4.6 Characteristics of protective clothing proposed

Refer to Annex Point IIIA 4.4.5

IIIA 4.4.7 Suitability and effectiveness of protective clothing and equipment

Refer to Annex Point IIIA 4.4.5

IIIA 4.4.8 Procedures to minimise the generation of waste

Product:

Do not contaminate ponds, waterways or ditches with chemical or used container. Do not dispose of waste into sewer. Where possible recycling is preferred to disposal or incineration. If recycling is not practicable, dispose of in compliance with local regulations.

Only purchase and store quantities of product required in the short term. Do not open larger containers than is necessary for immediate requirements. Do not a mix a volume of spray solution greater than is required for immediate use.

Where possible recycling is preferred to disposal or incineration. It must undergo special treatment, e.g. at suitable disposal site, to comply with local regulations.

Contaminated packaging:

Empty remaining contents. Triple rinse containers. Empty containers should be taken to an approved waste handling site for recycling or disposal. Do not re-use empty containers.

IIIA 4.4.9 Combustion products likely to be generated in the event of fire

Hazardous decomposition products:

Combustion or thermal decomposition will evolve toxic and irritant vapours.

Hazardous reactions:

None known. Hazardous polymerization does not occur. Stable under normal conditions.

IIIA 4.5 Detailed Procedures for Use in the Event of an Accident During Transport, Storage or Use

IIIA 4.5.1 Containment of spillages

Personal precautions:

Refer to protective measures listed in Annex Point IIIA 4.4.5.

Environmental precautions:

Prevent further leakage or spillage if safe to do so. Do not flush into surface water or sanitary sewer system.

Methods for cleaning up:

Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations.

Additional advice:

If the product contaminates rivers and lakes or drains inform respective authorities.

IIIA 4.5.2 Decontamination of areas, vehicles and buildings

Refer to Annex Point IIIA 4.5.1.

IIIA 4.5.3 Disposal of damaged packaging, adsorbents and other materials

Refer to Annex Point IIIA 4.5.1.

IIIA 4.5.4 Protection of emergency workers and bystanders

Refer to Annex Point IIIA 4.4.5.

IIIA 4.5.5 First aid measures

General advice:

Have the product container, label or Material Safety Data Sheet with you when calling the Syngenta emergency number, a poison control centre or physician, or going for treatment.

Inhalation:

Immediately move to fresh air. If breathing is irregular or stopped, administer artificial respiration. Keep patient warm and at rest. Call a physician or Poison Control Centre immediately.

Skin contact:

Take off all contaminated clothing immediately. Wash off immediately with plenty of water. If skin irritation persists, call a physician. Wash contaminated clothing before re-use.

Eye contact:

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses. Immediate medical attention is required.

Ingestion:

If swallowed, seek medical advice immediately and show this container or label. Do NOT induce vomiting.

Medical advice:

There is no specific antidote available. Treat symptomatically.

IIIA 4.6 Neutralisation Procedure for Use in the Event of Accidental Spillage

IIIA 4.6.1 Details of proposed procedures for small quantities

In the event of accidental spillage, neutralisation (with acid or base to neutral pH) is not an effective procedure for the destruction or decontamination of the formulation.

Therefore, the spilled liquid formulation should first be adsorbed onto a solid, such as sand, inert clay filler, saw dust or soil, before being swept up into a safe container to await disposal.

Also see Annex Point IIIA 4.5.1.

IIIA 4.6.2 Evaluation of products of neutralization (small quantities)

Refer to Annex Point IIIA 4.6.1

IIIA 4.6.3 Procedures for disposal of small quantities of neutralized waste

Refer to Annex Point IIIA 4.6.1

IIIA 4.6.4 Details of proposed procedures for large quantities

Refer to Annex Point IIIA 4.6.1

IIIA 4.6.5 Evaluation of products of neutralization (large quantities)

Refer to Annex Point IIIA 4.6.1

IIIA 4.6.6 Procedures for disposal of large quantities of neutralized waste

Refer to Annex Point IIIA 4.6.1

IIIA 4.7 Pyrolytic Behaviour of the Active Substance

The halogen content of pinoxaden and pyroxsulam, the active substance(s) in the A19786A formulation, is below the 60% limit, therefore this information is not required. It should be noted that Directive 96/47/EEC defines the controlled conditions for incineration.

IIIA 4.8 Disposal Procedures for the Plant Protection Product

IIIA 4.8.1 Detailed instructions for safe disposal of product and its packaging

As the halogen content of A19786A is below the trigger value (refer to Annex Point IIIA 4.7), high temperature incineration is the preferred means of disposal for the active substances, formulated products, contaminated materials or contaminated packaging. Incineration should be carried out in a licensed incinerator operating at a temperature above 800 °C and with a minimum gas phase residence time of 2 seconds.

Unused undiluted product and contaminated un-rinsed packaging should be treated as hazardous waste, and should be disposed of by controlled incineration or according to local regulations. Where large quantities of unused product are concerned, consult the supplier.

IIIA 4.8.2 Methods other than controlled incineration for disposal

No other methods for disposal of A19786A than those described in chapter 4.8.1 are available.

IIIA 4.9 Other/Special Studies

No additional studies were performed.

IIIA 11 FURTHER INFORMATION

IIIA 11.1 Information of Authorisations in Other Countries

see EU pesticide data base (http://ec.europa.eu/sanco_pesticides/public/)

IIIA 11.2 Information on Established Maximum Residue Limits (MRL) in Other Countries

MRLs are set at European level, see Regulation (EC) No. 396/2005.

IIIA 11.3 Justified Proposals for Classification and Labelling

The following is proposed in accordance with Regulation (EC) No. 1272/2008 as amended, and Commission Regulation (EU) No. 547/2011.

Physico-chemical properties

Table 11.3-1 Physico-chemical properties

Study Type	Findings (triggered risk phrase)	Reference
Explosivity	Not explosive (-)	Jackson, W. A., 2013, A19786A_10042
Oxidizing properties	Not oxidizing (-)	Jackson, W. A., 2013, A19786A_10042
Flammability	Auto-ignition temperature is 415 °C	Jackson, W. A., 2013, A19786A_10042
Content of hydrocarbon	< 10 % (w/w)	
Viscosity (dynamic)	25.5 mPas (shear rate range = 250 – 170 s^{-1} at 20°C) 11.5 mPas (shear rate range = 250 – 170 s^{-1} at 40°C)	Fumeaux, J., 2013a, A19786A_10040

Toxicology

see section 3.

Ecotoxicology/Environment

see section 6.

IIIA 11.4 Proposals for Risk and Safety Phrases

Please refer to Registration Report – Part A.

IIIA 11.5 Proposed Label

Please refer to Registration Report – Part A.

IIIA 11.6 Specimens of Proposed Packaging

Specimens of the packaging were not provided as there was no request.

Appendix 1: List of data used in support of the evaluation

Annex point/ reference No	Author(s)	Year	Title Source (where different from company) Report-No. GLP or GEP status (where relevant)	Data protection claimed	Owner	How considered in dRR Study-Status / Usage*
KIIIA 1.7	de la Fuente, K.	2003	NOA407855 - EU - Document I - Part 1 - Identity, physical and chemical properties, further information and proposed classification ERA7143 Syngenta File No NOA407855/0468 Syngenta Crop Protection AG, Basel, Switzerland Not GLP not published	N	SYN	1
KIIIA 2 KIIIA 2.6.1	De Benedictis, S.	2013	A19786A - Chemical characterization of batch SMU3AP001 Report No. 10528734 Syngenta File No A19786A_10039 Syngenta GLP not published	N	SYN	1
KIIIA 2.1 KIIIA 2.4.2 KIIIA 2.7.4 KIIIA 2.8.2 KIIIA 2.8.7.1 KIIIA 2.8.7.2 KIIIA 2.8.7.3 KIIIA 2.8.7.4	Fumeaux, J.	2013	A19786A - Technical properties of batch SMU3AP001 Report No. 10539387 Syngenta File No A19786A_10041 Syngenta Not GLP not published	N	SYN	1
KIIIA 2.2.1 KIIIA 2.2.2 KIIIA 2.3.1 KIIIA 2.3.3	Jackson, W.	2013	A19786A - Safety study Report No. 10535694 Syngenta File No A19786A_10042 Syngenta GLP not published	N	SYN	1

Annex point/ reference No	Author(s)	Year	Title Source (where different from company) Report-No. GLP or GEP status (where relevant)	Data protection claimed	Owner	How considered in dRR Study-Status / Usage*
KIIIA 2.4.1 KIIIA 2.4.2 KIIIA 2.5.2 KIIIA 2.5.3	Fumeaux J.	2013a	A19786A - Physical properties of batch SMU3AP001 Report No. 10538576 Syngenta File No A19786A_10040 Syngenta GLP not published	N	SYN	1
KIIIA 2.7.1 KIIIA 4.1.3	Fumeaux J.	2013b	A19786A - Storage stability and shelf life statement (2 weeks 54 °C) in packaging made of HDPE according to CIPAC MT 46.3 Report No. 10539476 Syngenta File No A19786A_10045 Syngenta Not GLP not published	N	SYN	1
KIIIA 2.7.1 KIIIA 4.1.3	Fumeaux J.	2013c	A19786A - Storage stability and shelf life statement (2 weeks 54 °C) in packaging made of fluorinated HDPE according to CIPAC MT 46.3 Report No. 10539482 Syngenta File No A19786A_10044 Syngenta Not GLP not published	N	SYN	1
KIIIA1 2.7.5	Wochner, F.	2015	A19786A - Storage Stability and Shelf Life Statement (2 Years 20 °C) in Packaging Made of Fluorinated HDPE	J	SYN	1
KIIIA1 2.7.5	Wochner, F.	2015	A19786A - Storage Stability and Shelf Life Statement (2 Years 20 °C) in Packaging Made of HDPE	J	SYN	1

Annex point/ reference No	Author(s)	Year	Title Source (where different from company) Report-No. GLP or GEP status (where relevant)	Data protection claimed	Owner	How considered in dRR Study-Status / Usage*
KIIIA 4.4	Anonymous	2013	Safety data sheet A19786A Syngenta File N° A19786A_10071 Not GLP not published	N	SYN	1

* 1 accepted (study valid and considered for evaluation)
2 not accepted (study not valid and not considered for evaluation)
3 not considered (study not relevant for evaluation)
4 not submitted but necessary (study not submitted by applicant but necessary for evaluation)
5 supplemental (additional information, alone not sufficient to fulfil a data requirement, considered for evaluation)

Appendix 2: Critical Uses – Justification and GAP tables

Please refer to Part B Section 7.

Appendix 3: Experimental testing of the product's physico-chemical and technical characteristics:

The following physical, chemical and technical properties of the plant protection product were experimentally tested:
density, colour, pH, surface tension, storage stability at high temperatures (14 d at 54 °C), low temperature stability (7 d at 0 °C), persistent foaming and emulsion properties.
No significant deviations from the data submitted by the applicant were detected.
The formulation complies with the chemical, physical and technical criteria which are stated for this type of formulation in the FAO/WHO manual (2016).

REGISTRATION REPORT
Part B

Section 2: Analytical Methods
Detailed summary of the risk assessment

Product name:	**AVOXA**
Product code:	**A19786A**
Active Substance:	**Pinoxaden 33.3 g/L**
	Pyroxsulam 8.33 g/L
Safener:	**Cloquintocet-mexyl 8.33 g/L**

Central Zone
Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant:	**Syngenta**
Submission Date:	**28/03/2014**
Date:	**23/02/2018**

Table of Contents

IIIA 5 METHODS OF ANALYSIS

This document summarises the information related to the analytical methods for the product A19786A containing the active substances pinoxaden and pyroxsulam which were approved according to Regulation (EC) No 1107/2009. Cloquintocet-mexyl is a safener which is not yet reviewed according to Article 26 of Regulation (EC) No 1107/2009.

This product was not the representative formulation. The product has not been previously evaluated according to Uniform Principles.

Appendix 1 of this document contains the list of references included in this document for support of the evaluation.

Information on the detailed composition of A19786A can be found in the confidential dossier of this submission (Registration Report - Part C).

IIIA 5.1 Analytical Standards and Samples

IIIA 5.1.1 Samples of the preparation

A sample of the preparation was provided by the applicant but no analysis of the contents of the active substances was performed.

IIIA 5.1.2 Analytical standards for the pure active substance

Analytical standards were not provided because there was no request.

IIIA 5.1.3 Samples of the active substance as manufactured

No samples were provided because there was no request.

IIIA 5.1.4 Analytical standards for relevant metabolites and all other components included in the residue definition

No samples were provided because there was no request.

IIIA 5.1.5 Samples of reference substances for relevant impurities

No samples were provided because there was no request.

IIIA 5.2 Methods for the Analysis of the Plant Protection Product

Analytical methods for determination of pinoxaden and pyroxsulam, impurities and relevance of CIPAC methods in A19786A have not been evaluated as part of an EU review. Therefore all relevant data are provided and are considered adequate.

IIIA 5.2.1 Description of the analytical methods for the determination of the active substance in the plant protection product

Please refer to chapter 5.2.2 as A19786A contains two active substances.

IIIA 5.2.2 For preparations containing more than one active substance, description of method for determining each in the presence of the other

An analytical method has been developed for the determination of the active substances pinoxaden and pyroxsulam and the safener cloquintocet-mexyl in A19786A.

Report:	5.2.2/01, De Benedictis S. (2013)
Title:	SF-609/1 Determination of Pinoxaden/Pyroxsulam in Formulation EC (33.3/8.33)
Document No:	Syngenta File No., A19786A_10069
Guidelines:	None
GLP	No

Full validation of SF-609/1 has been conducted.

Report:	5.2.2/02, De Benedictis S. (2013a)
Title:	A19786A – Validation of analytical method SF-609/1
Document No:	Syngenta File No., A19786A_10070
Guidelines:	SANCO/3030/99 rev. 4
GLP	Yes

Method description

Section 3.1 – HPLC-method
The analytes are determined by liquid chromatography (HPLC) on a Poroshell120 SB-C18 column (100 x 4.6 mm, dp = 2.7 µm) at 40 °C, using external calibration. Injection volume is 5 µl. The separation is achieved by using gradient flow (1 ml/min). Detection is performed with a UV detector at 255 nm. The mobile phase consists of 0.5 % aqueous trifluoroacetic acid / 0.5 % trifluoroacetic acid in acetonitrile (gradient). The analytes are quantified by comparing the specific response ratios of the samples with those of standards of known quality.

Section 4.1 – UHPLC-method
The analytes are determined by liquid chromatography (UHPLC) on a Zorbax SB-C18 column (50 x 2.1 mm, dp = 1.8 µm) at 50 °C, using external calibration. Injection volume is 1 µl. The separation is achieved by using gradient flow conditions (1 ml/min). Detection is performed with a UV detector at 255 nm. The mobile phase consists of 0.5 % aqueous trifluoroacetic acid / 0.5 % trifluoroacetic acid in acetonitrile / methanol (gradient). The analytes are quantified by comparing the specific response ratios of the samples with those of standards of known quality.

Method validation
It was with respect to precision, accuracy, linearity and specificity proved that the method is suitable for the determination of pinoxaden and pyroxsulam in the EC formulation.

Table containing the methods and validation of the HPLC method (SF-609/1 Section 3.1)

Analyte	Linearity n = 6	Accuracy n = 2	Repeatability n = 6	Specificity/Interferences

		Mean [%]	[%RSD]	
Pinoxaden	50 – 150 % of the nominal amounts 94.4 – 283.1 µg/mL r = 0.9999	100.2-101.5 (at 70, 90, 110 and 130 % fortification)	0.63 (mean content 3.16 %) RSDr = 2.25 %	No interferences were noted. Chromatograms of formulation with and without active substances present were submitted.
Pyroxsulam	50 – 150 % of the nominal amounts 24.2 –72.5 µg/mL r = 0.9999	98.1-99.7 (at 70, 90, 110 and 130 % fortification)	0.51 (mean content 0.78 %) RSDr = 2.78 %	No interferences were noted. Chromatograms of formulation with and without active substances present were submitted.
Cloquintocet-mexyl	50 – 150 % of the nominal amounts 23.9 – 71.6 µg/mL r = 0.9999	98.2-99.4 (at 70, 90, 110 and 130 % fortification)	0.99 (mean content 0.81 %) RSDr = 2.77 %	No interferences were noted. Chromatograms of formulation with and without active substances present were submitted.

Table containing the methods and validation of the method UHPLC method (SF-609/1 Section 4.1)

Analyte	Linearity n = 6	Accuracy n = 4 Mean [%]	Repeatability n = 6 [% RSD]	Specificity/Interferences
Pinoxaden	50 – 150 % of the nominal amounts 189.5 – 568.4 µg/mL r = 0.9997	100.5-101.3 (at 70, 90, 110 and 130 % fortification)	0.26 (mean content 3.08 %) RSDr = 2.26 %	No interferences were noted. Chromatograms of formulation with and without active substances present were submitted.
Pyroxsulam	50 – 150 % of the nominal amounts 47.9 – 143.7 µg/mL r = 0.9997	96.5-98.6 (at 70, 90, 110 and 130 % fortification)	0.51 (mean content 0.78 %) RSDr = 2.78 %	No interferences were noted. Chromatograms of formulation with and without active substances present were submitted.
Cloquintocet-mexyl	50 – 150 % of the nominal amounts 47.4 – 142.2 µg/mL r = 0.9996	98.1-101.7 (at 70, 90, 110 and 130 % fortification)	0.61 (mean content 0.82 %) RSDr = 2.76 %	No interferences were noted. Chromatograms of formulation with and without active substances present were submitted.

Summary

The active substances pinoxaden and pyroxsulam and the safener cloquintocet-mexyl can be determined in the formulation A19786A by HPLC or UHPLC. The method(s) are sufficiently validated according to SANCO/3030/99 rev. 4.

IIIA 5.2.3 Applicability of existing CIPAC methods

There is no CIPAC method available for the determination of pinoxaden, pyroxsulam or cloquintocet-mexyl in single or mixed formulations.

IIIA 5.2.4 Description of analytical methods for the determination of relevant impurities

According to Regulation (EU) No 2016/340 a maximum content of 1 g/kg was set for pinoxaden technical. A validated analytical method to determine toluene in the formulation or the demonstration of the applicability of CIPAC method MT 198 is missing.

IIIA 5.2.5 Description of analytical methods for the determination of formulants

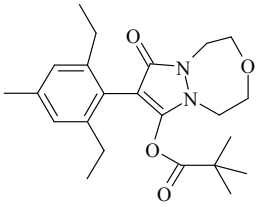
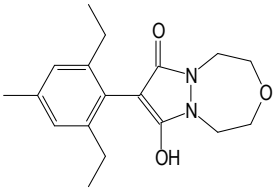
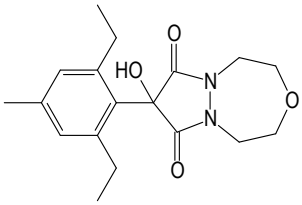
No formulants with toxicological or ecotoxicological relevant compounds are present in the formulation. Therefore, no analytical methods for the determination of formulants are necessary.

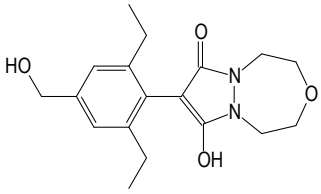
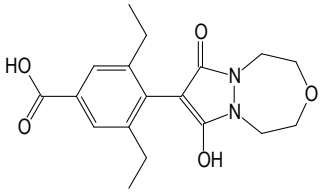
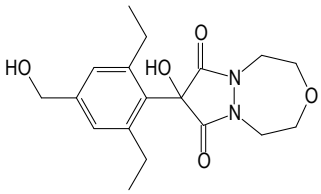
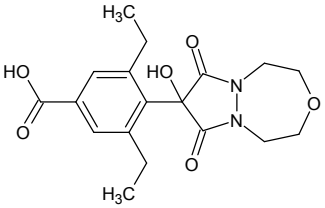
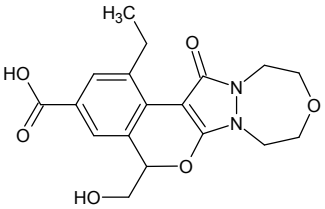
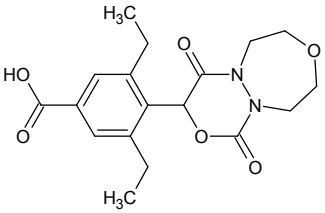
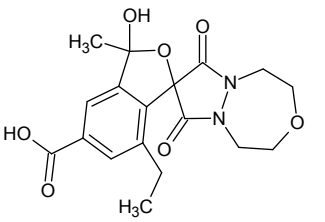
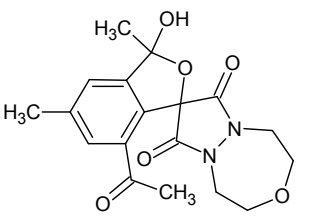
IIIA 5.3 Description of Analytical Methods for the Determination of Residues

IIIA 5.3.1 Evaluation of Pinoxaden

The conclusion regarding the peer review of the analytical methods for residues of pinoxaden are summarized in SANCO/11794/2013 rev 3 (29 January 2016) and in the EFSA Conclusion (EFSA Journal 2013;11(8):3269; ASB2013-10732)

Table 5.3-1: Information on the active substance pinoxaden

Name of component of residue definition **Substance code** **IUPAC name** **Formula** **Molecular weight**	**Structural formula**
Pinoxaden NOA 407855 8-(2,6-diethyl-*p*-tolyl)-1,2,4,5-tetrahydro-7-oxo-7*H*-pyrazolo[1,2-*d*][1,4,5]oxadiazepin-9-yl 2,2-dimethylpropionate $C_{23}H_{32}N_2O_4$ 400.5 g/mol	
NOA 407854, M2 -(2,6-Diethyl-4-methyl-phenyl)-tetrahydro-pyrazolo[1,2,-d][1,4,5]oxadiazepin-7-9-dion $C_{18}H_{24}N_2O_3$ 316.4 g/mol	
NOA 447204, M3 8-(2,6-diethyl-4-methyl-phenyl)-8-hydroxy-tetrahydro-pyrazolo[1,2,-d][1,4,5]oxadiazepi-7,9-dione $C_{18}H_{24}N_2O_4$ 332.4 g/mol	

SYN 505164, M4 8-(2,6-Diethyl-4-hydroxymethyl-phenyl)-9-hydroxy-1,2,4,5-tetrahydro-pyrazolo[1,2-d][1,4,5]oxadiazepin-7-one $C_{18}H_{24}N_2O4$ 332.4 g/mol	
SYN 502836, M6 3,5-diethyl-4-(9-hydroxy-7-oxo-1,2,4,5-tetrahydro-7H-pyrazolo[1,2-d][1,4,5]oxadiazepin-8-yl)-benzoic acid $C_{18}H_{22}N_2O_5$ 346.4 g/mol	
SYN 505887, M10 8-(2,6-diethyl-4-hydroxymethyl-phenyl)-8-hydroxy-tetrahydro-pyrazolo[1,2-d][1,2,5]oxodiazepine-7,9-dione $C_{18}H_{24}N_2O_5$ 348.4 g/mol	
SYN 504574, M11 3,5-diethyl-4-(8-hydroxy-7,9-dioxo-hexahydro-pyrazolo[1,2-d][1,4,5]oxadiazepin-8-yl)-benzoic acid $C_{18}H_{22}N_2O_6$ 362.4 g mol^{-1}	
SYN 546105, M52 1-Ethyl-5-hydroxymethyl-12-oxo-7,8,10,11-tetrahydro-5H,12H-6,9-dioxa-6b,11a-diaza-naphtho[2,1-a]azulene-3-carboxylic acid $C_{18}H_{20}N_2O_6$ 360.3 g mol^{-1}	
SYN 546106, M54 4-(1,4-Dioxo-hexahydro-2,7-dioxa-4a,9a-diaza-benzocyclohepten-3-yl)-3,5-diethyl-benzoic acid $C_{18}H_{22}N_2O_6$ 362.4 g mol^{-1}	
SYN 546107, M55 7-ethyl-3-hydroxy-3-methyl-3H-spiro[2-benzofuran-1,8'-pyrazolo[1,2-d][1,4,5]oxadiazepine]-7',9'-dione-5-carboxylic acid $C_{18}H_{20}N_2O_7$ 376.4 g mol^{-1}	
SYN 546108, M56 7-methylcarboxy-5-methyl-3-hydroxy-3-methyl-3H-spiro[2-benzuofuran-1,8'-pyrazolo[1,2-d][1,4,5]oxadiazepine]-7',9'-dione $C_{18}H_{20}N_2O_6$ 360.4 g mol^{-1}	

IIIA 5.3.1.1 Overview of residue definitions and levels for which compliance is required

The current legal residue definition for food of plant is not the same as the one proposed in the Draft Assessment Report (incl. its addenda) and the respective EFSA conclusion (see below).

Table 5.3-2: Relevant residue definitions

Matrix	Relevant residue	Reference Remarks
Plant material	Pinoxaden [1]	Regulation (EC) No 839/2008, annex III part A
	Sum of M4 and M6 expressed as parent pinoxaden (to include free and conjugated residues of M4 and M6)	EFSA Journal 2013;11(8):3269; ASB2013-10732
Foodstuff of animal origin	Not defined	Regulation (EC) No 839/2008, annex III part A
	None strictly needed	EFSA Journal 2013;11(8):3269; ASB2013-10732
Soil	NOA 407854 (M2) and NOA 447204 (M3)	EFSA Journal 2013;11(8):3269; ASB2013-10732
Surface water	NOA 407854 (M2)	EFSA Journal 2013;11(8):3269; ASB2013-10732
Drinking/ground water	Pinoxaden	Minimal requirement of the Drinking Water Act (Trinkwasser-VO)
	Pinoxaden (NOA 407855), NOA 407854 (M2), NOA 447204 (M3), M11, M52, M54, M55, M56	EFSA Journal 2013;11(8):3269; ASB2013-10732
Air	Pinoxaden	EFSA Journal 2013;11(8):3269; ASB2013-10732
Body fluids/tissue	No relevant residues	Not classified as T / T+

[1] In plant metabolism studies, fast degradation of parent pinoxaden to the metabolites M4 and M6 was observed. Therefore parent pinoxaden, as set in the currently legal residue definition (Regulation (EC) No 839/2008, annex III part A), is not suitable as a marker compound and was not considered in the assessment.

Table 5.3-3: Levels for which compliance is required

Matrix	MRL	Reference for MRL/level Remarks
Plant, high water content	0.02 mg/kg	Regulation (EC) No 839/2008, annex III part A
Plant, acidic commodities	0.02 mg/kg	
Plant, dry commodities	0.02 mg/kg	
Plant, high oil content	0.02 mg/kg	
Meat	Such MRLs do not exist	
Milk		
Eggs		
Fat		

Matrix	MRL	Reference for MRL/level Remarks
Liver, kidney		
Soil	0.05 mg/kg	Common limit
Drinking water	0.1 µg/L	General limit for drinking water
Surface water	880 µg/L (pinoxaden) 6250 µg/L (M2)	EC_{50} *Crassostrea virginica* NOEC *Daphnia magna* EFSA Journal 2013;11(8):3269; ASB2013-10732
Air	30 µg/m^3	AOEL sys: 0.1 mg/kg bw/d; EFSA Journal 2013;11(8):3269; ASB2013-10732
Tissue (meat or liver)	Not necessary	Not classified as T / T+
Body fluids	Not necessary	Not classified as T / T+

IIIA 5.3.1.2 Description of Analytical Methods for the Determination of Residues of Pinoxaden in Plant Matrices (OECD KIII A 5.3.1)

An overview of the acceptable methods and the data gaps (if appropriate) for analysis of pinoxaden in plant matrices is given in the following tables. New studies were not provided.

Table 5.3-4: Overview of independently validated methods and confirmatory methods for food and feed of plant origin (always required for first 4 matrix types)

Matrix type	Primary method	ILV	Confirmatory method
High water content	Crook,2004*	Peatman, 2003*	Amic, 2012*
Acidic	Crook,2004*	Peatman, 2003*	Amic, 2012*
Fatty	Amic, 2012*	Missing	Amic, 2012*
Dry	Crook,2004*[1]	Peatman, 2003*[1]	Amic, 2012*
Difficult	Not required for the intended GAP	Not required for the intended GAP	Not required for the intended GAP

*EU agreed method (see Draft Assessment Report)
[1] Since extraction in the methods by Crook (2004) and Peatman (2003) occurred under acidic conditions, the method is suitable for acidic matrices as well.

Table 5.3-5: Statement on extraction efficiency

	Method for products of plant origin
Required, available from:	[1] Hamlet & Crook, 2003, MET2004-743 [2] Sandmeier, 2003, RIP2004-1973

[1] Wheat samples (grains, straw and husks) from a nature of residue study were used for a radio-validation study for the solvent used in the studies by Crook (2004) and Peatman (2003). In brief, samples were extracted with 1 M hydrochloric acid under reflux conditions. For all three matrices, the total extracted radioactivity reached 77 – 97%, while the components of the residue definition reached 76 – 101% compared to the finding from the nature of residue study. Hence extraction efficiency was demonstrated for 1 M hydrochloric acid in dry matrices.

[2] Wheat samples (plant, grains and straw) were extracted with acetonitrile/water (8+2, v/v). Additionally, one grain sample was extracted with 1M hydrochloric acid. In the plant samples (high water content matrix) the extractable radioactive residue (ERR) ranged between 96 – 105 %, with the components of the residue definition (metabolite M4 and M6) accounting for 49 – 61%. In the grain samples the ERR and the corresponding components of the residue definition differed significantly depending on the extraction method employed. Using acetonitrile/water, the ERR resulted in 60% with M4/M6 accounting for 49%, compared to an ERR of 103% with 90% accounting for M4/M6 when hydrochloric acid is used.

As acetonitrile/water has been used as an extraction solvent in the method by Amic (2012), extraction efficiency has been proven in high water content matrices. For wheat grain, extraction with acetonitrile/water seems not optimal, as demonstrated by the additional liberation metabolite M4/M6 when acidic hydrolysis is employed.

Table 5.3-6: Methods suitable for the determination of residues (enforcement) in products of plant origin

Author(s), year	Matrix group	Method LOQ	Principle of method	Comment	Evaluated in
Crook, 2004 RIP2004-1980	High water content dry	0.02 mg/kg per analyte 0.01 mg/kg per analyte	LC-MS/MS, Ultracarb ODS 30, M4: ESI+, m/z 333→101 M6: ESI-, m/z 345→173	No confirmation	Vol. 3, B.5.2 of the DAR ASB2010-10613
Peatman, 2003 MET2004-748	High water content dry	0.02 mg/kg per analyte 0.01 mg/kg per analyte	LC-MS/MS, Ultracarb ODS 30, , M4: ESI+, m/z 333→101 M6: ESI-, m/z 345→173	No confirmation; ILV of Crook (2004)	Vol. 3, B.5.2 of the DAR ASB2010-10613
Amic, 2012 ASB2013-394	High water content, acidic, fatty, dry	0.01 mg/kg per analyte	LC-MS/MS, RP 8 column, M4: ESI+, m/z 333→303, 333→315 M6: ESI-, m/z 345→173, 345→158	Confirmation included	Addendum 3, Vol. 3, B.5.2.1 of the DAR ASB2013-6761

IIIA 5.3.1.3 Description of Analytical Methods for the Determination of Residues of Pinoxaden in Animal Matrices (OECD KIII A 5.3.1)

Methods for animal matrices are not required, because no MRLs have been set.

IIIA 5.3.1.4 Description of Methods for the Analysis of Pinoxaden in Soil (OECD KIII A 5.4)

An overview of the acceptable methods and the data gaps (if appropriate) for analysis of residues of

pinoxaden in soil is given in the following tables. New studies were not provided.

Table 5.3-7: Overview of suitable primary and confirmatory methods for soil

Component(s) of residue definition	Primary method	Confirmatory method
M2	Hargreaves, 2007*	Hargreaves, 2007*
M3		

*EU agreed method (see Draft Assessment Report)

Table 5.3-8: Methods for soil

Author(s), year	Method LOQ	Principle of method	Comment	Evaluated in
Hargreaves, 2007 MET2007-162	0.0005 mg/kg per analyte	LC-MS/MS; phenyl-hexyl column, ESI+ pinoxaden: m/z 401→317, 401→57; M2: m/z 317→289, 317→131; M3: m/z 333→149, 333→121	Confirmation included	Addendum 3, Vol. 3, B.5.3.1 of the DAR ASB2013-6761

IIIA 5.3.1.5 Description of Methods for the Analysis of Pinoxaden in Water (OECD KIII A 5.6)

An overview of the acceptable methods and the data gaps (if appropriate) for analysis of pinoxaden in surface and drinking water is given in the following table. For the detailed evaluation of new/additional studies it is referred to Appendix 2.

Table 5.3-9: Overview of suitable primary and confirmatory methods for water

Component(s) of residue definition	Matrix	Primary method	Confirmatory method
Pinoxaden	Drinking water, groundwater	Hargreaves, 2006*	Hargreaves, 2006*
M2	Surface water, groundwater	Hargreaves, 2007*	Hargreaves, 2007*
M3	Drinking water, groundwater		
M11	Drinking water, groundwater	Langridge, 2015	Langridge, 2015
M52	Drinking water, groundwater		
M54	Drinking water, groundwater		
M55	Drinking water, groundwater		
M56	Drinking water, groundwater		

*EU agreed method (see Draft Assessment Report)

Table 5.3-10: Methods for drinking/groundwater and surface water

Author(s), year	Method LOQ	Principle of method	Comment	Evaluated in
Hargreaves, 2006 MET2007-164	0.05 µg/L	LC-MS/MS; RP18 column, ESI+,	Confirmation included	Addendum 3, Vol. 3, B.5.3.2 of the

Author(s), year	Method LOQ	Principle of method	Comment	Evaluated in
		pinoxaden: m/z 401→317, 401→57		DAR ASB2013-6761
Hargreaves, 2007 MET2007-166	0.05 µg/L per analyte	LC-MS/MS; phenyl-hexyl column, ESI+ M2: m/z 317→289, 317→131; M3: m/z 333→149, 333→121	Confirmation included	Addendum 3, Vol. 3, B.5.3.2 of the DAR ASB2013-6761
Langridge, 2015 ASB2016-2671	0.05 µg/L per analyte	LC-MS/MS; C18 column, ESI+, pinoxaden: m/z 401→317, 401→57 M2: m/z 317→289, 317→131; M3: m/z 333→149, 333→121, M56: m/z 343→243, 343→115 ESI-, M11: m/z 361→300, 361→305 M52: m/z 359→159, 359→144 M54: m/z 361→173, 361→217 M55: m/z 375→271, 375→241	Confirmation included	Appendix 2

IIIA 5.3.1.6 Description of Methods for the Analysis of Pinoxaden in Air (OECD KIII A 5.7)

An overview of the acceptable methods and the data gaps (if appropriate) for analysis of pinoxaden in air is given in the following table. New studies were not provided.

Table 5.3-11: Overview of suitable primary and confirmatory methods for air

Component(s) of residue definition	Primary method	Confirmatory method
Pinoxaden	Tummon, 2006*	Not required

*EU agreed method (see Draft Assessment Report)

Table 5.3-12: Methods for air

Author(s), year	Method LOQ	Principle of method	Comment	Evaluated in
Tummon/ 2006 ASB2013-395	1 µg/m^3	LC-MS/MS, C18 column, APCI+; pinoxaden: m/z 401→317	Tests at unknown temperature and humidity	Addendum 3, Vol. 3, B.5.3.3 of the DAR ASB2013-6761

IIIA 5.3.1.7 Description of Methods for the Analysis of Pinoxaden in Body Fluids and Tissues (OECD KIII A 5.8)

Methods for body fluids and tissues are not required, because pinoxaden is not considered to be toxic or very toxic (T / T+) nor is it classified according to GHS as follows: Acute toxicity (cat. 1 - 3), CMR (cat. 1) or STOT (cat. 1).

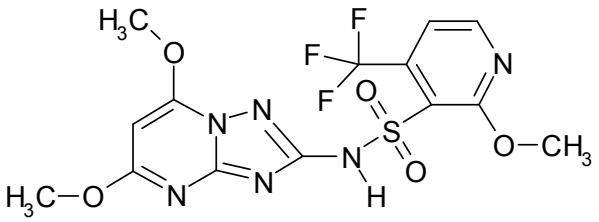
IIIA 5.3.1.8 Other Studies/ Information

None

IIIA 5.3.2 Evaluation of Pyroxsulam

The conclusion regarding the peer review of the analytical methods for residues of pyroxsulam is summarized in EFSA Scientific Report (2013) 11(4), 3182, ASB2013-5919.

Table 5.3-13: Information on the active substance Pyroxsulam

Name of component of residue definition **substance code** **IUPAC name** **formula**	**Structural formula**
Pyroxsulam XDE-742 N-(5,7-dimethoxy[1,2,4]triazolo[1,5-a]pyrimidin-2-yl)-2-methoxy-4-(trifluoromethyl)pyridine-3-sulfonamide $C_{14}H_{13}F_3N_6O_5S$	

IIIA 5.3.2.1 Overview of residue definitions and levels for which compliance is required

The current legal residue definition for food of animal origin is not the same as the one proposed in the Draft Assessment Report (incl. its addenda) and the respective EFSA conclusion. There it is concluded that a residue definition and MRLs for animal products are not necessary.

Table 5.3-14: Relevant residue definitions

Matrix	**Relevant residue**	**Reference** **Remarks**
Plant material	Pyroxsulam	Regulation (EC) No 839/2008, annex III part A
Foodstuff of animal origin	Pyroxsulam	Regulation (EC) No 839/2008, annex III part A
Soil	Pyroxsulam	EFSA Journal 2013; 11(4):3182, ASB2013-5919

Matrix	Relevant residue	Reference Remarks
Surface water	Pyroxsulam	EFSA Journal 2013; 11(4):3182, ASB2013-5919
Drinking/ground water	Pyroxsulam	EFSA Journal 2013; 11(4):3182, ASB2013-5919
Air	Pyroxsulam	Generally defined
Body fluids/tissue	Not residue relevant	Not classified as T / T+

Table 5.3-15: Levels for which compliance is required

Matrix	MRL	Reference for MRL/level Remarks
Plant, high water content	0.01 mg/kg	Regulation (EC) No 839/2008, annex III part A
Plant, acidic commodities	0.01 mg/kg	Regulation (EC) No 839/2008, annex III part A
Plant, dry commodities	0.01 mg/kg	Regulation (EC) No 839/2008, annex III part A
Plant, high oil content	0.01 mg/kg	Regulation (EC) No 839/2008, annex III part A
Plant, difficult matrices (hops, spices, tea)	0.02 mg/kg	Regulation (EC) No 839/2008, annex III part A
Meat	0.01 mg/kg	Regulation (EC) No 839/2008, annex III part A
Milk	0.01 mg/kg	Regulation (EC) No 839/2008, annex III part A
Eggs	0.01 mg/kg	Regulation (EC) No 839/2008, annex III part A
Fat	0.01 mg/kg	Regulation (EC) No 839/2008, annex III part A
Liver, kidney	0.01 mg/kg	Regulation (EC) No 839/2008, annex III part A
Soil	0.05 mg/kg	Common limit
Drinking water	0.1 µg/L	General limit for drinking water
Surface water	2.6 µg/L	EC_{50} *Lemna gibba,* EFSA Journal 2013; 11(4):3182, ASB2013-5919
Air	210 µg/m^3	AOEL sys/AOEL inhal: 0.7 mg/kg bw/d
Tissue (meat or liver)	Not required	Not classified as T / T+
Body fluids	Not required	Not classified as T / T+

IIIA 5.3.2.2 Description of Analytical Methods for the Determination of Residues of Pyroxsulam in Plant Matrices (OECD KIII A 5.3.1)

An overview of the acceptable methods and the data gaps (if appropriate) for analysis of pyroxsulam in plant matrices is given in the following tables. New studies were not provided.

Table 5.3-16: Overview of independently validated methods and confirmatory methods for food and feed of plant origin (always required for first 4 matrix types)

Matrix type	Primary method	ILV	Confirmatory method
High water content	Bacher, 2005*	Robaugh & Pinkerton, 2006*	Bacher, 2005*
Acidic	Bacher, 2005*	not necessary	Bacher, 2005*
Fatty	Bacher, 2005*	not necessary	Bacher, 2005*
Dry	Bacher, 2005*	Robaugh & Pinkerton, 2006*	Bacher, 2005*
Difficult	Not required for the intended GAP	Not required for the intended GAP	Not required for the intended GAP

*EU agreed method (see Draft Assessment Report)

Table 5.3-17: Statement on extraction efficiency

	Method for products of plant origin
Required, available from:	Class, 2005; MET2006-540

An investigation of extraction efficiency using wheat plant tissue samples from a plant metabolism study is included in Appendix B of the residue analytical method (Class, 2005). The extraction of ^{14}C-radiolabeled pyroxsulam is performed by acetonitrile/water (8/2, v/v). For wheat plant tissue samples high extractability is given (> 90 % of TRR). The extraction solvent of this study (acetonitrile/water) and of the multi-residue monitoring method (acetone/water) is comparable.

Table 5.3-18: Methods suitable for the determination of residues (enforcement) in products of plant origin

Author(s), year	Matrix group	Method LOQ	Principle of method	Comment	Evaluated in
Bacher, 2005 MET2006-536	High water content, acidic, dry, fatty	0.01 mg/kg	LC-MS/MS Phenomenex Aqua column, ESI+, m/z 435→195, 435→82	Confirmation included; DFG S19	section 5.2.1 a) of the DAR ASB2010-10632
Robaugh & Pinkerton, 2006 MET2006-539	High water content, dry	0.01 mg/kg	LC-MS/MS Phenomenex Aqua column, ESI+, m/z 435→195, 435→82	Confirmation included; DFG S19; ILV of Bacher, 2005	section 5.2.1 b) of the DAR ASB2010-10632

IIIA 5.3.2.3 Description of Analytical Methods for the Determination of Residues of Pyroxsulam in Animal Matrices (OECD KIII A 5.3.1)

An overview of the acceptable methods and the data gaps (if appropriate) for analysis of pyroxsulam in animal matrices is given in the following tables. New studies were not provided.

Table 5.3-19: Overview of independently validated methods and confirmatory methods for food and feed of animal origin (if appropriate)

Matrix type	Primary method	ILV	Confirmatory method
Milk	Bacher, 2005*	Robaugh & Pinkerton, 2006*	Bacher, 2005*
Eggs	Bacher, 2005*	Not necessary	Bacher, 2005*
Meat	Bacher, 2005*	Robaugh & Pinkerton, 2006*	Bacher, 2005*
Fat	Bacher, 2005*	Not necessary	Bacher, 2005*
Kidney, liver	Bacher, 2005*	Not necessary	Bacher, 2005*

*EU agreed method (see Draft Assessment Report)

Table 5.3-20: Statement on extraction efficiency

	Method for products of animal origin
Not required, because:	animal intakes were calculated to be far below the trigger value of 0.1 mg/kg feed per day (see EFSA conclusion)

Table 5.3-21: Methods suitable for the determination of residues (enforcement) in products of animal origin

Author(s), year	Matrix	Method LOQ	Principle of method	Comment	Evaluated in
Bacher, 2005 MET2006-536	Milk, eggs, meat, fat, liver	0.01 mg/kg	LC-MS/MS Phenomenex Aqua column, ESI+, m/z 435→195, 435→82	Confirmation included; DFG S19	section 5.2.2 a) of the DAR ASB2010-10632
Robaugh & Pinkerton, 2006 MET2006-539	Milk, meat	0.01 mg/kg	LC-MS/MS Phenomenex Aqua column, ESI+, m/z 435→195, 435→82	Confirmation included; DFG S19; ILV of Bacher, 2005	section 5.2.2 b) of the DAR ASB2010-10632

IIIA 5.3.2.4 Description of Methods for the Analysis of Pyroxsulam in Soil (OECD KIII A 5.4)

An overview of the acceptable methods and the data gaps (if appropriate) for analysis of pyroxsulam in soil is given in the following tables. New studies were not provided.

Table 5.3-22: Overview of suitable primary and confirmatory methods for soil

Component(s) of residue definition	Primary method	Confirmatory method
Pyroxsulam	Bacher, 2005*	Bacher, 2005*

*EU agreed method (see Draft Assessment Report)

Table 5.3-23: Methods for soil

Author(s), year	Method LOQ	Principle of method	Comment	Evaluated in
Bacher, 2005 MET2006-536	0.01 mg/kg	LC-MS/MS Phenomenex Aqua column, ESI+, m/z 435→195, 435→82	Confirmation included; DFG S19	section 5.3.1 of the DAR ASB2010-10632

IIIA 5.3.2.5 Description of Methods for the Analysis of Pyroxsulam in Water (OECD KIII A 5.6)

An overview of the acceptable methods and the data gaps (if appropriate) for analysis of pyroxsulam in surface and drinking water is given in the following table. New studies were not provided.

Table 5.3-24: Overview of suitable primary and confirmatory methods for water

Component(s) of residue definition	Matrix	Primary method	Confirmatory method
Pyroxsulam	Drinking water/ surface water	Shackelford, 2006*	Richter, 2006*

*EU agreed method (see Draft Assessment Report)

Table 5.3-25: Methods for drinking and surface water

Author(s), year	Method LOQ	Principle of method	Comment	Evaluated in
Shackelford, 2006 MET2006-545	0.05 µg/L	LC-MS/MS, Synergi Hydro RP column, ESI+, m/z 435→195	No confirmation	section 5.3.2 of the DAR ASB2010-10632
Richter, 2006 MET2006-546	0.05 µg/L	LC-MS/MS, Synergi Hydro RP column, ESI+, m/z 435→195, 435→82	Confirmation, ILV for Shackelford, 2006	section 5.3.2 of the DAR ASB2010-10632

IIIA 5.3.2.6 Description of Methods for the Analysis of Pyroxsulam in Air (OECD KIII A 5.7)

An overview of the acceptable methods and the data gaps (if appropriate) for analysis of pyroxsulam in air is given in the following table.

Table 5.3-26: Overview of suitable primary and confirmatory methods for air

Component(s) of residue definition	Primary method	Confirmatory method
Pyroxsulam	Class & Richter, 2004*	Not necessary

*EU agreed method (see Draft Assessment Report)

Table 5.3-27: Methods for air

Author(s), year	Method LOQ	Principle of method	Comment	Evaluated in
Class & Richter, 2004	2.7 µg/m^3	LC-MS/MS an	No confirmation	section 5.4.1 of the

Author(s), year	Method LOQ	Principle of method	Comment	Evaluated in
MET2006-547		Phenomenex Aqua C18 column, ESI+, m/z 435→195		DAR ASB2010-10632

IIIA 5.3.2.7 Description of Methods for the Analysis of Pyroxsulam in Body Fluids and Tissues (OECD KIII A 5.8)

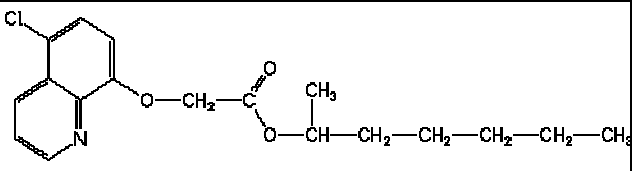
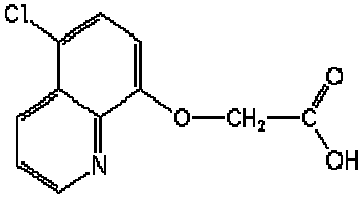
Methods for body fluids and tissues are not required, because pyroxsulam is not considered to be toxic or very toxic (T / T+) nor is it classified according to GHS as follows: Acute toxicity (cat. 1 - 3), CMR (cat. 1) or STOT (cat. 1).

IIIA 5.3.2.8 Other Studies/ Information

None

IIIA 5.3.3 Evaluation of Cloquintocet-mexyl

Table 5.3-28: Information on the safener Cloquintocet-mexyl

Name of component of residue definition substance code IUPAC name formula	Structural formula
Cloquintocet-mexyl CGA 185072 1-methylhexyl (5-chloroquinolin-8-yloxy)acetate $C_{18}H_{22}ClNO_3$	
Cloquintocet CGA 153433 (5-chloroquinolin-8-yloxy)acetic acid $C_{11}H_8ClNO_3$	

IIIA 5.3.3.1 Overview of residue definitions and levels for which compliance is required

For the safener cloquintocet-mexyl no residue definition for food of plant and/or animal origin is listed in Regulation (EC) No 396/2005.

Table 5.3-29: Relevant residue definitions

Matrix	Relevant residue	Reference Remarks

Matrix	Relevant residue	Reference Remarks
Plant material	Not defined	Regulation (EC) No 396/2005
	Cloquintocet-mexyl	German MRL Regulation (RHmV)
	Cloquintocet	Applicants proposal MET2005-318
Foodstuff of animal origin	Not defined	Regulation (EC) No 396/2005 and German MRL Regulation (RHmV)
	Cloquintocet	Applicants proposal MET2005-318
Soil	Not residue relevant	Assessment zRMS
Surface water	Not residue relevant	Assessment zRMS
Drinking/ground water	Cloquintocet-mexyl	Minimal requirement of the Drinking Water Act
Air	Cloquintocet-mexyl	Generally defined
Body fluids/tissue	Not residue relevant	Not classified as T / T+

Table 5.3-30: Levels for which compliance is required

Matrix	MRL	Reference for MRL/level Remarks
Plant, high water content	0.05 mg/kg	German MRL Regulation (RHmV)
Plant, acidic commodities	0.05 mg/kg	German MRL Regulation (RHmV)
Plant, dry commodities	0.05 mg/kg	German MRL Regulation (RHmV)
Plant, high oil content	0.05 mg/kg	German MRL Regulation (RHmV)
Meat	Not defined	Regulation (EC) No 396/2005 and German MRL Regulation (RHmV)
Milk	Not defined	

Matrix	MRL	Reference for MRL/level Remarks
Eggs	Not defined	
Fat	Not defined	
Liver, kidney	Not defined	
Soil	Not required	No residue definition
Drinking water	0.1 µg/L	General limit for drinking water
Surface water	Not required	No residue definition
Air	15 µg/m^3	AOEL sys/AOEL inhal: 0.05 mg/kg bw/d
Tissue (meat or liver)	Not required	Not classified as T / T+
Body fluids	Not required	Not classified as T / T+

IIIA 5.3.3.2 Description of Analytical Methods for the Determination of Residues of Cloquintocet-mexyl in Plant Matrices (OECD KIII A 5.3.1)

An overview of the acceptable methods and the data gaps (if appropriate) for analysis of cloquintocet-mexyl in plant matrices is given in the following tables. For the detailed evaluation of the studies it is referred to Appendix 2.

Table 5.3-31: Overview of independently validated methods and confirmatory methods for food and feed of plant origin (always required for first 4 matrix types)

Matrix type	Primary method	ILV	Confirmatory method
High water content	Anonymous, 2010	Anonymous, 2010	Class, 2005
Acidic	Anonymous, 2010	Anonymous, 2010	Class, 2005
Fatty	Anonymous, 2010	Anonymous, 2010	Missing
Dry	Anonymous, 2010	Anonymous, 2010	Class, 2005
Difficult	Not required for the intended GAP	Not required for the intended GAP	Not required for the intended GAP

Table 5.3-32: Statement on extraction efficiency

	Method for products of plant origin
Required, available from:	Muir et al., 2002 (RIP2004-2111)

Extraction efficiency was determined with radio-labelled ^{14}C-cloquintocet-mexyl. ^{14}C-cloquintocet-mexyl was applied to spring wheat at rates of 19.4 g a.i./ha (1 N) and 175.7 g a.i./ha (10 N). The plants were treated at developmental stages BBCH 22 – 30. Forage samples were harvested 7 and 30 days after treatment. Mature wheat was harvested 61 days after application. The total ^{14}C levels were determined by LSC. Samples with TRR > 0.01 mg/kg cloquintocet-mexyl were extracted with acetonitrile/water (8/2, v/v). The used extraction solvent is comparable to the monitoring method.

In the extracts of wheat grain treated at a rate of 175.7 g a.i./ha only 29 % TRR was analysed. 56 - 64 % of the TRR was determined in the extracts of forage samples treated at a rate of 19.4 g a.i./ha. 50 - 73 % of the TRR was determined in the extracts of forage samples treated at a rate of 175.7 g a.i./ha. In the not extractable part no cloquintocet-mexyl was detected.

Study has been shown that acetonitrile/water (8/2, v/v) efficiently extract cloquintocet-mexyl from wheat samples.

Table 5.3-33: Methods suitable for the determination of residues (enforcement) in products of plant origin

Author(s), year	**Matrix group**	**Method LOQ**	**Principle of method**	**Comment**	**Evaluated in section**
Anonymous, 2010 ASB2013-8342	Dry, high water content, fatty, acidic	0.05 mg/kg	GC(MS)-multimethod	For cloquintocet-mexyl, ILV included; § 64 method L 00.00-34	Appendix 2
Class, 2005 MET2006-541	Dry, high water content	0.01 mg/kg	LC-MS/MS, ESI+, Aquasil C18 column, m/z 336→238 (cloquintocet-mexyl)	For cloquintocet-mexyl, cloquin-tocet-acid; no confirmation	Appendix 2

IIIA 5.3.3.3 Description of Analytical Methods for the Determination of Residues of Cloquintocet-mexyl in Animal Matrices (OECD KIII A 5.3.1)

Methods for animal matrices are not required, because no MRLs are proposed for the determination of cloquintocet-mexyl in milk, eggs, meat, fat and liver or kidney.

IIIA 5.3.3.4 Description of Methods for the Analysis of Cloquintocet-mexyl in Soil (OECD KIII A 5.4)

Methods for soil are not required, because no residues of cloquintocet-mexyl are expected in soil.

IIIA 5.3.3.5 Description of Methods for the Analysis of Cloquintocet-mexyl in Water (OECD KIII A 5.6)

An overview of the acceptable methods and the data gaps (if appropriate) for analysis of cloquintocet-mexyl in drinking water is given in the following table. For the detailed evaluation of the additional study it is referred to Appendix 2.

Methods for surface water are not required, because no residues of cloquintocet-mexyl are expected.

Table 5.3-34: Overview of suitable primary and confirmatory methods for water

Component(s) of residue definition	Matrix	Primary method	Confirmatory method
Cloquintocet-mexyl	Drinking water	Missing	Abrar & Anderon, 1997

Table 5.3-35: Methods for drinking water

Author(s), year	Method LOQ	Principle of method	Comment	Evaluated in
Abrar & Anderon, 1997 MET2004-763	0.05 µg/L	LC-MS/MS, ESI+, Aquasil C18 column, m/z 336→238 (cloquintocet-mexyl)	For cloquintocet-mexyl, cloquintocet-acid; no confirmation, accepted for drinking water	Appendix 2

IIIA 5.3.3.6 Description of Methods for the Analysis of Cloquintocet-mexyl in Air (OECD KIII A 5.7)

Methods for air are not required, because no residues of cloquintocet-mexyl are expected.

IIIA 5.3.3.7 Description of Methods for the Analysis of Cloquintocet-mexyl in Body Fluids and Tissues (OECD KIII A 5.8)

Methods for body fluids and tissues are not required, because cloquintocet-mexyl is not considered to be toxic or very toxic (T / T+) nor is it classified according to GHS as follows: Acute toxicity (cat. 1 - 3), CMR (cat. 1) or STOT (cat. 1).

IIIA 5.3.3.8 Other Studies/ Information

None

IIIA 5.4 Conclusion on the availability of analytical methods for the determination of residues

For **pinoxaden** sufficiently sensitive and selective analytical methods are not available for all analytes included in the residue definitions.

The following data gaps were noticed:
- An independent laboratory validation of the method by Amic (2012) is missing for fatty plant commodities

This data gap is considered being of minor relevance and it is sufficient to fill this gap in the context of the next application for the approval of pinoxaden according to Reg. (EC) No 1107/2009 or in the context of the assessment of existing MRLs of pinoxaden according to Reg. (EC) No 396/2005.

For **pyroxsulam** sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions.

For **cloquintocet-mexyl** sufficiently sensitive and selective analytical methods are not available for all analytes included in the residue definitions.

The following data gaps were noticed:
- A confirmatory method for determination of cloquintocet-mexyl in fatty plant commodities is missing.
- A primary method for determination of cloquintocet-mexyl in drinking water is missing.

These data gaps are considered being of minor relevance. It should be taken into account that in EU Review Process residue analytical methods for safeners are not yet required. A Review program is planned under Regulation (EC) 1107/2009 (articles 25 and 26). Therefore, the applicant should be informed merely regarding the data gaps.

Appendix 1 – List of data submitted in support of the evaluation

Annex point/ reference No	Author(s)	Year	Title Source (where different from company) Report-No. GLP or GEP status (where relevant), Published or not	Data protection claimed	Owner	How considered in dRR Study-Status / Usage*
KIIIA 5.2.2/01	De Benedictis, S.	2013	Analytical method SF-609/1 - Determination of pinoxaden / pyroxsulam / cloquintocet-mexyl in formulation EC (033.3/008.33/008.33), by HPLC not GLP, not published BVL no. 2603143	Y	SYN	1
KIIIA 5.2.2/02	De Benedictis, S.	2013a	A19786A - Validation of analytical method SF-609/1 Report no. 10531648 Syngenta File no. A19786A_10070 GLP, not published BVL no. 2603144	Y	SYN	1

* 1 accepted (study valid and considered for evaluation)
2 not accepted (study not valid and not considered for evaluation)
3 not considered (study not relevant for evaluation)
4 not submitted but necessary (study not submitted by applicant but necessary for evaluation)
5 supplemental (additional information, alone not sufficient to fulfil a data requirement, considered for evaluation)

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
	EFSA	2013	Conclusion on the peer review of the pesticide risk assessment of the active substance Pyroxsulam EFSA Journal 2013;11(4):3182 ASB2013-5919			
	EFSA	2013	Conclusion on the peer review of the pesticide risk assessment of the active substance Pinoxaden EFSA Journal 2013;11(8):3269 ASB2013-10732			
	United Kingdom	2005	Pinoxaden: (Draft Assessment Report) Volume 1-4 GLP: Open Published: Yes ASB2010-10613			
	United Kingdom	2008	Pyroxsulam (Draft Assessment Report); Volume 1-3 GLP: Open Published: Yes ASB2010-10632			
	United Kingdom	2013	Pinoxaden (NOA 407855): Addendum 3 und 4 to Annex B (Volume 3) ASB2013-6761			

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
	Anon.	2010	Untersuchung von Lebensmitteln - Modulare Multimethode zur Bestimmung von Pflanzenschutzmittelrückständen in Lebensmitteln (Erweiterte Neufassung der DFG-Methode S 19) (Amtliche Sammlung von Untersuchungsverfahren nach § 64 LFGB) L 00.00-34 ASB2013-8342			Add
KIIA 4.3	Amic, S.	2012	Pinoxaden - Validation of the QuEChERS method for the determination of residues of Pinoxaden metabolites M4 (SYN505164) and M6 (SYN502836) in crops matrices by LC-MS/MS SYN505164_10000 ! S12-04302 ! TK0171736 GLP: Open Published: Open BVL-2597518, ASB2013-394	Yes	Syngenta Agro	Y
KIIA 4.3	Bour, D.	2005	Independent laboratory validation of residue method REM 199.04 for the determination of Pinoxaden metabolite NOA407854 in or on wheat grain and whole plant T004327-05 ! NOA407854/0060 GLP: Open Published: Open BVL-2211913, MET2006-486	Yes	Syngenta Agro	N
KIIA 4.3	Class, T.	2005	Independent laboratory validation of Dow AgroSciences LLC Method GRM 04.17 - Determination of residues of XDE-742 in agricultural commodities by liquid chromatography with tandem mass spectrometry 040095 ! 10000233-5008-1 ! P 799 G GLP: Open Published: Open BVL-1933225, MET2006-540	Yes	DOW	Y
KIIA 4.3	Class, T.	2005	Cloquintocet-mexyl: Independent laboratory validation of an analytical method for the determination of Cloquintocet-mexyl and its acid metabolite in cereal 40096 ! P 798 G ! 10000233-5008-2 GLP: Open Published: Open BVL-1933226, MET2006-541	Yes	DOW	Y
KIIA 4.3	Crook, S. J.	2006	Residue method for the determination of residues of NOA407854 (metabolite of NOA407855) in cereal samples and cereal process fractions. Final determination by LC-MS/MS REM 199.04 ! NOA407854/0059 GLP: Open Published: Open BVL-2211924, MET2006-485	Yes	Syngenta Agro	N
KIIA 4.3	Faltynski, K.	2003	Independent laboratory validation of Syngenta method T001530-03, "analytical method for determination of NOA 407855 Metabolites, 505164 (M4) and SYN 502836 (M6) in animal tissues, milk and eggs by LC/MS/MS including validation data" NOA407855/0502 ! 1467-03 ! 03-0013 GLP: Open Published: Open BVL-2211927, MET2004-749	Yes	Syngenta Agro	N
KIIA 4.3	Gasser, A.	2002	Determination of NOA 407855, SYN 505164, SYN 502836, SYN 505887 (metabolites of NOA 407855) and CGA 153433 (metabolite of CGA 185072) in cereals by LC/LC-MS/MS (Validated) NOA407855/0057 ! REM 199.02 GLP: Open Published: Open BVL-2211915, MET2004-746	Yes	Syngenta Agro	N

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
KIIA 4.3	Gasser, A.	2002	Validation of method REM 199.02: Validation by analysis of wheat specimens (whole plant, straw and grains) fortified with NOA 407855, SYN 505164, SYN 502836, SYN 505887 and CGA 153433 and determination of recoveries NOA407855/0058 ! 02-S302 ! REM 199.02 GLP: Open Published: Open BVL-2211911, MET2004-744	Yes	Syngenta Agro	N
KIIA 4.3	Hamlet, J. M.; Crook, S. J.; Benner, J. P.	2003	NOA 407855: Assessment of the efficiency of extraction of metabolites from cereal samples following residue methods REM 199.02 and REM 199.03 and Syngenta method 117-01. NOA407854/0042 ! RJ3408B ! 03JH020 GLP: Open Published: Open BVL-2211910, MET2004-743	Yes	Syngenta Agro	Y
KIIA 4.3	Lakaschus, S.	2006	Validation of multi-residue method DFG S19 (L 00.00-34) for the determination of residues of NOA407854 (M2 metabolite of Pinoxaden) in wheat grain, straw and forage with LC-MS/MS detection NOA407854/0057 ! SYN-0511V GLP: Open Published: Open BVL-2211906, MET2006-487	Yes	Syngenta Agro	N
KIIA 4.3	Lin, K.	2003	Analytical method for determination of NOA 407855 metabolites, SYN 505164 (M4) and SYN 502836 (M6) in animal tissues, milk and eggs by LC/MS/MS including validation data NOA407855/0261 ! T001530-03 GLP: Open Published: Open BVL-2211909, MET2004-742	Yes	Syngenta Agro	N
KIIA 4.3	McLean, N.; Bruns, G.	2006	Method validation report for the determination of Cloquintocet-mexyl and its acid metabolite in wheat using Enviro-Test Laboratories method M313 ETL04DOW05 ! 10000233-5001-2 ! 10000233-5003-2 GLP: Open Published: Open BVL-1933223, MET2006-538	Yes	DOW	N
KIIA 4.3	Peatman, M. H.	2003	NOA 407854, SYN 505164, SYN 502836, SYN 505887 and CGA 153433: Independent laboratory validation of REM 199.03 analytical method for the determination of residues in cereal whole plant and grain NOA407854/0036 ! 1983/060-D2149 GLP: Open Published: Open BVL-2211905, MET2004-748	Yes	Syngenta Agro	Y
KIIA 4.3	Rutherford, L. A.; Hastings, M. J.; Lindsay, D. A.	2005	Method validation report for the determination of XDE-742 in agricultural commodities by liquid chromatography with tandem mass spectrometry using Dow AgroSciences LLC method GRM 04.17 041026 ! 10000233-5002-1 GLP: Open Published: Open BVL-1933222, MET2006-537	Yes	DOW	N
KIIA 4.3, KIIA 4.4, KIIA 4.8	Bacher, R.	2005	XDE-742: Assessment and validation of european multi-residue enforcement method(s) for the determination of XDE-742 in plant materials, in foodstuffs of animal origin, in soil, and in body fluids 51001 ! 10000233-5010-1 ! P 845 G GLP: Open Published: Open BVL-1933221, BVL-1933436, BVL-1933437, MET2006-536	Yes	DOW	Y

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
KIIA 4.3, KIIA 4.4, KIIA 4.8	Robaugh, D. A.; Pinkerton, B.	2006	Independent laboratory validation of XDE-742: Assessment and validation of the european multi-residue enforcement method(s) for the determination of XDE-742 in plant material, in foodstuffs of animal origin, in soil, and in body fluids 050045 ! 10000233-5008-9 GLP: Open Published: Open BVL-1933224, BVL-1933439, BVL-1933440, MET2006-539	Yes	DOW	Y
KIIA 4.3, KIIA 6.2.1	Crook, S. J.	2004	Residue method for the determination of residues of NOA 407854, SYN 505164, SYN 502836, SYN 505887 (metabolites of NOA 407855) and CGA 153433 (metabolite of CGA 185072) in cereal samples, and cereal process fractions. Final determination by LC-MS/MS NOA407855/0457 ! REM 199.03 GLP: Open Published: Open BVL-1854769, BVL-1855047, BVL-2211923, RIP2004-1980	Yes	SYD Syngenta Agro	N
KIIA 4.3, KIIA 6.3	Anderson, L.	2003	Residue study with Cloquintocet-Mexyl (CGA 185072) and NOA 407855 in or on spring barley in France (South) NOA407855/0156 ! 3030/01 GLP: Open Published: Open BVL-1855082, BVL-2211916, MET2004-745	Yes	Syngenta Agro	N
KIIA 4.4	Abrar, M.; Anderson, C.	1997	CGA184927 (herbicide) and its metabolites CGA193469, CGA302371 and CGA185072 (safener) and its metabolite CGA153433: The validation of an analytical method for the determination of residues in soil 621/26-1019 ! CGA184927/0668 NCP/Novartis Crop Protection AG GLP: Open Published: Open BVL-1854770, MET2004-763	Yes	SYD	N
KIIA 4.4	Chamkasem, N.	2003	Analytical method 35-01 for the determination of NOA407855 and its degradates NOA407854 and NOA447204 and CGA185072 (safener) and its degradate CGA153433 in soil by high performance chromatography with mass spectrometric detection NOA407855/0322 ! 35-01 GLP: Open Published: Open BVL-2211925, MET2004-750	Yes	Syngenta Agro	N
KIIA 4.4	Hargreaves, S. L.	2007	Pinoxaden - Residue method for the determination of Pinoxaden (NOA407855) and its metabolites NOA407854 and NOA447204 in soil NOA407855/1033 ! GRM017.05A GLP: Open Published: Open BVL-2211928, MET2007-162	Yes	Syngenta Agro	Y
KIIA 4.4	Hastings, M. J.	2006	Method validation report for the determination of residues of XDE-742 and its metabolites in soil and sediment by liquid chromatography with tandem mass spectrometry detection using Dow AgroSciences method GRM 05.05 041024 ! 10000233-5003-1 GLP: Open Published: Open BVL-1933227, MET2006-542	Yes	DOW	N

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
KIIA 4.4	Hastings, M. J.	2006	Method validation report for the determination of residues of XDE-742 in soil and sediment by liquid chromatography with tandem mass spectrometry detection using Dow AgroSciences method GRM 06.01 051038 ! 10000233-5003-1 GLP: Open Published: Open BVL-1933228, MET2006-543	Yes	DOW	N
KIIA 4.4	Nagra, B. S.	2007	Pinoxaden (NOA407855): Validation of a residue method (GRM017.05A) for the determination of residues of Pinoxaden and its metabolites NOA407854 and NOA447204 in soil NOA407855/1032 ! T008124-05-REG ! GRM017.05A GLP: Open Published: Open BVL-2211912, MET2007-163	Yes	Syngenta Agro	N
KIIA 4.4	Richter, M.	2006	XDE-742: Independent laboratory validation of Dow AgroSciences LLC analytical method GRM 05.05 - Determination of residues of XDE-742 and its metabolites in soil and sediment by liquid chromatography with tandem mass spectrometry detection 050003 ! 10000233-5008-3 ! P 848 G GLP: Open Published: Open BVL-1933229, MET2006-544	Yes	DOW	N
KIIA 4.5	Emburey, S. N.	2007	Pinoxaden: Validation of an analytical method for the determination of residues of its metabolites NOA407854 and NOA447204 and the safener CGA185072 and its metabolite CGA153433 in water NOA407854/0063 ! T004028-06-REG GLP: Open Published: Open BVL-2211907, MET2007-167	Yes	Syngenta Agro	N
KIIA 4.5	Figueiredo, J. N.	2001	Determination of metabolites NOA 407854 and NOA 447204 by LC/LC-ESI/MS/MS-MS, potable water, surface water NOA407855/0044 ! REM0199.01 GLP: Open Published: Open BVL-2211926, MET2004-753	Yes	Syngenta Agro	N
KIIA 4.5	Hargreaves, S. L.	2006	Pinoxaden: Residue method for the determination of residues in water NOA407855/0986 ! GRM017.01A GLP: Open Published: Open BVL-2211920, MET2007-164	Yes	Syngenta Agro	Y
KIIA 4.5	Hargreaves, S. L.	2007	Pinoxaden - Residue method for the determination of metabolites NOA407854 and NOA447204 and CGA185072 (safener) and its metabolite CGA153433 in water NOA407854/0062 ! GRM017.04A GLP: Open Published: Open BVL-2211921, MET2007-166	Yes	Syngenta Agro	Y
KIIA 4.5	Kissling, M.	2001	Validation of method REM 199.01: Validation by analysis of specimens fortified with NOA 407854 and NOA 447204 and determination of recoveries NOA407855/0045 ! 329/00 ! method REM 199.01 GLP: Open Published: Open BVL-2211908, MET2004-754	Yes	Syngenta Agro	N
KIIA 4.5	Mair, P.	1993	Determination of CGA 184927 and CGA 185072 by HPLC - potable water CGA184927/0304 ! REM 138.08 NCP/Novartis Crop Protection AG GLP: Open Published: Open BVL-1854771, MET9700010	Yes	SYD	N

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
KIIA 4.5	Mair, P.	1993	Determination of metabolites of CGA 184927 and CGA 185072 by HPLC - potable water CGA184927/0305 ! REM 138.09 NCP/Novartis Crop Protection AG GLP: Open Published: Open BVL-1854773, MET9700009	Yes	SYD	N
KIIA 4.5	Mair, P.	1999	Validation of method REM 138.08 for the use with surface and portable water 322/99 ! CGA184927/4683 ! REM 138.08 GLP: Open Published: Open BVL-1854772, MET2004-765	Yes	SYD	N
KIIA 4.5	Mair, P.	1999	Validation of method REM 138.09 for the use with surface and potable water 323/99 ! CGA153433/0026! REM 138.09 Novartis Crop Protection AG GLP: Open Published: Open BVL-1854774, MET2004-767	Yes	SYD	N
KIIA 4.5	Richter, M.	2006	Independent laboratory validation of Dow AgroSciences LLC method GRM 05.19 - Determination of residues of XDE-742 and its metabolites in drinking water, ground water, and surface water by liquid chromatography with tandem mass spectrometry detection 060006 ! 10000233-5008-7 ! P 1001 G GLP: Open Published: Open BVL-1933231, MET2006-546	Yes	DOW	Y
KIIA 4.5	Robinson, N. J.	2003	NOA-407855 - Validation of an analytical method for the determination of residues in water NOA407855/0140 ! RJ3381B GLP: Open Published: Open BVL-2211914, MET2004-752	Yes	Syngenta Agro	N
KIIA 4.5	Robinson, N. J.	2004	Residue analytical method for the determination of residues of NOA407855 in water NOA407855/0520 ! RAM414/02 GLP: Open Published: Open BVL-2211922, MET2004-751	Yes	Syngenta Agro	N
KIIA 4.5	Shackelford, D. D.	2006	Validation report for method GRM 05.19 - Determination of residues of XDE-742 and its metabolites in drinking water, ground water and surface water by Liquid chromatography with tandem mass spectrometry 051039 ! 10000233-5004-1 GLP: Open Published: Open BVL-1933230, MET2006-545	Yes	DOW	Y
KIIA 4.5	Tummon, O. J.	2006	Pinoxaden (NOA407855): Validation of an analytical method for the determination of residues of Pinoxaden in water NOA407855/0987 ! T008126-05-REG GLP: Open Published: Open BVL-2211917, MET2007-165	Yes	Syngenta Agro	N
KIIA 4.7	Class, T.; Richter, M.	2004	The development and validation of a method for the analysis of XR-742 in air 144973 ! 041004 ! P 738 G ! 10000233-5154-1 GLP: Open Published: Open BVL-1933232, MET2006-547	Yes	DOW	Y
KIIA 4.7	Köhne, A.	2003	Validation of the method A.13.S267_1: Determination of NOA407855 in air by LC-MS/MS NOA407855/0345 ! L03-004816 ! AS294 GLP: Open Published: Open BVL-2211919, MET2004-756	Yes	Syngenta Agro	N

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
KIIA 4.7	Robinson, N. J.	2005	Residue analytical method for the determination of Cloquintocet-mexyl in air CGA185072/0214 ! RAM 445/01 GLP: Open Published: Open BVL-1854776, ASB2009-11040	Yes	SYD	N
KIIA 4.7	Strebler, A.	2003	Determination of NOA407855 in air by LC-MS/MS NOA407855/0344 ! A.13S267_1 GLP: Open Published: Open BVL-2211918, MET2004-755	Yes	Syngenta Agro	N
KIIA 4.7	Tribolet, R.	1994	Sampling of air and determination of residues of parent compound and safener by high performance liquid chromatography REM138.13 ! CGA184927/0401 NCP/Novartis Crop Protection AG GLP: Open Published: Open BVL-1854775, MET9700014	Yes	SYD	N
KIIA 4.7	Tummon, O. J.	2005	Validation of an analytical method for the environmental monitoring determination of Pinoxaden in air NOA407855/0750 ! RJ3588B GLP: Open Published: Open BVL-2597519, ASB2013-395	Yes	Syngenta Agro	Y
KIIA 4.7	Wolf, S.	2004	Validation of a residue analytical method for Cloquintocet-mexyl in air CGA185072/0213 ! 856141 GLP: Open Published: Open BVL-1854777, ASB2009-11041	Yes	SYD	N
KIIA 6.2	Leuthold, U.; Dichtel, W.	2001	CGA 185072 Cloquintocet-mexyl - Residue definition CGA185072/0146 ! RT 6.31 UL/WD GLP: Open Published: Open BVL-1854816, MET2004-761	Yes	Syngenta Agro	N
KIIA 6.2	Muir, G. T.; Benner, J. P.; Kennedy, E.	2002	[Quinoline-3-14C]-CGA 185072 - Nature of the residue in spring wheat RJ3328B ! CGA185072/0199 GLP: Open Published: Open BVL-1854813, RIP2004-2111	Yes	Syngenta Agro	Y
KIIA 6.2.1	Sandmeier, P.	2003	Metabolism of NOA 407855 in field grown winter wheat after spring application of [Phenyl-1-14C] labeled material (+ Amendment v. 08.12.2003) NOA407855/0088 ! 00PSA58 GLP: Open Published: Open BVL-1855046, RIP2004-1973	Yes	Syngenta Agro	Y
KIIIA1 5.6	Crook, S.; Langridge, G.; McCarthy, I.	2015	Pinoxaden - Residue method GRM017.06A for the determination of Pinoxaden and its metabolites, NOA407854, NOA447204, SYN504574, SYN546105, SYN546106, SYN546107, SYN546108 in water by LC-MS/MS analysis NOA407855_10321 ! GRM017.06A ! TK0201316 GLP: No Published: No BVL-3015233, BVL-3015233, ASB2016-2670	Yes	Syngenta Agro	N
KIIIA1 5.6	Langridge, G.	2015	Pinoxaden - Validation of draft residue method GRM017.06A for the determination of Pinoxaden and its metabolites NOA407854, NOA447204, SYN504574, SYN546105, SYN546106, SYN546107 and SYN546108 in water NOA407855_10320 ! CEMR-6750-REG ! CEMS-6750 ! TK0202317 GLP: Yes Published: No BVL-3015234, BVL-3015234, ASB2016-2671	Yes	Syngenta Agro	Y

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
KIIIA1 5.9	West, J.	2004	Cloquintocet-mexyl (co-formulant in A-12303 C): Document I, Part 2 - Other toxicological and environmental data - Analytical methods - Tier 2, IIA-4 ERA7144 ! Doc. I ! NOA407855/0575 ! MII / Sec. 2 Syngenta Crop Protection AG, Basel, Switzerland GLP: No Published: No BVL-2603145, MET2005-318	No	Syngenta Agro	Y
MIIIA1 Sec 2	Applicant	2013	Cloquintocet + Pinoxaden + Pyroxsulam / A19786A: Analytical methods - Tier 2, IIIA-5 - Draft Registration Report - Part B - Core assessment A19786A_10036 ! MIII / Sec. 2 Syngenta European Product Registration, Basel, Switzerland GLP: No Published: No BVL-2603760, BVL-2603761, ASB2014-11481	No	Syngenta Agro	N
MIIIA1 Sec 2	Applicant	2013	Cloquintocet + Pinoxaden + Pyroxsulam / A19786A: Analytical methods - Tier 2, IIIA-5 - Draft Registration Report - Part B - National addendum - Netherlands MIII / Sec. 2 ! A19786A_10058 Syngenta European Product Registration, Basel, Switzerland GLP: No Published: No BVL-2603762, BVL-2603763, ASB2014-11482	No	Syngenta Agro	N

* Y Yes , relied on
N No, not relied on
Add: Relied on, study not submitted by applicant but necessary for evaluation

Appendix 2 – Detailed evaluation of the additional studies relied upon

A 1.1 Analytical methods for Pinoxaden

A 1.1.1 Description of Methods for the Analysis of Water

A 1.1.1.1 Analytical method 1

Reference:

Report: Langridge, G. (2015) Pinoxaden - Validation of draft residue method GRM017.06A for the determination of Pinoxaden and its metabolites NOA407854, NOA447204, SYN504574, SYN546105, SYN546106, SYN546107 and SYN546108 in water, Report No.: CEMR-6750-REG, Study No.: CEMS-6750, ASB2016-2671

Guideline(s): Yes (OCSPP 850.6100 (2012), SANCO/3029/99 Rev. 4 (2000), SANCO/825/00 Rev. 8.1 (2010))

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods

Water samples were acidified with formic acid to pH 2 and enriched by SPE using Oasis HLB cartridges. Analytes were eluted with acetonitrile followed by acetonitrile containing 1% formic acid. The solvent was evaporated to dryness and the remainder reconstituted in 0.2% formic acid in water+ 0.2% formic acid/acetonitrile (90/10 v/v). The sample concentration in final extract was 0.02 L/mL.
Final quantification is accomplished by LC-MS/MS using an Ace C18 column. The following MS/MS transitions are monitored: In ESI+ mode: m/z 401→317, 401→57 (Pinoxaden), m/z 317→115, 317→91 (M2), m/z 343→243, 343→115 (M56), m/z 333→149, 333→121 (M3). In ESI- mode: m/z 361→300, 361→305 (M11), m/z 359→159, 359→144 (M52), m/z 361→173, 361→217 (M54), m/z 375→271, 375→241 (M55).

Results and discussions

Table A 1: Recovery results from method validation of pinoxaden surface and groundwater using the analytical method. Standards were prepared in acetonitrile/methanol (9+1 v/v)

Matrix	Fortification level (µg/L)	No of samples per fortification level	Mean recovery	RSD (%)	Comments
Surface water	0.05 0.5	5 5	71 70	2.9 4.2	m/z 401→317
Groundwater	0.05 0.5	5 5	79 75	4.4 6.8	
Surface water	0.05 0.5	5 5	72 70	3.5 4.2	m/z 401→57
Groundwater	0.05 0.5	5 5	78 74	3.7 6.6	

Table A 2: Recovery results from method validation of metabolite M2 surface and groundwater using the analytical method. Standards were prepared in acetonitrile/methanol (9+1 v/v)

Matrix	Fortification level (µg/L)	No of samples per fortification level	Mean recovery	RSD (%)	Comments
Surface water	0.05 0.5	5 5	95 92	3.3 1.4	m/z 317→115
Groundwater	0.05 0.5	5 5	84 87	1.1 5.5	
Surface water	0.05 0.5	5 5	95 90	2.8 1.2	m/z 317→91
Groundwater	0.05 0.5	5 5	82 88	2.7 6.7	

Table A 3: Recovery results from method validation of metabolite M3 surface and groundwater using the analytical method. Standards were prepared in acetonitrile/methanol (9+1 v/v)

Matrix	Fortification level (µg/L)	No of samples per fortification level	Mean recovery	RSD (%)	Comments
Surface water	0.05 0.5	5 5	92 90	7.3 1.4	m/z 333→149
Groundwater	0.05 0.5	5 5	89 87	10.5 1.6	
Surface water	0.05 0.5	5 5	98 91	5.0 1.9	m/z 333→121
Groundwater	0.05 0.5	5 5	91 90	8.1 2.3	

Table A 4: Recovery results from method validation of metabolite M11 surface and groundwater using the analytical method. Standards were prepared in blank matrix

Matrix	Fortification level (µg/L)	No of samples per fortification level	Mean recovery	RSD (%)	Comments
Surface water	0.05 0.5	5 5	88 87	1.7 1.4	m/z 361→300
Groundwater	0.05 0.5	5 5	100 91	4.7 1.2	
Surface water	0.05 0.5	5 5	91 88	3.1 1.9	m/z 361→305
Groundwater	0.05 0.5	5 5	106 94	5.2 2.2	

Table A 5: Recovery results from method validation of metabolite M52 surface and groundwater using the analytical method. Standards were prepared in blank matrix

Matrix	Fortification level (µg/L)	No of samples per fortification level	Mean recovery	RSD (%)	Comments
Surface water	0.05 0.5	5 5	92 83	7.9 0.7	m/z 359→159
Groundwater	0.05 0.5	5 5	91 86	11.0 2.1	
Surface water	0.05 0.5	5 5	102 84	7.3 2.0	m/z 359→144
Groundwater	0.05 0.5	5 5	89 89	18.2 2.4	

Table A 6: Recovery results from method validation of metabolite M54 surface and groundwater using the analytical method. Standards were prepared in blank matrix

Matrix	Fortification level (µg/L)	No of samples per fortification level	Mean recovery	RSD (%)	Comments
Surface water	0.05 0.5	5 5	88 89	7.8 2.6	m/z 361→173
Groundwater	0.05 0.5	5 5	96 101	9.8 3.3	
Surface water	0.05 0.5	5 5	92 90	5.7 3.2	m/z 361→217
Groundwater	0.05 0.5	5 5	103 101	7.2 2.3	

Table A 7: Recovery results from method validation of metabolite M55 surface and groundwater using the analytical method. Standards were prepared in blank matrix

Matrix	Fortification level (µg/L)	No of samples per fortification level	Mean recovery	RSD (%)	Comments
Surface water	0.05 0.5	5 5	100 88	6.6 2.5	m/z 375→271
Groundwater	0.05 0.5	5 5	102 91	3.0 1.8	
Surface water	0.05 0.5	5 5	98 87	4.2 2.0	m/z 375→241

Groundwater	0.05 0.5	5 5	95 89	7.4 2.8	

Table A 8: Recovery results from method validation of metabolite M56 surface and groundwater using the analytical method. Standards were prepared in acetonitrile/methanol (9+1 v/v)

Matrix	Fortification level (µg/L)	No of samples per fortification level	Mean recovery	RSD (%)	Comments
Surface water	0.05 0.5	5 5	93 95	1.6 1.8	m/z 343→243
Groundwater	0.05 0.5	5 5	91 94	3.9 3.3	
Surface water	0.05 0.5	5 5	103 98	3.0 1.6	m/z 343→115
Groundwater	0.05 0.5	5 5	93 92	4.3 2.1	

Table A 9: Characteristics for the analytical method used for the quantitation of pinoxaden and metabolites residues in water

	Pinoxaden	**M2**	**M3**	**M11**	**M52**	**M54**	**M55**	**M56**
Calibration function	y = 910886x-139032 x in ng/mL r^2 = 0.9993	y = 49975x- -1471 x in ng/mL r^2 = 0.9998	y = 24670x- -1577 x in ng/mL r^2 = 0.9997	y = 24710x -2379 x in ng/mL r^2 = 0.9996	y = 8045x -798 x in ng/mL r^2 = 0.9987	y = 5460x – 2251 x in ng/mL r^2 = 0.9995	y = 16426x – -1485 x in ng/mL r^2 = 0.9983	y = 114227x- -5336 x in ng/mL r^2 = 0.9997
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	0.3 – 15 ng/mL	0.3 – 15 ng/mL	0.3 – 15 ng/mL	0.3 – 15 ng/mL	0.3 – 15 ng/mL	0.3 – 15 ng/mL	0.3 – 15 ng/mL	0.3 – 15 ng/mL
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.015 – 0.75 µg/L	0.015 – 0.75 µg/L	0.015 – 0.75 µg/L	0.015 – 0.75 µg/L	0.015 – 0.75 µg/L	0.015 – 0.75 µg/L	0.015 – 0.75 µg/L	0.015 – 0.75 µg/L
Does the calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/ no)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Assessment of matrix effects is presented (yes/no)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Interference >30% of LOQ in blank sample is absent (yes/no)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Conclusion

The method is successfully validated for the quantification of pinoxaden and metabolites M2, M3, M11, M52, M54, M55 and M56 in surface and groundwater. The validated limit of quantification is 0.05 µg/L. A confirmation of the results is included by validation of a second MRM transition.

Comments of zRMS:	Acceptable

A 1.2 Analytical methods for Cloquintocet-mexyl

A 1.2.1 Methods for enforcement of residues in food and feed of plant origin

A 1.2.1.1 Analytical method 1

Reference: OECD KIII A, 5.3.1

Report: Analysis of foodstuffs: Modular multiple analytical method for the determination of pesticide residues in foodstuffs (Extended and revised version of the DFG method S 19) (Collection of official methods under article 35 of the German Federal Food Act), Anonymous, 2010, L 00.00-34, ASB2013-8342

Guideline(s): No

Deviations: Not applicable

GLP: Not applicable

Acceptability: Yes

Materials and methods

Dry crops, acidic commodities, high water content commodities, and commodities with high oily content are analyzed according to the multiresidue method L 00.00-34 (Extended and revised version of the DFG method S 19).
The sample material is extracted by homogenization with acetone/water (8/2, v/v).
Using the extraction modules E1or E2 NaCl is added to the extracts and partitioned into ethyl acetate/cyclohexane. It is evaporated to aqueous reminder, diluted with ethyl acetate/cyclohexane and dried with sodium sulphate/sodium chloride. Using the extraction modules E4 or E5 NaCl is added to the extracts and partitioned into dichloromethane. It is evaporated to aqueous reminder, diluted with ethyl acetate/cyclohexane and dried with sodium sulphate. All extracts are cleaned by size exclusion chromatography. The eluates are evaporated to dryness and dissoluted in hexane/toluene (65/35). Subsequently a chromatography on silica (1.5% water) is performed. Residues are eluted with toluene. The eluate is evaporated to dryness and reconstituted in toluene. Final quantification is done by GC-NPD using a DB-5 column.

Results and discussions

Table A 10: Recovery results from method validation of matrices with high water content, dry commodities, acidic and fatty matrices using the analytical multi-method.

Matrix	Fortification level (mg/kg)	Method	Mean recovery	RSD (%)	No of analyses
High water content	0.05 – 0.5	E1 E1+C1 E4+C1	89 95 73	10 5 22	9 (2 labs) 3 (1 labs) 9 (3 labs)

Dry	0.05 – 0.5	E2 E2+C1 E5+C1	83 99 80	20 9 28	18 (2 labs) 6 (1 labs) 18 (3 labs)
Acidic	0.05 – 0.5	E1 E1+C1 E4+C1	86 89 79	12 7 21	9 (2 labs) 3 (1 labs) 9 (3 labs)
Fatty	0.05 – 0.5	E1 E1+C1 E4+C1	74 98 99	24 12 47	9 (2 labs) 3 (1 labs) 6 (2 labs)

Table A 11: Characteristics for the analytical method used for the quantitation of Cloquintocet-mexyl residues in matrices with high water content, dry commodities, acidic and fatty matrices

	Cloquintocet-mexyl
Calibration function	Not stated
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	Not stated
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	Not stated
Does the calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/ no)	Yes
Assessment of matrix effects is presented (yes/no)	No
Interference >30% of LOQ in blank sample is absent (yes/no)	Yes

Conclusion

The multiresidue method L 00.00-34 (Extended and revised version of the DFG method S 19) is validated for the quantification of cloquintocet-mexyl in dry, acidic, high water content and high oily content plant commodities using GC-NPD detection. The validated limit of quantification is 0.05 mg/kg. The applicability of the method is proven by proficiency tests in 1 - 3 labs.

Comments of zRMS:	acceptable

A 1.2.1.2 Analytical method 2

Reference: OECD KIII A, 5.3.1

Report: Cloquintocet-mexyl: Independent Laboratory Validation of an Analytical Method for the Determination of Cloquintocet-mexyl and Its Acid Metabolite in Cereal, Class, T., 2005, 40096 ! P 798 G ! 10000233-5008-2; MET2006-541

Guideline(s): Yes (SANCO/825/00/rev.7, OPPTS 860.1340© (6))

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods

Sample material of dry crops (wheat grain, wheat straw) and of commodities with high water content (wheat shoots) is extracted by homogenization with acetone/citrate buffer 88/2, v/v). The extracts are cleaned by solid phase extraction on Strata X. Residues are elute with 0.1% formic acid in methanol. The sample concentration in the final extract is 0.0125 g/mL.
Final quantification is done by LC-MS/MS using a C18 column, electrospray ionization in positive mode and monitoring the MS/MS transitions m/z 336→238 for cloquintocet-mexyl and m/z 238→179 for cloquintocet-acid. Quantification is performed using stable isotope internal standards ^{13}C-cloquintocet-mexyl and ^{13}C-cloquintocet-acid.

Results and discussions

Table A 12: Recovery results from the method validation of dry crops and commodities with high water content using the analytical method. Standards were prepared in methanol

Matrix	Fortification level (mg/kg)	No of samples per fortification level	Mean recovery	RSD (%)	Comments
Wheat grain	0.01 0.1	5 5	106 109	8 5	m/z 336→238 cloquintocet-mexyl
Wheat straw	0.01 0.1	5 5	98 102	2 6	
Wheat shoots	0.01 0.1	5 5	96 104	7 5	
Wheat grain	0.01 0.1	5 5	89 108	11 6	m/z 238→179 cloquintocet-acid
Wheat straw	0.01 0.1	5 5	79 100	5 5	
Wheat shoots	0.01 0.1	5 5	85 101	11 12	

Table A 13: Characteristics for the confirmatory method used for the quantitation of cloquintocet-mexyl residues in dry crops and commodities with high water content

	Cloquintocet-mexyl	Cloquintocet-acid
Calibration function	linear R^2=0.9993	linear R^2=0.9996
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	0.05 – 2 ng/mL	0.05 – 2 ng/mL
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.004 – 0.16 mg/kg	0.004 – 0.16 mg/kg
Does the calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/ no)	Yes	Yes
Assessment of matrix effects is presented (yes/no)	No	No

Interference >30% of LOQ in blank sample is absent (yes/no)	Yes	Yes

Conclusion

The method is sufficiently validated for the quantification of cloquintocet-mexyl and cloquintocet-acid in dry crops and in commodities with high water content using MS/MS detection. The validated limit of quantification is 0.01 mg/kg. Validation data for a second transition are missing.

Comments of zRMS:	acceptable

A 1.2.2 Description of Methods for the Analysis of Water

A 1.2.2.1 Analytical method 1

Reference: OECD KIIIA, 5.6

Report: CGA 184927 and its metabolite CGA 193469 and CGA 185072 and its metabolite CGA 153433: The validation of an analytical method for the determination of residues in water, Abrar, M., Anderon, C., 1997, 621/25-1019 ! CGA184927/0667, MET2004-763

Guideline(s): Yes (Commission Directive 4701/VI/94-Rev.4, 1995)

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods

The analytical method is validated for determination of cloquintocet-mexyl and cloquintocet-acid in surface water (sand water). Sampling site of water samples is given in the report. After addition of methanol/5% formic acid in water (3/4, v/v) the sample is applied to solid phase extraction cartridge (Bond-Elut C18). Residues are eluted with methanol/formic acid (99/1, v/v). After addition of water the eluate is evaporated to the aqueous residue. It is diluted with water/methanol/formic acid (50/50/1, v/v/v). The sample concentration in the final extract is 0.03 L/mL.
Final determination is done by LC-MS/MS using an Inertsil Phenyl column, electrospay ionization in positive mode and monitoring the MS/MS transitions m/z 336→238 for cloquintocet-mexyl and m/z 238→179 for cloquintocet-acid.

Results and discussions

Table A 14: Recovery results from method validation of surface water using the analytical method. Standards were prepared in ethanol

Matrix	Fortification level (µg/L)	No of samples per fortification level	Mean recovery	RSD (%)	Comments
Surface water	0.05 0.25 1	3 3 3	89 79 85	18.5 7.4 6.5	m/z 336→238 cloquintocet-mexyl
Surface water	0.05 0.25 1	3 3 3	79 86 91	1.3 4.9 3.8	m/z 238→179 cloquintocet-acid

Table A 15: Characteristics for the analytical method used for the quantitation of Cloquintocet-mexyl residues in surface water

	cloquintocet-mexyl	**cloquintocet-acid**
Calibration function	Linear R^2=0.9997	Linear R^2=0.9994
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	0.78 – 50 ng/mL	0.78 – 50 ng/mL
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.026 – 1.667 µg/L	0.026 – 1.667 µg/L
Does the calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/ no)	Yes	Yes
Assessment of matrix effects is presented (yes/no)	No	No
Interference >30% of LOQ in blank sample is absent (yes/no)	Yes	Yes

Conclusion

The method is validated for the quantification of cloquintocet-mexyl and cloquintocet-acid in surface water using MS/MS detection. Since analysis of surface water is usually more demanding the method is accepted for drinking water also. According to SANCO/825/00 rev. 8.1 a number of three fortified samples per level is insufficient. The validated limit of quantification is 0.05 µg/L. Validation data for a second transition are missing.

Comments of zRMS:	acceptable for confirmatory purposes

REGISTRATION REPORT
Part B

Section 3: Mammalian Toxicology
Detailed summary of the risk assessment

Product name: AVOXA
Active Substances:
Cloquintocet-mexyl 8.33 g/L
Pinoxaden 33.3 g/L
Pyroxsulam 8.33 g/L

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Syngenta Agro GmbH
Date: March 2017

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3 Mammalian Toxicology (IIIA 7)

3.1 Summary

Table 3.1-1: Information on A19786A*

Product name and code	A19786A
Formulation type	Emulsifiable concentrate
Active substance(s) (incl. content)	Cloquintocet-mexyl; 8.33 g/L Pinoxaden; 33.3 g/L Pyroxsulam; 8.33 g/L
Function	Herbicide
Product already evaluated as the 'representative formulation' during the Annex I inclusion	No
Product previously evaluated in another MS according to Uniform Principles	No

* Information on the detailed composition of A19786A can be found in the confidential dRR Part C.

Justified proposals for classification and labelling

In accordance with the criteria given in Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 the following classification and labelling with regard to toxicological data is proposed for the preparation:

Table 3.1-2: Justified proposals for classification and labelling

C&L according to Regulation (EC) No 1272/2008	
Hazard class(es), categories:	Skin Sens. 1, Eye Irrit. 2, Repr. 2
Signal word:	Warning
Hazard statement(s):	317-319-361d
Precautionary statement(s):	101-102-201-280-302+352-305+351+338-308+313-362+364-405-501
Additional labelling phrases:	To avoid risks to human health and the environment, comply with the instructions for use. [EUH401]
	'Contains cloquintocet-mexyl (CAS No. 99607-70-2), pinoxaden (CAS No. 243973-20-8), and pyroxsulam (CAS No. 422556-08-9). May produce an allergic reaction.' [EUH208]

Table 3.1-3: Summary of risk assessment for operators, workers, bystanders and residents for A19786A

	Result	**PPE / Risk mitigation measures**
Operators	Acceptable	- Avoid any unnecessary contact with the product. Misuse can lead to health damage [SB001]. - Concerning the requirements for personal protective gear for handling the plant protection product the material safety data sheet and the instructions for use of the plant protection product as well as the guideline "Personal protective gear for handling plant protection products" of the Federal Office of Consumer Protection and Food Safety

		(www.bvl.bund.de) must be observed. [SB111]. - Do not eat, drink or smoke when using this product [SB166]. - Wear standard protective gloves (plant protection) when handling the undiluted product [SS110]. - Working clothes (if no specific protective suit is required) and sturdy footwear (e.g. rubber boots) must be worn when applying/handling plant protection products [SS206]. - Wear a protective suit against pesticides and sturdy shoes (e.g. rubber boots) when handling the undiluted product [SS2101]. - Wear face protection when handling the undiluted product. [SS530]. - Wear a rubber apron when handling the undiluted product [SS610].
Workers	Acceptable	- Treated areas/crops may not be entered until the spray coating has dried [SF245-01].
Bystanders	Acceptable	None
Residents	Acceptable	None

According to the German model, no unacceptable risk for operators, workers, bystanders and residents was identified when the product is used as intended. No specific PPE is necessary.

The risk assessment according to the UK-POEM has shown that the estimated exposure towards cloquintocet-mexyl and pinoxaden in A19786A will exceed the particular systemic AOEL for operators, unless prescribed PPE is worn.

Further reduction of exposure is to be expected due to necessary PPE allocated according to dangerous substances regulations.

A summary of the critical uses and the overall conclusion regarding exposure for operators, workers and bystanders/residents is presented in Table 3.1-4.

Table 3.1-4 Critical uses and overall conclusion of exposure assessment

1	2	3	4	5	6	7	8			
Crops [1] and situation (e.g. growth stage of crop)	**F/G or I [2]**	**Application**		**Application rate**		**Remarks:** **(e.g. surfactant (L /ha))**	**Acceptability of exposure assessment**			
		Method / Kind (incl. application technique [3])	**Max. number (min. interval between applications)** **a) per use** **b) per crop/ season**	**kg as/ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**Water L/ha** **min / max**	**critical gap for operator, worker, bystander or resident exposure based on [*Exposure model*]**	**Operator**	**Worker**	**Bystander**	**Residents**
Winter wheats	F	HCTM	a) 1	a) 0.015 (cloquintocet-mexyl); 0.06 (pinoxaden); 0.015 (pyroxsulam)	100-300	German model				
			b) 1	b) 0.015 (cloquintocet-mexyl); 0.06 (pinoxaden); 0.015 (pyroxsulam)		UK POEM				

	Exposure acceptable without PPE / risk mitigation measures
	Further refinement and/or risk mitigation measures required
	Exposure not acceptable/ Evaluation not possible

[1] Pooled critical GAPS with the same max. application rate per application and using the same application technique
[2] F: field or outdoor application, G: greenhouse application, I: indoor application
[3] HC: high crop, TM: tractor-mounted

3.2 Toxicological Information on Active Substance(s)

Information regarding classification of the active substances and on EU endpoints and critical areas of concern identified during the EU review are given in Table 3.2-1. Information regarding the safener are given in Table 3.2-2.

Table 3.2-1: Information on active substance(s)

	Active substance A	**Active substance B**
Common Name	Pinoxaden	Pyroxsulam
CAS-No.	243973-20-8	422556-08-9
Classification and proposed labelling		
With regard to toxicological enpoints (according to the criteria in Reg. 1272/2008)	Hazard symbol(s): no harmonized classification and labelling Indication(s) of danger: - Risk phrases: -	Hazard symbol(s): no harmonized classification and labelling Indication(s) of danger: - Risk phrases: -
Additional C&L proposal	Proposal EU Peer Review (EFSA Journal 2013;11(8):3269 [ASB2013-10732]): Warning, Skin Irr. 2, H315: Causes skin irritation Warning, Skin Sens. 1A, H317: May cause an allergic skin reaction Warning, Eye Irrit. 2, H319: Causes serious eye irritation Warning, Acute Tox. 4, H332: Harmful if inhaled Warning, STOT SE 3, H335: May cause respiratory irritation Warning, Repr. 2, H361d: Suspected of damaging the unborn child RAC opinion (ECHA, CLH-O-0000001412-86-127/F, September 2016): Warning, Skin Sens. 1A, H317: May cause an allergic skin reaction Warning, Eye Irrit. 2, H319: Causes serious eye irritation Warning, Acute Tox. 4, H332: Harmful if inhaled Warning, STOT SE 3, H335: May cause respiratory irritation Warning, Repr. 2, H361d: Suspected of damaging the unborn child	Proposal EU Peer Review (EFSA Journal 2013;11(4):3182): Warning, Skin Sens. 1A, H317: May cause an allergic skin reaction RAC opinion (ECHA, CLH-O-0000001412-86-102/F, March 2016): Warning, Skin Sens. 1, H317
Agreed EU endpoints		
AOEL systemic	0.1 mg/kg bw/d	0.7 mg/kg bw/d (corrected for 75 % oral absorption)
Reference	EFSA Journal 2013;11(8):3269(2013-06-14)	(EFSA Journal 2013;11(4):3182
Conditions to take into account/critical areas of conern with regard to toxicology		
Review Report for active substance	None	None

Table 3.2-2: Information on the safener cloquintocet-mexyl

	Safener
Common Name	Cloquintocet-mexyl
CAS-No.	243973-20-8
Classification and proposed labelling	
With regard to toxicological enpoints (according to the criteria in Reg. 1272/2008)	Hazard symbol(s): no harmonized classification and labelling Indication(s) of danger: - Risk phrases: -
Additional C&L proposal	Proposal BfR: Warning, Skin Sens. 1, H317: May cause an allergic skin reaction
Endpoints (not agreed on EU level)	
AOEL systemic	0.05 mg/kg bw/d (corrected for 50 % oral absorption)
Reference	Proposal BfR
Review Report for active substance	None

3.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for A19786A is given in Table 3.3-1. Full summaries of studies on the product are presented in Appendix 2. MSDS on A19786A can be found in the confidential dRR Part C.

Table 3.3-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for A19786A

Type of test, model system (Guideline)	**Result**	**Acceptability**	**Classification (acc. to the criteria in Reg. 1272/2008)**	**Reference**
LD_{50} oral, rat (OECD 425)	>2000 mg/kg bw	Yes	None	[redacted] 2013 ASB2014-11469
LD_{50} dermal, rat (OECD 402)	>2000 mg/kg bw	Yes	None	[redacted], 2013 ASB2014-11470
LC_{50} inhalation, rat	Not submitted, not necessary. Justification presented in Annex 2.*)			
Skin irritation, rabbit (OECD 404)	Non-irritant	Yes	None	[redacted] 2013 ASB2014-11471
Eye irritation, rabbit (OECD 405)	Irritant	Yes	Warning, Eye Irrit. 2, H319	[redacted] 2013 ASB2014-11472
Skin sensitisation, mouse (OECD 429, LLNA)	Sensitising	Yes	Warning, Skin Sens. 1, H317	[redacted] 2013 ASB2014-11473
Supplementary studies for combinations of plant protection products	No data – not required			

*) LC_{50} inhalation >5 mg/L air according to EFSA calculation method, no classification required

Table 3.3-2: Additional toxicological information relevant for classification/labelling of A19786A

	Substance (Concentration in product, % w/w)	**Classification of the substance (acc. to the criteria in Reg. 1272/2008)**	**Reference**	**Classification of product (acc. to the criteria in Reg. 1272/2008)**
Toxicological properties of active substance(s) (relevant for classification of product)	Cloquintocet-mexyl (0.8 % (w/w)) Pinoxaden (3.2 % (w/w)) Pyroxsulam (0.8 % (w/w))	EUH208 (≥ 0.01 %) H317 (≥ 0.1 %), EUH208 (≥ 0.01 %) EUH208 (≥ 0.01 %)	EFSA conclusion, BfR proposal, RAC-opinion, MSDS by the applicant	EUH208 H317 EUH208 EUH208
	Pinoxaden (3.2 % (w/w))	H361d (≥ 3 %),	EFSA Journal 2013;11(8):3269; RAC opinion	H361d
Toxicological properties of non-active substance(s) (relevant for classification of product)				
Further toxicological information	No data – not required			

A summary of the toxicological evaluation for A19786A based on the Regulation (EC) No 1272/2008 calculation method is given in Table 3.3-3.

Table 3.3-3: Summary of evaluation of the acute toxicity including irritancy and skin sensitisation for A19786A according to the calculation method (acc. to Reg. 1272/2008)

Endpoint	**Result**	**Classification (acc. to the criteria in Reg. 1272/2008)**
LD_{50} oral*	1303 mg/kg bw	H302
LD_{50} dermal**	1303 mg/kg bw	H312
LC_{50} inhalation**	6.14 mg/L	None
Skin corrosion (Category 1 A, 1 B, 1 C)	No calculation possible since no known skin corrosive components	
Skin irritation (Category 2)	7.0% content equivalents	None
Eye damage (Category 1)	No calculation possible since no known eye damaging components	
Eye irritation (Category 2)	38.2%	H319
Skin sensitisation	> 1% of known skin sensitising substance in A19786A	H317
Supplementary studies for combinations of plant protection products	No data – not required	

* based on using legal classification/labelling of benzyl benzoate with H302 corresponding to ATE of 500 mg/kg bw which reflects the agreed classification rather than the observed experimental results of an acute LD_{50} of >2000 mg/kg bw in rats (see registration report in ECHA data base), there is no other known acutely oral toxic component in A19786A.

** ATE of 500 mg/kg bw for acute oral toxicity of benzyl benzoate used as a point of departure for route-to-route extrapolation taking into account other relevant acute toxic components where necessary.

As can be seen, the calculation method results in a more conservative classification/labelling of product A19786A than using the study results on the product.
Since available animal studies using the product are considered valid, classification/labelling for A19786A with respect to acute toxicity, skin and eye irritation as well as skin sensitisation is carried out according to the study results by the zRMS (please, see Table 3.1-2).

3.4 Toxicological evaluation of groundwater metabolites

A relevance assessment of the following groundwater metabolites of pinoxaden and pyroxsulam is required.

Pinoxaden metabolites:
- M3
- M11
- M52
- M54
- M55
- M56

Pyroxsulam metabolites
- PSA
- 6-Cl-7-OH

The relevance assessment of these groundwater metabolites of pinoxaden and pyroxsulam according to the EU guidance document SANCO/221/2000-rev. 10 is reported in Section 8 of the dRR.
Evaluations of those studies that have not been previously reviewed at EU level are found in A 2.11 of this document.

3.5 Dermal Absorption (IIIA 7.6)

A summary of the dermal absorption endpoints for the active substances in A19786A is presented in Table 3.5-1 and Table 3.5-2.

Table 3.5-1: Dermal absorption endpoints for the active substances in A19786A

	Pinoxaden		Pyroxsulam	
	Value	**Reference**	**Value**	**Reference**
Concentrate	75 %	EFSA Journal 2012;10(4):2665	75 %	EFSA Journal 2012;10(4):2665
Dilutions	75 %	EFSA Journal 2012;10(4):2665	75 %	EFSA Journal 2012;10(4):2665

Table 3.5-2: Dermal absorption endpoints for the safener in A19786A

	Cloquintocet-mexyl	
	Value	**Reference**
Concentrate	75 %	EFSA Journal 2012;10(4):2665 (bridging from oral absorption of active substance not acceptable)
Dilutions	75 %	EFSA Journal 2012;10(4):2665 (bridging from oral absorption of active substance not acceptable)

3.5.1 Justification for proposed values - Pinoxaden

No data on dermal absorption for Pinoxaden in A19786A are available. Justification for default values according to Guidance on Dermal Absorption (EFSA Journal 2012; 10(4):2665) are presented in Table Table 3.5-3.

Table 3.5-3: Default dermal absorption endpoints for Pinoxaden

	Value	Justification for value	Acceptability of justification
Concentrate	75 %	According to EFSA Journal 2012;10(4):2665 (conc. of a. s. is ≤ 5%)	Yes
Dilution	75 %	According to EFSA Journal 2012;10(4):2665 (conc. of a. s. is ≤ 5%)	Yes

3.5.2 Justification for proposed values - Pyroxsulam

No data on dermal absorption for Pyroxsulam in A19786A is available. Justification for default values according to Guidance on Dermal Absorption (EFSA Journal 2012; 10(4):2665) are presented in Table 3.5-4.

Table 3.5-4: Default dermal absorption endpoints for Pyroxsulam

	Value	Justification for value	Acceptability of justification
Concentrate	75 %	According to EFSA Journal 2012;10(4):2665 (conc. of a. s. is ≤ 5%)	Yes
Dilution	75 %	According to EFSA Journal 2012;10(4):2665 (conc. of a. s. is ≤ 5%)	Yes

3.5.3 Justification for proposed values – Cloquintocet-mexyl

No data on dermal absorption for Cloquintocet-mexyl in A19786A is available. Justification for default values according to Guidance on Dermal Absorption (EFSA Journal 2012; 10(4):2665) are presented in Table 3.5-5.

Table 3.5-5: Default dermal absorption endpoints for Cloquintocet-mexyl

	Value	Justification for value	Acceptability of justification
Concentrate	75 %	According to EFSA Journal 2012;10(4):2665 (conc. of a. s. is ≤ 5%, bridging from oral absorption of active substance not acceptable)	Yes
Dilution	75 %	According to EFSA Journal 2012;10(4):2665 (conc. of a. s. is ≤ 5%, bridging from oral absorption of active substance not acceptable)	Yes

3.6 Exposure Assessment of Plant Protection Product

Table 3.6-1: Product information and toxicological reference values used for exposure assessment

Product name and code	A19786A		
Formulation type	Emulsifiable concentrate		
Category	Herbicide		
Container size(s), short description	HDPE cannnisters: 1 L (45 mm screw cap opening) 5 and 10 L (63 mm screw cap opening) 20 L (screw cap opening)		
Active substance(s) (incl. content)	**Cloquintocet-mexyl** 8.33 g/L	**Pinoxaden** 33.3 g/L	**Pyroxsulam** 8.33 g/L
AOEL systemic	0.05	0.1 mg/kg bw/d	0.7 mg/kg bw/d
Inhalative absorption	100 %	100 %	100 %
Oral absorption	50 %	100 %	75 %

3.6.1 Selection of critical use(s) and justification

The critical GAP used for the exposure assessment of the plant protection product is shown in see Table 3.1-4.

3.6.2 Operator exposure (IIIA 7.3)

3.6.2.1 Estimation of operator exposure

A summary of the exposure models used for estimation of operator exposure to the active substance(s) during application of A19786A according to the critical use(s) is presented in Table 3.6-2. Outcome of the estimation is presented in Table 3.6-3. Detailed calculations are in Appendix 3.

Table 3.6-2: Exposure models for intended uses

Critical use(s)	Winter wheats (max. 1 x 1.8 L product/ha)
Model(s)	German model [Uniform Principles for Safeguarding the Health of Applicators of Plant Protection Products (Uniform Principles for Operator Protection), Mitteilungen aus der Biologischen Bundesanstalt für Land-und Forstwirtschaft, Berlin-Dahlem, Heft 277, 1992] Revised UK-POEM [Estimation of Exposure and Absorption of Pesticides by Spray Operators, Scientific subcommittee on Pesticides and British Agrochemical Association Joint Medical Panel Report (UK MAFF), 1986 and the Predictive Operator Exposure Model (POEM) V 1.0, (UK MAFF), 1992]

Table 3.6-3: Estimated operator exposure

		Cloquintocet-mexyl		Pinoxaden		Pyroxsulam	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Tractor mounted boom spray application outdoors to low crops Application rate:		0.015 kg a.s./ha		0.06 kg a.s./ha		0.015 kg a.s./ha	
German Model Body weight: 70 kg	no PPE*)	0.014	28.6	0.057	57.0	0.014	2.0
	+ PPE (Gloves mixing/loading)	0.007	13.3	0.027	26.5	0.007	0.9
UK POEM Application volume: 1.8 L/ha Container: 10 L (63 mm opening) Body weight: 60 kg	no PPE**)	0.125	249.8	0.499	499.0	0.125	17.8
	+ PPE (Gloves mixing/loading, gloves application)	0.017	33.9	0.068	67.6	0.083	11.8

*) no PPE: Operator wearing T-shirt and shorts

**) no PPE: Operator wearing long sleeved shirt, long trousers ("permeable") but no gloves

3.6.2.2 Measurement of operator exposure

Since the operator exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses, where appropriate with personal protective equipment, a study to provide measurements of operator exposure was not necessary and was therefore not performed.

3.6.3 Worker exposure (IIIA 7.5)

3.6.3.1 Estimation of worker exposure

Table 3.6-4 shows the exposure model(s) used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with A19786A according to the critical use(s). Outcome of the estimation is presented in Table 3.6-5. Detailed calculations are in Appendix 3.

Table 3.6-4: Exposure models for intended uses

Critical use(s)	Winter wheats (max. 1 x 1.8 L product/ha)
Model	German re-entry model, Krebs et al. (2000) [Uniform Principles for Safeguarding the Health of Workers Re-entering Crop Growing Areas after Application of Plant Protection Products, Nachrichtenbl. Deut. Pflanzenschutzdienst., 52(1), p. 5-9]

Table 3.6-5: Estimated worker exposure

		Cloquintocet-mexyl		Pinoxaden		Pyroxsulam	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Number of applications and application rate:		1 x 0.015 kg a.s./ha		1 x 0.06 kg a.s./ha		1 x 0.015 kg a.s./ha	
2 hours/day *), TC: 12500 cm^2/person/h **) DFR: 1 µg/cm^2 Body weight: 60 kg	no PPE***)	0.0047	9.4	0.019	18.7	0.005	0.7

*) for professional applications for maintenance, inspection or irrigation activities etc.

**) total potential exposure; EFSA, 2014, Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products, *EFSA Journal*, 12(10):3874.

***) at an assumed 3 µg/cm^2/kg a.s., exploitation of AOEL would amount to 28.1 % (cloquintocet-mexyl), 56.2 % (pinoxaden), and 2.0 (pyroxsulam)

3.6.3.2 Measurement of worker exposure

Since the worker exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses, a study to provide measurements of worker exposure was not necessary and was therefore not performed.

3.6.4 Bystander and resident exposure (IIIA 7.4)

3.6.4.1 Estimation of bystander and resident exposure

Table 3.6-6 shows the exposure model(s) used for estimation of bystander and resident exposure to pinoxaden and pyroxsulam. Outcome of the estimation is presented in Table 3.6-7. Detailed calculations are in Appendix 3.

Table 3.6-6: Exposure models for intended uses

Critical use(s)	Winter wheats (max. 1 x 1.8 L product/ha)
Model	Martin, S. et al. (2008) [Guidance for Exposure and Risk Evaluation for Bystanders and Residents Exposed to Plant Protection Products During and After Application; J. Verbr. Lebensm. 3 (2008): 272-281 Birkhäuser Verlag Basel] and Bundesanzeiger (BAnz), 06 January 2012, Issue No. 4, pp. 75-76

Table 3.6-7: Estimated bystander and resident exposure

	Cloquintocet-mexyl		Pinoxaden		Pyroxsulam	
Model data	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Tractor mounted boom spray application outdoors to low crops Application rate:	0.015 kg a.s./ha		0.060 kg a.s./ha		0.015 kg a.s./ha	
Bystanders (adult) Drift rate: 2.77 % (1 m) Body weight: 60 kg	0.0005	1.0	0.0021	2.1	0.0005	0.1
Bystanders (children) Drift rate: 2.77 % (1 m) Body weight: 16.15 kg	0.0004	0.8	0.0016	1.6	0.0004	0.1
Residents (adult) Drift rate: 2.77 % (1 m) Body weight: 60 kg	0.00004	0.1	0.0002	0.2	0.00004	0.01
Residents (children) Drift rate: 2.77 % (1 m) Body weight: 16.15 kg	0.00005	0.1	0.0002	0.2	0.00006	0.01

3.6.4.2 Measurement of bystander and/or resident exposure

Since the bystander and/or resident exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) for pinoxaden and pyroxsulam will not be exceeded under conditions of intended uses, a study to provide measurements of bystander/resident exposure was not necessary and was therefore not performed.

3.6.5 Statement on combined exposure

The product is a mixture of two active substances and a safener. Therefore a combined exposure assessment has been performed for operators.

Table 3.6-8: Risk assessment from combined exposure (longer term exposure)

Application scenario	Active Ingredient	Estimated exposure / AOEL (HQ, Hazard Quotient)
Operators – winter wheats, FCTM, German model, without PPE	Pinoxaden	0.57
	Pyroxsulam	0.02
	Cloquintocet-mexyl	0.286
	Cumulative risk Operators (HI, Hazard Index)	**0.876**

Under considerations applied, the Hazard Index is < 1.

Based on this assessment of combined exposure a health risk for operators can be excluded. Thus, there is no need for refinement.

Appendix 1 Reference list

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
	EFSA	2013	Conclusion on the peer review of the pesticide risk assessment of the active substance Pinoxaden EFSA Journal 2013;11(8):3269 ! EFSA-Q-2009-00329 ASB2013-10732			
KIIIA1 7.1.6	[redacted]	2013	Pinoxaden/Pyroxsulam/Cloquintocet-mexyl EC (A19786A): Local lymph node assay in the mouse A19786A ! 12/343-037E GLP: Yes Published: No BVL-2603150, ASB2014-11473	Yes	Syngenta Agro	Y
KIIIA1 7.1.1	[redacted]	2013	Pinoxaden/Pyroxsulam/Cloquintocet-mexyl EC (A19786A): Acute oral toxicity study in the rat A19786A ! 12/343-001P GLP: Yes Published: No BVL-2603146, ASB2014-11469	Yes	Syngenta Agro	Y
KIIIA1 7.1.2	[redacted]	2013	Pinoxaden/Pyroxsulam/Cloquintocet-mexyl EC (A19786A): Acute dermal toxicity study in rats A19786A ! 12/343-002P GLP: Yes Published: No BVL-2603147, ASB2014-11470	Yes	Syngenta Agro	Y
KIIIA1 7.1.4	[redacted]	2013	Pinoxaden/Pyroxsulam/Cloquintocet-mexyl EC (A19786A): Primary skin irritation study in rabbits A19786A ! 12/343-006N GLP: Yes Published: No BVL-2603148, ASB2014-11471	Yes	Syngenta Agro	Y
KIIIA1 7.1.5	[redacted]	2013	Pinoxaden/Pyroxsulam/Cloquintocet-mexyl EC (A19786A): Acute eye irritation study in rabbits A19786A ! 12/343-005N GLP: Yes Published: No BVL-2603149, ASB2014-11472	Yes	Syngenta Agro	Y
KIIA 5.8	[redacted]	2011	SYN546108: Micronucleus assay in bone marrow cells of the mouse SYN546108_10001 ! 1422502 ! TK0060522 BVL-2600064, BVL-3015267, BVL-3015267, ASB2013-398	Yes	Syngenta Agro	Y
KIIA 5.8	[redacted]	2014	XDE-742 Sulfonic Acid: Acute oral toxicity study in F344/DuCrl rats 141089 GLP: Yes Published: No BVL-2797976, ASB2015-4380	Yes	DOW	Add
KIIA 5.8	Sokolowski, A.	2011	SYN546108: Salmonella typhimurium and Escherichia coli reverse mutation assay SYN546108_10000 ! 1422501 ! TK0060521 BVL-2599895, BVL-3015265, BVL-3015265, ASB2013-397	Yes	Syngenta Agro	Y
KIIA 5.8	Tendulkar, K. E.	2014	In vitro Mammalian chromosome aberration test of 6-CI-7-0H-742 metabolite in human peripheral blood lymphocytes 140428 ! 488-1-06-8448 GLP: Open Published: No BVL-2797972, ASB2015-4378	Yes	DOW	Add

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
KIIA 5.8	Tendulkar, K. E.	2014	In vitro mammalian cell gene forward mutation test at the hgprt locus of the chinese hamster ovary (CHO)-Kl cell line using 6-CI-7-0H-742 metabolite 140429 ! 482-1-06-8449 GLP: Yes Published: No BVL-2797981, ASB2015-4379	Yes	DOW	Add
KIIA 5.8	Wollny, H.-E.	2011	SYN546108: Cell mutation assay at the thymidine kinase locus (TK +/-) in mouse lymphoma L5178Y cells SYN546108_10002 ! 1422503 ! TK0060523 BVL-2600026, BVL-3015266, BVL-3015266, ASB2013-396	Yes	Syngenta Agro	Y

*Y, Yes/relied on; N, No/not relied on; Add, Additional, Relied on/study not submitted by applicant but necessary for evaluation

Appendix 2 Detailed evaluation of the studies relied upon

A 2.1 Statement on bridging possibilities

Bridging was not necessary as all studies were performed with the proper formulation.

A 2.2 Acute oral toxicity (IIIA1 7.1.1)

Comments of zRMS:	Study acceptable according to mentioned guidelinesused in evaluation
Reference:	OECD KIIIA1 7.1.1
Report	Pinoxaden/Pyroxsulam/Cloquintocet-mexyl EC (A19786A): Acute oral toxicity study in the rat [redacted] 2013, A19786A ! 12/343-001P, ASB2014-11469
Guideline(s):	OECD Guideline 425 (2008) EPA OPPTS 870.1100 (2002)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No, according to available information.

Materials and methods

Test material (Lot/Batch No.)	A19786A (SMU2FL001)
Species	CRL:(WI)
No. of animals (group size)	5 females
Dose(s)	2000 mg/kg bw
Exposure	Once by gavage
Vehicle/Dilution	None
Post exposure observation period	14 days
Remarks	None

Results and discussions

Table A 1: Results of acute oral toxicity study in rats of A19786A

Dose (mg/kg bw)	Toxicological results *	Duration of signs	Time of death	LD50 (mg/kg bw) (14 days)
Female rats				
2000	0/2/5	24 hours	-	> 2000

* Number of animals which died/number of animals with clinical signs/number of animals used

Table A 2: Summary of findings of acute oral toxicity study in rats of A19786A

Mortality:	No mortality occurred.
Clinical signs:	Yes, clinical signs of toxicity were observed. (during the first 24 hours after exposure one or more of the following observations were made in two test animals: hunched back, piloerection, decreased activity, vocalisation, increased respiratory rate)

Body weight:	Body weight gain was considered to be normal.
Macroscopic examination:	The necropsies performed at the end of the study revealed no apparent findings.

Conclusion

Under the experimental conditions, the oral LD_{50} of A19786A is higher than 2000 mg/kg bw in rats. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

A 2.3 Acute percutaneous (dermal) toxicity (IIIA1 7.1.2)

Comments of zRMS:	Study acceptable according to mentioned guidelines used in evaluation
Reference:	OECD KIIIA1 7.1.2
Report	Pinoxaden/Pyroxsulam/Cloquintocet-mexyl EC (A19786A): Acute dermal toxicity study in rats; [redacted] 2013, A19786A ! 12/343-002P, ASB2014-11470
Guideline(s):	OECD Guideline 402 (1987) EU Method B.3 (2008) EPA OPPTS 870.1200 (1998)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No, according to available information.

Materials and methods

Test material (Lot/Batch No.)	A19786A (SMU2FL001)
Species	CRL:(WI)
No. of animals (group size)	5 male, 5 female
Dose(s)	2000 mg/kg bw
Exposure	24 hours (dermal, semi-occlusive)
Vehicle/Dilution	None
Post exposure observation period	14 days
Remarks	None

Results and discussions

Table A 3: Results of acute dermal toxicity study in rats of A19786A

Dose (mg/kg bw)	Toxicological results *	Duration of signs	Time of death	LD50 (mg/kg bw) (14 days)
Male rats				
2000	0/0/5	-	-	> 2000
Female rats				
2000	0/0/5	-	-	> 2000

* Number of animals which died/number of animals with clinical signs/number of animals used

Table A 4: Summary of findings of acute dermal toxicity study in rats of A19786A

Mortality:	No mortality occurred.
Clinical signs:	No clinical signs of toxicity were observed.
Body weight:	Body weight gain was considered to be normal.
Macroscopic examination:	The necropsies performed at the end of the study revealed no apparent findings.

Conclusion

Under the experimental conditions, the dermal LD_{50} of A19786A is higher than 2000 mg/kg bw in rats. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

A 2.4 Acute inhalation toxicity (IIIA1 7.1.3)

Comments of zRMS:	Justification for waiving of the study acceptable.

No inhalation studies have been conducted on A19786A. According to point 7.1.3 of Regulation (EU) No 545/2011 (implementing Regulation (EC) No 1107/2009), the criteria triggering an acute inhalation toxicity study are not met, as detailed below.

The inhalation toxicity of a plant protection product must be reported where it is:	**Response**
- a gas or liquefied gas	According to the applicant, those criteria are not met. However, data was not provided.
- is a smoke generating formulation or fumigant	
- is used with fogging equipment	
- is a vapour releasing preparation	
- is an aerosol	
- is a powder containing a significant proportion of particles of diameter < 50 µm (> 1 % on a weight basis)	
- is to be applied in a manner which generates a significant proportion of particles or droplets of diameter < 50	
- contains an Active Substance with a vapour pressure > 1 x 10^{-2} Pa and is to be used in enclosed spaces such as warehouses or glasshouses	The vapour pressure of cloquintocet-mexyl is 5.3 x 10^{-6} Pa at 25°C, that of pinoxaben is 2.0 x 10^{-7} Pa at 20 °C, and that of pyroxsulam is <1.0 x 10^{-5} Pa at 20°C. Moreover, A19786A will not be used in enclosed spaces.

A19786A does not fall into any of the above categories; hence testing for inhalation toxicity is not relevant for this product. No classification is necessary according to the EFSA calculation method (corresponding LC_{50} >5 mg/L air).

A 2.5 Skin irritation (IIIA1 7.1.4)

Comments of zRMS:	Study acceptable according to mentioned guidelines, used in evaluation

Reference: OECD KIIIA1 7.1.4

Report: Pinoxaden/Pyroxsulam/Cloquintocet-mexyl EC (A19786A): Primary skin irritation study in rabbits
[redacted] 2013,
A19786A ! 12/343-006N, ASB2014-11471

Guideline(s):	OECD Guideline 404 (2002) EU Method B.4 (2008) EPA OPPTS 870.2500 (1998)
Deviations:	Yes On seven occasions the relative humidity was outside (max. 77 %) the guideline range (30 – 70 %) during the study. This deviation is considered unlikely to have an impact on the outcome of the study and interpretation of the results.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No, according to available information.

Materials and methods

Test material (Lot/Batch No.)	A19786A (SMU2FL001)
Species	Rabbit, New Zealand White
No. of animals (group size)	3 males
Initial test using one animal	Yes
Exposure	0.5 mL (4 hours, semi-occlusive)
Vehicle/Dilution	None
Post exposure observation period	14 days
Remarks	After 4 h-exposure, skin flushed with lukewarm tap water.

Results and discussions

Table A 5: Skin irritation of A19786A

Animal No.		Scores after treatment *				Mean scores (24-72 h)	Reversible (day)
		1 h	24 h	48 h	72 h		
1	Erythema Oedema	1 0	1 0	1 0	1 0	1 0	14 -
2	Erythema Oedema	0 0	0 0	0 0	0 0	0 0	- -
3	Erythema Oedema	0 0	0 0	0 0	0 0	0 0	- -

* scores in the range of 0 to 4

Clinical signs:	No clinical signs of toxicity were observed.

Conclusion
Under the experimental conditions, A19786A is not a skin irritant. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

A 2.6 Eye irritation (IIIA1 7.1.5)

Comments of zRMS:	Study acceptable according to mentioned guidelines, used in evaluation
Reference:	OECD KIIIA1 7.1.5
Report	Pinoxaden/Pyroxsulam/Cloquintocet-mexyl EC (A19786A): Acute eye irritation study in rabbits

[redacted] 2013,
A19786A ! 12/343-005N, ASB2014-11472

Guideline(s): OECD Guideline 405 (2002)
EU Method B.5 (2008)
EPA OPPTS 870.2400 (1998)

Deviations: Yes
On two occasions the relative humidity was outside (max. 78 %) the guideline range (30-70 %) during the study. This deviation is considered unlikely to have an impact on the outcome of the study and interpretation of the results.

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study): No, according to available information.

Materials and methods

Test material (Lot/Batch No.)	A19786A (SMU2FL001)
Species	Rabbit, New Zealand White
No. of animals (group size)	3 males
Initial test using one animal	Yes
Exposure	0.1 mL (single instillation in conjunctival sac)
Irrigation (time point)	Yes (with physiological saline solution 24 hours after exposure, 30 sec after fluorescein introduction)
Vehicle/Dilution	None
Post exposure observation period	14 days (1 rabbit), 7 days (2 rabbits)
Remarks	No anaesthesis, initial pain reaction = 2 of 5.

Results and discussions

Table A 6: Eye irritation of A19786A

Animal No.		Scores after treatment *				Mean scores (24-72 h)	Reversible (day)
		1 h	24 h	48 h	72 h		
1	Corneal opacity	1	1	1	1	1	7
	Iritis	0	0	0	0	0	-
	Redness conjunctivae	2	2	2	1	1,7	7
	Chemosis conjunctivae	3	1	1	1	1	7
2	Corneal opacity	1	1	1	1	1	7
	Iritis	0	0	0	0	0	-
	Redness conjunctivae	2	2	2	1	1,7	7
	Chemosis conjunctivae	3	1	1	1	1	7
3	Corneal opacity	1	1	1	1	1	7
	Iritis	0	0	0	0	0	-
	Redness conjunctivae	2	2	2	1	1,7	7
	Chemosis conjunctivae	3	1	1	1	1	7

* scores in the range of 0 to 4 for cornea opacity and chemosis, 0 to 3 for redness of conjunctivae and 0 to 2 for iritis

Clinical signs:	No clinical signs of toxicity were observed.

Conclusion

Under the experimental conditions, A19786A is an eye irritant. Thus labelling with Warning, Eye Irrit. 2, H319 is required according to Regulation (EC) No. 1272/2008.

A 2.7 Skin sensitisation (IIIA1 7.1.6)

Comments of zRMS:	Study acceptable albeit deviations from mentioned guidelines, used in evaluation
Reference:	OECD KIIIA1 7.1.6
Report	Pinoxaden/Pyroxsulam/Cloquintocet-mexyl EC (A19786A): Local lymph node assay in the mouse [redacted] 2013, A19786A ! 12/343-037E, ASB2014-11473
Guideline(s):	OECD Guideline 429 (2010)
Deviations:	Yes Several deviations are listed below. Briefly, the study was largely inconsistent, repetitive, and partially lacking negative controls. Moreover, lymph nodes should have been pooled prior to processing as only 4 animals were used per group in this study. However, based on the results, those deviations are unlikely to alter the outcome of the study.
GLP:	Yes
Acceptability:	Yes, with limitations
Duplication (if vertebrate study)	No, according to available information.

Materials and methods

Test material (Lot/Batch No.)	A19786A (SMU2FL001)
Species	Mouse, CBA/J Rj
No. of animals (group size)	Test substance group: 4 female mice Vehicle control goup: 4 female mice
Range finding:	Yes
Exposure (concentration(s), no. of applications)	100, 50, 25, 10, 5, 2, and 0.5 % (1/day on day 1, day 2, and day 3)
Vehicle	1% aqueous Pluronic® PE9200
Reliability check	α-Hexylcinnamaldehyde (25 %)

Remarks

- A total of 3 experiments were conducted: 1 (Oct 2012): 100, 50, 25, and 10 %, 2 (Mar 2013): 10 %, 3 (Jun 2013): 5, 2, and 0.5 %; no negative control group was assessed in experiment 2 (instead, data from a contemporaneous study was applied)
- Reasoning: experiment 1 offered high SI, but comparably normal lymph node size, thus one concentration (10 %) was repeated in experiment 2 for verification; as experiment 2 confirmed prior results, experiment 3 was conducted for EC3 deduction. The repetition of experiments should be more carefully considered to prevent redundant animal testing.
- Lymph nodes were processed individually in each group of four animals. According to the guideline, an additional animal would have been required or nodes should have been pooled. In this study, lymph node cells were pooled after lymph node processing.
- Due to the afore mentioned inconsistencies in addition to atypical body weight development patterns in experiment 1 and 2, further categorisation into Skin Sens. 1B is not supported.

Results and discussions

Table A 7: Results of skin sensitisation study of A19786A

	No. of animals	Concentration [%]	DPM / group	Stimulation index (SI)
A19786A	4	100	9352.9	307.9
	4	50	6723.3	221.3
	4	25	5800.6	191.0
	4	10	708.3	23.3
Test Vehicle Control Group (experiment 1)	4	0	30.4	1.0
A19786A	4	10	942.6	19.0
Test Vehicle Control Group (experiment 2[1)])	5	0	49.6	1.0
A19786A	4	5	82.9	0.9
	4	2	81.9	0.9
	4	0.5	128.9	1.4
Test Vehicle Control Group (experiment 3)	4	0	90.3	1.0
Positive control (histological, updated Jan 2013)	40	25	801.6	7.2

1) no negative control group was assessed in experiment 2 (instead, data from a contemporary study was applied)

Clinical signs:	Yes (increased ear thickness and ear weight was detected in the 100, 50, and 25 % dose groups, larger than normal lymph node size was detected in the 100, 50, 25, and 10 % dose groups; on average, weight loss was observed in all treatment groups (including negative control) of the 1st and 2nd experiment, while animals in experiment 3 gained weight over the duration of the experiment)

Conclusion

Under the experimental conditions, A19786A is a skin sensitiser. Thus, classification is required with Warning, Skin Sens. 1; H317 according to Regulation (EC) No. 1272/2008.

A 2.8 Supplementary studies for combinations of plant protection products (IIIA1 7.1.7)

There are no supplementary studies available for combination of plant protection products.

A 2.9 Data on co-formulants (III1 7.9)

A 2.9.1 Material safety data sheet for each co-formulant

Material safety data sheets of the co-formulants can be found in the confidential dossier of this submission (Registration Report - Part C).

A 2.9.2 Available toxicological data for each co-formulant

Available toxicological data for each co-formulant can be found in the confidential dossier of this submission (Registration Report - Part C).

A 2.10 Studies on dermal absorption (IIIA 7.6)

No studies on dermal absorption were submitted for this product.

A 2.11 Studies on groundwater metabolites (KIIA 5.8)

A 2.11.1 Pinoxaden metabolite SYN546108 (M56)

Study 1 – M56

Comments of zRMS:	Acceptable.

Reference:	KIIA 5.8
Report	Sokolowski A (2011) SYN546108 – Salmonella. Typhimurium and Escherichia.Coli Reverse Mutation Assay. Harlan Cytotest cell research GmH. Unpublished Report No. 1422501 (Syngenta No. SYN546108_10000) Study dates 06 July 2011 to 18 July 2011 ASB2013-397
Guideline(s):	EC 440/2008 B.13/B.14 (2008) / OECD 471 (1997) / OPPTS 870.5100 (1998)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

SYN546108 Batch No. MES 244/1; analysed purity 95% (±2%).
SYN546108 was evaluated in a bacterial mutagenicity assay over a range of concentrations using four strains of Salmonella typhimurium (TA1535, TA1537, TA98, and TA100) and two strains of Escherichia coli (WP2pKM101 and WP2P uvrApKm101) in a plate incorporation assay (experiment 1) and a pre-incubation test (experiment 2). The assay was performed with and without liver microsomal activation (Phenobarbital/?-naphthoflavone induced Wistar rat liver S9). Each concentration, including the controls, was tested in triplicate. The test item was tested at the following concentrations:
Pre-Experiment/Experiment I: 3; 10; 33; 100; 333; 1000; 2500 and 5000 µg/plate
Experiment II: 33; 100; 333; 1000; 2500 and 5000 µg/plate
For each experiment, positive control substances were tested to validate the bacterial strain and to confirm the activity of the S9-mix used (Table XX)

Table: Positive control substances used in the assay

Strain	S9 mix	Compound
TA1535, TA1537, TA98, TA100, TA102, WP2pKM010 WP2P uvrA pKM010	+	2-Aminoanthracene
TA1537 and TA 98 TA1535 and TA100 WP2P uvrA pKM010 and WP2pKM010	- - -	4-nitro-o-phenylene-diamine Sodium azide Methyl methane sulfonate

Results and discussions

No reduced background growth was observed with or without metabolic activation in all strains used and in both experiments.
No toxic effects, evident as a reduction in the number of revertants (below the indication factor of 0.5) were observed with or without metabolic activation.
No precipitation of the test item was observed either in the overlay agar in the test tubes or on the incubated agar plates.
No substantial increase in revertant colony numbers of any of the six tester strains was observed

following treatment with SYN546108 at any dose level, neither in the presence nor absence of metabolic activation (S9 mix). There was also no tendency of higher mutation rates with increasing concentrations in the range below the generally acknowledged border of biological relevance.
Appropriate reference mutagens were used as positive controls. They showed a distinct increase of induced revertant colonies.

Conclusion

During the described mutagenicity tests and under the experimental conditions reported, SYN546108 did not induce gene mutations by base pair changes or frameshifts in the genome of the tester strains used.
SYN546108 is considered to be non-mutagenic in the Salmonella typhimurium and Escherichia coli reverse mutation assay.

Study 2 – M56

Comments of zRMS:	Acceptable.

Reference:	KIIA 5.8
Report	Wollny H-E (2011) SYN546108 – Cell Mutation Assay at the Thymidine Locus ($TK^{+/-}$) in Mouse Lymphoma L5178Y cells, Harlan Cytotest cell research GmbH Unpublished Report No. 1422503 (Syngenta No. SYN546108_10002). Study dates 15 June 2011 to 11 July 2011 ASB2013-396
Guideline(s):	2008/440/EC B.17 (2008) / OECD 476 (1997) / OPPTS 870.5300 (1998)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

SYN546108 Batch No. MES 244/1; analysed purity 95%.
To assess the potential of SYN546108 to cause gene mutation or clastogenic effects in mammalian cells, L57187Y $TK^{+/-}$ mouse lymphoma cells were treated in vitro with various concentrations of the test substance, both in the presence and absence of a rat liver derived auxiliary metabolic system (S9-mix) for a period of 4 hours. The test item was then removed by washing and the cells were re-suspended in culture assessed by cell growth in the presence of trifluorothymidine after the 48-hour expression time. The test material was dissolved in dimethylsulphoxide which was used as the negative control. Positive control materials were methyl methanesulphonate (in the absence of S9-mix) and cyclophosphamide (in the presence of S9-mix).

Results and discussions

The assay was performed in two independent experiments, using two parallel cultures each. The main experiments I and II were performed with and without liver microsomal activation and a treatment period of 4 hours.
The main experiments were evaluated at the following concentrations:
Experiment I:
Without S9 mix: 37.5; 75.0; 150.0; 300.0; and 600.0 µg/ml
With S9 mix: 75.0; 150.0; 300.0; 600.0 and 1200 µg/ml

Experiment II:
Without S9 mix: 75.0; 150.0; 300.0; 600.0 and 1200 µg/ml
With S9 mix: 75.0; 150.0; 300.0; 600.0 and 1200 µg/ml

The test medium was checked for precipitation visible to the naked eye at the end of the treatment period

just before the test item was removed. Precipitation meeting the criteria mentioned above was noted in experiment I at 300.0 µg/ml and above without metabolic activation and at 600.0 and 1200.0 µg/ml with metabolic activation. In experiment II precipitation occurred at 1200.0 µg/ml with and without metabolic activation.
No relevant cytotoxic effect indicated by a relative cloning efficiency 1 (survival) or a relative total growth (RTG) of less than 50% in both parallel cultures occurred in the first and second experiment with and without metabolic activation.
No substantial and reproducible dose dependent increase of the mutation frequency exceeding the threshold of 126 above the corresponding solvent control was observed in any of the experimental parts with and without metabolic activation. The threshold of 126 above the corresponding solvent control was not reached.
A linear regression analysis was performed to assess possible dose dependent increase in mutant frequencies. No significant dose dependent trend, indicated by a probability value of <0.05, was determined in any of the experimental groups.
In this study, the range of the solvent controls was from 86 to 157 mutant colonies per 10^6 cells; the range of the groups treated with the test item was from 52 to 245 mutant colonies per 10^6 cells.
MMS (19.5 µg/ml) and CPA (3.0 and 4.5 µg/ml) were used as positive controls and showed a distinct increase in induced total mutant colonies at acceptable levels of toxicity with at least one of the concentrations of the controls.

Conclusion

Under the experimental conditions reported the test item SYN546108 did not induce mutations in the mouse lymphoma thymidine kinase locus assay using the cell line L5178Y in the absence and presence of metabolic activation. SYN546108 is considered to be non-mutagenic in the mouse lymphoma assay.

Study 3 – M56

Comments of zRMS:	Acceptable.

Reference:	KIIA 5.8
Report	[redacted] (2011) SYN546108 – Micronucleus Assay in Bone Marrow Cells of the Mouse. [redacted]. Unpublished Report No. 1422502 (Syngenta No. SYN546108_10001 Study dates 17 June 2011 to 21 July 2011 ASB2013-398
Guideline(s):	EC 440/2008 B.12 (2008) / OECD 474 (1997) / OPPTS 870.5395 (1998)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

SYN546108 Batch No. MES 244/1; analysed purity 95%.
In pre-experiments 2 male and 2 female mice per test received a single oral dose of 2000 mg/kg SYN546108 in 30% DMSO/70% PEG 400 and 2 female mice received a single oral dose of 1250 mg/kg SAN546108. As there were no substantial gender differences in toxicity, males were chosen for the main study.
In the main study, three dose levels (2000, 1000 and 500 mg/kg; 14, 7 and 7 animals/group) were used and bone marrow samples were collected 24 hours after treatment. At the top dose level and additional 7 animals were used and bone marrow collected after 48 hours. A vehicle control group acted as the negative control for this study and a positive control group was dosed with 40 mg/kg bw cyclophosphamide (CPA). Both control groups contained 5 males / time point.

Results and discussions

Signs of toxicity were noted in animals treated with 2000 and 1000 mg/kg SYN546108. One animal died in the 2000 mg/kg dosed group assigned for 48-hour evaluation.
The mean number of polychromatic erythrocytes was not decreased after treatment with the test item as compared to the mean value of PCEs of the vehicle control, indicating that SYN546108 did not have any significant cytotoxic properties in the bone marrow.
In comparison to the corresponding vehicle control values, there was no biologically relevant or statistically significant enhancement in the frequency of the detected micronuclei at any preparation interval and dose level after administration of the test item. The mean values of micronuclei observed after treatment with SYN546108 were below or near the value of the vehicle control group and additionally were within the historical vehicle control range. Additionally, no dose dependent increase was observed.
A dose of 40 mg/kg bw cyclophosphamide administered orally was used as a positive control and showed a statistically significant increase of induced micronucleus frequency.

Conclusion

Under the experimental conditions of this study SYN546108 did not induce micronuclei as determined by the mouse bone marrow micronucleus test. SYN546108 is considered to be non-mutagenic in this bone marrow micronucleus assay.

A 2.11.2 Pyroxsulam metabolite PSA

Study 4 – PSA

Comments of zRMS:	Acceptable.

Reference:	KIIA 5.8
Report	[redacted] (2014) XDE-742 Sulfonic Acid: Acute oral toxicity study in F344/DuCrl Rats. [redacted], Study ID: 141089, 15 December 2014 ASB2015-4380
Guideline(s):	OECD 423 (2001), EC Acute oral toxicity (2004), USEPA OPPTS 870.1100 (2002) JMAFF Acute oral toxicity (2002)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

The purpose of this study was to assess the acute oral toxicity of XDE-742 sulfonic acid in fats. Following an overnight fast from feed and a 6-hour water deprivation period, five female F344/DuCrl rats were given 3 mg/ml XDE-742sulfonic acid in flavoured drinking water for a 24-hour exposure, which resulted in a dose of approximately 612 mg/kg bs. Animals were observed for signs of toxicity twice on the day of material administration and daily for 14 days after the 24-hour dosing period. In addition, detailed clinical observations, body weights, body weight gains, water consumption, test material intake and mortality were evaluated. Necropsy was conducted on all animals at study termination to evaluate potential gross pathological changes.

Results and discussions

All rats survived the two week observation period. There were no treatment-related effects on clinical observations, body weights or body weight gains. Water consumption was increased during the treatment period compared to the pre-treatment period. There were no gross pathological observations at necropsy.

Conclusion

Under the conditions of this study, there were no signs of acute toxicity and the oral LD50 of XDE-742 sulfonic acid in female F344/DuCrl rats was greater than 612 mg/kg bw.

Study 5 – 6-Cl-7-OH

Comments of zRMS:	Acceptable.

Reference:	KIIA 5.8
Report	Tendulkar, K.E. (2014) In vitro Mammalian Chromosome Aberration test of 6-Cl-7-OH-742 metabolite in Human Peripheral Blood Lymphocytes. Jai Research Foundation, Department of toxicology, Valvada, India. Unpublished Report No. 488-1-06-8448, july 02, 2014 ASB2015-4378
Guideline(s):	OECD 473 (1997), OPPTS (OCSPP) 870.5375 (1998), EC B.10 (2008), JMAFF 2-1-19-2 (2012)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

In a mammalian chromosome aberration test, human peripheral blood lymphocytes cultured in vitro were exposed to 6-Cl-7-OH-742 metabolite at different concentrations, both in the absence and presence of metabolic activation (2% and 4% v/v S9).

Results and discussions

6-Cl-7-OH-742 metabolite did not induce statistically significant or biologically relevant increases in the number of cells with chromosome aberrations in the absence and presence of S9-mix in either of the two independently conducted experiments. No effects of 6-Cl-7-OH-742 metabolite on the number of polyploid cells or number of cells with endoreduplicated chromosomes were observed either in the absence or presence of S9-mix. All negative controls were within the historical limits and positive controls showed an increase in the incidence of cells with chromosome aberrations.

Conclusion

All criteria for a valid study were met as described in the protocol. From the results of this study, it is concluded that 6-Cl-7-OH-742 metabolite did not show potential to induce chromosomal aberrations both in the absence and presence of metabolic activation system under the described experimental conditions and is negative for clastogenicity.

Study 6 – 6-Cl-7-OH

Comments of zRMS:	Acceptable.

Reference:	KIIA 5.8
Report	Tendulkar, K.E. (2014) In vitro Mammalian Cell Gene Forward Mutation Test at the HGPRT Locus of the Chinese Hamster Ovary (CHO)-K1 Cell Line using 6-Cl-7-OH-742 metabolite. Jai Research Foundation, Department of toxicology, Valvada, India. Unpublished Report No. 482-1-06-8449, July 14, 2014 ASB2015-4379

Guideline(s):	OECD 463 (1997), OPPTS (OCSPP) 870.5300, EC B.17
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

In a mammalian cell gene mutation assay (hgprt locus), CHO-K1 cells cultured in vitro were exposed to 6-Cl-7-OH-742 metabolite at different concentrations, both in the absence and presence of metabolic activation (2% v/v S9) for a period of 4 hours.
6-Cl-7-OH-742 metabolite was tested in two independent experiments. Cultures were exposed to 6-Cl-7-OH-742 metabolite at 6 dose levels (two cultures / dose level) between 143.75 and 4600 µg/ml of culture medium,selected from a preliminary cytotoxicity test both in the absence and presence of metabolic activation (2% v/v S9) for a period of 4 hours.

Results and discussions

A significant dose-related increase in the mutation frequency was not observe in any of the treatment concentrations between 143.75 and 4600 µg/ml of culture medium both in the absence and presence of metabolic activation system (2% v/v S9) and the induced mutation frequency was comparable to that from the negative control group. All negative controls were within the historical limits and positive controls showed an increase in the mutant frequency. No relevant influence of the test item on pH value of osmolality was observed both in the absence and presence of metabolic activation during both the trials.

Conclusion

All criteria for a valid study were met as described in the protocol. From the results of this study, it is concluded that 6-Cl-7-OH-742 metabolite does not have the potential to induce gene mutations at the hgprt locus of CHO-K1 cells both in the absence and presence of metabolic activation system under the present experimental conditions.

Appendix 3 Exposure calculations

A 3.1 Operator exposure calculations (IIIA1 7.3.1)

A 3.1.1 Calculations for cloquintocet-mexyl

Table A 8: Input parameters considered for the estimation of operator exposure

Formulation type:	EC		**Application technique:**	Field Crop Tractor Mounted (FCTM)	
Application rate (AR):	0.015	kg a.s./ha			
Area treated per day (A):	20	ha	**Dermal hands m/l ($D_{M(H)}$):**	2.4	mg/person/kg a.s.
Dermal absorption (DA):	75	% (concentr.)	**Dermal hands appl. ($D_{A(H)}$):**	0.38	mg/person/kg a.s.
	75	% (dilution)	**Dermal body appl. ($D_{A(B)}$):**	1.6	mg/person/kg a.s.
Inhalation absorption (IA):	100	%	**Dermal head appl. ($D_{A(C)}$):**	0.06	mg/person/kg a.s.
Body weight (BW):	70	kg/person	**Inhalation m/l (I_M):**	0.0006	mg/person/kg a.s.
AOEL	0.05	mg/kg bw/d	**Inhalation appl. (I_A):**	0.001	mg/person/kg a.s.

Table A 9: Estimation of operator exposure towards cloquintocet-mexyl using the German model

Without PPE			**With PPE*)**		
Operators: Systemic dermal exposure after application in winter wheats					
Dermal exposure during mixing/loading					
Hands			Hands		
$SDE_{OM(H)} = (D_{M(H)} \times AR \times A \times DA) / BW$			$SDE_{OM(H)} = (D_{M(H)} \times AR \times A \times PPE^{*)} \times DA) / BW$		
(2.4 x 0.015 x 20 x 75%) / 70			(2.4 x 0.015 x 20 x 0.01 x 75%) / 70		
External dermal exposure	0.72	mg/person	External dermal exposure	0.0072	mg/person
External dermal exposure	0.010286	mg/kg bw/d	External dermal exposure	0.000103	mg/kg bw/d
Systemic dermal exposure	**0.007714**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000077**	**mg/kg bw/d**
Dermal exposure during application					
Hands			Hands		
$SDE_{OA(H)} = (D_{A(H)} \times AR \times A \times DA) / BW$			$SDE_{OA(H)} = (D_{A(H)} \times AR \times A \times PPE \times DA) / BW$		
(0.38 x 0.015 x 20 x 75%) / 70			(0.38 x 0.015 x 20 x 1 x 75%) / 70		
External dermal exposure	0.114	mg/person	External dermal exposure	0.114	mg/person
External dermal exposure	0.001629	mg/kg bw/d	External dermal exposure	0.001629	mg/kg bw/d
Systemic dermal exposure	**0.001221**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.001221**	**mg/kg bw/d**
Body			Body		
$SDE_{OA(B)} = (D_{A(B)} \times AR \times A \times DA) / BW$			$SDE_{OA(B)} = (D_{A(B)} \times AR \times A \times PPE \times DA) / BW$		
(1.6 x 0.015 x 20 x 75%) / 70			(1.6 x 0.015 x 20 x 1 x 75%) / 70		
External dermal exposure	0.48	mg/person	External dermal exposure	0.48	mg/person
External dermal exposure	0.006857	mg/kg bw/d	External dermal exposure	0.006857	mg/kg bw/d
Systemic dermal exposure	**0.005143**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.005143**	**mg/kg bw/d**
Head			Head		
$SDE_{OA(C)} = (D_{A(C)} \times AR \times A \times DA) / BW$			$SDE_{OA(C)} = (D_{A(C)} \times AR \times A \times PPE \times DA) / BW$		
(0.06 x 0.015 x 20 x 75%) / 70			(0.06 x 0.015 x 20 x 1 x 75%) / 70		
External dermal exposure	0.018	mg/person	External dermal exposure	0.018	mg/person
External dermal exposure	0.000257	mg/kg bw/d	External dermal exposure	0.000257	mg/kg bw/d
Systemic dermal exposure	**0.000193**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000193**	**mg/kg bw/d**
Total systemic dermal exposure: $SDE_O = SDE_{OM(H)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$			Total systemic dermal exposure: $SDE_O = SDE_{OM(H)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$		
Total external dermal exposure	1.332	mg/person	Total external dermal exposure	0.6192	mg/person
Total external dermal exposure	0.019029	mg/kg bw/d	Total external dermal exposure	0.008846	mg/kg bw/d
Total systemic dermal exposure	**0.014271**	**mg/kg bw/d**	**Total systemic dermal exposure**	**0.006634**	**mg/kg bw/d**
Operators: Systemic inhalation exposure after application in winter wheats					
Inhalation exposure during mixing/loading					
$SIE_{OM} = (I_M \times AR \times A \times IA) / BW$			$SIE_{OM} = (I_M \times AR \times A \times PPE \times IA) / BW$		
(0.0006 x 0.015 x 20 x 100%) / 70			(0.0006 x 0.015 x 20 x 1 x 100%) / 70		
External inhalation exposure	0.00018	mg/person	External inhalation exposure	0.00018	mg/person
External inhalation exposure	0.000003	mg/kg bw/d	External inhalation exposure	0.000003	mg/kg bw/d

Systemic inhalation exposure	**0.000003**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000003**	**mg/kg bw/d**
Inhalation exposure during application					
$SIE_{OA} = (I_A$ x AR x A x IA) / BW			$SIE_{OA} = (I_A$ x AR x A x PPE x IA) / BW		
(0.001 x 0.015 x 20 x 100%) / 70			(0.001 x 0.015 x 20 x 1 x 100%) / 70		
External inhalation exposure	0.0003	mg/person	External inhalation exposure	0.0003	mg/person
External inhalation exposure	0.000004	mg/kg bw/d	External inhalation exposure	0.000004	mg/kg bw/d
Systemic inhalation exposure	**0.000004**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000004**	**mg/kg bw/d**
Total systemic inhalation exposure: $SIE_O = SIE_{OM} + SIE_{OA}$			Total systemic inhalation exposure: $SIE_O = SIE_{OM} + SIE_{OA}$		
Total external inhalation exposure	0.00048	mg/person	Total external inhalation exposure	0.00048	mg/person
Total external inhalation exposure	0.000007	mg/kg bw/d	Total external inhalation exposure	0.000007	mg/kg bw/d
Total systemic inhalation exposure	**0.000007**	**mg/kg bw/d**	**Total systemic inhalation exposure**	**0.000007**	**mg/kg bw/d**
Total systemic exposure: $SE_O = SDE_O + SIE_O$			Total systemic exposure: $SE_O = SDE_O + SIE_O$		
Total systemic exposure	0.99948	mg/person	Total systemic exposure	0.46488	mg/person
Total systemic exposure	**0.014278**	**mg/kg bw/d**	**Total systemic exposure**	**0.006641**	**mg/kg bw/d**
% of AOEL	**28.6**	**%**	**% of AOEL**	**13.3**	**%**

*) reduction factor for gloves is 0.01 (professional appl.)

Table A 10: Estimation of operator exposure towards cloquintocet-mexyl using the UK-POEM (without PPE)

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)					
Active substance	**Cloquintocet-mexyl**				
Product	A19786A				
Formulation type	organic solvent-based				
Concentration of a.s.	8.33	mg/mL			
Dose	1.801	L preparation/ha	(0.015)		
Application volume	100	L/ha			
Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles				
Container	10 litres 63 mm closure				
Work rate/day	50	ha			
Duration of spraying	6	h			
PPE during mix./loading	None				
PPE during application	None				
Dermal absorption from product	75	%			
Dermal absorption from spray	75	%			
EXPOSURE DURING MIXING AND LOADING					
Container size	10	Litres			
Hand contamination/operation	0,05	mL			
Application dose	1.801	Litres product/ha			
Work rate	50	ha/day			
Number of operations	9	/day			
Hand contamination	0.45	mL/day			
Protective clothing	None				
Transmission to skin	100	%			
Dermal exposure to formulation	0.45	mL/day			
DERMAL EXPOSURE DURING SPRAY APPLICATION					
Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles				
Application volume	100	spray/ha			
Volume of surface contamination	10	mL/h			
Distribution	Hands		Trunk	Legs	
	65%		10%	25%	
Clothing	None		Permeable	Permeable	
Penetration	100%		5%	15%	
Dermal exposure	6.5		0.05	0.375	mL/h
Duration of exposure	6	h			
Total dermal exposure to spray	41.55	mL/day			

ABSORBED DERMAL DOSE				
	Mix/load		Application	
Dermal exposure	0.45	mL/day	41.55	mL/day
Concen. of a.s. product or spray	8.33	mg/mL	0.15	mg/mL
Dermal exposure to a.s.	3.749	mg/day	6.233	mg/day
Percent absorbed	75	%	75	%
Absorbed dose	2.811	mg/day	4.674	mg/day
INHALATION EXPOSURE DURING SPRAYING				
Inhalation exposure	0.01	mL/h		
Duration of exposure	6	h		
Concentration of a.s. in spray	0.15	mg/mL		
Inhalation exposure to a.s.	0.009	mg/day		
Percent absorbed	100	%		
Absorbed dose	0.009	mg/day		
PREDICTED EXPOSURE				
Total absorbed dose	7.495	mg/day		
Operator body weight	60	kg		
Operator exposure	0.125	mg/kg bw/day		
Amount of AOEL	**249.8**	**%**		

Table A 11: Estimation of operator exposure towards cloquintocet-mexyl using the UK-POEM (with PPE)

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)				
Active substance	**Cloquintocet-mexyl**			
Product	A19786A			
Formulation type	organic solvent-based			
Concentration of a.s.	8.33	mg/mL		
Dose	1.801	L preparation/ha	(0.015)	
Application volume	100	L/ha		
Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles			
Container	10 litres 63 mm closure			
Work rate/day	50	ha		
Duration of spraying	6	h		
PPE during mix./loading	Gloves			
PPE during application	Gloves			
Dermal absorption from product	75	%		
Dermal absorption from spray	75	%		
EXPOSURE DURING MIXING AND LOADING				
Container size	10	Litres		
Hand contamination/operation	0,05	mL		
Application dose	1.801	Litres product/ha		
Work rate	50	ha/day		
Number of operations	9	/day		
Hand contamination	0.45	mL/day		
Protective clothing	Gloves			
Transmission to skin	10	%		
Dermal exposure to formulation	0.045	mL/day		
DERMAL EXPOSURE DURING SPRAY APPLICATION				
Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles			
Application volume	100	spray/ha		
Volume of surface contamination	10	mL/h		
Distribution	Hands	Trunk	Legs	
	65%	10%	25%	
Clothing	Gloves	Permeable	Permeable	
Penetration	10%	5%	15%	
Dermal exposure	0.65	0.05	0.375	mL/h
Duration of exposure	6	h		

Total dermal exposure to spray	6.45	mL/day		
ABSORBED DERMAL DOSE				
	Mix/load		Application	
Dermal exposure	0.045	mL/day	6.45	mL/day
Concen. of a.s. product or spray	8.33	mg/mL	0.15	mg/mL
Dermal exposure to a.s.	0.375	mg/day	0.968	mg/day
Percent absorbed	75	%	75	%
Absorbed dose	0.281	mg/day	0.726	mg/day
INHALATION EXPOSURE DURING SPRAYING				
Inhalation exposure	0.01	mL/h		
Duration of exposure	6	h		
Concentration of a.s. in spray	0.15	mg/mL		
Inhalation exposure to a.s.	0.009	mg/day		
Percent absorbed	100	%		
Absorbed dose	0.009	mg/day		
PREDICTED EXPOSURE				
Total absorbed dose	1.016	mg/day		
Operator body weight	60	kg		
Operator exposure	0.017	mg/kg bw/day		
Amount of AOEL	**33.9**	**%**		

A 3.1.2 Calculations for pinoxaden

Table A 12: Input parameters considered for the estimation of operator exposure

Formulation type:	EC		**Application technique:**	Field Crop Tractor Mounted (FCTM)	
Application rate (AR):	0.0599	kg a.s./ha			
Area treated per day (A):	20	ha	**Dermal hands m/l ($D_{M(H)}$):**	2.4	mg/person/kg a.s.
Dermal absorption (DA):	75	% (concentr.)	**Dermal hands appl. ($D_{A(H)}$):**	0.38	mg/person/kg a.s.
	75	% (dilution)	**Dermal body appl. ($D_{A(B)}$):**	1.6	mg/person/kg a.s.
Inhalation absorption (IA):	100	%	**Dermal head appl. ($D_{A(C)}$):**	0.06	mg/person/kg a.s.
Body weight (BW):	70	kg/person	**Inhalation m/l (I_M):**	0.0006	mg/person/kg a.s.
AOEL	0.1	mg/kg bw/d	**Inhalation appl. (I_A):**	0.001	mg/person/kg a.s.

Table A 13: Estimation of operator exposure towards pinoxaden using the German model

Without PPE			**With PPE*)**		
Operators: Systemic dermal exposure after application in winter wheats					
Dermal exposure during mixing/loading					
Hands			Hands		
$SDE_{OM(H)} = (D_{M(H)} \times AR \times A \times DA) / BW$			$SDE_{OM(H)} = (D_{M(H)} \times AR \times A \times PPE^{*)} \times DA) / BW$		
(2.4 x 0.0599 x 20 x 75%) / 70			(2.4 x 0.0599 x 20 x 0.01 x 75%) / 70		
External dermal exposure	2.8752	mg/person	External dermal exposure	0.028752	mg/person
External dermal exposure	0.041074	mg/kg bw/d	External dermal exposure	0.000411	mg/kg bw/d
Systemic dermal exposure	**0.030806**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000308**	**mg/kg bw/d**
Dermal exposure during application					
Hands			Hands		
$SDE_{OA(H)} = (D_{A(H)} \times AR \times A \times DA) / BW$			$SDE_{OA(H)} = (D_{A(H)} \times AR \times A \times PPE \times DA) / BW$		
(0.38 x 0.0599 x 20 x 75%) / 70			(0.38 x 0.0599 x 20 x 1 x 75%) / 70		
External dermal exposure	0.45524	mg/person	External dermal exposure	0.45524	mg/person
External dermal exposure	0.006503	mg/kg bw/d	External dermal exposure	0.006503	mg/kg bw/d
Systemic dermal exposure	**0.004878**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.004878**	**mg/kg bw/d**
Body			Body		
$SDE_{OA(B)} = (D_{A(B)} \times AR \times A \times DA) / BW$			$SDE_{OA(B)} = (D_{A(B)} \times AR \times A \times PPE \times DA) / BW$		
(1.6 x 0.0599 x 20 x 75%) / 70			(1.6 x 0.0599 x 20 x 1 x 75%) / 70		
External dermal exposure	1.9168	mg/person	External dermal exposure	1.9168	mg/person
External dermal exposure	0.027383	mg/kg bw/d	External dermal exposure	0.027383	mg/kg bw/d
Systemic dermal exposure	**0.020537**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.020537**	**mg/kg bw/d**
Head			Head		

$SDE_{OA(C)} = (D_{A(C)}$ x AR x A x DA) / BW			$SDE_{OA(C)} = (D_{A(C)}$ x AR x A x PPE x DA) / BW		
(0.06 x 0.0599 x 20 x 75%) / 70			(0.06 x 0.0599 x 20 x 1 x 75%) / 70		
External dermal exposure	0.07188	mg/person	External dermal exposure	0.07188	mg/person
External dermal exposure	0.001027	mg/kg bw/d	External dermal exposure	0.001027	mg/kg bw/d
Systemic dermal exposure	**0.00077**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.00077**	**mg/kg bw/d**
Total systemic dermal exposure: $SDE_O = SDE_{OM(H)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$			Total systemic dermal exposure: $SDE_O = SDE_{OM(H)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$		
Total external dermal exposure	5.31912	mg/person	Total external dermal exposure	2.472672	mg/person
Total external dermal exposure	0.075987	mg/kg bw/d	Total external dermal exposure	0.035324	mg/kg bw/d
Total systemic dermal exposure	**0.056991**	**mg/kg bw/d**	**Total systemic dermal exposure**	**0.026493**	**mg/kg bw/d**
Operators: Systemic inhalation exposure after application in winter wheats					
Inhalation exposure during mixing/loading					
$SIE_{OM} = (I_M$ x AR x A x IA) / BW			$SIE_{OM} = (I_M$ x AR x A x PPE x IA) / BW		
(0.0006 x 0.0599 x 20 x 100%) / 70			(0.0006 x 0.0599 x 20 x 1 x 100%) / 70		
External inhalation exposure	0.000719	mg/person	External inhalation exposure	0.000719	mg/person
External inhalation exposure	0.00001	mg/kg bw/d	External inhalation exposure	0.00001	mg/kg bw/d
Systemic inhalation exposure	**0.00001**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.00001**	**mg/kg bw/d**
Inhalation exposure during application					
$SIE_{OA} = (I_A$ x AR x A x IA) / BW			$SIE_{OA} = (I_A$ x AR x A x PPE x IA) / BW		
(0.001 x 0.0599 x 20 x 100%) / 70			(0.001 x 0.0599 x 20 x 1 x 100%) / 70		
External inhalation exposure	0.001198	mg/person	External inhalation exposure	0.001198	mg/person
External inhalation exposure	0.000017	mg/kg bw/d	External inhalation exposure	0.000017	mg/kg bw/d
Systemic inhalation exposure	**0.000017**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000017**	**mg/kg bw/d**
Total systemic inhalation exposure: $SIE_O = SIE_{OM} + SIE_{OA}$			Total systemic inhalation exposure: $SIE_O = SIE_{OM} + SIE_{OA}$		
Total external inhalation exposure	0.001917	mg/person	Total external inhalation exposure	0.001917	mg/person
Total external inhalation exposure	0.000027	mg/kg bw/d	Total external inhalation exposure	0.000027	mg/kg bw/d
Total systemic inhalation exposure	**0.000027**	**mg/kg bw/d**	**Total systemic inhalation exposure**	**0.000027**	**mg/kg bw/d**
Total systemic exposure: $SE_O = SDE_O + SIE_O$			Total systemic exposure: $SE_O = SDE_O + SIE_O$		
Total systemic exposure	3.991257	mg/person	Total systemic exposure	1.856421	mg/person
Total systemic exposure	**0.057018**	**mg/kg bw/d**	**Total systemic exposure**	**0.02652**	**mg/kg bw/d**
% of AOEL	**57.0**	**%**	**% of AOEL**	**26.5**	**%**

*) reduction factor for gloves is 0.01 (professional appl.)

Table A 14: Estimation of operator exposure towards pinoxaden using the UK-POEM (without PPE)

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)			
Active substance	**pinoxaden**		
Product	A19786A		
Formulation type	organic solvent-based		
Concentration of a.s.	33.3	mg/mL	
Dose	1.799	L preparation/ha	(0.06)
Application volume	100	L/ha	
Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles		
Container	10 litres 63 mm closure		
Work rate/day	50	ha	
Duration of spraying	6	h	
PPE during mix./loading	None		
PPE during application	None		
Dermal absorption from product	75	%	
Dermal absorption from spray	75	%	
EXPOSURE DURING MIXING AND LOADING			
Container size	10	Litres	
Hand contamination/operation	0,05	mL	
Application dose	1.799	Litres product/ha	
Work rate	50	ha/day	
Number of operations	9	/day	

Hand contamination	0.45	mL/day			
Protective clothing	None				
Transmission to skin	100	%			
Dermal exposure to formulation	0.45	mL/day			
DERMAL EXPOSURE DURING SPRAY APPLICATION					
Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles				
Application volume	100	spray/ha			
Volume of surface contamination	10	mL/h			
Distribution	Hands		Trunk	Legs	
	65%		10%	25%	
Clothing	None		Permeable	Permeable	
Penetration	100%		5%	15%	
Dermal exposure	6.5		0.05	0.375	mL/h
Duration of exposure	6	h			
Total dermal exposure to spray	41.55	mL/day			
ABSORBED DERMAL DOSE					
	Mix/load			Application	
Dermal exposure	0.45	mL/day		41.55	mL/day
Concen. of a.s. product or spray	33.3	mg/mL		0.599	mg/mL
Dermal exposure to a.s.	14.985	mg/day		24.888	mg/day
Percent absorbed	75	%		75	%
Absorbed dose	11.239	mg/day		18.666	mg/day
INHALATION EXPOSURE DURING SPRAYING					
Inhalation exposure	0.01	mL/h			
Duration of exposure	6	h			
Concentration of a.s. in spray	0.599	mg/mL			
Inhalation exposure to a.s.	0.036	mg/day			
Percent absorbed	100	%			
Absorbed dose	0.036	mg/day			
PREDICTED EXPOSURE					
Total absorbed dose	29.941	mg/day			
Operator body weight	60	kg			
Operator exposure	0.499	mg/kg bw/day			
Amount of AOEL	**499**	**%**			

Table A 15: Estimation of operator exposure towards pinoxaden using the UK-POEM (with PPE)

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)			
Active substance	**pinoxaden**		
Product	A19786A		
Formulation type	organic solvent-based		
Concentration of a.s.	33.3	mg/mL	
Dose	1.799	L preparation/ha	(0.06)
Application volume	100	L/ha	
Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles		
Container	10 litres 63 mm closure		
Work rate/day	50	ha	
Duration of spraying	6	h	
PPE during mix./loading	Gloves		
PPE during application	Gloves		
Dermal absorption from product	75	%	
Dermal absorption from spray	75	%	
EXPOSURE DURING MIXING AND LOADING			
Container size	10	Litres	
Hand contamination/operation	0,05	mL	
Application dose	1.799	Litres product/ha	
Work rate	50	ha/day	

Number of operations	9	/day			
Hand contamination	0.45	mL/day			
Protective clothing	Gloves				
Transmission to skin	10	%			
Dermal exposure to formulation	0.045	mL/day			
DERMAL EXPOSURE DURING SPRAY APPLICATION					
Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles				
Application volume	100	spray/ha			
Volume of surface contamination	10	mL/h			
Distribution	Hands		Trunk	Legs	
	65%		10%	25%	
Clothing	Gloves		Permeable	Permeable	
Penetration	10%		5%	15%	
Dermal exposure	0.65		0.05	0.375	mL/h
Duration of exposure	6	h			
Total dermal exposure to spray	6.45	mL/day			
ABSORBED DERMAL DOSE					
	Mix/load			Application	
Dermal exposure	0.045	mL/day		6.45	mL/day
Concen. of a.s. product or spray	33.3	mg/mL		0.599	mg/mL
Dermal exposure to a.s.	1.499	mg/day		3.864	mg/day
Percent absorbed	75	%		75	%
Absorbed dose	1.124	mg/day		2.898	mg/day
INHALATION EXPOSURE DURING SPRAYING					
Inhalation exposure	0.01	mL/h			
Duration of exposure	6	h			
Concentration of a.s. in spray	0.599	mg/mL			
Inhalation exposure to a.s.	0.036	mg/day			
Percent absorbed	100	%			
Absorbed dose	0.036	mg/day			
PREDICTED EXPOSURE					
Total absorbed dose	4.057	mg/day			
Operator body weight	60	kg			
Operator exposure	0.068	mg/kg bw/day			
Amount of AOEL	**67.6**	**%**			

A 3.1.3 Calculations for pyroxsulam

Table A 16: Input parameters considered for the estimation of operator exposure

Formulation type:	EC		**Application technique:**	Field Crop Tractor Mounted (FCTM)	
Application rate (AR):	0.015	kg a.s./ha			
Area treated per day (A):	20	ha	**Dermal hands m/l ($D_{M(H)}$):**	2.4	mg/person/kg a.s.
Dermal absorption (DA):	75	% (concentr.)	**Dermal hands appl. ($D_{A(H)}$):**	0.38	mg/person/kg a.s.
	75	% (dilution)	**Dermal body appl. ($D_{A(B)}$):**	1.6	mg/person/kg a.s.
Inhalation absorption (IA):	100	%	**Dermal head appl. ($D_{A(C)}$):**	0.06	mg/person/kg a.s.
Body weight (BW):	70	kg/person	**Inhalation m/l (I_M):**	0.0006	mg/person/kg a.s.
AOEL	0.7	mg/kg bw/d	**Inhalation appl. (I_A):**	0.001	mg/person/kg a.s.

Table A 17: Estimation of operator exposure towards pyroxsulam using the German model

Without PPE			**With PPE*)**		
Operators: Systemic dermal exposure after application in winter wheats					
Dermal exposure during mixing/loading					
Hands			Hands		
$SDE_{OM(H)} = (D_{M(H)} \times AR \times A \times DA) / BW$			$SDE_{OM(H)} = (D_{M(H)} \times AR \times A \times PPE^{*)} \times DA) / BW$		
(2.4 x 0.015 x 20 x 75%) / 70			(2.4 x 0.015 x 20 x 0.01 x 75%) / 70		
External dermal exposure	0.72	mg/person	External dermal exposure	0.0072	mg/person

External dermal exposure	0.010286	mg/kg bw/d	External dermal exposure	0.000103	mg/kg bw/d
Systemic dermal exposure	**0.007714**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000077**	**mg/kg bw/d**
Dermal exposure during application					
Hands			Hands		
$SDE_{OA(H)} = (D_{A(H)} \times AR \times A \times DA) / BW$			$SDE_{OA(H)} = (D_{A(H)} \times AR \times A \times PPE \times DA) / BW$		
(0.38 x 0.015 x 20 x 75%) / 70			(0.38 x 0.015 x 20 x 1 x 75%) / 70		
External dermal exposure	0.114	mg/person	External dermal exposure	0.114	mg/person
External dermal exposure	0.001629	mg/kg bw/d	External dermal exposure	0.001629	mg/kg bw/d
Systemic dermal exposure	**0.001221**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.001221**	**mg/kg bw/d**
Body			Body		
$SDE_{OA(B)} = (D_{A(B)} \times AR \times A \times DA) / BW$			$SDE_{OA(B)} = (D_{A(B)} \times AR \times A \times PPE \times DA) / BW$		
(1.6 x 0.015 x 20 x 75%) / 70			(1.6 x 0.015 x 20 x 1 x 75%) / 70		
External dermal exposure	0.48	mg/person	External dermal exposure	0.48	mg/person
External dermal exposure	0.006857	mg/kg bw/d	External dermal exposure	0.006857	mg/kg bw/d
Systemic dermal exposure	**0.005143**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.005143**	**mg/kg bw/d**
Head			Head		
$SDE_{OA(C)} = (D_{A(C)} \times AR \times A \times DA) / BW$			$SDE_{OA(C)} = (D_{A(C)} \times AR \times A \times PPE \times DA) / BW$		
(0.06 x 0.015 x 20 x 75%) / 70			(0.06 x 0.015 x 20 x 1 x 75%) / 70		
External dermal exposure	0.018	mg/person	External dermal exposure	0.018	mg/person
External dermal exposure	0.000257	mg/kg bw/d	External dermal exposure	0.000257	mg/kg bw/d
Systemic dermal exposure	**0.000193**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000193**	**mg/kg bw/d**
Total systemic dermal exposure: $SDE_O = SDE_{OM(H)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$			Total systemic dermal exposure: $SDE_O = SDE_{OM(H)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$		
Total external dermal exposure	1.332	mg/person	Total external dermal exposure	0.6192	mg/person
Total external dermal exposure	0.019029	mg/kg bw/d	Total external dermal exposure	0.008846	mg/kg bw/d
Total systemic dermal exposure	**0.014271**	**mg/kg bw/d**	**Total systemic dermal exposure**	**0.006634**	**mg/kg bw/d**
Operators: Systemic inhalation exposure after application in winter wheats					
Inhalation exposure during mixing/loading					
$SIE_{OM} = (I_M \times AR \times A \times IA) / BW$			$SIE_{OM} = (I_M \times AR \times A \times PPE \times IA) / BW$		
(0.0006 x 0.015 x 20 x 100%) / 70			(0.0006 x 0.015 x 20 x 1 x 100%) / 70		
External inhalation exposure	0.00018	mg/person	External inhalation exposure	0.00018	mg/person
External inhalation exposure	0.000003	mg/kg bw/d	External inhalation exposure	0.000003	mg/kg bw/d
Systemic inhalation exposure	**0.000003**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000003**	**mg/kg bw/d**
Inhalation exposure during application					
$SIE_{OA} = (I_A \times AR \times A \times IA) / BW$			$SIE_{OA} = (I_A \times AR \times A \times PPE \times IA) / BW$		
(0.001 x 0.015 x 20 x 100%) / 70			(0.001 x 0.015 x 20 x 1 x 100%) / 70		
External inhalation exposure	0.0003	mg/person	External inhalation exposure	0.0003	mg/person
External inhalation exposure	0.000004	mg/kg bw/d	External inhalation exposure	0.000004	mg/kg bw/d
Systemic inhalation exposure	**0.000004**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000004**	**mg/kg bw/d**
Total systemic inhalation exposure: $SIE_O = SIE_{OM} + SIE_{OA}$			Total systemic inhalation exposure: $SIE_O = SIE_{OM} + SIE_{OA}$		
Total external inhalation exposure	0.00048	mg/person	Total external inhalation exposure	0.00048	mg/person
Total external inhalation exposure	0.000007	mg/kg bw/d	Total external inhalation exposure	0.000007	mg/kg bw/d
Total systemic inhalation exposure	**0.000007**	**mg/kg bw/d**	**Total systemic inhalation exposure**	**0.000007**	**mg/kg bw/d**
Total systemic exposure: $SE_O = SDE_O + SIE_O$			Total systemic exposure: $SE_O = SDE_O + SIE_O$		
Total systemic exposure	0.99948	mg/person	Total systemic exposure	0.46488	mg/person
Total systemic exposure	**0.014278**	**mg/kg bw/d**	**Total systemic exposure**	**0.006641**	**mg/kg bw/d**
% of AOEL	**2.0**	**%**	**% of AOEL**	**0.9**	**%**

*) reduction factor for gloves is 0.01 (professional appl.)

Table A 18: Estimation of operator exposure towards pyroxsulam using the UK-POEM (without PPE)

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)	
Active substance	**pyroxsulam**
Product	A19786A
Formulation type	organic solvent-based
Concentration of a.s.	8.33 mg/mL

Dose	1.801	L preparation/ha	(0.015 kg a.s./ha)	
Application volume	100	L/ha		
Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles			
Container	10 litres 63 mm closure			
Work rate/day	50	ha		
Duration of spraying	6	h		
PPE during mix./loading	None			
PPE during application	None			
Dermal absorption from product	75	%		
Dermal absorption from spray	75	%		
EXPOSURE DURING MIXING AND LOADING				
Container size	10	Litres		
Hand contamination/operation	0,05	mL		
Application dose	1.801	Litres product/ha		
Work rate	50	ha/day		
Number of operations	9	/day		
Hand contamination	0.45	mL/day		
Protective clothing	None			
Transmission to skin	100	%		
Dermal exposure to formulation	0.45	mL/day		
DERMAL EXPOSURE DURING SPRAY APPLICATION				
Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles			
Application volume	100	spray/ha		
Volume of surface contamination	10	mL/h		
Distribution	Hands	Trunk	Legs	
	65%	10%	25%	
Clothing	None	Permeable	Permeable	
Penetration	100%	5%	15%	
Dermal exposure	6.5	0.05	0.375	mL/h
Duration of exposure	6	h		
Total dermal exposure to spray	41.55	mL/day		
ABSORBED DERMAL DOSE				
	Mix/load		Application	
Dermal exposure	0.45	mL/day	41.55	mL/day
Concen. of a.s. product or spray	8.33	mg/mL	0.15	mg/mL
Dermal exposure to a.s.	3.749	mg/day	6.233	mg/day
Percent absorbed	75	%	75	%
Absorbed dose	2.811	mg/day	4.674	mg/day
INHALATION EXPOSURE DURING SPRAYING				
Inhalation exposure	0.01	mL/h		
Duration of exposure	6	h		
Concentration of a.s. in spray	0.15	mg/mL		
Inhalation exposure to a.s.	0.009	mg/day		
Percent absorbed	100	%		
Absorbed dose	0.009	mg/day		
PREDICTED EXPOSURE				
Total absorbed dose	7.495	mg/day		
Operator body weight	60	kg		
Operator exposure	0.125	mg/kg bw/day		
Amount of AOEL	**17.8**	**%**		

Table A 19: Estimation of operator exposure towards pyroxsulam using the UK-POEM (with PPE)

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)	
Active substance	**pyroxsulam**
Product	A19786A
Formulation type	organic solvent-based

Concentration of a.s.	8.33	mg/mL		
Dose	1.801	L preparation/ha	(0.015 kg a.s./ha)	
Application volume	100	L/ha		
Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles			
Container	10 litres 63 mm closure			
Work rate/day	50	ha		
Duration of spraying	6	h		
PPE during mix./loading	Gloves			
PPE during application	None			
Dermal absorption from product	75	%		
Dermal absorption from spray	75	%		
EXPOSURE DURING MIXING AND LOADING				
Container size	10	Litres		
Hand contamination/operation	0,05	mL		
Application dose	1.801	Litres product/ha		
Work rate	50	ha/day		
Number of operations	9	/day		
Hand contamination	0.45	mL/day		
Protective clothing	Gloves			
Transmission to skin	10	%		
Dermal exposure to formulation	0.045	mL/day		
DERMAL EXPOSURE DURING SPRAY APPLICATION				
Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles			
Application volume	100	spray/ha		
Volume of surface contamination	10	mL/h		
Distribution	Hands	Trunk	Legs	
	65%	10%	25%	
Clothing	None	Permeable	Permeable	
Penetration	100%	5%	15%	
Dermal exposure	6.5	0.05	0.375	mL/h
Duration of exposure	6	h		
Total dermal exposure to spray	41.55	mL/day		
ABSORBED DERMAL DOSE				
	Mix/load		Application	
Dermal exposure	0.045	mL/day	41.55	mL/day
Concen. of a.s. product or spray	8.33	mg/mL	0.15	mg/mL
Dermal exposure to a.s.	0.375	mg/day	6.233	mg/day
Percent absorbed	75	%	75	%
Absorbed dose	0.281	mg/day	4.674	mg/day
INHALATION EXPOSURE DURING SPRAYING				
Inhalation exposure	0.01	mL/h		
Duration of exposure	6	h		
Concentration of a.s. in spray	0.15	mg/mL		
Inhalation exposure to a.s.	0.009	mg/day		
Percent absorbed	100	%		
Absorbed dose	0.009	mg/day		
PREDICTED EXPOSURE				
Total absorbed dose	4.965	mg/day		
Operator body weight	60	kg		
Operator exposure	0.083	mg/kg bw/day		
Amount of AOEL	**11.8**	**%**		

A 3.2 Worker exposure calculations (IIIA1 7.5.1)

A 3.2.1 Calculations for cloquintocet-mexyl

Table A 20: Input parameters considered for the estimation of worker exposure

Intended use(s):	winter wheats		**Dislodgeable foliar residues (DFR):**	1	µg/cm²/kg a.s.
Application rate (AR):	0.015	kg a.s./ha	**Transfer coefficient (TC):**	12500	cm²/person/h
Number of applications (NA):	1		**Work rate per day (WR):**	2	h/d
Body weight (BW):	60	kg/person	**PPE**	5	%
Dermal absorption (DA):	75	% ('worst case')			
AOEL	0.05	mg/kg bw/d			

Table A 21: Estimation of worker exposure towards cloquintocet-mexyl using the German re-entry model

Without PPE *)			**With PPE** **)		
Worker (re-entry): Systemic dermal exposure after application in winter wheats					
SDE_W = (DFR x TC x WR x AR x NA x DA) / BW			SDE_W = (DFR x TC x WR x AR x NA x PPE x DA) / BW		
(1 x 12500 x 2 x 0.015 x 1 x 75%) / 60			(1 x 12500 x 2 x 0.015 x 1 x 5% x 75%) / 60		
External dermal exposure	0.375	mg/person	External dermal exposure	0.01875	mg/person
External dermal exposure	0.00625	mg/kg bw/d	External dermal exposure	0.000313	mg/kg bw/d
Total systemic exposure	0.28125	mg/person	Total systemic exposure	0.014063	mg/person
Total systemic exposure	**0.004688**	**mg/kg bw/d**	**Total systemic exposure**	**0.000234**	**mg/kg bw/d**
% of AOEL	**9.4**[2)]	**%**	**% of AOEL**	**0.5**[2)]	**%**

*) acceptable without PPE: potential exposure
**) at an assumed 3 µg/cm²/kg a.s. DFR values would amount to 28.1 % of AOEL without PPE and 1.4 % of AOEL with PPE

A 3.2.2 Calculations for pinoxaden

Table A 22: Input parameters considered for the estimation of worker exposure

Intended use(s):	winter wheats		**Dislodgeable foliar residues (DFR):**	1	µg/cm²/kg a.s.
Application rate (AR):	0.0599	kg a.s./ha	**Transfer coefficient (TC):**	12500	cm²/person/h
Number of applications (NA):	1		**Work rate per day (WR):**	2	h/d
Body weight (BW):	60	kg/person	**PPE**	5	%
Dermal absorption (DA):	75	% ('worst case')			
AOEL	0.1	mg/kg bw/d			

Table A 23: Estimation of worker exposure towards pinoxaden using the German re-entry model

Without PPE *			**With PPE** **)		
Worker (re-entry): Systemic dermal exposure after application in winter wheats					
SDE_W = (DFR x TC x WR x AR x NA x DA) / BW			SDE_W = (DFR x TC x WR x AR x NA x PPE x DA) / BW		
(1 x 12500 x 2 x 0.0599 x 1 x 75%) / 60			(1 x 12500 x 2 x 0.0599 x 1 x 5% x 75%) / 60		
External dermal exposure	1.4975	mg/person	External dermal exposure	0.074875	mg/person
External dermal exposure	0.024958	mg/kg bw/d	External dermal exposure	0.001248	mg/kg bw/d
Total systemic exposure	1.123125	mg/person	Total systemic exposure	0.056156	mg/person
Total systemic exposure	**0.018719**	**mg/kg bw/d**	**Total systemic exposure**	**0.000936**	**mg/kg bw/d**
% of AOEL	**18.7**[2)]	**%**	**% of AOEL**	**0.9**[2)]	**%**

*) acceptable without PPE: potential exposure
**) at an assumed 3 µg/cm²/kg a.s. DFR values would amount to 56.2 % of AOEL without PPE and 2.8 % of AOEL with PPE

A 3.2.3 Calculations for pyroxsulam

Table A 24: Input parameters considered for the estimation of worker exposure

Intended use(s):	winter wheats		**Dislodgeable foliar residues (DFR):**	1	µg/cm²/kg a.s.
Application rate (AR):	0.015	kg a.s./ha	**Transfer coefficient (TC):**	12500	cm²/person/h
Number of applications (NA):	1		**Work rate per day (WR):**	2	h/d
Body weight (BW):	60	kg/person	**PPE**	5	%
Dermal absorption (DA):	75	% ('worst case')			
AOEL	0.7	mg/kg bw/d			

Table A 25: Estimation of worker exposure towards pinoxaden using the German re-entry model

Without PPE *)			**With PPE** **)		
Worker (re-entry): Systemic dermal exposure after application in winter wheats					
SDE_W = (DFR x TC x WR x AR x NA x DA) / BW			SDE_W = (DFR x TC x WR x AR x NA x PPE x DA) / BW		
(1 x 12500 x 2 x 0.015 x 1 x 75%) / 60			(1 x 12500 x 2 x 0.015 x 1 x 5% x 75%) / 60		
External dermal exposure	0.375	mg/person	External dermal exposure	0.01875	mg/person
External dermal exposure	0.00625	mg/kg bw/d	External dermal exposure	0.000313	mg/kg bw/d
Total systemic exposure	0.28125	mg/person	Total systemic exposure	0.014063	mg/person
Total systemic exposure	**0.004688**	**mg/kg bw/d**	**Total systemic exposure**	**0.000234**	**mg/kg bw/d**
% of AOEL	**0.7** [2)]	**%**	**% of AOEL**	**0** [2)]	**%**

*) acceptable without PPE: potential exposure
**) at an assumed 3 µg/cm²/kg a.s. DFR values would amount to 2.0 % of AOEL without PPE and 0.1 % of AOEL with PPE

A 3.3 Bystander and resident exposure calculations (IIIA1 7.4.1)

A 3.3.1 Calculations for cloquintocet-mexyl

Table A 26: Input parameters considered for the estimation of bystander exposure

Intended use(s):	winter wheats		**Drift (D):**	2.77	% (FC, 1 m)
Application rate (AR):	0.015	kg a.s./ha	**Exposed body surface area (BSA):**	1	m² (adults)
	1.5	mg/m²		0.21	m² (children)
Body weight (BW):	60	kg/person (adults)	**Specific Inhalation Exposure (I^*_A):**	0.001	mg/kg a.s. (6 hours, adults)
	16.15	kg/person (children)		0.000575	mg/kg a.s. (6 hours, children)
Dermal absorption (DA):	75	% ('worst case')	**Area Treated (A):**	20	ha/d (based on FCTM)
Inhalation absorption (IA):	100	%			
AOEL:	0.05	mg/kg bw/d	**Exposure duration (T):**	5	min

Table A 27: Estimation of bystander exposure towards cloquintocet-mexyl

Adults			**Children**		
Bystander: Systemic dermal exposure during/after application (via spray drift)					
SDE_B = (AR x D x BSA x DA) / BW			SDE_B = (AR x D x BSA x DA) / BW		
(1.5 x 2.77% x 1 x 75%) / 60			(1.5 x 2.77% x 0.21 x 75%) / 16.15		
External dermal exposure	0.04155	mg/person	External dermal exposure	0.008726	mg/person
External dermal exposure	0.000693	mg/kg bw/d	External dermal exposure	0.00054	mg/kg bw/d
Systemic dermal exposure	**0.000519**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000405**	**mg/kg bw/d**
Bystander: Systemic inhalation exposure during/after application (via spray drift)					
SIE_B = (I^*_A x AR x A x T x IA) / BW			SIE_B = (I^*_A x AR x A x T x IA) / BW		
(0.001 / 360 x 0.015 x 20 x 5 x 100%) / 60			(0.000575 / 360 x 0.015 x 20 x 5 x 100%) / 16.15		
External inhalation exposure	0.000004	mg/person	External inhalation exposure	0.000002	mg/person
External inhalation exposure	0	mg/kg bw/d	External inhalation exposure	0	mg/kg bw/d
Systemic inhalation exposure	**0**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0**	**mg/kg bw/d**
Total systemic exposure: $SE_B = SDE_B + SIE_B$			Total systemic exposure: $SE_B = SDE_B + SIE_B$		
Total systemic exposure	0.031167	mg/person	Total systemic exposure	0.006547	mg/person
Total systemic exposure	**0.000519**	**mg/kg bw/d**	**Total systemic exposure**	**0.000405**	**mg/kg bw/d**

% of AOEL	**1.04**	**%**	**% of AOEL**	**0.81**	**%**

Table A 28: Input parameters considered for the estimation of resident exposure

Intended use(s):	winter wheats		**Drift (D):**	2.77	% (FC, 1 m)
Application rate (AR):	0.015	kg a.s./ha	**Transfer coefficient (TC):**	7300	cm^2/h (adults)
	0.00015	mg/cm^2		2600	cm^2/h (children)
Number of applications (NA):	1		**Turf Transferable Residues (TTR):**	5	%
Body weight (BW):	60	kg/person (adults)	**Exposure Duration (H):**	2	h
	16.15	kg/person (children)	**Airborne Concentration of Vapour (ACV):**	0	mg/m^3
Dermal absorption (DA):	75	% ('worst case')	**Inhalation Rate (IR):**	16.57	m^3/d (adults)
Inhalation absorption (IA):	100	%		8.31	m^3/d (children)
Oral absorption (OA):	50	%	**Saliva Extraction Factor (SE):**	50	%
AOEL:	0.05	mg/kg bw/d	**Surface Area of Hands (SA):**	20	cm^2
			Frequency of Hand to Mouth (Freq):	20	events/h
			Dislodgeable foliar residues (DFR):	20	%
			Ingestion Rate for Mouthing of Grass/Day (IgR):	25	cm^2/d

Table A 29: Estimation of resident exposure towards cloquintocet-mexyl

Adults			**Children**		
Residents: Systemic dermal exposure after application (via deposits caused by spray drift)					
SDE_R = (AR x NA x D x TTR x TC x H x DA) / BW			SDE_R = (AR x NA x D x TTR x TC x H x DA) / BW		
(0.00015 x 1 x 2.77% x 5% x 7300 x 2 x 75%) / 60			(0.00015 x 1 x 2.77% x 5% x 2600 x 2 x 75%) / 16.15		
External dermal exposure	0.003033	mg/person	External dermal exposure	0.00108	mg/person
External dermal exposure	0.000051	mg/kg bw/d	External dermal exposure	0.000067	mg/kg bw/d
Systemic dermal exposure	**0.000038**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.00005**	**mg/kg bw/d**
Residents: Systemic inhalation exposure after application (via vapour)					
SIE_R = (AC_V x IR x IA) / BW			SIE_R = (AC_V x IR x IA) / BW		
(0 x 16.57 x 100%) / 60			(0 x 8.31 x 100%) / 16.15		
External inhalation exposure		none	External inhalation exposure		none
Systemic inhalation exposure		**none**	**Systemic inhalation exposure**		**none**
			Residents: Systemic oral exposure (hand-to-mouth transfer)		
			$SOE_{R(H)}$ = (AR x NA x D x TTR x SE x SA x Freq x H x OA) / BW		
			(0.00015 x 1 x % x 5% x 50% x 20 x 20 x 2 x 50%) / 16.15		
			External oral exposure	0.000083	mg/person
			External oral exposure	0.000005	mg/kg bw/d
			Systemic oral exposure	**0.000003**	**mg/kg bw/d**
			Residents: Systemic oral exposure (object-to-mouth transfer)		
			$SOE_{R(O)}$ = (AR x NA x D x DFR x IgR x OA) / BW		
			(0.00015 x 1 x % x 20% x 25 x 50%) / 16.15		
			External oral exposure	0.000021	mg/person
			External oral exposure	0.000001	mg/kg bw/d
			Systemic oral exposure	**0.000001**	**mg/kg bw/d**
Total systemic exposure: $SE_R = SDE_R + SIE_R$			Total systemic exposure: $SE_R = SDE_R + SIE_R + SOE_{R(H)} + SOE_{R(O)}$		
Total systemic exposure	0.002275	mg/person	Total systemic exposure	0.000862	mg/person
Total systemic exposure	**0.000038**	**mg/kg bw/d**	**Total systemic exposure**	**0.000053**	**mg/kg bw/d**
% of AOEL	**0.08**	**%**	**% of AOEL**	**0.11**	**%**

A 3.3.2 Calculations for pinoxaden

Table A 30: Input parameters considered for the estimation of bystander exposure

Intended use(s):	winter wheats		**Drift (D):**	2.77	% (FC, 1 m)
Application rate (AR):	0.0599	kg a.s./ha	**Exposed body surface area (BSA):**	1	m² (adults)
	5.99	mg/m^2		0.21	m² (children)
Body weight (BW):	60	kg/person (adults)	**Specific Inhalation Exposure (I^*_A):**	0.001	mg/kg a.s. (6 hours, adults)

	16.15	kg/person (children)		0.000575	mg/kg a.s. (6 hours, children)
Dermal absorption (DA):	75	% ('worst case')	**Area Treated (A):**	20	ha/d (based on FCTM)
Inhalation absorption (IA):	100	%			
AOEL:	0.1	mg/kg bw/d	**Exposure duration (T):**	5	min

Table A 31: Estimation of bystander exposure towards pinoxaden

Adults			**Children**		
Bystander: Systemic dermal exposure during/after application (via spray drift)					
SDE_B = (AR x D x BSA x DA) / BW			SDE_B = (AR x D x BSA x DA) / BW		
(5.99 x 2.77% x 1 x 75%) / 60			(5.99 x 2.77% x 0.21 x 75%) / 16.15		
External dermal exposure	0.165923	mg/person	External dermal exposure	0.034844	mg/person
External dermal exposure	0.002765	mg/kg bw/d	External dermal exposure	0.002158	mg/kg bw/d
Systemic dermal exposure	**0.002074**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.001618**	**mg/kg bw/d**
Bystander: Systemic inhalation exposure during/after application (via spray drift)					
SIE_B = (I^*_A x AR x A x T x IA) / BW			SIE_B = (I^*_A x AR x A x T x IA) / BW		
(0.001 / 360 x 0.0599 x 20 x 5 x 100%) / 60			(0.000575 / 360 x 0.0599 x 20 x 5 x 100%) / 16.15		
External inhalation exposure	0.000017	mg/person	External inhalation exposure	0.00001	mg/person
External inhalation exposure	0	mg/kg bw/d	External inhalation exposure	0.000001	mg/kg bw/d
Systemic inhalation exposure	**0**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000001**	**mg/kg bw/d**
Total systemic exposure: $SE_B = SDE_B + SIE_B$			Total systemic exposure: $SE_B = SDE_B + SIE_B$		
Total systemic exposure	0.124459	mg/person	Total systemic exposure	0.026142	mg/person
Total systemic exposure	**0.002074**	**mg/kg bw/d**	**Total systemic exposure**	**0.001619**	**mg/kg bw/d**
% of AOEL	**2.07**	**%**	**% of AOEL**	**1.62**	**%**

Table A 32: Input parameters considered for the estimation of resident exposure

Intended use(s):	winter wheats		**Drift (D):**	2.77	% (FC, 1 m)
Application rate (AR):	0.0599	kg a.s./ha	**Transfer coefficient (TC):**	7300	cm^2/h (adults)
	0.000599	mg/cm^2		2600	cm^2/h (children)
Number of applications (NA):	1		**Turf Transferable Residues (TTR):**	5	%
Body weight (BW):	60	kg/person (adults)	**Exposure Duration (H):**	2	h
	16.15	kg/person (children)	**Airborne Concentration of Vapour (ACV):**	0	mg/m^3
Dermal absorption (DA):	75	% ('worst case')	**Inhalation Rate (IR):**	16.57	m^3/d (adults)
Inhalation absorption (IA):	100	%		8.31	m^3/d (children)
Oral absorption (OA):	100	%	**Saliva Extraction Factor (SE):**	50	%
AOEL:	0.1	mg/kg bw/d	**Surface Area of Hands (SA):**	20	cm^2
			Frequency of Hand to Mouth (Freq):	20	events/h
			Dislodgeable foliar residues (DFR):	20	%
			Ingestion Rate for Mouthing of Grass/Day (IgR):	25	cm^2/d

Table A 33: Estimation of resident exposure towards pinoxaden

Adults			**Children**		
Residents: Systemic dermal exposure after application (via deposits caused by spray drift)					
SDE_R = (AR x NA x D x TTR x TC x H x DA) / BW			SDE_R = (AR x NA x D x TTR x TC x H x DA) / BW		
(0.000599 x 1 x 2.77% x 5% x 7300 x 2 x 75%) / 60			(0.000599 x 1 x 2.77% x 5% x 2600 x 2 x 75%) / 16.15		
External dermal exposure	0.012112	mg/person	External dermal exposure	0.004314	mg/person
External dermal exposure	0.000202	mg/kg bw/d	External dermal exposure	0.000267	mg/kg bw/d
Systemic dermal exposure	**0.000151**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.0002**	**mg/kg bw/d**
Residents: Systemic inhalation exposure after application (via vapour)					
SIE_R = (AC_V x IR x IA) / BW			SIE_R = (AC_V x IR x IA) / BW		
(0 x 16.57 x 100%) / 60			(0 x 8.31 x 100%) / 16.15		
External inhalation exposure		none	External inhalation exposure		none
Systemic inhalation exposure		**none**	**Systemic inhalation exposure**		**none**
			Residents: Systemic oral exposure (hand-to-mouth transfer)		

			$SOE_{R(H)}$ = (AR x NA x D x TTR x SE x SA x Freq x H x OA) / BW		
			(0.000599 x 1 x % x 5% x 50% x 20 x 20 x 2 x 100%) / 16.15		
			External oral exposure	0.000332	mg/person
			External oral exposure	0.000021	mg/kg bw/d
			Systemic oral exposure	**0.000021**	**mg/kg bw/d**
			Residents: Systemic oral exposure (object-to-mouth transfer)		
			$SOE_{R(O)}$ = (AR x NA x D x DFR x IgR x OA) / BW		
			(0.000599 x 1 x % x 20% x 25 x 100%) / 16.15		
			External oral exposure	0.000083	mg/person
			External oral exposure	0.000005	mg/kg bw/d
			Systemic oral exposure	**0.000005**	**mg/kg bw/d**
Total systemic exposure: $SE_R = SDE_R + SIE_R$			Total systemic exposure: $SE_R = SDE_R + SIE_R + SOE_{R(H)} + SOE_{R(O)}$		
Total systemic exposure	0.009084	mg/person	Total systemic exposure	0.00365	mg/person
Total systemic exposure	**0.000151**	**mg/kg bw/d**	**Total systemic exposure**	**0.000226**	**mg/kg bw/d**
% of AOEL	**0.15**	**%**	**% of AOEL**	**0.23**	**%**

A 3.3.3 Calculations for pyroxsulam

Table A 34: Input parameters considered for the estimation of bystander exposure

Intended use(s):	winter wheats		**Drift (D):**	2.77	% (FC, 1 m)
Application rate (AR):	0.015	kg a.s./ha	**Exposed body surface area (BSA):**	1	m² (adults)
	1.5	mg/m²		0.21	m² (children)
Body weight (BW):	60	kg/person (adults)	**Specific Inhalation Exposure (I^*_A):**	0.001	mg/kg a.s. (6 hours, adults)
	16.15	kg/person (children)		0.000575	mg/kg a.s. (6 hours, children)
Dermal absorption (DA):	75	% ('worst case')	**Area Treated (A):**	20	ha/d (based on FCTM)
Inhalation absorption (IA):	100	%			
AOEL:	0.7	mg/kg bw/d	**Exposure duration (T):**	5	min

Table A 35: Estimation of bystander exposure towards pyroxsulam

Adults			**Children**		
Bystander: Systemic dermal exposure during/after application (via spray drift)					
SDE_B = (AR x D x BSA x DA) / BW			SDE_B = (AR x D x BSA x DA) / BW		
(1.5 x 2.77% x 1 x 75%) / 60			(1.5 x 2.77% x 0.21 x 75%) / 16.15		
External dermal exposure	0.04155	mg/person	External dermal exposure	0.008726	mg/person
External dermal exposure	0.000693	mg/kg bw/d	External dermal exposure	0.00054	mg/kg bw/d
Systemic dermal exposure	**0.000519**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000405**	**mg/kg bw/d**
Bystander: Systemic inhalation exposure during/after application (via spray drift)					
$SIE_B = (I^*_A$ x AR x A x T x IA) / BW			$SIE_B = (I^*_A$ x AR x A x T x IA) / BW		
(0.001 / 360 x 0.015 x 20 x 5 x 100%) / 60			(0.000575 / 360 x 0.015 x 20 x 5 x 100%) / 16.15		
External inhalation exposure	0.000004	mg/person	External inhalation exposure	0.000002	mg/person
External inhalation exposure	0	mg/kg bw/d	External inhalation exposure	0	mg/kg bw/d
Systemic inhalation exposure	**0**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0**	**mg/kg bw/d**
Total systemic exposure: $SE_B = SDE_B + SIE_B$			Total systemic exposure: $SE_B = SDE_B + SIE_B$		
Total systemic exposure	0.031167	mg/person	Total systemic exposure	0.006547	mg/person
Total systemic exposure	**0.000519**	**mg/kg bw/d**	**Total systemic exposure**	**0.000405**	**mg/kg bw/d**
% of AOEL	**0.07**	**%**	**% of AOEL**	**0.06**	**%**

Table A 36: Input parameters considered for the estimation of resident exposure

Intended use(s):	winter wheats		**Drift (D):**	2.77	% (FC, 1 m)
Application rate (AR):	0.015	kg a.s./ha	**Transfer coefficient (TC):**	7300	cm²/h (adults)
	0.00015	mg/cm²		2600	cm²/h (children)
Number of applications (NA):	1		**Turf Transferable Residues (TTR):**	5	%
Body weight (BW):	60	kg/person (adults)	**Exposure Duration (H):**	2	h
	16.15	kg/person (children)	**Airborne Concentration of Vapour (ACV):**	0	mg/m³
Dermal absorption (DA):	75	% ('worst case')	**Inhalation Rate (IR):**	16.57	m³/d (adults)

Inhalation absorption (IA):	100	%		8.31	m^3/d (children)
Oral absorption (OA):	75	%	**Saliva Extraction Factor (SE):**	50	%
AOEL:	0.7	mg/kg bw/d	**Surface Area of Hands (SA):**	20	cm^2
			Frequency of Hand to Mouth (Freq):	20	events/h
			Dislodgeable foliar residues (DFR):	20	%
			Ingestion Rate for Mouthing of Grass/Day (IgR):	25	cm^2/d

Table A 37: Estimation of resident exposure towards pyroxsulam

Adults			**Children**		
Residents: Systemic dermal exposure after application (via deposits caused by spray drift)					
SDE_R = (AR x NA x D x TTR x TC x H x DA) / BW			SDE_R = (AR x NA x D x TTR x TC x H x DA) / BW		
(0.00015 x 1 x 2.77% x 5% x 7300 x 2 x 75%) / 60			(0.00015 x 1 x 2.77% x 5% x 2600 x 2 x 75%) / 16.15		
External dermal exposure	0.003033	mg/person	External dermal exposure	0.00108	mg/person
External dermal exposure	0.000051	mg/kg bw/d	External dermal exposure	0.000067	mg/kg bw/d
Systemic dermal exposure	**0.000038**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.00005**	**mg/kg bw/d**
Residents: Systemic inhalation exposure after application (via vapour)					
SIE_R = (AC_V x IR x IA) / BW			SIE_R = (AC_V x IR x IA) / BW		
(0 x 16.57 x 100%) / 60			(0 x 8.31 x 100%) / 16.15		
External inhalation exposure		none	External inhalation exposure		none
Systemic inhalation exposure		**none**	**Systemic inhalation exposure**		**none**
			Residents: Systemic oral exposure (hand-to-mouth transfer)		
			$SOE_{R(H)}$ = (AR x NA x D x TTR x SE x SA x Freq x H x OA) / BW		
			(0.00015 x 1 x % x 5% x 50% x 20 x 20 x 2 x 75%) / 16.15		
			External oral exposure	0.000083	mg/person
			External oral exposure	0.000005	mg/kg bw/d
			Systemic oral exposure	**0.000004**	**mg/kg bw/d**
			Residents: Systemic oral exposure (object-to-mouth transfer)		
			$SOE_{R(O)}$ = (AR x NA x D x DFR x IgR x OA) / BW		
			(0.00015 x 1 x % x 20% x 25 x 75%) / 16.15		
			External oral exposure	0.000021	mg/person
			External oral exposure	0.000001	mg/kg bw/d
			Systemic oral exposure	**0.000001**	**mg/kg bw/d**
Total systemic exposure: $SE_R = SDE_R + SIE_R$			Total systemic exposure: $SE_R = SDE_R + SIE_R + SOE_{R(H)} + SOE_{R(O)}$		
Total systemic exposure	0.002275	mg/person	Total systemic exposure	0.000888	mg/person
Total systemic exposure	**0.000038**	**mg/kg bw/d**	**Total systemic exposure**	**0.000055**	**mg/kg bw/d**
% of AOEL	**0.01**	**%**	**% of AOEL**	**0.01**	**%**

REGISTRATION REPORT
Part B

Section 4: Metabolism and Residues

Detailed summary of the risk assessment

Product name: AVOXA

Active Substances:

Cloquintocet-mexyl 8.33 g/L

Pinoxaden 33.3 g/L

Pyroxsulam 8.33 g/L

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Syngenta Agro GmbH

Date: November 2017

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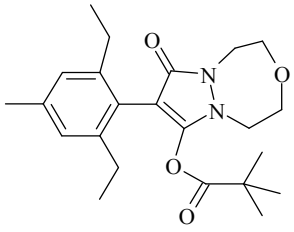
4 METABOLISM AND RESIDUES DATA

4.1 Evaluation of the active substances

4.1.1 Pinoxaden

Table 4.1-1: Identity of the active substance

Structural formula	
Common Name	Pinoxaden
CAS number	243973-20-8

4.1.1.1 Storage stability

A brief summary of the storage stability data on pinoxaden is given in the following table. Data have been previously evaluated at the EU level and are described in detail in the DAR (UK, 2005 ASB2010-10613), Addenda to the DAR (ASB2012-3150, ASB2013-6761) and the conclusion on the peer review of the pesticide risk assessment of the active substance pinoxaden (EFSA 2013; ASB2013-10732).

Table 4.1-2: Stability of residues (Annex IIA, point 6.1)

Stability of pinoxaden metabolites M2 (NOA 407854), M4 (SYN 505164), M6 (SYN 502836) and M10 (SYN 505887)	Samples of wheat grain, whole wheat plant and straw were fortified with metabolites M2, M4, M6 and M10, respectively. Fortification levels were 0.1 mg/kg in wheat grain and 0.2 mg/kg in whole wheat plant and wheat straw. Samples were stored for up to 28 months at ≤-18ºC, with intermediate analyses made at 0, 1, 4, 6, 9, 15, 19/20 and 24/26 months (RIP2004-1966, ASB2014-5354). All metabolites were stable for at least 28 months when stored frozen at ≤-18ºC. The metabolites M4 and M6 were stable for at least 3 months stored at -20°C in milk, eggs, chicken muscle and bovine liver (RIP2004-1976). Spiking level was 0.5 mg/kg.

4.1.1.2 Metabolism in plants and plant residue definition(s)

A brief summary of the metabolism of pinoxaden in plants is given in the following table. Data have been previously evaluated at the EU level and are described in detail in the DAR (UK, 2005 ASB2010-10613), in Addenda to the DAR (ASB2012-3150, ASB2013-6761) and the conclusion on the peer review of the pesticide risk assessment of the active substance pinoxaden (EFSA 2013; ASB2013-10732).

Table 4.1-3: Metabolism in plants (Annex IIA, point 6.2.1; 6.5.1, 6.5.2, 6.6.2 and 6.7.1)

Plant groups covered	Cereals (wheat) Winter wheat RIP2004-1971: 0.069 kg as/ha, pyrazol-3,5-^{14}C label, at BBCH 13 Winter wheat RIP2004-1973: 0.064 kg as/ha and 0.32 kg as/ha, phenyl-1-^{14}Clabel, at BBCH 49 Spring wheat RIP2004-1982: 0.062-0.066 kg as/ha phenyl-1-^{14}C and oxadiazepine-3,6-^{14}C label at BBCH 37-39 Immature and mature samples were investigated. Pinoxaden was extensively metabolised and only detectable shortly after application. The first step was rapid hydrolysis of the ester bond to yield metabolite M2 which was then hydroxylated to M4 followed by oxidation and and conjugation reactions. Major residues in wheat plants were M4 and M6. Low levels of other metabolites were also observed, such as M3, M5, M7, M8, M9, M10 and several unknown compounds.It appears that the basic degradation steps of pinoxaden were similar for all labels. Cleavage between the ring systems of pinoxaden was not observed.
Rotational crops	RIP2004-2037: ^{14}C-phenyl label, 60.3 g as/ha applied to bare soil, rotational crops lettuce, radish and wheat, PBIs 1, 4 or 6 and 12 months At 30 days PBI TRRs at harvest were up to 0.011 mg/kg in lettuce; 0.014 mg/kg and 0.001 mg/kg in radish tops and roots; 0.024 mg/kg in wheat forage, 0.005 mg/kg in wheat grain and 0.035 mg/kg in wheat fodder (straw plus husks). RIP2004-2039: ^{14}C-oxadiazepin label, 65.5 g as/ha applied to bare soil, rotational crops lettuce, radish and wheat, PBIs 1, 4-6 and 12 months At 29 days PBI TRRs at harvest were up to 0.014 mg/kg in lettuce; 0.022 mg/kg and 0.002 mg/kg in radish tops and roots; 0.048 mg/kg in wheat forage, 0.007 mg/kg in wheat grain and 0.077 mg/kg in wheat fodder (straw plus husks). The metabolism in rotational crops was similar for all labels. Metabolite identification was only carried out for samples with residues > 0.01 mg/kg. Parent was not found in any sample and no metabolite exceeded 0.01 mg/kg with the exception of M3 (0.0237 mg/kg; 49.3 % TRR, PBI 29 days) in spring wheat forage from the oxadiazepine study. Significant residues in rotational crops are therefore not expected.
Metabolism in rotational crops similar to metabolism in primary crops? (yes/no)	yes
Distribution of the residue in peel/ pulp	Not applicable

Processed commodities (nature of residue)	The behaviour of [phenyl-1-^{14}C]-labelled pinoxaden was studied under simulated processing conditions (RIP2004-2029). Total recoveries ranged from 91 to 94 % of the applied radioactivity. Under pasteurization conditions (pH4, 90°C, 20 minutes) a minor degradation to M2 (5 %) was observed. A more pronounced degradation to M2 (20 %) was detected under baking/brewing/boiling conditions (pH 5, 100°C, 60 minutes). Under sterilization conditions (pH 6, 120°C, 20 minutes) the degradation of pinoxaden yielded 40 % M2, which was the only degradation product.
Residue pattern in raw and processed commodities similar? (yes/no)	yes
Plant residue definition for monitoring	Pinoxaden (Reg. (EC) No 396/2005) proposed by EFSA (ASB2013-10732): sum of M4 and M6 expressed as parent pinoxaden (to include free and conjugated residues of M4 and M6)
Plant residue definition for risk assessment	proposed by EFSA (ASB2013-10732): sum of M4 and M6 expressed as parent pinoxaden (to include free and conjugated residues of M4 and M6)
Conversion factor(s) (monitoring to risk assessment)	none currently required

4.1.1.3 Metabolism in livestock and animal residue definition(s)

A brief summary of the metabolism of pinoxaden in livestock is given in the following table. Data have been previously evaluated at the EU level and are described in detail in the DAR (UK, 2005 ASB2010-10613) in Addenda to the DAR (ASB2012-3150, ASB2013-6761) and the conclusion on the peer review of the pesticide risk assessment of the active substance pinoxaden (EFSA 2013; ASB2013-10732).

Table 4.1-4: Metabolism in livestock (Annex IIA, point 6.2.2 to 6.2.5 and 6.7.1)

Animals covered	Lactating goats (RIP2004-1983): ^{14}C-phenyl-pinoxaden at 120.6 mg/kg for 4 days 46 % TRR was eliminated via urine, 18 % via faeces and 0.01 % via milk. Unchanged parent was not detected in milk, tissues or excreta. M2 accounted for 89 % TRR in muscle, 79 % in fat, 86 % in liver, 90 % in kidneys, and 88 % in milk. Minor metabolites M4 and M3 were also identified in tissues and excrements. Lactating goats (RIP2004-1984): ^{14}C-pyrazol labelled metabolite M4 at 9.8 mg/kg for 4 days 60 % TRR was eliminated via faeces and < 0.1 % was transferred to milk and tissues. Laying hens (RIP2004-1985): ^{14}C-phenyl-pinoxaden at 96.7 mg/kg for 4 days. 75 % TRR was eliminated via excrements and 0.007 % were detected in eggs. M2 accounted for 46 % TRR in egg white and 18.5 % in excreta. M4 was the major metabolite in lean meat (44.3 %), fat with skin (30.2 %), egg yolk (23.7 %) and excreta (43.2 %). Pinoxaden was extensively metabolised. The metabolism of pinoxaden appeared to proceed via hydrolysis of the ester moiety to form M2, which was then metabolised to several minor metabolites including M4. Pinoxaden was

	not found in any tissues. The identified metabolites did not indicate a cleavage between the ring systems.
Time needed to reach a plateau concentration in milk and eggs	Milk 2 days Egg white 1-2 days, egg yolk > 3 days
Animal residue definition for monitoring	According to the conclusions of the peer review no definition is deemed necessary (ASB2013-10732).
Animal residue definition for risk assessment	According to the conclusions of the peer review no definition is deemed necessary (ASB2013-10732).
Conversion factor(s) (monitoring to risk assessment)	Not applicable
Metabolism in rat and ruminant similar (yes/no)	yes
Fat soluble residue: (yes/no)	No (log $P_{O/W}$ = 3.2 at 25°C, but no indication for fat soluble residue in metabolism/feeding studies)

4.1.1.4 Residues in rotational crops

Field rotational crop studies on pinoxaden are not available. A justification is given in the following table.

Table 4.1-5: Residues in rotational crops (Annex IIA, point 6.6.3)

Field studies	Significant residues are not expected in food and feed commodities obtained from succeeding crops (consequent to uses in compliance with cGAP).

4.1.1.5 Residues in livestock

An actual calculation of the dietary burden is provided in the following table.

Table 4.1-6: Calculation of livestock dietary burden based on all relevant uses authorized in Germany and the representative use in the EU

Feedstuff	% DM	Percent of daily livestock diet (dry feed basis)				Residue (mg/kg)	Intake (mg/kg, dry feed basis)			
		Chicken	Dairy cattle	Beef cattle	Pig		Chicken	Dairy cattle	Beef cattle	Pig
		1.9 kg bw	550 kg bw	350 kg bw	75 kg bw					
		daily maximum feed (DM) 120 g	daily maximum feed (DM) 20 kg	daily maximum feed (DM) 15 kg	daily maximum feed (DM) 3 kg					
cereals (grain)	86	70	40	50	80	0.12[a]	0.098	0.056	0.070	0.112
cereals (straw)	86	--	20	50	--	0.83[b]	--	0.193	0.483	--
				Intake (mg/kg dry weight feed)			0.098	0.249	0.522	0.112
				Intake (mg/kg bw/d)			0.006	0.009	0.024	0.004
				Intake (mg/animal/d)			0.012	4.977	8.288	0.335

[a] STMR (SEU), based on the following cGAP: 1 x 0.060 kg as/ha, up to BBCH 39, PHI: F (i.e. not specified), ASB2013-10732
[b] HR (SEU), based on the following cGAP: 1 x 0.060 kg as/ha, up to BBCH 39, PHI: F (i.e. not specified), ASB2013-10732

Table 4.1-7: Conditions of requirement of livestock feeding studies on pinoxaden

	Ruminant:	**Poultry:**	**Pig:**
Expected intakes by livestock ≥0.1 mg/kg diet (dry weight basis) (yes/no – If yes, specify the level)	yes (0.25 dairy cattle, 0.52 beef cattle)	no	no
Potential for accumulation (yes/no):	no	no	see ruminant
Metabolism studies indicate potential level of residues ≥0.01 mg/kg in edible tissues (yes/no)	no	no	see ruminant

A brief summary of the available livestock feeding studies is given in the following table. Data have been previously evaluated at the EU level and are described in detail in the DAR (UK, 2005 ASB2010-10613) and in Addenda to the DAR (ASB2012-3150, ASB2013-6761).

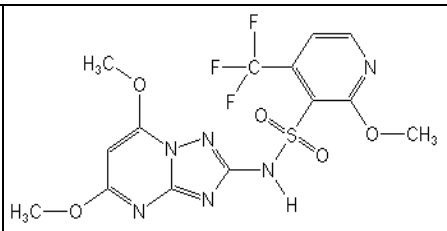
Table 4.1-8: Results of livestock feeding studies (Annex IIA, point 6.4)

	Ruminant:	**Poultry:**	**Pig:**
Feeding studies	Dairy cow (RIP2004-2025, feeding of M4 over 29-30 days)	Laying hen (RIP2004-2027, feeding of M4 over 28 days)	see ruminant
Feeding levels in mg/kg feed DM	1, 3, 10	0.5, 1.5, 3.5	see ruminant
Feeding levels in mg/kg bw	0.04; 0.12; 0.4	0.04; 0.12; 0.4	see ruminant
Relevant dosing levels in feeding study:	1	0.5	1
	Expected residue levels in animal matrices at calculated dietary burden (mg/kg)#:		
Muscle	<0.01	<0.01	<0.01
Liver	<0.01	<0.01	<0.01
Kidney	<0.01	<0.01	<0.01
Fat	<0.01	<0.01	<0.01
Milk	<0.01	–	–
Eggs	–	<0.01	–

Because residues were < LOQ of 0.02 mg/kg in the highest dose groups (cow: 10 mg/kg feed, hens: 3.5 mg/kg feed), samples from the lower dose groups were not analysed. No residues are expected in edible matrices of animal origin.

4.1.2 Pyroxsulam

Table 4.1-9: Identity of the active substance

Structural formula	
Common Name	Pyroxsulam
CAS number	422556-08-9

4.1.2.1 Storage stability

A brief summary of the storage stability data on pyroxsulam is given in the following table. Data that have been previously evaluated at the EU level are described in detail in the DAR and its Addendum (UK, 2012 ASB2012-5575, ASB2012-15206) and in EFSA's Conclusion on the peer review (EFSA Journal, 2013 ASB2013-5919).

Table 4.1-10: Stability of residues (Annex IIA, point 6.1)

Stability of pyroxsulam	Pyroxsulam residues were stable at -20°C for at least 6 months in a broad range of plant matrices, namely spinach, tomatoes, potatoes, soyabeans, wheat grain, wheat forage and wheat straw (RIP2006-1693).

4.1.2.2 Metabolism in plants and plant residue definition(s)

A brief summary of the metabolism of pyroxsulam in plants is given in the following table. Data that have been previously evaluated at the EU level are described in detail in the DAR and its Addendum (UK, 2012 ASB2012-5575, ASB2012-15206) and in EFSA's Conclusion on the peer review (EFSA Journal, 2013 ASB2013-5919).

Table 4.1-11: Metabolism in plants (Annex IIA, point 6.2.1; 6.5.1, 6.5.2, 6.6.2 and 6.7.1)

Plant groups covered	Wheat (RIP2006-1695): outdoors; sites of [^{14}C] radio-labelling were pyridine ring and the pyrimidinyl ring, single application at 37.5 g/ha of each radiolabelled form at growth stage BBCH 30-31 (using a formulation containing a safener at the same ratio as proposed in the commercial product). Pyroxsulam was readily metabolised, accounting for less than 7% TRR at 7 DAA in forage (7 DAA) and 1-2% in hay samples. In mature plants 92 days after the treatment, TRRs were only 0.03 mg/kg in straw and less than 0.002 mg/kg in grain, and therefore characterisation of the residues was not attempted. 5-OH pyroxsulam was the most abundant metabolite and further underwent conjugation reactions. Other metabolites were present in only marginal amounts (< 1%). No cleavage of the sulfonamide bridge was observed.
Rotational crops	Due to the low DT_{50} in soil (2 to 16 days at 20°C, laboratory conditions) a rotational crop study is not triggered but a confined study was conducted, limited to a single (worst csase) plant back interval of 30 days. Confined study (RIP2006-1719): sites of [^{14}C] radio-labelling were pyridine ring and the pyrimidinyl ring, single application of 18.75 g a.s./ha to bare soil, rotational crops potatoes, wheat and lettuce planted after a PBI of 30 days. For both labels, TRRs in potato, lettuce and wheat at harvest were almost all below 0.005 mg/kg with a maximum value of 0.036 mg/kg in potato foliage.
Metabolism in rotational crops similar to metabolism in primary crops? (yes/no)	yes
Distribution of the residue in peel/ pulp	Not applicable
Processed commodities (nature of residue)	not provided/not required due to low residues at harvest

Residue pattern in raw and processed commodities similar? (yes/no)	not applicable
Plant residue definition for monitoring	Pyroxsulam (Reg. (EC) No 396/2005)
Plant residue definition for risk assessment	Pyroxsulam
Conversion factor(s) (monitoring to risk assessment)	not applicable

4.1.2.3 Metabolism in livestock and animal residue definition(s)

A brief summary of the metabolism of pyroxsulam in livestock is given in the following table. Data that have been previously evaluated at the EU level are described in detail in the DAR and its Addendum (UK, 2012 ASB2012-5575, ASB2012-15206) and in EFSA's Conclusion on the peer review (EFSA Journal, 2013 ASB2013-5919).

Table 4.1-12: Metabolism in livestock (Annex IIA, point 6.2.2 to 6.2.5 and 6.7.1)

Animals covered	Lactating goats (RIP2006-1697): 12 mg/kg feed for 7 consecutive days, separate animals treated with ^{14}C-pyridine (PY) and ^{14}C-triazolo-pyrimidine (TP) TRRs were greater than 0.01 mg as-eq/kg only in liver (0.013 (TP) and 0.022 (TP)) and kidney (0.013 (TP) and 0.025 (TP)), in milk 0.007 mg as-eq/kg (TP) and 0.013 mg as-eq/kg (PY) were found. Unchanged parent made up almost all of the residues in urine, faeces but also in milk (96%). It was also the most abundant compound in solvent extracts of liver and kidney, representing 5% and 10% of the TRR, respectively. Laying hens (RIP2006-1696): 10 mg/kg feed (corresponding to 0.4 mg/kg bw) for 7 consecutive days, separate animals treated with ^{14}C-pyridine (PY) and ^{14}C-triazolo-pyrimidine (TP). More than 99% of the dose were detected in the excreta (unmetabolized); TRRs in liver were 0.019 mg as-eq/kg (TP), <0.0043 mg as-eq/kg in skin with fat (TP), 0.0047 mg as-eq/kg in eggs (TP), <0.0006 mg as-eq/kg in muscle (TP) and <0.0004 mg as-eq/kg in fat (TP and PY). Residue components were only identified in liver: 30% (TP) and 15% (PY) were parent, the rest of extractable residues consisted of polar compounds.
Time needed to reach a plateau concentration in milk and eggs	milk: 5 days eggs: ≤ 7 days
Animal residue definition for monitoring	not required Nevertheless MRLs have been established in Reg. (EC) No 396/2005 for products of animal origin (0.01* mg/kg) based on the residue definition "pyroxsulam".
Animal residue definition for risk assessment	not required
Conversion factor(s) (monitoring to risk assessment)	not applicable
Metabolism in rat and ruminant similar (yes/no)	not concluded
Fat soluble residue: (yes/no)	no indication of fat solubility due to log $P_{O/W}$ = -1 (at pH 7), -1.6 (at pH 9), 1.08 (at pH 4)

4.1.2.4 Residues in rotational crops

Field rotational crop studies on pyroxsulam are neither available nor required.

4.1.2.5 Residues in livestock

An actual calculation of the dietary burden (based on all relevant uses authorized in Germany and the representative use in the EU) is provided in the following table.

Table 4.1-13: Calculation of livestock dietary burden (based on all relevant uses authorized in Germany and the representative use in the EU

Feedstuff	% DM	Percent of daily livestock diet (dry feed basis)				Residue (mg/kg)	Intake (mg/kg, dry feed basis)			
		Chicken 1.9 kg bw daily maximum feed (DM) 120 g	Dairy cattle 550 kg bw daily maximum feed (DM) 20 kg	Beef cattle 350 kg bw daily maximum feed (DM) 15 kg	Pig 75 kg bw daily maximum feed (DM) 3 kg		Chicken	Dairy cattle	Beef cattle	Pig
cereal grain	86	70	40	80	80	0.01[a)]	0.008	0.005	0.009	0.009
cereal straw	86	00	20	20	00	0.01[b)]	0.000	0.002	0.002	0.002
				Intake (mg/kg dry weight feed)			0.008	0.007	0.012	0.009
				Intake (mg/kg bw/d)			0.001	0.000	0.000	0.000
				Intake (mg/animal/d)			0.001	0.140	0.174	0.028

[a] STMR, based on: 1 x 18.5 kg as/ha, PHI: n.a. (EFSA, ASB2013-5919)
[b] HR, based based on: 1 x 18.5 kg as/ha, PHI: n.a. (EFSA, ASB2013-5919)

Table 4.1-14: Conditions of requirement of livestock feeding studies on pyroxsulam

	Ruminant:	**Poultry:**	**Pig:**
Expected intakes by livestock ≥0.1 mg/kg diet (dry weight basis) (yes/no – If yes, specify the level)	no	no	no
Potential for accumulation (yes/no):	no	not applicable	see ruminant
Metabolism studies indicate potential level of residues ≥0.01 mg/kg in edible tissues (yes/no)	no	not applicable	see ruminant

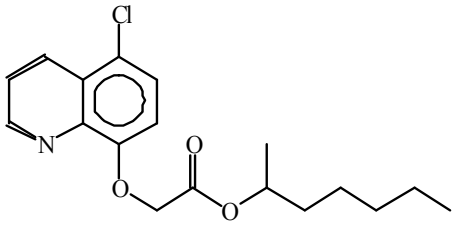
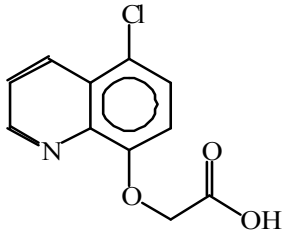
Livestock feeding studies are neither available nor required.

Table 4.1-15: Results of livestock feeding studies (Annex IIA, point 6.4)

	Ruminant:	**Poultry:**	**Pig:**
Feeding studies	no data	no data	no data
Feeding levels in mg/kg feed DM	not applicable	not applicable	not applicable
Feeding levels in mg/kg bw	not applicable	not applicable	not applicable
Relevant dosing levels in feeding study:	not applicable	not applicable	not applicable
	Expected residue levels in animal matrices at calculated dietary burden (mg/kg):		
Muscle	<0.01	<0.01	<0.01
Liver	<0.01	<0.01	<0.01
Kidney	<0.01	<0.01	<0.01
Fat	<0.01	<0.01	<0.01
Milk	<0.01	–	–
Eggs	–	<0.01	–

4.1.3 Cloquintocet(-mexyl)

Table 4.1-16: Identity of the active substance

Structural formula	
Common Name	Cloquintocet-mexyl (CGA 185072)
CAS number	99607-70-2
Structural formula	
Common Name	Cloquintocet (CGA 153433)
CAS number	88349-88-6

4.1.3.1 Storage stability

A brief summary of the storage stability data on cloquintocet(-mexyl) is given in the following table. Cloquintocet-mexyl has been evaluated and approved under various national registrations but has not yet been reviewed at the EU level. A review program for safeners is scheduled under Reg (EC) 1107/2009.

Table 4.1-17: Stability of residues (Annex IIA, point 6.1)

Stability of cloquintocet-mexyl and cloquintocet	Cloquintocet-mexyl and cloquintocet are stable in spinach, tomatoes, soy beans, potatoes and wheat (grain, straw, forage) stored at -20 °C for at least nine months (RIP2006-1694).

4.1.3.2 Metabolism in plants and plant residue definition(s)

A brief summary of the metabolism of cloquintocet-mexyl in plants is given in the following table. Cloquintocet-mexyl has been evaluated and approved under various national registrations but has not yet been reviewed at the EU level. A review program for safeners is scheduled under Reg (EC) 1107/2009.

Table 4.1-18: Metabolism in plants (Annex IIA, point 6.2.1; 6.5.1, 6.5.2, 6.6.2 and 6.7.1)

Plant groups covered	Wheat (RIP2004-2111): spring wheat was treated at growth stage BBCH 22-30 with [quinoline-3-^{14}C]-cloquintocet-mexyl at rates of 17.5 and 175 g/ha, respectively. Forage samples were harvested 7 and 30 DAT, mature wheat at 61 DAT. Residues in the mature crop were < 0.01 mg/kg at the 1N rate (17.5 g/ha). Residues in forage decreased from 0.438 mg/kg 7 DAT to 0.019 mg/kg 30 DAT. Parent occurred at low levels only (7-day forage: 3.4% TRR, 0.015 mg/kg at the 1N rate). No parent was detected in the 30-day forage or any mature crop, even with the exaggerated rate (175 g/ha). Parent was hydrolyzed to CGA 153433 (free acid cloquintocet) and OH-CGA 153433. Further metabolism and conjugation with sugars to polar compounds was observed.
Rotational crops	Confined study (ASB2009-11484): ^{14}C-Cloquintocet-mexyl was applied to field plots of spring wheat or to bare soil at a rate of 50 g/ha. The formulation contained also the herbicide clodinafop-propargyl at twice the safener concentration. Rotational crops winter wheat, sugar beet, maize and lettuce were planted either after harvest of the treated crop or after soil treatment (PBI: lettuce - 85 days, winter wheat - 146 days, sugar beet - 321 days, maize - 351 days). Residues in all rotational crops were ≤ 0.001 mg/kg for all PBI.
Metabolism in rotational crops similar to metabolism in primary crops? (yes/no)	Not concluded, due to low residues no identification was possible
Distribution of the residue in peel/ pulp	Not applicable
Processed commodities (nature of residue)	No data available and none required due to the low residues.
Residue pattern in raw and processed commodities similar? (yes/no)	Not applicable
Plant residue definition for monitoring	Cloquintocet-mexyl according to national German legislation (RHmV) which is still applicable for this safener
Plant residue definition for risk assessment	Sum of cloquintocet-mexyl and cloquintocet (CGA 153433), expressed as cloquintocet-mexyl
Conversion factor(s) (monitoring to risk assessment)	None, no residues above LOQ expected

4.1.3.3 Metabolism in livestock and animal residue definition(s)

A brief summary of the metabolism of cloquintocet-mexyl in livestock is given in the following table. Cloquintocet-mexyl has been evaluated and approved under various national registrations but has not yet been reviewed at the EU level. A review program for safeners is scheduled under Reg (EC) 1107/2009.

Table 4.1-19: Metabolism in livestock (Annex IIA, point 6.2.2 to 6.2.5 and 6.7.1)

Animals covered	Lactating goat (RIP2004-2114): were dosed at 127 mg/kg feed for 4 consecutiv days, [quinoline-3-^{14}C]-cloquintocet-mexyl. Rapid excretion via urine/faeces was observed and no accumulation in edible animal tissues. Total residues in milk and edible tissues were very low. Parent was rapidly hydrolysed to the corresponding free acid (CGA 153433). The M-2 metabolite, resulting from hydrolysis of the ester followed by intramolecular cyclization, hydroxylation and reduction of the pyridine ring, is formed from CGA 153433 at a much slower rate. M-1 (glucuronic acid conjugate) is then formed from M-2. Only parent was present at significant levels.
Time needed to reach a plateau concentration in milk and eggs	Not concluded
Animal residue definition for monitoring	Not necessary, as no relevant residue levels are expected in food of animal origin.
Animal residue definition for risk assessment	Not necessary, as no relevant residue levels are expected in food of animal origin.
Conversion factor(s) (monitoring to risk assessment)	Not applicable
Metabolism in rat and ruminant similar (yes/no)	yes
Fat soluble residue: (yes/no)	yes (cloquintocet-mexyl: log Pow ca. 5 at 25°C)

4.1.3.4 Residues in rotational crops

No respective studies are available and none are required. This is briefly explained in the following table.

Table 4.1-20: Residues in rotational crops (Annex IIA, point 6.6.3)

Field studies	Substantiated by the low application rate at cGAP the fast degradation of parent and metabolite CGA 153433 in soil and the results of supervised residue trials as well as rotational crop metabolism studies, significant residues in rotational crops are not expected.

4.1.3.5 Residues in livestock

An actual calculation of the dietary burden (based on all relevant uses authorized in Germany) is provided in Table 4.1-21.

Table 4.1-21: Calculation of livestock dietary burden (based on all relevant uses authorized in Germany

Feedstuff	% DM	Percent of daily livestock diet (dry feed basis)				Residue (mg/kg)	Intake (mg/kg, dry feed basis)			
		Chicken	Dairy cattle	Beef cattle	Pig		Chicken	Dairy cattle	Beef cattle	Pig
		1.9 kg bw	550 kg bw	350 kg bw	75 kg bw					
		daily max. feed (DM) 120 g	daily max. feed (DM) 20 kg	daily max. feed (DM) 15 kg	daily max. feed (DM) 3 kg					
cereals (grain)	86	70	40	50	80	0.02 [a]	0.016	0.009	0.019	0.019
cereals (straw)	86	--	20	50	--	0.02 [b]	--	0.005	0.005	--
				Intake (mg/kg dry weight feed)			0.016	0.014	0.023	0.019
					Intake (mg/kg bw/d)		0.001	0.001	0.001	0.001
					Intake (mg/animal/d)		0.002	0.279	0.349	0.056

[a] STMR, based on the following cGAP: 1 x 15 g as/ha, F
[b] HR, based on the following cGAP: 1 x 15 g as/ha, F

Table 4.1-22: Conditions of requirement of livestock feeding studies on cloquintocet-mexyl

	Ruminant:	**Poultry:**	**Pig:**
Expected intakes by livestock ≥0.1 mg/kg diet (dry weight basis) (yes/no – If yes, specify the level)	No	No	No
Potential for accumulation (yes/no):	No	No	No
Metabolism studies indicate potential level of residues ≥0.01 mg/kg in edible tissues (yes/no)	No	No	No

No livestock feeding studies are currently available and none are required.

Table 4.1-23: Results of livestock feeding studies (Annex IIA, point 6.4)

	Ruminant:	**Poultry:**	**Pig:**
Feeding levels (mg/kg feed dry matter) in feeding studies	No study available and none required		
Relevant dosing levels in feeding study:			
	Expected residue levels in animal matrices (mg/kg):		
Muscle	<0.01	<0.01	<0.01
Liver	<0.01	<0.01	<0.01
Kidney	<0.01	<0.01	<0.01
Fat	<0.01	<0.01	<0.01
Milk	<0.01	–	–
Eggs	–	<0.01	–

4.2 Evaluation of the intended use

4.2.1 Selection of critical use and justification

The GAP reported for the central zone (including Germany) is presented in Table 4.2-1. It has been used for consumer intake and risk assessment.

Table 4.2-1: Critical Use (worst case) used for consumer intake and risk assessment

1	2	3	4	5	6	7	8	9	10	11	12	13
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)** **(a)**	**F G or I** **(b)**	**Pests or Group of pests controlled** **(additionally: developmental stages of the pest or pest group)** **(c)**	**Application**			**Application rate**			**PHI (days) (i)**	**Remarks:** **e.g. safener/synergist per ha** **e.g. recommended or mandatory tank mixtures** **(j)**
					Method / Kind **(d-f)**	**Timing / Growth stage of crop & season** **(g)**	**Max. number (min. interval between applications)** **a) per use** **b) per crop/ season** **(h)**	**L product / ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**g as/ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**Water L/ha** **min / max**		
1	DE, AT, BE, CZ, LU, NL, PL, SK	Winter rye (0500070) Winter soft wheat (0500090) Winter triticale (0500090)	F	Blackgrass (*Alopecurus myosuroides*), bromegrass (*Bromus species),* catchweed bedstraw *(Galium aparine)*	spraying	BBCH 10-32 Post-emergence, spring	a) 1 b) 1	a) 1.8 b) 1.8	a) pinoxaden: 60 pyroxsulam: 15 cloquintocet-mexyl (safener): 15	200-400	F	--
2	DE, AT, BE, CZ, LU, NL, PL, SK	Winter rye (0500070) Winter soft wheat (0500090) Winter triticale (0500090)	F	Windgrass *(Apera* spica-venti) ryegrass (*Lolium species),* annual dicotyledonous weeds	spraying	BBCH 10-32 Post-emergence, spring	c) 1 d) 1	c) 1.35 d) 1.35	b) pinoxaden: 45 pyroxsulam: 11.3 cloquintocet-mexyl (safener): 11.3	200-400	F	--

Remarks:
(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
(d) All abbreviations used must be explained
(e) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(f) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(g) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(h) The minimum and maximum number of application possible under practical conditions of use must be provided
(i) PHI - minimum pre-harvest interval
(j) Remarks may include: Extent of use/economic importance/restrictions

4.2.2 Winter rye, Winter wheat, winter triticale

4.2.2.1 Residues in primary crops

Preliminary remark:
According to the extrapolation guidance document SANCO 7525/VI/95 – rev. 10.1, due to the proposed early treatment (BBCH 10-32, consumable parts have not started to form), residue data on wheat may be extrapolated to rye and triticale.

Pinoxaden
The following table gives a brief overview of the supervised residue trials selected for the assessment of pinoxaden in winter rye, winter wheat and winter triticale. Data have been previously evaluated at the EU level and are described in detail in the DAR (UK, 2005 ASB2010-10613), Addenda to the DAR (ASB2012-3150, ASB2013-6761) and the conclusion on the peer review of the pesticide risk assessment of the active substance pinoxaden (EFSA 2013; ASB2013-10732).

Table 4.2-2: Overview of the selected supervised residue trials for pinoxaden

Commodity	Region [a]	Outdoor/ Indoor	Individual trial results (mg/kg)		STMR (mg/kg) [b]	HR (mg/kg) [c]	Existing MRL (mg/kg)	Median CF [d]
			Enforcement (sum of free and conjugated residues of M4 and M6, expressed as pinoxaden)	Risk assessment (sum of free and conjugated residues of M4 and M6, expressed as pinoxaden)				
Wheat ➔ Rye, Triticale	NEU	Outdoor	Grain: <0.02; 2 x 0.04; 0.05; 3 x 0.06; 0.08; 0.10 Straw: <0.05; 0.06; 0.08; 0.09; 2 x 0.11; 0.23; 0.27; 0.32	Grain: <0.02; 2 x 0.04; 0.05; 3 x 0.06; 0.08; 0.10 Straw: <0.05; 0.06; 0.08; 0.09; 2 x 0.11; 0.23; 0.27; 0.32	Grain: 0.06 Straw: 0.11	Grain: 0.10 Straw: 0.32	Grain: 1 Straw: -	1

(a): NEU, SEU, EU or Import (country code).
(b): Median value of the individual trial results according to the risk assessment residue definition.
(c): Highest value of the individual trial results according to the risk assessment residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial.

Pyroxsulam
The following table gives a brief overview of the supervised residue trials selected for the assessment of pyroxsulam in winter rye, winter wheat and winter triticale. Data has been previously evaluated at EU level and is described in detail in the DAR and its Addendum (UK, 2012 ASB2012-5575, ASB2012-15206) and in EFSA´s Conclusion on the peer review (EFSA Journal, 2013 ASB2013-5919).

Table 4.2-3: Overview of the selected supervised residue trials for pyroxsulam

Commodity	Region [a]	Outdoor/ Indoor	Individual trial results (mg/kg)		STMR (mg/kg) [b]	HR (mg/kg) [c]	Existing MRL (mg/kg)	Median CF [d]
			Enforcement (pyroxsulam)	Risk assessment (pyroxsulam)				
Wheat ➔ Rye, Triticale	NEU	Outdoor	Formulations without adjuvant Grain: 8 x <0.01 Straw: 8 x <0.01 Formulations with adjuvant (methylated rapeseed oil) Grain: 8 x <0.01 Straw: 8 x <0.01	Formulations without adjuvant Grain: 8 x <0.01 Straw: 8 x <0.01 Formulations with adjuvant (methylated rapeseed oil) Grain: 8 x <0.01 Straw: 8 x <0.01	Grain: 0.01 Straw: 0.01	Grain: 0.01 Straw: 0.01	Grain: 0.01* Straw: -	1

(a): NEU, SEU, EU or Import (country code).
(b): Median value of the individual trial results according to the risk assessment residue definition.
(c): Highest value of the individual trial results according to the risk assessment residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial.

Cloquintocet
The following table gives a brief overview of the supervised residue trials selected for the assessment of cloquintocet in winter rye, winter wheat and winter triticale. For the detailed evaluation of the residue trials, it is referred to Appendix 2.

Table 4.2-4: Overview of the selected supervised residue trials for cloquintocet

Commodity	Region [a]	Outdoor/ Indoor	Individual trial results (mg/kg)		STMR (mg/kg) [b]	HR (mg/kg) [c]	Existing MRL (mg/kg)*	Median CF [d]
			Enforcement (cloquintocet-mexyl)	Risk assessment (sum of cloquintocet-mexyl and cloquintocet)				
Wheat ➔ Rye, Triticale	NEU	Outdoor	Formulations without adjuvant Grain: 12 x <0.01 Straw: 12 x <0.01 Formulations with adjuvant (methylated rapeseed oil) Grain: 15 x <0.01 Straw: 12 x <0.01; 3 x <0.02	Formulations without adjuvant Grain: 12 x <0.02 Straw: 12 x <0.02 Formulations with adjuvant (methylated rapeseed oil) Grain: 12 x <0.02 Straw: 12 x <0.02	Grain: 0.02 Straw: 0.02	Grain: 0.02 Straw: 0.02	Grain: 0.05 Straw: -	1

(a): NEU, SEU, EU or Import (country code).
(b): Median value of the individual trial results according to the risk assessment residue definition.
(c): Highest value of the individual trial results according to the risk assessment residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial.
(*): according to German RHmV

4.2.2.2 Distribution of the residue in peel/pulp

Not relevant.

4.2.2.3 Residues in processed commodities

Pinoxaden
The following table gives a brief overview of the results of processing studies for pinoxaden in wheat, which have already been described in detail in the DAR (UK, 2005 ASB2010-10613), Addenda to the DAR (ASB2012-3150, ASB2013-6761) and the conclusion on the peer review of the pesticide risk assessment of the active substance pinoxaden (EFSA 2013; ASB2013-10732).

Table 4.2-5: Overview of the available processing studies for M4 and M6 in wheat

Processed commodity	Number of studies	Median PF [(a)]	Comments
Flour type 550 including low grade meal (toppings)/straight flour	4 (2 processes for each of 2 field trials)	M4: 0.2 M6: <1	-
Flour type 550 including low grade meal (toppings)/middlings	4 (2 processes for each of 2 field trials)	M4: 2.9 M6: 2.4	-
Flour type 550 including low grade meal (toppings)/coarse bran	4 (2 processes for each of 2 field trials)	M4: 4.2 M6: 3.5	-
Flour type 550 including low grade meal (toppings)/total bran	4 (2 processes for each of 2 field trials)	M4: 4.5 M6: 3.6	-
M4/Wheat/ processing to flour type 550 including low grade meal (toppings)/ low grade meal (toppings)	4 (2 processes for each of 2 field trials)	M4: 1.3 M6: 1.3	-
M4/Wheat/ processing to flour type 550 including low grade meal (toppings)/ flour (type 550) incl. toppings	4 (2 processes for each of 2 field trials)	M4: 0.2 M6: <1	-
M4/Wheat/ processing to wholemeal flour and wholemeal bread/ straight flour	4 (2 processes for each of 2 field trials)	M4: 0.2 M6: <1	-
M4/Wheat/ processing to wholemeal flour and wholemeal bread/ total bran	4 (2 processes for each of 2 field trials)	M4: 4.5 M6: 3.6	-
M4/Wheat/ processing to wholemeal flour and wholemeal bread/ wholemeal flour	4 (2 processes for each of 2 field trials)	M4: 1.1 M6: <1	-
M4/Wheat/ processing to wholemeal flour and wholemeal bread/ dough	4 (2 processes for each of 2 field trials)	M4: 0.7 M6: <1	-
M4/Wheat/ processing to wholemeal flour and wholemeal bread/ wholemeal bread	4 (2 processes for each of 2 field trials)	M4: 0.6 M6: <1	-
M4/Wheat/ processing to wheat germs/ wheat germ	4 (2 processes for each of 2 field trials)	M4: 0.4 M6: 2	-

(a): The median processing factor (PF) is obtained by calculating the median of the individual PFs of each processing study.
(b): The median conversion factor (CF) for enforcement to risk assessment is obtained by calculating the median of the individual CFs of each processing study.

Pyroxsulam and cloquintocet(-mexyl)
Due to the low residues at harvest (<0.01 mg/kg), processing studies are not required.

4.2.2.4 Proposed pre-harvest intervals, withholding periods

The pre-harvest interval (PHI) is covered by the time elapsing between application and commercial harvest. Setting of a specific PHI in days is not required.

4.3 Consumer intake and risk assessment

4.3.1 Pinoxaden

The key data for consumer intake assessment, which have been derived from residue studies for the intended uses, are summarized in Table 4.3-1.

Table 4.3-1: Key data for consumer intake assessment derived for the intended uses

Commodity	Long-term intake		Short-term intake	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Rye	0.06	STMR	0.06	STMR
Wheat (include. triticale)	0.06	STMR	0.06	STMR

The toxicological reference values and all input values used for consumer risk assessment are stated in Table 4.3-2. To illustrate the results of the chronic risk assessment, a screenshot of the TMDI results obtained with EFSA PRIMO is displayed in Appendix 4.

Table 4.3-2: Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

Chronic risk assessment	
ADI	0.1 mg/kg bw/d
TMDI (% ADI) according to EFSA PRIMo	10 % (based on DK children, mean body weight)
NTMDI (% ADI) according to German NVS II	6 % (based on DE children, individual consumption/body weight ratio)
IEDI (% ADI) according to EFSA PRIMo rev.2	not required
NEDI (% ADI) according to German NVS II	not required
Factors included in IEDI and NEDI	n/a
Acute risk assessment	
ARfD	0.1 mg/kg bw
IESTI (% ARfD) according to EFSA PRIMo rev.2	rye: <1 % (based on UK toddler) wheat (including triticale): 1 % (based on UK 4-6 years old children)
NESTI (% ARfD) according to German NVS II	rye: <1 % (based on DE children, individual consumption/body weight ratio) wheat (including triticale): 1 % (based on DE children, individual consumption/body weight ratio)
Factors included in IESTI and NESTI	n/a

4.3.2 Pyroxsulam

The key data for consumer intake assessment, which have been derived from residue studies for the intended uses, are summarized in Table 4.3.3.

Table 4.3-3: Key data for consumer intake assessment derived for the intended uses

Commodity	Long-term intake		Short-term intake	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Rye	0.01	STMR	Not conducted since no ARfD was allocated	
Wheat (include. triticale)	0.01	STMR		

The toxicological reference values and all input values used for consumer risk assessment are stated in Table 4.3-4. To illustrate the results of the chronic risk assessment, a screenshot of the TMDI results obtained with EFSA PRIMO is displayed in Appendix 4.

Table 4.3-4: Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

Chronic risk assessment	
ADI	0.9 mg/kg bw/d (EFSA; ASB2013-5919)
TMDI (% ADI) according to EFSA PRIMo	0.1 % (based on FR toddlers, mean body weight)
NTMDI (% ADI) according to German NVS II	0.1 % (based on DE children, individual consumption/body weight ratio)
IEDI (% ADI) according to EFSA PRIMo rev.2	not required
NEDI (% ADI) according to German NVS II	not required
Factors included in IEDI and NEDI	not applicable
Acute risk assessment	
ARfD	not allocated / not necessary (EFSA, ASB2013-5919)
IESTI (% ARfD) according to EFSA PRIMo rev.2	Not conducted
NESTI (% ARfD) according to German NVS II	Not conducted
Factors included in IESTI and NESTI	Not applicable

4.3.3 Cloquintocet(-mexyl)

The key data for consumer intake assessment, which have been derived from residue studies for the intended uses, are summarized in Table 4.3-5.

Table 4.3-5: Key data for consumer intake assessment derived for the intended uses

Commodity	**Long-term intake**		**Short-term intake**	
	Input value (mg/kg)	**Comment**	**Input value (mg/kg)**	**Comment**
Rye	0.02	STMR	0.02	STMR
Wheat (includ triticale)	0.02	STMR	0.02	STMR

The toxicological reference values and all input values used for consumer risk assessment are stated in Table 4.3-6. To illustrate the results of the chronic risk assessment, a screenshot of the TMDI results obtained with EFSA PRIMO is displayed in Appendix 4.

Table 4.3-6: Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

Chronic risk assessment	
ADI	0.04 mg/kg bw
TMDI (% ADI) according to EFSA PRIMo	5.4 % (based on UK toddlers, mean body weight)
NTMDI (% ADI) according to German NVS II	4.8 % (based on DE children, individual consumption/body weight ratio)
IEDI (% ADI) according to EFSA PRIMo rev.2	not required
NEDI (% ADI) according to German NVS II	not required

Factors included in IEDI and NEDI	not applicable
Acute risk assessment	
ARfD	1 mg/kg bw
IESTI (% ARfD) according to EFSA PRIMo rev.2	rye: <1 % (based on UK toddler) wheat (including triticale): <1 % (based on UK 4-6 years old children)
NESTI (% ARfD) according to German NVS II	Rye, wheat (including triticale): <1 % (based on DE children, individual consumption/body weight ratio)
Factors included in IESTI and NESTI	none

4.4 Combined exposure and risk assessment

The product is a mixture of two active substances and a safener, but for only for the active substance pinoxaden and the safener cloquintocet-mexyl an acute reference dose have been allocated.

The cumulative short-term intake of pinoxaden and cloquintocet-mexyl residues in grains of rye, wheat and triticale is unlikely to present a public health concern.

Concerning the cumulative risk arising from the acute exposure to animal commodities the contribution of pinoxaden and cloquintocet-mexyl residues is insignificant.

4.5 Proposed maximum residue levels (MRLs)

No new MRLs are required.

4.6 Conclusion

The available data are sufficient for dietary risk assessment.

An exceedance of the current MRLs of 1 mg/kg for pinoxaden and 0.01*mg/kg pyroxsulam in grains of rye, wheat and triticale as laid down in Reg. (EU) 396/2005 is not expected. Furthermore, an exceedance of the MRL of 0.05 mg/kg for the safener cloquintocet-mexyl in cereal grains as established in the national RHmV is not expected.

The long-term and the short-term intake of pinoxaden, pyroxsulam and cloquintocet residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, BfR/Germany agrees with the authorization of the intended use.

Appendix 1 List of data submitted in support of the evaluation

Table A 1: List of data submitted in support of the evaluation

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
	EFSA	2013	Conclusion on the peer review of the pesticide risk assessment of the active substance Pyroxsulam EFSA Journal 2013;11(4):3182 ! EFSA-Q-2009-00344 EFSA Journal 2013;11(4):3182 ASB2013-5919			
	EFSA	2013	Conclusion on the peer review of the pesticide risk assessment of the active substance Pinoxaden EFSA Journal 2013;11(8):3269 ! EFSA-Q-2009-00329 EFSA Journal 2013;11(8):3269 ASB2013-10732			
	United Kingdom	2005	Pinoxaden: (Draft Assessment Report) Vol. 1-4 GLP: Open Published: Yes ASB2010-10613			
	United Kingdom	2012	Pyroxsulam (Draft Assessment Report); Volume 1-3; Addendum B5-B9 ASB2012-15206			
	United Kingdom	2012	Pyroxsulam (Draft Assessment Report); Volume 1-3 ASB2012-5575			
	United Kingdom	2013	Pinoxaden (NOA 407855): Addendum 3 und 4 to Annex B (Volume 3) ASB2013-6761			
	United Kingdom;	2012	Pinoxaden: Draft Assessment Report, Addenda Volume 3 B.2, B.5, B.6, B.7, B.8, B.9, Appendix 1 ASB2012-3150			
KIIA 6.1	Kwiatkowski, A.	2003	Stability of residues of NOA 407854, SYN 505164, SYN 502836 and SYN 505887 in deep freeze stored analytical specimens of wheat (whole plant, straw, grains) NOA407854/0041 ! 02-S305/1 GLP: Open Published: Open BVL-1855044, RIP2004-1966	Yes	Syngenta Agro	Y
KIIA 6.1	Kwiatkowski, A.	2004	Pinoxaden (NOA407855): Stability of residues of NOA407854, SYN505164, SYN502836, and SYN505887 in deep freeze stored analytical specimens of wheat (whole plant, straw, grains) - final report 02-S305/3 ! NOA407855/0740 GLP: Open Published: Open BVL-2600473, ASB2014-5354	Yes	Syngenta Agro	Y
KIIA 6.1	Lin, K.	2003	Stability of SYN-505164 (M4) and SYN-502836 (M6), metabolites of NOA 407855 in animal tissues under freezer storage conditions NOA407855/0259 ! T001241-03 GLP: Open Published: Open BVL-1870532, RIP2004-1976	Yes	Syngenta Agro	Y
KIIA 6.1.1	Class, T.	2006	XDE-742: Freezer storage stability in plant materials (XDE-742) and in soil (XDE-742 and three of its metabolites) 050001 ! P 846 G ! B 846-1 G ! 10000233-5001-1 GLP: Open Published: Open BVL-1948839, RIP2006-1693	Yes	DOW	Y
KIIA 6.1.1	Class, T.	2006	Cloquintocet-mexyl and its acid metabolite: Freezer storage stability in plant materials and in soil 10000233-5001-2 ! 050002 ! P 847 G ! B 847-1 G ! P847-1 G GLP: Open Published: Open BVL-1948840, RIP2006-1694	Yes	DOW	Y
KIIA 6.2	Leuthold, U.; Dichtel, W.	2001	CGA 185072 Cloquintocet-mexyl - Residue definition CGA185072/0146 ! RT 6.31 UL/WD GLP: Open Published: Open BVL-1854816, MET2004-761	Yes	Syngenta Agro	N

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
KIIA 6.2.1	Leuthold, U.; Dichtl, W.	2001	CGA 185072 Cloquintocet-mexyl - Plant metabolism CGA185072/0059 ! RT 6.91 UL/WD GLP: Open Published: Open BVL-1854811, RIP2005-789	Yes	Syngenta Agro	N
KIIA 6.2	Muir, G. T.; Benner, J. P.; Kennedy, E.	2002	[Quinoline-3-14C]-CGA 185072 - Nature of the residue in spring wheat RJ3328B ! CGA185072/0199 GLP: Open Published: Open BVL-1854813, RIP2004-2111	Yes	Syngenta Agro	Y
KIIA 6.2.1	Chapleo, S.; Green, M. A.	2005	The metabolism of [14C]-XDE-742 in wheat 804764 GLP: Open Published: Open BVL-1948841, RIP2006-1695	Yes	DOW	Y
KIIA 6.2.1	Sandmeier, P.	2001	Metabolism of NOA 407855 in field grown winter wheat after fall application of [Pyrazol-3,5-14C] labelled material NOA407855/0035 ! 99PSA55 GLP: Open Published: Open BVL-1855045, RIP2004-1971	Yes	Syngenta Agro	Y
KIIA 6.2.1	Sandmeier, P.	2003	Metabolism of NOA 407855 in field grown winter wheat after spring application of [Phenyl-1-14C] labeled material (+ Amendment v. 08.12.2003) NOA407855/0088 ! 00PSA58 GLP: Open Published: Open BVL-1855046, RIP2004-1973	Yes	Syngenta Agro	Y
KIIA 6.2.1	Stingelin, J.	2002	Metabolism of [Phenyl-1-14C] and [Oxadiazepin-3,6-14C] NOA 407855 in field grown spring wheat (+ Addendum v. 27.06.2003) NOA407855/0071 ! 01MK16 GLP: Open Published: Open BVL-1855050, RIP2004-1982	Yes	Syngenta Agro	Y
KIIA 6.2.2	[redacted]	2005	Nature of the residue study in laying hens using 14C-XDE-742 206466 ! 040001 GLP: Open Published: Open BVL-1948842, RIP2006-1696	Yes	DOW	Y
KIIA 6.2.3	[redacted]	2003	[7-14C]-SYN-505164: Nature of the residue in lactating goat NOA407855/0165 ! 751-02 GLP: Open Published: Open BVL-1855052, RIP2004-1984	Yes	Syngenta Agro	Y
KIIA 6.2.3	[redacted]	2003	[Quinolinyl-3-14C] CGA-185072: Nature of the residue in lactating goats CGA185072/0202 ! 157-00 GLP: Open Published: Open BVL-1854821, RIP2004-2114	Yes	Syngenta Agro	Y
KIIA 6.2.3	[redacted]	2005	Investigation of the nature and identity of metabolites of [14C] XDE-742 in goat tissues 206430 GLP: Open Published: Open BVL-1948843, RIP2006-1697	Yes	DOW	Y
KIIA 6.2.3	[redacted]	1993	Residue situation of CGA 185072 (Cloquintocet-methyl) in farm animals CGA185072/0140 ! PP 2.56 UL/PE GLP: Open Published: Open BVL-1854814, RIP2005-791	Yes	Syngenta Agro	N
KIIA 6.3	Anderson, L.	2003	Residue study with Cloquintocet-Mexyl (CGA 185072) and NOA 407855 in or on spring barley in France (South) NOA407855/0156 ! 3030/01 GLP: Open Published: Open BVL-1855082, BVL-2211916, MET2004-745	Yes	Syngenta Agro	N
KIIA 6.3	Anderson, L.	2003	Residue study with Cloquintocet-Mexyl (CGA 185072) and NOA 407855 in or on winter barley in France (North) NOA407855/0217 ! 3085/1 GLP: Open Published: Open BVL-1855077, RIP2004-2009	Yes	Syngenta Agro	N

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
KIIA 6.3	Anderson, L.	2003	Residue study with Cloquintocet-mexyl (CGA 185072) and NOA 407855 in or on spring barley in France (North) NOA407855/0238 ! 3029/01 GLP: Open Published: Open BVL-1855071, c	Yes	Syngenta Agro	N
KIIA 6.3	Balluff, M.	2005	Residues of XDE-742 in winter wheat at interval or at harvest following a single spring application of GF-1742, Northern European Zone (Germany, France, UK) - 2004 GHE-P-11084 ! 20044010/E1-FPWW GLP: Open Published: Open BVL-1948844, RIP2006-1698	Yes	DOW	Y
KIIA 6.3	Balluff, M.	2005	Residues of XDE-742 in winter wheat at interval or at harvest following a single application of GF-1274, Southern European Zone (France, Italy, Spain) - 2004 GHE-P-11085 ! 20044010/E2-FPWW GLP: Open Published: Open BVL-1948845, RIP2006-1701	Yes	DOW	N
KIIA 6.3	Balluff, M.	2005	Residues of XDE-742 in winter wheat at harvest following a single autumn application of GF-1274, Northern European Zone (Germany, France, UK) - 2004 GHE-P-11257 ! 20044010/E3-FPWW GLP: Open Published: Open BVL-1948846, RIP2006-1708	Yes	DOW	Y
KIIA 6.3	Balluff, M.	2005	Residues of XDE-742 in winter wheat at harvest following a single autumn application of GF-1274, Southern European Zone (France, Italy, Spain) - 2004 GHE-P-11258 ! 20044010/E4-FPWW GLP: Open Published: Open BVL-1948847, RIP2006-1711	Yes	DOW	N
KIIA 6.3	Balluff, M.	2005	Residues of XDE-742 in winter wheat at interval or at harvest following a single spring application of GF-1361, Northern European Zone (Germany, France, UK) - 2005 GHE-P-11259 ! 20054022/E1-FPWW 1 GF-1361 GLP: Open Published: Open BVL-1948850, RIP2006-1699	Yes	DOW	Y
KIIA 6.3	Balluff, M.	2005	Residues of XDE-742 in winter wheat at interval or at harvest following a single spring application of GF-1361, Southern European Zone (France, Italy, Spain) - 2005 GHE-P-11260 ! 20054022/E2-FPWW ! GF-1361 GLP: Open Published: Open BVL-1948851, RIP2006-1717	Yes	DOW	N
KIIA 6.3	Balluff, M.	2005	Residues of XDE-742, Cloquintocet-Mexyl and Cloquintocet-Acid in winter wheat at interval or at harvest following a single spring application of GF-1274, Northern European Zone (Germany, France, UK) - 2005 GHE-P-11261 ! 20054023/E1-FPWW GLP: Open Published: Open BVL-1948848, RIP2006-1713	Yes	DOW	Y
KIIA 6.3	Balluff, M.	2005	Residues of XDE-742, Cloquintocet-Mexyl and Cloquintocet acid in winter wheat at interval or at harvest follwing a single spring application of GF-1274, Southern European Zone (France, Italy, Spain) - 2005 GHE-P-11262 ! 20054023/E2-FPWW GLP: Open Published: Open BVL-1948849, RIP2006-1715	Yes	DOW	N
KIIA 6.3	Clarke, D.	2003	Residue study with Cloquintocet-Mexyl (CGA 185072) and NOA 407855 in or on winter wheat in France (North) NOA407855/0246 ! 3089/01 Syngenta Crop Protection AG, Basel, Switzerland GLP: Yes Published: No BVL-2603159, RIP2004-1992	Yes	Syngenta Agro	Y
KIIA 6.3	Gasser, A.	2003	Residue study with Cloquintocet-Mexyl (CGA 185072) and NOA 407855 in or on winter barley in France (North) NOA407855/0092 ! 3000/01 GLP: Open Published: Open BVL-1855073, RIP2004-2005	Yes	Syngenta Agro	N

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
KIIA 6.3	Gasser, A.	2003	Residue study with Cloquintocet-Mexyl (CGA 185072) and NOA 407855 in or on winter barley in France (North) NOA407855/0102 ! 3001/01 GLP: Open Published: Open BVL-1855074, RIP2004-2006	Yes	Syngenta Agro	N
KIIA 6.3	Gasser, A.	2003	Residue study with Cloquintocet-Mexyl (CGA 185072) and NOA 407855 in or on durum wheat in Italy NOA407855/0126 ! 3014/01 Syngenta Crop Protection AG, Basel, Switzerland GLP: Yes Published: No BVL-2603162, RIP2004-1995	Yes	Syngenta Agro	N
KIIA 6.3	Gasser, A.	2003	Residue study with Cloquintocet-Mexyl (CGA 185072) and NOA 407855 in or on durum wheat in Italy NOA407855/0127 ! 3015/01 Syngenta Crop Protection AG, Basel, Switzerland GLP: Yes Published: No BVL-2603163, RIP2004-1996	Yes	Syngenta Agro	N
KIIA 6.3	Gasser, A.	2003	Residue study with Cloquintocet-Mexyl (CGA 185072) and NOA 407855 in or on winter barley in Italy NOA407855/0128 ! 3012/01 GLP: Open Published: Open BVL-1855085, RIP2004-2018	Yes	Syngenta Agro	N
KIIA 6.3	Gasser, A.	2003	Residue study with Cloquintocet-Mexyl (CGA 185072) and NOA 407855 in or on winter wheat in France (South) NOA407855/0170 ! 3023/01 Syngenta Crop Protection AG, Basel, Switzerland GLP: Yes Published: No BVL-2603167, RIP2004-2000	Yes	Syngenta Agro	N
KIIA 6.3	Gasser, A.	2003	Residue study with Cloquintocet-Mexyl (CGA 185072) and NOA 407855 in or on spring barley in France (South) NOA407855/0174 ! 3031/01 GLP: Open Published: Open BVL-1855083, RIP2004-2015	Yes	Syngenta Agro	N
KIIA 6.3	Gasser, A.	2003	Residue study with Cloquintocet-Mexyl (CGA 185072) and NOA 407855 in or on winter wheat in France (North) NOA407855/0179 ! 3004/01 Syngenta Crop Protection AG, Basel, Switzerland GLP: Yes Published: No BVL-2603153, RIP2004-1986	Yes	Syngenta Agro	Y
KIIA 6.3	Gasser, A.	2003	Residue study with Cloquintocet-Mexyl (CGA 185072) and NOA 407855 in or on winter barley in Italy NOA407855/0180 ! 3013/01 GLP: Open Published: Open BVL-1855086, RIP2004-2019	Yes	Syngenta Agro	N
KIIA 6.3	Gill, J. P.	2003	Residue study with Cloquintocet-Mexyl (CGA 185072) and NOA 407855 in or on winter wheat in France (North) NOA407855/0223 ! 3021/01 Syngenta Crop Protection AG, Basel, Switzerland GLP: Yes Published: No BVL-2603156, RIP2004-1989	Yes	Syngenta Agro	Y
KIIA 6.3	Gill, J. P.	2003	Residue study with Cloquintocet-Mexyl (CGA 185072) and NOA 407855 in or on winter barley in France (South) NOA407855/0234 ! 3026/01 GLP: Open Published: Open BVL-1855087, RIP2004-2020	Yes	Syngenta Agro	N
KIIA 6.3	Gill, J. P.	2003	Residue study with Cloquintocet-Mexyl (CGA 185072) and NOA 407855 in or on winter barley in France (North) NOA407855/0235 ! 3025/01 GLP: Open Published: Open BVL-1855076, RIP2004-2008	Yes	Syngenta Agro	N
KIIA 6.3	Gill, J. P.	2003	Residue study with Cloquintocet-Mexyl (CGA 185072) and NOA 407855 in or on winter barley in France (North) (+ Amendment v. 01.09.2003) NOA407855/0237 ! 3024/01 GLP: Open Published: Open BVL-1855075, RIP2004-2007	Yes	Syngenta Agro	N

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
KIIA 6.3	Gill, J. P.	2003	Residue study with Cloquintocet-Mexyl (CGA 185072) and NOA 407855 in or on winter wheat in France (South) NOA407855/0240 ! 3022/01 Syngenta Crop Protection AG, Basel, Switzerland GLP: Yes Published: No BVL-2603166, RIP2004-1999	Yes	Syngenta Agro	N
KIIA 6.3	Kwiatkowski, A.	2003	Residue study with Cloquintocet-Mexyl (CGA 185072) and NOA 407855 in or on spring barley in Spain NOA407855/0182 ! 3044/01 GLP: Open Published: Open BVL-1855084, RIP2004-2016	Yes	Syngenta Agro	N
KIIA 6.3	Kwiatkowski, A.	2003	Residue study with Cloquintocet-Mexyl (CGA 185072) and NOA 407855 in or on winter wheat in Spain NOA407855/0245 ! 02-3002 Syngenta Crop Protection AG, Basel, Switzerland GLP: Yes Published: No BVL-2603168, RIP2004-2001	Yes	Syngenta Agro	N
KIIA 6.3	Richards S.	2003	Residue study with Cloquintocet-Mexyl (CGA 185072) and NOA 407855 in or on winter barley in Italy (+ Amendment v. 18.07.2003) NOA407855/0254 ! 02-3004 GLP: Open Published: Open BVL-1855088, RIP2004-2022	Yes	Syngenta Agro	N
KIIA 6.3	Richards, S.	2003	Residue study with Cloquintocet-Mexyl (CGA 185072) and NOA 407855 in or on durum wheat in Italy NOA407855/0181 ! 02-3007 Syngenta Crop Protection AG, Basel, Switzerland GLP: Yes Published: No BVL-2603164, RIP2004-1997	Yes	Syngenta Agro	N
KIIA 6.3	Richards, S.	2003	Residue study with Cloquintocet-Mexyl (CGA 185072) and NOA 407855 in or on winter barley in Italy NOA407855/0232 ! 02-3005 GLP: Open Published: Open BVL-1855089, RIP2004-2023	Yes	Syngenta Agro	N
KIIA 6.3	Richards, S.	2003	Residue study with Cloquintocet-Mexyl (CGA 185072) and NOA 407855 in or on durum wheat in Italy (+ Amendment v. 18.07.2003) NOA407855/0255 ! 02-3006 Syngenta - Jealott's Hill International, Bracknell, Berkshire, United Kingdom GLP: Yes Published: No BVL-2603165, RIP2004-1998	Yes	Syngenta Agro	N
KIIA 6.3	Stolze, K.	2003	Determination of residues of NOA 407855 and CGA 185072 in winter barley after application of A 12303 C in Germany, 2001 NOA407855/0118 ! gba10501 GLP: Open Published: Open BVL-1855081, RIP2004-2013	Yes	Syngenta Agro	N
KIIA 6.3	Stolze, K.	2003	Determination of a decline curve for residues of NOA 407855 and CGA 185072 in spring barley after application of A 12303 C in Germany, 2001 NOA407855/0119 ! gba10401 GLP: Open Published: Open BVL-1855072, RIP2004-2004	Yes	Syngenta Agro	N
KIIA 6.3	Stolze, K.	2003	Determination of residues of NOA 407855 and CGA 185072 in winter wheat after application of A 12303 C in Germany, 2001 NOA407855/0120 ! gr 03201 Syngenta Crop Protection AG, Basel, Switzerland GLP: Yes Published: No BVL-2603155, RIP2004-1988	Yes	Syngenta Agro	Y
KIIA 6.3	Stolze, K.	2003	Determination of residues of NOA 407855 and CGA 185072 in winter wheat after application of A 12303 C in Germany, 2001 NOA407855/0121 ! gwh10601 Syngenta Crop Protection AG, Basel, Switzerland GLP: Yes Published: No BVL-2603157, RIP2004-1990	Yes	Syngenta Agro	Y

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
KIIA 6.3	Stolze, K.	2003	Determination of residues of NOA 407855 and CGA 185072 in winter wheat after application of A 12303 C in Germany, 2001 NOA407855/0122 ! gwh40601 Syngenta Crop Protection AG, Basel, Switzerland GLP: Yes Published: No BVL-2603158, RIP2004-1991	Yes	Syngenta Agro	Y
KIIA 6.3	Stolze, K.	2003	Determination of residues of NOA 407855 and CGA 185072 in winter wheat after application of A 12303 C in Germany, 2001 NOA407855/0123 ! gr 03101 Syngenta Crop Protection AG, Basel, Switzerland GLP: Yes Published: No BVL-2603154, RIP2004-1987	No	Syngenta Agro	Y
KIIA 6.3	Stolze, K.	2003	Determination of a decline curve for residues of NOA 407855 and CGA 185072 in winter wheat after application of A 12303 C in Germany, 2002 NOA407855/0133 ! gwh029002 Syngenta Crop Protection AG, Basel, Switzerland GLP: Yes Published: No BVL-2603161, RIP2004-1994	Yes	Syngenta Agro	Y
KIIA 6.3	Stolze, K.	2003	Determination of a decline curve for residues of NOA 407855 and CGA 185072 in winter barley after application of A 12303 C in Germany, 2002 NOA407855/0166 ! gba013102 GLP: Open Published: Open BVL-1855079, RIP2004-2011	Yes	Syngenta Agro	N
KIIA 6.3	Stolze, K.	2003	Determination of a decline curve for residues of NOA 407855 and CGA 185072 in winter barley after application of A 12303 C in Germany, 2001 NOA407855/0167 ! gba40501 GLP: Open Published: Open BVL-1855080, RIP2004-2012	Yes	Syngenta Agro	N
KIIA 6.3	Stolze, K.	2003	Determination of residues of NOA 407855 and CGA 185072 in spring barley after application of A12303C in Germany, 2002 NOA407855/0168 ! gba30401 GLP: Open Published: Open BVL-1855070, RIP2004-2002	Yes	Syngenta Agro	N
KIIA 6.3	Stolze, K.	2003	Determination of residues of NOA 407855 and CGA 185072 in winter barley after application of A 12303 C in Germany, 2002 NOA407855/0247 ! gba014002 GLP: Open Published: Open BVL-1855078, RIP2004-2010	Yes	Syngenta Agro	N
KIIA 6.3	Stolze, K.	2003	Determination of residues of NOA 407855 and CGA 185072 in winter wheat after application of A 12303 C in Germany, 2002 NOA407855/0248 ! gwh021002 Syngenta Crop Protection AG, Basel, Switzerland GLP: Yes Published: No BVL-2603160, RIP2004-1993	Yes	Syngenta Agro	Y
KIIA 6.4.1	[redacted]	2003	SYN-505164 (M4) and SYN-502836 (M6), metabolites of NOA-407855 - Magnitude of the residues in meat and eggs resulting from the feeding of three-levels of SYN 505164 to laying hens NOA407855/0263 ! 747-02 GLP: Open Published: Open BVL-1855091, RIP2004-2027	Yes	Syngenta Agro	Y
KIIA 6.4.1	[redacted]	2002	The metabolism of [Phenyl-1-14C] NOA 407855 after multiple oral administration to laying hens NOA407855/0075 ! 046AM06 GLP: Open Published: Open BVL-1855053, RIP2004-1985	Yes	Syngenta Agro	Y

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
KIIA 6.4.2	[redacted]	2003	SYN-505164 (M4) and SYN-502836 (M6), metabolites of NOA-407855 - Magnitude of the residues in meat and milk resulting from the feeding of three-levels of SYN 505164 to dairy cattle NOA407855/0262 ! 746-02 GLP: Open Published: Open BVL-1855090, RIP2004-2025	Yes	Syngenta Agro	Y
KIIA 6.4.2	[redacted]	2002	The metabolism of [Phenyl-1-14C] NOA 407855 after multiple oral administration to lactating goats NOA407855/0054 ! 046AM04 GLP: Open Published: Open BVL-1855051, RIP2004-1983	Yes	Syngenta Agro	Y
KIIA 6.5	Stingelin, J.	2002	Hydrolysis of [Phenyl-1- 14C] labelled NOA407855 under processing conditions NOA407855/0064 ! 02JS34 GLP: Open Published: Open BVL-1855092, RIP2004-2029	Yes	Syngenta Agro	Y
KIIA 6.5	Stolze, K.	2003	Determination of residues of NOA 407855 and CGA 185072 in spring barley and processing products after application of A 12303 C in Germany, 2002 NOA407855/0287 ! gba033102 GLP: Open Published: Open BVL-1855095, RIP2004-2034	Yes	Syngenta Agro	Y
KIIA 6.5	Stolze, K.	2003	Determination of residues of NOA 407855 and CGA 185072 in winter wheat and processing products after application of A 12303 C in Germany, 2002 NOA407855/0309 ! gwh049002 GLP: Open Published: Open BVL-1855094, RIP2004-2033	Yes	Syngenta Agro	Y
KIIA 6.5	Stolze, K.	2004	Amended: Determination of residues of NOA 407855 and CGA 185072 in spring barley and processing products after application of A 12303 C in Germany, 2002 NOA407855/0465 ! gba039002 GLP: Open Published: Open BVL-1855096, RIP2004-2036	Yes	Syngenta Agro	Y
KIIA 6.5	Stolze, K.	2004	Amended: Determination of residues of NOA 407855 and CGA 185072 in winter wheat and processing products after application of A 12303 C in Germany, 2002 NOA407855/0466 ! gwh043102 GLP: Open Published: Open BVL-1855093, RIP2004-2030	Yes	Syngenta Agro	Y
KIIA 6.6	Donzel, B.	1993	Outdoor confined accumulation study on rotational crops after application of [3-14C]quinoline CGA 185072 PP 2.52 ! 88BD16PR1 ! CGA185072/0127 GLP: Open Published: Open BVL-1854822, ASB2009-11484	Yes	SYD	Y
KIIA 6.6.2	Graper, L. K.; Smith, K. P.	2006	A confined rotational crop study with 14C-XDE-742 040003 ! R050401 GLP: Open Published: Open BVL-1948852, RIP2006-1719	Yes	DOW	Y
KIIA 6.6.3	Sandmeier P.	2003	Outdoor confined accumulation study on rotational crops after bareground application of [Oxadiazepin-3,6-14C1] NOA 407855 (+ Amendment v. 14.8.03) NOA407855/0146 ! 01PSA59 GLP: Open Published: Open BVL-2121399, RIP2004-2039	Yes	Syngenta Agro	Y
KIIA 6.6.3	Sandmeier, P.	2002	Outdoor confined accumulation study on rotational crops after bareground application of [Phenyl-1-14C] NOA 407855 NOA407855/0056 ! 00PSA57 GLP: Open Published: Open BVL-1855098, RIP2004-2037	Yes	Syngenta Agro	Y

Y: Yes, relied on
N: No, not relied on
Add: Relied on, study not submitted by applicant but necessary for evaluation

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Storage stability

No further study on storage stability submitted/needed.

A 2.2 Residues in primary crops

A 2.2.1 Magnitude of residues of cloquintocet mexyl in wheat

Reference:	OECD KIIA 6.3
Report	see authority registration numbers cited in the remarks columns of the tables below (and study identification as laid down in the reference list)
Guideline(s):	in accordance with agreed guidance unless stated otherwise in the commenting box
Deviations:	no relevant deviations unless stated otherwise in the commenting box
GLP:	see reference list
Acceptability:	acceptable unless stated otherwise in the commenting box

A 2.2.2 Magnitude of residues of cloquintocet(-mexyl) in winter wheat

Appendix 3 RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Content of a.i. (g/kg or g/l) : 26 g/L
Formulation (e.g. WP) : EC (emulsifiable concentrate)
Commercial product (name) : AXIAL
Applicant : Syngenta Agro GmbH

Active ingredient : Cloquintocet-mexyl
Crop / crop group : Winter soft wheat
Submission date : 2004-09-13
Indoors / Outdoors : Outdoors (European North)
Other a.i. in formulation (content and common name) : 100 g/L Pinoxaden
Residues calculated as : Cloquintocet-mexyl CGA 153433

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
gwh 10601 (plot 2) Germany (DE) 23821 Rohlstorf 2003-05-15	Ritmo	1) 2000-09-11 (sowing) 2) 2001-06-12 - 2001-06-27 3) 2001-08-14	0.016	300	0.0052	2001-05-02[4)]	BBCH 31-32	plant grain straw	0.36 0.020 <0.020 <0.020 <0.020 <u>≤0.010</u> <u>≤0.020</u>	0 7 14 28 35 104 104	4) spraying LOQ(s): 0.01 mg/kg (grain), 0.02 mg/kg (plant, straw), max. sample storage time in month(s): 15, formulation with adjuvant RIP2004-1990

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment kg a.i./ha	Water l/ha	kg a.i./hl	Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
	(a)	(b)				(c)		(a)		(d)	(e)
gwh 10601 (plot 3) Germany (DE) 23821 Rohlstorf 2003-05-15	Ritmo	1) 2000-09-11 (sowing) 2) 2001-06-12 - 2001-06-27 3) 2001-08-14	0.016	300	0.0052	2001-05-21[4)]	BBCH 37-39	plant ears of grain rest of plant grain straw	0.37 0.020 0.020 <0.020 <0.020 <0.020 <0.020 <0.010 <0.020	0 7 14 28 35 28 35 85 85	4) spraying LOQ(s): 0.01 mg/kg (grain), 0.02 mg/kg (plant, straw), max. sample storage time in month(s): 15, formulation with adjuvant RIP2004-1990
gwh 40601 (plot 2) Germany (DE) 94522 See 2003-05-15	Flair	1) 2000-09-29 (sowing) 2) 2001-06-01 - 2001-06-13 3) 2001-07-26	0.016	300	0.0052	2001-04-19[4)]	BBCH 31	plant grain straw	0.55 <0.010 <0.020	0 98 98	4) spraying LOQ(s): 0.01 mg/kg (grain), 0.02 mg/kg (plant, straw), max. sample storage time in month(s): 15, formulation with adjuvant RIP2004-1991
gwh 40601 (plot 3) Germany (DE) 94522 See 2003-05-15	Flair	1) 2000-09-29 (sowing) 2) 2001-06-01 - 2001-06-13 3) 2001-07-26	0.016	300	0.0052	2001-05-21[4)]	BBCH 39	plant grain straw	0.14 <0.010 0.020	0 66 66	4) spraying LOQ(s): 0.01 mg/kg (grain), 0.02 mg/kg (plant, straw), max. sample storage time in month(s): 15, formulation with adjuvant RIP2004-1991
SAM No. 0223, 3021/01 (A) France (FR) 45480 Izy 2003-07-25	Cezanne	1) 2000-11-05 (sowing) 2) 3) 2001-07	0.016	400	0.0039	2001-04-12[4)]	BBCH 31-32	grain straw	<0.010 <0.020	103 103	4) spraying LOQ(s): 0.01 mg/kg (grain), 0.02 mg/kg (plant, straw), max. sample storage time in month(s): 15, formulation with adjuvant RIP2004-1989
SAM No. 0223,	Cezanne	1) 2000-11-05	0.016	400	0.0039	2001-05-11[4)]	BBCH 39	grain	<0.010	74	4) spraying

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
								straw	<0.020	74	

Remarks: (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Note: All entries to be filled in as appropriate

Comments of zRMS:	Trials with BBCH 31-32 (GAP compliant) were selected for the assessment.

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Content of a.i. (g/kg or g/l) : 75 g/kg
Formulation (e.g. WP) : WG (water dispersible granule)
Commercial product (name) : BROADWAY
Applicant : Dow AgroSciences GmbH

Active ingredient : Cloquintocet
Crop / crop group : Winter soft wheat

Submission date : 2006-07-13

Indoors / Outdoors : Outdoors (European North)
Other a.i. in formulation
(content and common name) : 75 g/kg Pyroxsulam
Residues calculated as : 8.1 Cloquintocet-acid (CGA 153 433)
8.2 Cloquintocet-mexyl (CGA 185072)

1	2	3	4			5	6	7	8.1	8.2	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl							
	(a)	(b)				(c)		(a)			(d)	(e)
GHE-P-11084, 20044010/E1-FPWW, G04W021R (A) Germany (DE) 21739 Dollern (Lower Saxony) 2005-06-21	Drifter	1) 2003-10-03 (sowing) 2) 2004-06-15 3) 2004-08-10	0.019	310	0.0062	2004-05-21[4)]	BBCH 39	grain straw	<0.010 <0.010	<0.010 <0.010	81 81	4) spraying analytical method: GRM 04.17 (HPLC/MS/MS), LOQ(s): 8.1/8.2: 0.01 mg/kg, max. sample storage time in month(s):2 treated with formulation GF-1274, WG, with adjuvant (methylated rapeseed oil) RIP2006-1698
GHE-P-11084,	Solstice	1) 2003-10-16	0.019	250	0.0075	2004-05-10[4)]	BBCH 39	grain	<0.010	<0.010	94	4) spraying

1	2	3	4			5	6	7	8.1	8.2	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment kg a.i./ha	Water l/ha	kg a.i./hl	Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
	(a)	(b)				(c)		(a)			(d)	(e)
								straw	<0.010	<0.010	94	
GHE-P-11084, 20044010/E1-FPWW, G04W021R (B) Germany (DE) 21739 Dollern (Lower Saxony) 2005-06-21	Drifter	1) 2003-10-03 (sowing) 2) 2004-06-15 3) 2004-08-10	0.020	330	0.0062	2004-05-21[4)]	BBCH 39	grain straw	<0.010 <0.010	<0.010 <0.010	81 81	4) spraying analytical method: GRM 04.17 (HPLC/MS/MS), LOQ(s): 8.1/8.2: 0.01 mg/kg, max. sample storage time in month(s):2 treated with formulation GF-1274, WG, without adjuvant (methylated rapeseed oil) RIP2006-1698
GHE-P-11084, 20044010/E1-FPWW, GB04W001R (B) United Kingdom OX27 9AS Stratton Audley (Oxfordshire) 2005-06-21	Solstice	1) 2003-10-16 (sowing) 2) 2004-06-01 - 2004-06-14 3) 2004	0.019	250	0.0075	2004-05-10[4)]	BBCH 39	grain straw	<0.010 <0.010	<0.010 <0.010	94 94	4) spraying analytical method: GRM 04.17 (HPLC/MS/MS), LOQ(s): 8.1/8.2: 0.01 mg/kg, max. sample storage time in month(s):2 treated with formulation GF-1274, WG, without adjuvant (methylated rapeseed oil) RIP2006-1698
GHE-P-11084,	Criterium	1) 2003-10-16	0.022	290	0.0075	2004-05-03[4)]	BBCH 39	grain	<0.010	<0.010	79	4) spraying

1	2	3	4			5	6	7	8.1	8.2	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment kg a.i./ha	Water l/ha	kg a.i./hl	Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
	(a)	(b)				(c)		(a)			(d)	(e)
								straw	<0.010	<0.010	79	
GHE-P-11084, 20044010/E1-FPWW, F04W044R (B) France (FR) 67410 Drusenheim (Alsace) 2005-06-21	Criterium	1) 2003-10-16 (sowing) 2) 2004-06-01 3) 2004-07-21	0.020	270	0.0075	2004-05-03[4)]	BBCH 39	grain straw	<0.010 <0.010	<0.010 <0.010	79 79	4) spraying analytical method: GRM 04.17 (HPLC/MS/MS), LOQ(s): 8.1/8.2: 0.01 mg/kg, max. sample storage time in month(s):2 treated with formulation GF-1274, WG, without adjuvant (methylated rapeseed oil) RIP2006-1698
GHE-P-11084, 20044010/E1-FPWW, F04W045R (A) France (FR) 67140 Gertwiller (Alsace) 2005-06-21	Nirvana, Frelon	1) 2003-10-15 (sowing) 2) 3) 2004-07-21	0.020	270	0.0075	2004-04-30[4)]	BBCH 39	plant grain straw	0.12 <0.010 <0.010 <0.010 <0.010 <0.010	0.32 <0.010 <0.010 <0.010 <0.010 <0.010	0 7 28 59 82 82	4) spraying analytical method: GRM 04.17 (HPLC/MS/MS), LOQ(s): 8.1/8.2: 0.01 mg/kg, max. sample storage time in month(s):2 treated with formulation GF-1274, WG, with adjuvant (methylated rapeseed oil) RIP2006-1698
GHE-P-11084, 20044010/E1-FPWW, F04W045R (B)	Nirvana, Frelon	1) 2003-10-15 (sowing) 2) 3) 2004-07-21	0.020	260	0.0075	2004-04-30[4)]	BBCH 39	plant	0.020 <0.010 <0.010 <0.010	0.38 0.070 <0.010 <0.010	0 7 28 59	4) spraying analytical method: GRM 04.17 (HPLC/MS/MS), LOQ(s): 8.1/8.2: 0.01

1	2	3	4			5	6	7	8.1	8.2	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment kg a.i./ha	Water l/ha	kg a.i./hl	Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
	(a)	(b)				(c)		(a)			(d)	(e)
								grain straw	<0.010 <0.010	<0.010 <0.010	82 82	
GHE-P-11257, 20044010/E3-FPWW, G04W095R (A) Germany (DE) 21729 Freiburg (Lower Saxony) 2005-12-15	Magnus	1) 2004-09-18 (sowing) 2) 2005-06-14 - 2005-06-21 3) 2005-08-12	0.020	320	0.0062	2004-10-26[4)]	BBCH 13	grain straw	<0.010 <0.010	<0.010 <0.010	290 290	4) spraying analytical method: GRM 04.17 (HPLC/MS/MS), LOQ(s): 8.1/8.2: 0.01 mg/kg, max. sample storage time in month(s):2 treated with formulation GF-1274, WG, with adjuvant (methylated rapeseed oil) RIP2006-1708
GHE-P-11257, 20044010/E3-FPWW, G04W095R (B) Germany (DE) 21729 Freiburg (Lower Saxony) 2005-12-15	Magnus	1) 2004-09-18 (sowing) 2) 2005-06-14 - 2005-06-21 3) 2005-08-12	0.020	320	0.0062	2004-10-26[4)]	BBCH 13	grain straw	<0.010 <0.010	<0.010 <0.010	290 290	4) spraying analytical method: GRM 04.17 (HPLC/MS/MS), LOQ(s): 8.1/8.2: 0.01 mg/kg, max. sample storage time in month(s):2 treated with formulation GF-1274, WG, without adjuvant (methylated rapeseed oil) RIP2006-1708
GHE-P-11257,	Solstice	1) 2004-09-29	0.018	240	0.0075	2004-11-17[4)]	BBCH 14	grain	<0.010	<0.010	258	4) spraying

1	2	3	4			5	6	7	8.1	8.2	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment kg a.i./ha	Water l/ha	kg a.i./hl	Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
	(a)	(b)				(c)		(a)			(d)	(e)
								straw	<0.010	<0.010	258	
GHE-P-11257, 20044010/E3-FPWW, GB04W004R (B) United Kingdom (GB) OX6 9NB Bucknell (Oxfordshire) 2005-12-15	Solstice	1) 2004-09-29 (sowing) 2) 2005-06-13 - 2005-06-24 3) 2005-08-02	0.019	250	0.0075	2004-11-17[4)]	BBCH 14	grain straw	<0.010 <0.010	<0.010 <0.010	258 258	4) spraying analytical method: GRM 04.17 (HPLC/MS/MS), LOQ(s): 8.1/8.2: 0.01 mg/kg, max. sample storage time in month(s):1 treated with formulation GF-1274, WG, without adjuvant (methylated rapeseed oil) RIP2006-1708
GHE-P-11257, 20044010/E3-FPWW, F04W074R (A) France (FR) 67310 Cosswiller (Alsace) 2005-12-15	Soisson	1) 2004-10-21 (sowing) 2) 3) 2005-07-22	0.020	270	0.0075	2004-11-26[4)]	BBCH 12	grain straw	<0.010 <0.010	<0.010 <0.010	238 238	4) spraying analytical method: GRM 04.17 (HPLC/MS/MS), LOQ(s): 8.1/8.2: 0.01 mg/kg, max. sample storage time in month(s):2 treated with formulation GF-1274, WG, with adjuvant (methylated rapeseed oil) RIP2006-1708
GHE-P-11257,	Soisson	1) 2004-10-21	0.020	260	0.0075	2004-11-26[4)]	BBCH 12	grain	<0.010	<0.010	238	4) spraying

1	2	3	4			5	6	7	8.1	8.2	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment kg a.i./ha	Water l/ha	kg a.i./hl	Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
	(a)	(b)				(c)		(a)			(d)	(e)
								straw	<0.010	<0.010	238	
GHE-P-11257, 20044010/E3-FPWW, F04W075R (A) France (FR) 67750 Scherwiller (Alsace) 2005-12-15	Apache	1) 2004-10-14 (sowing) 2) 3) 2005-07-12	0.020	260	0.0075	2004-12-07[4)]	BBCH 13	grain straw	<0.010 <0.010	<0.010 <0.010	217 217	4) spraying analytical method: GRM 04.17 (HPLC/MS/MS), LOQ(s): 8.1/8.2: 0.01 mg/kg, max. sample storage time in month(s):2 treated with formulation GF-1274, WG, with adjuvant (methylated rapeseed oil) RIP2006-1708
GHE-P-11257, 20044010/E3-FPWW, F04W075R (B) France (FR) 67750 Scherwiller (Alsace) 2005-12-15	Apache	1) 2004-10-14 (sowing) 2) 3) 2005-07-12	0.019	260	0.0075	2004-12-07[4)]	BBCH 13	grain straw	<0.010 <0.010	<0.010 <0.010	217 217	4) spraying analytical method: GRM 04.17 (HPLC/MS/MS), LOQ(s): 8.1/8.2: 0.01 mg/kg, max. sample storage time in month(s):2 treated with formulation GF-1274, WG, without adjuvant (methylated rapeseed oil) RIP2006-1708
GHE-P-11261,	Magnus	1) 2004-09-18	0.020	330	0.0063	2005-05-24[4)]	BBCH 39	grain	<0.010	<0.010	80	4) spraying

1	2	3	4			5	6	7	8.1	8.2	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment kg a.i./ha	Water l/ha	kg a.i./hl	Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
	(a)	(b)				(c)		(a)			(d)	(e)
								straw	<0.010	<0.010	80	
GHE-P-11261, 20054023/E1-FPWW, G05W022R (B) Germany (DE) 21729 Freiburg (Lower Saxony) 2005-12-15	Magnus	1) 2004-09-18 (sowing) 2) 2005-06-14 - 2005-06-21 3) 2005-08-12	0.020	330	0.0063	2005-05-24[4)]	BBCH 39	grain straw	<0.010 <0.010	<0.010 <0.010	80 80	4) spraying analytical method: GRM 04.17 (HPLC/MS/MS), LOQ(s): 8.1/8.2: 0.01 mg/kg, max. sample storage time in month(s):2 treated with formulation GF-1274, WG, without adjuvant (methylated rapeseed oil) RIP2006-1713
GHE-P-11261, 20054023/E1-FPWW, GB05W005R (A) United Kingdom OX6 9NB Bucknell (Oxfordshire) 2005-12-15	Solstice	1) 2004-09-29 (sowing) 2) 2005-06-13 - 2005-06-24 3) 2005-08-02	0.019	250	0.0075	2005-05-11[4)]	BBCH 39	grain straw	<0.010 <0.010	<0.010 <0.010	83 83	4) spraying analytical method: GRM 04.17 (HPLC/MS/MS), LOQ(s): 8.1/8.2: 0.01 mg/kg, max. sample storage time in month(s):1 treated with formulation GF-1274, WG, with adjuvant (methylated rapeseed oil) RIP2006-1713
GHE-P-11261,	Solstice	1) 2004-09-29	0.019	250	0.0075	2005-05-11[4)]	BBCH 39	grain	<0.010	<0.010	83	4) spraying

1	2	3	4			5	6	7	8.1	8.2	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment kg a.i./ha	Water l/ha	kg a.i./hl	Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
	(a)	(b)				(c)		(a)			(d)	(e)
								straw	<0.010	<0.010	83	
GHE-P-11261, 20054023/E1-FPWW, F05W024R (A) France (FR) 67310 Cosswiller (Alsace) 2005-12-15	Soisson	1) 2004-10-21 (sowing) 2) 3) 2005-07-22	0.019	250	0.0075	2005-05-13[4)]	BBCH 39	plant grain straw	0.080 <0.010 <0.010 <0.010 <0.010 <0.010	0.17 <0.010 <0.010 <0.010 <0.010 <0.010	0 8 31 59 70 70	4) spraying analytical method: GRM 04.17 (HPLC/MS/MS), LOQ(s): 8.1/8.2: 0.01 mg/kg, max. sample storage time in month(s):4 treated with formulation GF-1274, WG, with adjuvant (methylated rapeseed oil) RIP2006-1713
GHE-P-11261, 20054023/E1-FPWW, F05W024R (B) France (FR) 67310 Cosswiller (Alsace) 2005-12-15	Soisson	1) 2004-10-21 (sowing) 2) 3) 2005-07-22	0.019	250	0.0075	2005-05-13[4)]	BBCH 39	plant grain straw	0.030 <0.010 <0.010 <0.010 <0.010 <0.010	0.33 <0.010 <0.010 <0.010 <0.010 <0.010	0 8 31 59 70 70	4) spraying analytical method: GRM 04.17 (HPLC/MS/MS), LOQ(s): 8.1/8.2: 0.01 mg/kg, max. sample storage time in month(s):4 treated with formulation GF-1274, WG, without adjuvant (methylated rapeseed oil) RIP2006-1713
GHE-P-11261,	Apache	1) 2004-10-14	0.019	260	0.0075	2005-05-10[4)]	BBCH 39	grain	<0.010	<0.010	63	4) spraying

1	2	3	4			5	6	7	8.1	8.2	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment kg a.i./ha	Water l/ha	kg a.i./hl	Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
	(a)	(b)				(c)		(a)			(d)	(e)
								straw	<0.010	<0.010	63	
GHE-P-11261, 20054023/E1-FPWW, F05W025R (B) France (FR) 67750 Scherwiller (Alsace) 2005-12-15	Apache	1) 2004-10-14 (sowing) 2) 3) 2005-07-12	0.019	250	0.0075	2005-05-10[4)]	BBCH 39	grain straw	<0.010 <0.010	<0.010 <0.010	63 63	4) spraying analytical method: GRM 04.17 (HPLC/MS/MS), LOQ(s): 8.1/8.2: 0.01 mg/kg, max. sample storage time in month(s):2 treated with formulation GF-1274, WG, without adjuvant (methylated rapeseed oil) RIP2006-1713

Remarks: (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Note: All entries to be filled in as appropriate

Comments of zRMS:	Acceptable. GAP compliant (+/-25% tolerance).

A 3.1 Residues in processed commodities

No new study on residues in processed commodities has been submitted/(and) none is needed due to low residues at harvest.

A 3.2 Residues in rotational crops

No new study on residues in rotational crops has been submitted.

A 3.3 Residues in livestock

No new study on residues in livestock has been submitted.

A 3.4 Other studies/information

None

Appendix 4 Pesticide Residue Intake Model (PRIMo rev.2)

TMDI calculation for *pinoxaden*

Pinoxaden			
Status of the active substance:		Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0,1	ARfD (mg/kg bw):	0,1
Source of ADI:	Reg. (EU) 2016/370	Source of ARfD:	Reg. (EU) 2016/370
Year of evaluation:	2016	Year of evaluation:	2016

Prepare workbook for refined calculations

Undo refined calculations

Explain choice of toxicological reference values.

The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity the highest national MRL was identified (proposed temporary MRL = pTMRL).

The pTMRLs have been submitted to EFSA in September 2006.

Chronic risk assessment

TMDI (range) in % of ADI minimum - maximum	
0	10
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)
10,2	DK child	5,5	Wheat	4,4	Rye	0,1	VEGETABLES	
9,5	WHO Cluster diet B	8,5	Wheat	0,3	VEGETABLES	0,3	Barley	
7,4	WHO cluster diet D	6,5	Wheat	0,4	Rye	0,2	Barley	
6,9	IT kids/toddler	6,6	Wheat	0,1	VEGETABLES	0,1	FRUIT (FRESH OR FROZEN)	
5,6	WHO cluster diet E	3,9	Wheat	0,8	Barley	0,4	Rye	
5,6	DE child	4,1	Wheat	0,8	Rye	0,5	FRUIT (FRESH OR FROZEN)	
5,5	NL child	4,7	Wheat	0,3	FRUIT (FRESH OR FROZEN)	0,2	VEGETABLES	
5,3	WHO Cluster diet F	3,6	Wheat	0,8	Rye	0,6	Barley	
4,7	UK Toddler	3,9	Wheat	0,5	SUGAR PLANTS	0,1	FRUIT (FRESH OR FROZEN)	
4,7	ES child	4,4	Wheat	0,1	FRUIT (FRESH OR FROZEN)	0,1	VEGETABLES	
4,4	PT General population	3,9	Wheat	0,1	Rye	0,1	FRUIT (FRESH OR FROZEN)	
4,3	IT adult	4,1	Wheat	0,1	VEGETABLES	0,1	FRUIT (FRESH OR FROZEN)	
4,2	IE adult	2,3	Wheat	1,2	Barley	0,2	FRUIT (FRESH OR FROZEN)	
3,8	SE general population 90th percentile	3,2	Wheat	0,3	Rye	0,2	VEGETABLES	
3,6	WHO regional European diet	3,0	Wheat	0,3	Barley	0,2	VEGETABLES	
3,5	FR all population	3,3	Wheat	0,1	FRUIT (FRESH OR FROZEN)	0,1	VEGETABLES	
3,2	FR toddler	2,6	Wheat	0,3	VEGETABLES	0,2	FRUIT (FRESH OR FROZEN)	
3,2	UK Infant	2,6	Wheat	0,2	SUGAR PLANTS	0,1	VEGETABLES	
3,0	ES adult	2,3	Wheat	0,5	Barley	0,1	FRUIT (FRESH OR FROZEN)	
2,8	DK adult	2,0	Wheat	0,7	Rye	0,1	VEGETABLES	
2,7	NL general	2,1	Wheat	0,4	Barley	0,1	VEGETABLES	
2,4	UK vegetarian	2,0	Wheat	0,1	SUGAR PLANTS	0,1	VEGETABLES	
2,4	LT adult	1,1	Rye	1,1	Wheat	0,1	VEGETABLES	
2,0	UK Adult	1,7	Wheat	0,1	SUGAR PLANTS	0,1	VEGETABLES	
1,8	FI adult	1,0	Wheat	0,7	Rye	0,1	VEGETABLES	
1,6	FR infant	0,8	Wheat	0,4	VEGETABLES	0,3	FRUIT (FRESH OR FROZEN)	
0,2	PL general population	0,1	VEGETABLES	0,1	FRUIT (FRESH OR FROZEN)	0,0	PULSES, DRY	

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.

A long-term intake of residues of Pinoxaden is unlikely to present a public health concern.

TMDI calculation for *pyroxsulam*

Pyroxsulam			
Status of the active substance:		Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0,9**	ARfD (mg/kg bw):	**n.n.**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2013**	Year of evaluation:	**2013**

Prepare workbook for refined calculations

Undo refined calculations

Explain choice of toxicological reference values.

The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity the highest national MRL was identified (proposed temporary MRL = pTMRL).
The pTMRLs have been submitted to EFSA in September 2006.

Chronic risk assessment

TMDI (range) in % of ADI minimum - maximum	
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)
0,1	FR toddler	0,0	PRODUCTS OF ANIMAL ORIGIN	0,0	VEGETABLES	0,0	FRUIT (FRESH OR FROZEN)	
0,1	UK Infant	0,0	PRODUCTS OF ANIMAL ORIGIN	0,0	SUGAR PLANTS	0,0	VEGETABLES	
0,1	UK Toddler	0,0	PRODUCTS OF ANIMAL ORIGIN	0,0	SUGAR PLANTS	0,0	FRUIT (FRESH OR FROZEN)	
0,1	NL child	0,0	PRODUCTS OF ANIMAL ORIGIN	0,0	FRUIT (FRESH OR FROZEN)	0,0	VEGETABLES	
0,1	FR infant	0,0	PRODUCTS OF ANIMAL ORIGIN	0,0	VEGETABLES	0,0	FRUIT (FRESH OR FROZEN)	
0,1	DE child	0,0	PRODUCTS OF ANIMAL ORIGIN	0,0	FRUIT (FRESH OR FROZEN)	0,0	VEGETABLES	
0,1	WHO Cluster diet B	0,0	VEGETABLES	0,0	CEREALS	0,0	FRUIT (FRESH OR FROZEN)	
0,0	DK child	0,0	PRODUCTS OF ANIMAL ORIGIN	0,0	CEREALS	0,0	VEGETABLES	
0,0	SE general population 90th percentile	0,0	PRODUCTS OF ANIMAL ORIGIN	0,0	VEGETABLES	0,0	FRUIT (FRESH OR FROZEN)	
0,0	ES child	0,0	PRODUCTS OF ANIMAL ORIGIN	0,0	FRUIT (FRESH OR FROZEN)	0,0	CEREALS	
0,0	IE adult	0,0	FRUIT (FRESH OR FROZEN)	0,0	VEGETABLES	0,0	CEREALS	
0,0	WHO cluster diet E	0,0	VEGETABLES	0,0	PRODUCTS OF ANIMAL ORIGIN	0,0	CEREALS	
0,0	WHO cluster diet D	0,0	VEGETABLES	0,0	CEREALS	0,0	PRODUCTS OF ANIMAL ORIGIN	
0,0	WHO regional European diet	0,0	PRODUCTS OF ANIMAL ORIGIN	0,0	VEGETABLES	0,0	CEREALS	
0,0	WHO Cluster diet F	0,0	PRODUCTS OF ANIMAL ORIGIN	0,0	VEGETABLES	0,0	CEREALS	
0,0	NL general	0,0	PRODUCTS OF ANIMAL ORIGIN	0,0	VEGETABLES	0,0	FRUIT (FRESH OR FROZEN)	
0,0	ES adult	0,0	PRODUCTS OF ANIMAL ORIGIN	0,0	FRUIT (FRESH OR FROZEN)	0,0	VEGETABLES	
0,0	UK vegetarian	0,0	SUGAR PLANTS	0,0	VEGETABLES	0,0	PRODUCTS OF ANIMAL ORIGIN	
0,0	FR all population	0,0	FRUIT (FRESH OR FROZEN)	0,0	PRODUCTS OF ANIMAL ORIGIN	0,0	VEGETABLES	
0,0	PT General population	0,0	FRUIT (FRESH OR FROZEN)	0,0	VEGETABLES	0,0	CEREALS	
0,0	UK Adult	0,0	PRODUCTS OF ANIMAL ORIGIN	0,0	SUGAR PLANTS	0,0	VEGETABLES	
0,0	DK adult	0,0	PRODUCTS OF ANIMAL ORIGIN	0,0	VEGETABLES	0,0	FRUIT (FRESH OR FROZEN)	
0,0	IT kids/toddler	0,0	CEREALS	0,0	VEGETABLES	0,0	FRUIT (FRESH OR FROZEN)	
0,0	LT adult	0,0	PRODUCTS OF ANIMAL ORIGIN	0,0	VEGETABLES	0,0	CEREALS	
0,0	FI adult	0,0	PRODUCTS OF ANIMAL ORIGIN	0,0	VEGETABLES	0,0	FRUIT (FRESH OR FROZEN)	
0,0	IT adult	0,0	CEREALS	0,0	VEGETABLES	0,0	FRUIT (FRESH OR FROZEN)	
0,0	PL general population	0,0	VEGETABLES	0,0	FRUIT (FRESH OR FROZEN)	0,0	PULSES, DRY	

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Pyroxsulam is unlikely to present a public health concern.

TMDI calculation for *cloquintocet*

Cloquintocet			
Status of the active substance:	#NV	Code no.	#NV
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0,04	ARfD (mg/kg bw):	1
Source of ADI:	DAR	Source of ARfD:	DAR
Year of evaluation:	2003	Year of evaluation:	2003

Prepare workbook for refined calculations

Undo refined calculations

Explain choice of toxicological reference values.

The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity the highest national MRL was identified (proposed temporary MRL = pTMRL).
The pTMRLs have been submitted to EFSA in September 2006.

Chronic risk assessment

TMDI (range) in % of ADI minimum - maximum	
1	5
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)
5,4	UK Toddler	2,9	SUGAR PLANTS	0,8	FRUIT (FRESH OR FROZEN)	0,7	VEGETABLES	
4,9	WHO Cluster diet B	1,8	VEGETABLES	1,5	CEREALS	0,9	FRUIT (FRESH OR FROZEN)	
4,7	FR infant	2,6	VEGETABLES	1,9	FRUIT (FRESH OR FROZEN)	0,1	CEREALS	
4,6	DE child	2,9	FRUIT (FRESH OR FROZEN)	0,9	VEGETABLES	0,7	CEREALS	
4,1	NL child	1,9	FRUIT (FRESH OR FROZEN)	1,4	VEGETABLES	0,7	CEREALS	
4,1	FR toddler	2,2	VEGETABLES	1,5	FRUIT (FRESH OR FROZEN)	0,4	CEREALS	
3,6	UK Infant	1,3	SUGAR PLANTS	0,8	VEGETABLES	0,7	FRUIT (FRESH OR FROZEN)	
3,4	IE adult	1,3	FRUIT (FRESH OR FROZEN)	1,1	VEGETABLES	0,8	CEREALS	
2,9	WHO cluster diet E	1,1	VEGETABLES	0,8	CEREALS	0,7	FRUIT (FRESH OR FROZEN)	
2,9	DK child	1,3	CEREALS	0,9	VEGETABLES	0,6	FRUIT (FRESH OR FROZEN)	
2,7	WHO cluster diet D	1,1	VEGETABLES	1,1	CEREALS	0,4	FRUIT (FRESH OR FROZEN)	
2,6	SE general population 90th percentile	1,3	VEGETABLES	0,7	FRUIT (FRESH OR FROZEN)	0,6	CEREALS	
2,3	PT General population	0,8	FRUIT (FRESH OR FROZEN)	0,7	VEGETABLES	0,7	CEREALS	
2,3	WHO Cluster diet F	0,9	VEGETABLES	0,7	CEREALS	0,5	FRUIT (FRESH OR FROZEN)	
2,2	ES child	0,7	FRUIT (FRESH OR FROZEN)	0,7	CEREALS	0,6	VEGETABLES	
2,2	WHO regional European diet	1,2	VEGETABLES	0,5	CEREALS	0,4	FRUIT (FRESH OR FROZEN)	
2,0	IT kids/toddler	1,0	CEREALS	0,5	VEGETABLES	0,4	FRUIT (FRESH OR FROZEN)	
2,0	UK vegetarian	0,5	SUGAR PLANTS	0,5	VEGETABLES	0,4	FRUIT (FRESH OR FROZEN)	
1,7	FR all population	0,8	FRUIT (FRESH OR FROZEN)	0,5	VEGETABLES	0,4	CEREALS	
1,7	NL general	0,7	VEGETABLES	0,6	FRUIT (FRESH OR FROZEN)	0,3	CEREALS	
1,7	UK Adult	0,5	SUGAR PLANTS	0,4	VEGETABLES	0,4	FRUIT (FRESH OR FROZEN)	
1,5	ES adult	0,5	FRUIT (FRESH OR FROZEN)	0,5	VEGETABLES	0,4	CEREALS	
1,5	IT adult	0,6	CEREALS	0,5	VEGETABLES	0,3	FRUIT (FRESH OR FROZEN)	
1,3	LT adult	0,6	VEGETABLES	0,3	CEREALS	0,3	FRUIT (FRESH OR FROZEN)	
1,2	DK adult	0,4	VEGETABLES	0,4	FRUIT (FRESH OR FROZEN)	0,4	CEREALS	
1,2	PL general population	0,8	VEGETABLES	0,4	FRUIT (FRESH OR FROZEN)	0,0	PULSES, DRY	
0,925	FI adult	0,3	VEGETABLES	0,3	FRUIT (FRESH OR FROZEN)	0,2	CEREALS	

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Cloquintocet is unlikely to present a public health concern.

REGISTRATION REPORT
Part B

Section 5 Environmental Fate

Detailed summary of the risk assessment

Product code:	**AVOXA / A19786A**		
Active Substances:	**Pinoxaden**	**33.3**	**g/L**
	Pyroxsulam	**8.33**	**g/L**

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: **Syngenta**
Submission date: **28/03/2014**
MS Finalisation date: January 2018

Table of Contents

FATE AND BEHAVIOUR IN THE ENVIRONMENT (KIIIA 9)

This document comprises the risk assessment for groundwater and the exposure assessment of surface water and soil for the plant protection product AVOXA containing Pinoxaden and Pyroxsulam in its intended uses in winter cereals according to Appendix 3 /Part B, Section 1, Appendix 2.

National Addenda are included containing country specific assessments for some annex points.

5.1 General Information on the formulation

Table 5.1-1: General information on the formulation AVOXA

Code	008178-00/00		
Plant protection product	AVOXA		
Applicant	Syngenta		
Date of application	28/03/2014		
Formulation type (WP, EC, SC, …; density)	EC		
Active substances (as)	Pinoxaden	Pyroxsulam	Cloquintocet-mexyl (safener)
Concentration of as (g/L)	33.3	8.33	8.33

5.2 Proposed use pattern

The critical GAPs used for exposure assessment is presented in Table 5.2-1. It has been selected from the individual GAPs in the zone for AVOXA. A list of all intended uses within the zone is given in Appendix 3 /Part B, Section 1, Appendix 2.

Table 5.2-1: Critical use pattern of AVOXA

Group*	**Crop/growth stage**	**Application method / Drift scenario**	**Number of applications, Minimum application interval, interception, application time (season)**	**Application rate, cumulative (g as/ha)**	**Soil effective application rate (g as/ha)**
A	winter wheat, winter triticale, winter rye BBCH 10-32	spraying / field crops	1 x, spring 1. 25 %	Pinoxaden 1 x 59.9 Pyroxsulam 1 x 15	Pinoxaden 1 x 45 Pyroxsulam 1 x 11.25
B	winter wheat, winter triticale, winter rye BBCH 10-32	spraying / field crops	1 x, spring 1. 25 %	Pinoxaden 1 x 45 Pyroxsulam 1 x 11.3	Pinoxaden 1 x 33.75 Pyroxsulam 1 x 8.5

* Group A covers all intended uses in winter cereals in the central zone. Lower applications rates are also intended for use in cereals (see Group B).

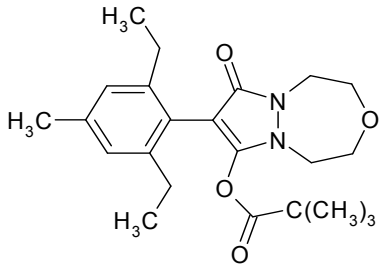
5.3 Information on the active substances

5.3.1 Pinoxaden

5.3.1.1 Identity, further information of Pinoxaden

Table 5.3-1: Identity, further information on Pinoxaden

Active substance (ISO common name)	Pinoxaden
IUPAC	8-(2,6-diethyl-p-tolyl)-1,2,4,5-tetrahydro-7-oxo-7H-pyrazolo[1,2-d][1,4,5]oxadiazepin-9-yl-2,2-dimethylpropionate
Function (e.g. fungicide)	herbicide
Status under Reg. (EC) No 1107/2009	approved
Date of approval	01/07/2016
Conditions of approval	According to Review Report SANCO/11794/2013 rev 3-29/01/2016: Member States shall pay particular attention to: - the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions. - Conditions of authorisation shall include risk mitigation measures, where appropriate. - The Member States concerned shall carry out monitoring programmes to verify potential groundwater contamination from the metabolite M2 in vulnerable zones, where appropriate.
Confirmatory data	According to Review Report SANCO/11794/2013 rev 3-29/01/2016: - A validated method of analysis of metabolites M11, M52, M54, M55 and M56 in ground water The applicant shall submit to the Commission, the Member States and the Authority the relevant information by 30 June 2018. - The concerned Member States shall request the submission of confirmatory information as regards the relevance of the metabolites M3, M11, M52, M54, M55 and M56, and the corresponding groundwater risk assessment, if pinoxaden is classified under Regulation (EC) No 1272/2008 as 'suspected of damaging the unborn child'. The notifier shall submit to the Commission, the Member States and the Authority the relevant information within six months from the notification date of the Regulation classifying pinoxaden.
RMS	UK
Minimum purity of the active substance as manufactured (g/kg)	970
Molecular formula	$C_{23}H_{32}N_2O_4$
Molecular mass	400.5 g/mol

Structural formula	

5.3.1.2 Physical and chemical properties of Pinoxaden

Physical and chemical properties of Pinoxaden as agreed at EU level (see EFSA Journal 2013;11(8): 3269) and considered relevant for the exposure assessment are listed in Table 5.3-2.

Table 5.3-2: EU agreed physical chemical properties of Pinoxaden relevant for exposure assessment

	Value	**Reference**
Vapour pressure (at 20 °C) (Pa)	2.0 x10^{-7} at 20 °C	EFSA Journal 2013;11(8): 3269
Henry's law constant (Pa × m³ × mol^{-1})	9.2 x10^{-7} at 25 °C	
Solubility in water (at 25 °C in mg/L)	200	
Partition co-efficient (at 25 °), log P_{OW}	3.2	
Dissociation constant, pKa	No dissociation observed experimentally	
Hydrolytic degradation	pH4: 24.1 (20°C) pH5: 25.3 (20°C) pH7: 14.9 (20°C) pH9: 0.3 (20°C) Metabolites: NOA 407854 (M2): pH 4 – pH 9: max. 64 – 100 % after 30 d NOA 447204 (M3): pH7: 57.5 d (25°C) pH9: 0.6 d (25°C)	
Photolytic degradation	NOA 407855: Xenon lamp, wavelengths >290 nm only, equivalent to 29.5 days natural summer sunlight at 30 – 50˚N. Mineralisation 7.4% AR at study end (dark control 0.1% AR mineralisation) pinoxaden (NOA 407855) DT50 10.1 30 – 50˚ summer sunlight days (dark control 18.4 days) NOA 407854 (M2): max 35.2% AR at 13 DAT, DT50 8.1 30 – 50˚ summer sunlight days (dark control max 72.2% AR at study end, stable) No other metabolites individually >5% AR NOA 447204 (M3): Conducted at pH 5, 7, 9. Xenon lamp, wavelengths >290 nm only, equivalent to 31.7 days natural summer sunlight at 30 – 50˚N. NOA 447204 (M3)	

	DT50 1.0 – 1.9 30 – 50°N summer sunlight days (dark control, stable at pH 5 and 7 days, DT50 <1 day at pH 9)	
Quantum yield of direct phototransformation in water > 290 nm	Pinoxaden (NOA 407855) Φ = 0.0117 NOA 407854 (M2) Φ = 0.0100	EFSA Journal 2013;11(8): 3269
Photochemical oxidative degradation in air (calculation according to Atkinson)	Pinoxaden (NOA 407855) DT_{50} =1.1 h NOA 407854 (M2) DT_{50} =1.1- 1.4 h (OH radical concentration 1.5 × 10^6 radicals/ cm^3, 12 h day)	

5.3.1.3 Metabolites of Pinoxaden

Environmental occurring metabolites of Pinoxaden requiring further assessment according to the results of the assessment of Pinoxaden for EU approval are summarized in Table 5.3-3.

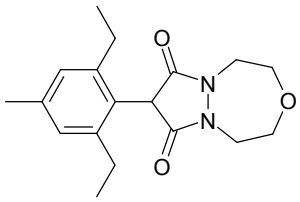
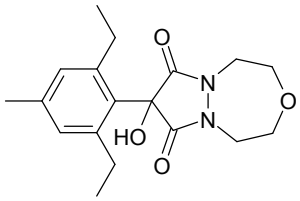
No new study on the fate and behaviour of Pinoxaden or AVOXA has been performed. Hence no potentially new metabolites need to be considered.

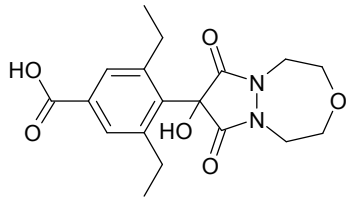
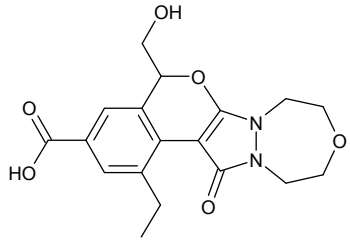
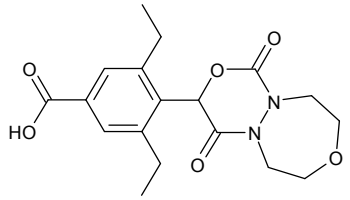
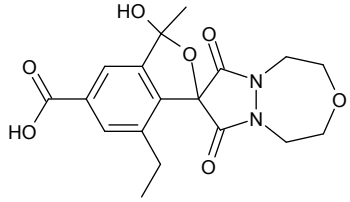
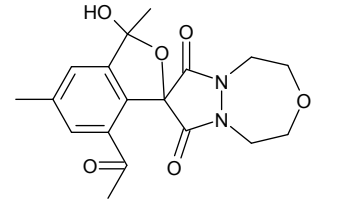
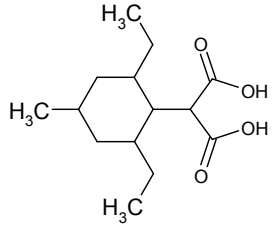
The risk assessment for these metabolites has already been performed for EU approval (see EFSA Journal 2013;11(8):3269). Therefore no new risk assessment hence no exposure assessment for these metabolites is necessary.

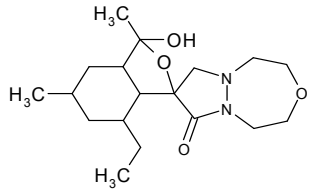
Potential ground water contamination by the soil metabolites M2, M3, M11, M52, M54, M55 and M56 was evaluated for EU approval of Pinoxaden. PECgw modelled with FOCUS PEARL (version 4.4.4) and FOCUS PELMO (version 4.4.3) was above 0.1 µg/L for the metabolites based on an application of 45 g as/ha (autumn application) or 60 g as/ha (spring application) in cereals.

However, the leaching potential into groundwater of the soil metabolites M2, M3, M11, M52, M54, M55 and M56 will be assessed for the application of the plant protection product and its intended uses.

Table 5.3-3: Metabolites of Pinoxaden potentially relevant for exposure assessment (> 10 % of as or > 5 % of as in 2 sequential measurements or > 5 % of as and maximum of formation not yet reached at the end of the study)

Metabolite	Structural formula/ Molecular mass	occurrence in compartments (Max. at day)	Status of Relevance (EFSA Journal 2013;11(8): 3269)
M2 (NOA 407854) (CSAA468548)	 316.4 g/mol	Soil: max. 90% after 3 d Water: max. 88.8% after 3 d Sediment: max. 29.6% after 35 d Soil-Photolysis: 78.7 % after 9 h	Aquatic organisms: Water: not relevant Sediment: not relevant Terrestrial organisms: not relevant Groundwater: relevant (Step 2/Step 3-4)[1)]
M3 (NOA 447204) (CSAA783052)		Soil: max. 31% after 120 d Soil-Photolysis: 15.3 % after 6 d Lysimeter leachate: 0.218 µg/L	Aquatic organisms: Water: not relevant Sediment: not relevant Terrestrial organisms: not relevant Groundwater: relevant (Step 2/Step 3-4)[1)]

	332.37 g/mol		
M11 (SYN 504574) (CSCC204395)	 362.36 g/mol	Lysimeter leachate: 0.263 µg/L	Aquatic organisms: Water: not applicable Sediment: not applicable Terrestrial organisms: not applicable Groundwater: relevant (Step 2/Step 3-4)[1)]
M52 (SYN546105) (CSCD704931)	 360.34 g/mol	Lysimeter leachate: 0.150 µg/L	Aquatic organisms: Water: not applicable Sediment: not applicable Terrestrial organisms: not applicable Groundwater: relevant (Step 2/Step 3-4)[1)]
M54 (SYN546106) (CSCD704932)	 362.4 g/mol	Lysimeter leachate: 0.173 µg/L	Aquatic organisms: Water: not applicable Sediment: not applicable Terrestrial organisms: not applicable Groundwater: relevant (Step 2/Step 3-4)[1)]
M55 (SYN546107) (CSCD704933)	 376.4 g/mol	Lysimeter leachate: 0.161 µg/L	Aquatic organisms: Water: not applicable Sediment: not applicable Terrestrial organisms: not applicable Groundwater: relevant (Step 2/Step 3-4)[1)]
M56 (SYN546108)	 360.34 g/mol	Lysimeter leachate: 0.307 µg/L	Aquatic organisms: Water: not applicable Sediment: not applicable Terrestrial organisms: not applicable Groundwater: relevant (Step 2/Step 3-4)[1)]
NOA 440626		Photolysis in water: max. 18.3 % after 23 d	Aquatic organisms: Water: not assessed Sediment: not assessed Terrestrial organisms: not applicable Groundwater: not applicable

SYN515622	 346 g/mol	Soil-Photolysis: 20.4% after day 6	Aquatic organisms: Water: not applicable Sediment: not applicable Terrestrial organisms: not assessed Groundwater: not assessed

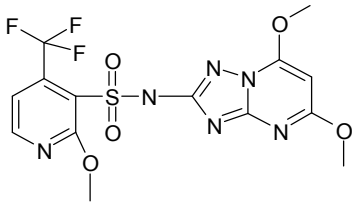
[1)] According to Guidance Document on the assessment of the relevance of metabolites in groundwater of substances regulated under council directive 91/414/EEC (SANCO/221/2000 –rev.10- final - 25 February 2003)

5.3.2 Pyroxsulam

5.3.2.1 Identity, further information of Pyroxsulam

Table 5.3-4: Identity, further information on Pyroxsulam

Active substance (ISO common name)	Pyroxsulam / XDE-742
IUPAC	*N*-(5,7-dimethoxy[1,2,4]triazolo[1,5-*a*]pyrimidin-2-yl)-2-methoxy-4-(trifluoromethyl)pyridine-3-sulfonamide
Function (e.g. fungicide)	herbicide
Status under Reg. (EC) No 1107/2009	approved
Date of approval	01/05/2014
Conditions of approval	According to Review Report SANCO/12099/2012 rev1-03/10/2013: Member States shall pay particular attention to: (a) the risk to groundwater, when the active substance is applied in regions with vulnerable soil or climatic conditions; (b) the risk to aquatic organisms. Conditions of use shall include risk mitigation measures, where appropriate.
Confirmatory data	According to Review Report SANCO/12099/2012 rev1-03/10/2013: Further studies were identified which were at this stage considered necessary in relation to the approval of pyroxsulam under the current approval conditions. This is particularly the case for information concerning: (1) the toxicological relevance of impurity number 3 (as referred to in table C.1.3 of Volume 4 of the draft Assessment Report); (2) the acute toxicity of the metabolite PSA; (3) the toxicological relevance of metabolite 6-Cl-7-OH-XDE-742. The notifier shall submit to the Commission, the Member States and the Authority that information by 30 April 2016. Confirmatory data requirements have been satisfactorily addressed (refers to EFSA Supporting publication 2017:EN-1168).
RMS	UK
Minimum purity of the active substance as manufactured (g/kg)	965
Molecular formula	$C_{14}H_{13}F_3N_6O_5S$
Molecular mass	434.4 g/mol

Structural formula	

5.3.2.2 Physical and chemical properties of Pyroxsulam

Physical and chemical properties of Pyroxsulam as agreed at EU level (see SANCO/12099/2012 rev1-03/10/2013) and considered relevant for the exposure assessment are listed in Table 5.3-5.

Table 5.3-5: EU agreed physical chemical properties of Pyroxsulam relevant for exposure assessment

	Value	**Reference**
Vapour pressure (at 20 °C) (Pa)	$<1 \times 10^{-7}$	EFSA Journal 2013;11(4):3182
Henry's law constant (Pa × m³ × mol⁻¹)	6.94×10^{-7} Pa m^3 mol^{-1} (20°C)	
Solubility in water (at 25 °C in mg/L)	0.0164 g/L (pH 4) 3.20 g/L (pH 7) 13.7 g/L (pH 9)	
Partition co-efficient (at 25 °), log Pow	1.08 ± 0.01 (pH 4) -1.01 ± 0.05 (pH 7) -1.60 ± 0.12 (pH 9)	
Dissociation constant, pKa	4.67 ± 0.01	
Hydrolytic degradation	stable at pH 5, pH 7 and pH 9	
Photolytic degradation	DT_{50} = 0.83 days Natural light, 40°N; DT_{50} = 4.1 days Pyridine sulfinic acid, DT_{50}= 32 days, 79.2 % AR (3.8 DAT) ADTP, DT_{50}= 41 days, 39.8 %AR (3.8 DAT) Estimated DT_{50} at 50°N (summer) = 3.6 days	
Quantum yield of direct phototransformation in water > 290 nm	$\Phi = 4.41 \times 10^{-1}$	
Photochemical oxidative degradation in air (calculation according to Atkinson)	DT_{50} =2.149 h (1.5×10^6 radicals/cm³, 12 h day)	

5.3.2.3 Metabolites of Pyroxsulam

Environmental occurring metabolites of Pyroxsulam requiring further assessment according to the results of the assessment of Pyroxsulam for EU approval are summarized in Table 5.3-6.

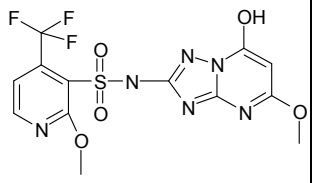
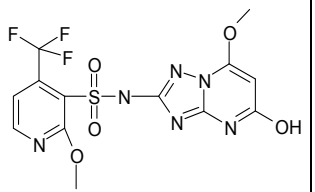
No new study on the fate and behaviour of Pyroxsulam or AVOXA has been performed. Hence no potentially new metabolites need to be considered.

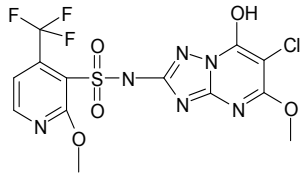
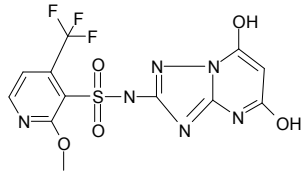
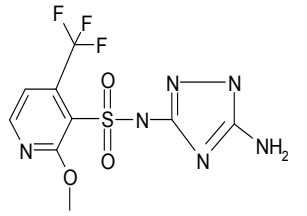
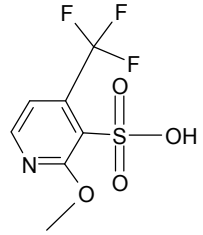
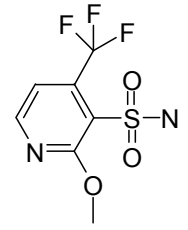
The risk assessment for these metabolites has already been performed for EU approval (see SANCO/12099/2012rev1-03/10/2013). Therefore no new risk assessment hence no exposure assessment for these metabolites is necessary.

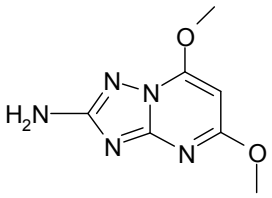
Potential ground water contamination by the soil metabolites 7-OH, 5-OH, 6-Cl-7-OH, 5,7-di-OH, Pyridine Sulfonamide and PSA was evaluated for EU approval of Pyroxsulam. PECgw modelled with FOCUS PEARL v4.4.4 and FOCUS PELMO v4.4.3 was less than 0.1 µg/L for the metabolites 5-OH, Pyridine Sulfonamide and 5,7-di-OH in all of 9 scenarios based on an application of 18.75 g as/ha. For the metabolites7-OH, 6-Cl-7-OH and PSA PECgw was above 0.1 µg/L.

However, the leaching potential into groundwater of the soil metabolites 7-OH, 5-OH, 6-Cl-7-OH, 5,7-di-OH, Pyridine Sulfonamide and PSA will be assessed for the application of the plant protection product AVOXA and its intended uses.

Table 5.3-6: Metabolites of Pyroxsulam potentially relevant for exposure assessment (> 10 % of as or > 5 % of as in 2 sequential measurements or > 5 % of as and maximum of formation not yet reached at the end of the study)

Metabolite	Structural formula/ Molecular weight	occurrence in compartments (Max. at day)	Status of Relevance (SANCO/12099/2012rev1-03/10/2013)
7-OH (7-OH-XDE-742)	 420.33 g/mol	Soil, aerobic: max. 13.7 % after 3 d (20°C) soil, anaerobic: 76.5% after 58 d → after 30 d, oxygen probably leaked in the anaerobic soil system, thus the amount of 7-OH formed in the anaerobic soil study will be considered in risk assessment also under aerobic conditions water/sediment-system: water: max. 32.7 % after 17d sediment: max. 25.8 % after 17d total system: max. 58.4 % after 17d	Aquatic organism: Water: not relevant Sediment: not relevant Terrestrial organism: not relevant Groundwater: not relevant (Step 3-4)[1)]
5-OH (5-OH-XDE-742)	 420.33 g/mol	Soil, aerobic: max. 24.1 % after 3 d (20°C)	Aquatic organism: Water: not relevant Sediment: not relevant Terrestrial organism: not relevant Groundwater: not relevant (Step 2)[1)]

6-Cl (6-Cl-7-OH-XDE-742)	 454.77 g/mol	<u>Soil, aerobic:</u> max. 26.2 % after 7 d (20°C)	Aquatic organism: Water: not relevant Sediment: not relevant Terrestrial organism: not relevant Groundwater: not relevant* (Step 3-4)[1)]
5,7-di-OH-XDE-742	 406.30	<u>Soil, anaerobic:</u> max. 27.3 % after 126 d → after 30 d, oxygen probably leaked in the anaerobic soil system, thus the amount of 5,7-di-OH formed in the anaerobic soil study will be considered in risk assessment also under aerobic conditions	Aquatic organism: Water: not relevant Sediment: not relevant Terrestrial organism: not assessed Groundwater: not relevant (Step 2)[1)]
XDE-742-ATSA	 338.27	<u>water/sediment-system:</u> water: 9.6, 7.8 and 8.7% after 54, 75 and 101 d (3x >5 %) Sediment: 5.3 % after 75 d (1x >5 %)	Aquatic organism: Water: not relevant Sediment: not relevant Terrestrial organism: not applicable Groundwater: not applicable
PSA (XDE-742 sulfonic acid) = Pyridin-sulfonic acid) = 2-methoxy-4-(trifluoromethyl)pyridine-3-sulfonic acid (IUPAC) = 2-methoxy-4-(trifluoromethyl)pyridine-3-sulfonamide	 257.19	<u>soil, aerobic:</u> max. 5.8 & 5.9 % max. after 21 & 29 d (2 x successively >5%) <u>aqueous photolysis</u> max. 79.2 % after 3.8 d	Aquatic organism: Water: not relevant Sediment: not relevant Terrestrial organism: not assessed Groundwater: not relevant* (Step 3-4)[1)]
XDE-742 Sulfonamide = Pyridine Sulfonamide =XDE-742 unsubstituted Sulfonamide Metabolite	 256.20	<u>soil, aerobic:</u> max. 13.2% after 29 d	Aquatic organism: Water: not relevant Sediment: not relevant Terrestrial organism: not relevant Groundwater: not relevant (Step 2)[1)]

742-ADTP	 195.18	Metabolite of aqueous photolysis max. 39.8 % after 3.8 d	Aquatic organism: Water: not relevant Sediment: not relevant Terrestrial organism: not applicable Groundwater: not applicable

[1)] According to Guidance Document on the assessment of the relevance of metabolites in groundwater of substances regulated under council directive 91/414/EEC (SANCO/221/2000 –rev.10- final - 25 February 2003)
* refers to EFSA Supporting publication 2017:EN-1168

5.4 Summary on input parameters for environmental exposure assessment

5.4.1 Rate of degradation in soil

5.4.1.1 Laboratory studies

Pinoxaden

No new study on the soil degradation of Pinoxaden has been submitted. However, new studies (Robinson, 2012a+b, Völkel, 2012a+b) on the soil degradation of the Pinoxaden metabolites M11, M52, M54 and M55 has been submitted. A detailed evaluation of these studies is presented in Appendix 2. The DT_{50} values for Pinoxaden, already evaluated in the EU assessment, are summarized in Table 5.4-1.

Table 5.4-1: Summary of aerobic degradation rates for Pinoxaden - laboratory studies

Soil type	**pH (H_2O)**	**T (°C)**	**Moi-sture**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20 °C pF2/10kPa**	**Fit χ^2**	**Method of calculation**	**Reference**
Gartenacker, loam/silt loam	7.23	20	40% MWHC	0.13	0.44	0.08	12.7	SFO	Reischmann, 2001a
Gartenacker, silt loam	7.32	20	40% MWHC	0.23	0.76	0.16	5.0	SFO	Reischmann, 2003
Geomean						**0.11**			
Plaza, loamy sand	8.00	25	75% FMC	0.15	0.48	0.21	8.9	SFO	Clark, 2003a
Plaza, loamy sand	7.70	25	75% FMC	0.23	0.75	0.29	6.6	SFO	Clark, 2003b
Plaza, loamy sand	7.70	25	75% FMC	0.19	0.62	0.24	4.4	SFO	McKillican, 2003
Geomean						**0.24**			
Birkenheide, sandy loam	6.04	20	40% MWHC	1.05	3.48	**0.70**	10.0	SFO	Fent, 2003

Borstel, loamy sand	5.10	20	40% MWHC	2.30	7.63		17.1	SFO	Phaff, 2003
Borstel, loamy sand	6.70	20	40% MWHC	0.43	1.43		19.2	SFO	Fent and Hein, 2003
Marsillargues, silty clay loam	7.90 H_2O	20	40% MWHC	0.39	1.31	0.30	4.6	SFO	Phaff, 2003
Marsillargues, silty loam	7.00	20	40% MWHC	0.37	1.21	0.27	12.8	SFO	Fent and Hein, 2003
Geomean						**0.28**			
18 Acres, sandy clay loam	5.80	20	40% MWHC	0.76	2.54	**0.81**	6.8	SFO	Phaff, 2003
Pappelacker, sand	6.70	20	40% MWHC	0.10	0.33		24.4	SFO	Fent and Hein, 2003
Welver-Borgeln, silt loam	6.70	20	40% MWHC	0.24	0.80		18.6	SFO	Fent and Hein, 2003
Aggregated DT_{50} (n=5)		**Coefficient of variation (%)**				72			
		Geometric mean (d)				**0.34**			
		90th percentile (d)				0.8			

The DT_{50} values of Pinoxaden do not show any pH dependency.

Table 5.4-2: Summary of aerobic degradation rates for metabolite M2 (NOA 407854) - laboratory studies

Soil type	**pH (H_2O)**	**T (°C)**	**Moi-sture**	**DT_{50} (d)**	**DT_{90} (d)**	**f.f.**	**DT_{50} (d) 20 °C pF2/ 10kPa**	**Fit χ^2**	**Method of calcula-tion**	**Reference**
Gartenacker, loam/silt loam	7.23 KCl	20	40% MWHC	15.8	54.4	0.8	10.3	11.7	SFO	Reischmann, 2001a
Gartenacker, silt loam	7.32	20	40% MWHC	12.3	41.0	0.77	8.4	12.3	SFO	Reischmann, 2003
Geomean							**9.3**			
Plaza, loamy sand	8.00	25	75% FMC	6.1	20.2	1.0	8.4	9.6	SFO	Clark, 2003a

Plaza, loamy sand	7.70	25	75% FMC	2.4	7.9	1.0	3.1	8.8	SFO	Clark, 2003b
Plaza, loamy sand	7.70	25	75% FMC	3.0	10.0	0.88	3.8	5.9	SFO	McKillican, 2003
Geomean							**4.6**			
Marsillargues, silty clay loam	7.90 H_2O	20	40% MWHC	42.2	140.1	0.9	32.9	4.5	SFO	Phaff, 2003
Marsillargues, silty loam	7.00	20	40% MWHC	57.8	192.1	0.93	41.7	3.5	SFO	Fent and Hein, 2003
Geomean							**37.0**			
Pappelacker, sand	6.70	20	40% MWHC	53.3	176.9	0.97	**53.3**	7.6	SFO	Fent and Hein, 2003
Aggregated DT_{50} (n=4)		**Coefficient of variation (%)**					89			
		Geomean (d)					**17.1**			
		90th percentile (d)					48.4			
Formation Fraction (n=8)		**Arithmetic mean**				0.91				
		Maximum				1.0				

Table 5.4-3: Summary of aerobic degradation rates for metabolite M3 (NOA 447204) - laboratory studies

Soil type	**pH (H_2O)**	**T (°C)**	**Moi-sture**	**DT_{50} (d)**	**DT_{90} (d)**	**f.f.**	**DT_{50} (d) 20 °C pF2/ 10kPa**	**Fit χ^2**	**Method of calcula-tion**	**Reference**
Plaza, loamy sand	8.00	25	75% FMC	36.9	122.6	0.25	50.9	16.9	SFO	Clark, 2003a
Plaza, loamy sand	7.70	25	75% FMC	50.6	168	0.21	64.8	8.6	SFO	Clark, 2003b
Plaza, loamy sand	7.70	25	75% FMC	39.6	131.6	0.26	50.7	17.5	SFO	McKillican, 2003
Marsillargues, silty clay loam	7.90 H_2O	20	40% MWHC	117.0	388.7	0.38	91.3	12.2	SFO	Phaff, 2003
Marsillargues, silty loam	7.00	20	40% MWHC	103.4	343.4	0.32	74.6	8.2	SFO	Fent and Hein, 2003

Geomean							**67.4**			
Krone, silt loam	6.42 H_2O	20	pF2	387.2	1286.3	-	**387.2**	1.4	HS (slow phase)	Adam, 2012
18 Acres, sandy clay loam	6.54 H_2O	20	pF2	129.7	430.8	-	**129.7**	3.9	SFO	Adam, 2012
Borstel, loamy sand	5.84 H_2O	20	pF2	179.0	594.6	-	**179.0**	4.6	SFO	Adam, 2012
Aggregated DT_{50} (n=3)		**Coefficient of variation (%)**					59			
		Geomean (d)					**208**			
		90th percentile (d)					346			
Formation Fraction (n=5)		**Arithmetic mean**				0.28				
		Maximum				0.38				

Table 5.4-4: Summary of aerobic degradation rates for metabolite M11 (SYN504574) - laboratory studies

Soil type	**pH (H_2O)**	**T (°C)**	**Moisture**	**DT_{50} (d)**	**DT_{90} (d)**	**f.f.**	**DT_{50} (d) 20 °C pF2/ 10kPa**	**Fit χ^2**	**Method of calculation**	**Reference**
Gartenacker, silt loam	7.53	20	pF2	7.6	25.2	-	7.6	6.1	SFO	Robinson, 2012a
18 Acres, sandy clay loam	6.10	20	pF2	13.0	43.3	-	23.8	1.9	DFOP (slow phase)	Robinson, 2012a
Marsillargues, silty clay loam	8.08	20	pF2	9.2	30.6	-	9.2	3.0	SFO	Robinson, 2012a
Aggregated DT_{50} (n=3)		**Coefficient of variation (%)**					66			
		Geomean (d)					**11.9**			
		90th percentile (d)					20.9			

Table 5.4-5: Summary of aerobic degradation rates for metabolite M52 (SYN546105) - laboratory studies

Soil type	pH (H_2O)	T (°C)	Moisture	DT_{50} (d)	DT_{90} (d)	f.f.	DT_{50} (d) 20 °C pF2/ 10kPa	Fit χ^2	Method of calculation	Reference
Gartenacker, silt loam	7.53	20	pF2	8.5	28.1	-	8.5	6.2	pseudo SFO*	Völkel, 2012a
18 Acres, sandy clay loam	6.10	20	pF2	5.6	18.7	-	5.6	5.9	pseudo SFO*	Völkel, 2012a
Marsillargues, silty clay loam	8.08	20	pF2	12.6	26.3	-	12.6	2.5	HS (slow phase)	Völkel, 2012a
Aggregated DT_{50} (n=3)		**Coefficient of variation (%)**					40			
		Geomean (d)					**8.4**			
		90th percentile (d)					11.8			

*DT_{90} FOMC / 3.32

Table 5.4-6: Summary of aerobic degradation rates for metabolite M54 (SYN546106) - laboratory studies

Soil type	pH (H_2O)	T (°C)	Moisture	DT_{50} (d)	DT_{90} (d)	f.f.	DT_{50} (d) 20 °C pF2/ 10kPa	Fit χ^2	Method of calculation	Reference
Gartenacker, silt loam	7.53	20	pF2	4.9	16.4	-	4.9	5.4	SFO	Völkel, 2012b
18 Acres, sandy clay loam	6.10	20	pF2	9.3	30.8	-	9.3	5.5	SFO	Völkel, 2012b
Marsillargues, silty clay loam	8.08	20	pF2	9.2	30.6	-	9.2	8.8	SFO	Völkel, 2012b
Aggregated DT_{50} (n=3)		**Coefficient of variation (%)**					32			
		Geomean (d)					**7.5**			
		90th percentile (d)					9.3			

Table 5.4-7: Summary of aerobic degradation rates for metabolite M55 (SYN546107) - laboratory studies

Soil type	pH (H_2O)	T (°C)	Moi-sture	DT_{50} (d)	DT_{90} (d)	f.f.	DT_{50} (d) 20 °C pF2/ 10kPa	Fit χ^2	Method of calcula-tion	Reference
Gartenacker, silt loam	7.53	20	pF2	9.6	31.9		9.6	7.1	SFO	Robinson, 2012b
18 Acres, sandy clay loam	6.49	20	pF2				105.7	1.1	DFOP slow phase	Robinson, 2012b
Marsillargues, silty clay loam	8.19	20	pF2	5.3	17.5		5.3	8.6	SFO	Robinson, 2012b
Aggregated DT_{50} (n=3)		**Coefficient of variation (%)**					141	For PEC_{GW} worst case of 106 d was used by the applicant.		
		Geomean (d)					**17.5**			
		90th percentile (d)					86.5			

The DT_{50} values of the metabolites M2, M11, M52, M54 and M55 of Pinoxaden do not show any pH dependency. The DT_{50} values of metabolite M3 show pH dependency.

Pyroxsulam

No new studies have been submitted regarding route and rate of degradation in soil of Pyroxsulam. The environmental exposure assessment is based on the EU agreed DT_{50} values from the laboratory as summarized in Table 5.4-8.

Table 5.4-8: Summary of aerobic degradation rates for Pyroxsulam - laboratory studies

Soil type	pH (H_2O)	T (°C)	Moi-sture	DT_{50} (d)	DT_{90} (d)	DT_{50} (d) 20 °C pF2		Fit	Kinetic	Reference (EFSA Journal 2013;11(4):3182)
Charentilly, sandy clay loam	6.2	20	40% MWHC	3.8	13	3.8	3.4	chi^2: 5.6%	SFO	Yoder, 2006a / Jackson (2011)
Charentilly, loam	6.2	20	40% MWHC	3.7	12.4	3.1		chi^2: 7.7%	SFO	Yoder, 2007a/ Jackson (2011)
LUFA 3A, sandy loam	7.8	20	40% MWHC	2.1	6.8	1.6	1.6	chi^2: 7.4%	SFO	Yoder, 2006a / Jackson (2011)
LUFA 3A, sandy clay loam	8.0	20	40% MWHC	2.1	6.8	1.7		chi^2: 11%	SFO	Yoder, 2007a/ Jackson (2011)
Borstel, sand	5.7	20	40% MWHC	10	33	10	11.4	chi^2: 3.6%	SFO	Yoder, 2006a / Jackson (2011)
Borstel, loamy sand	6.1	20	40% MWHC	14.6	48.4	13.0		chi^2: 3.9%	SFO	Yoder, 2007a/ Jackson (2011)

Bruch West, sandy loam	7.9	20	40% MWHC	2.7	9.1	2.7	3.7	chi^2: 11.0%	SFO	Yoder, 2006a / Jackson (2011)
Bruch west, loamy sand	6.8	20	40% MWHC	5.0	16.8	5.1		chi^2: 6.8%	SFO	Yoder, 2007a/ Jackson (2011)
Commerce/USA, sandy loam	7.1	20	40% MWHC	16.7	55.4	16.7		chi^2: 3.9%	SFO	Yoder, 2006b/ Jackson (2011)
LUFA 2.1, loamy sand	5.6	20	40% MWHC	9.0	29.9	9.0		chi^2: 2.8%	SFO	
LUFA 5M, sandy loam	7.8	20	40% MWHC	1.6	5.2	1.6		chi^2: 2.4%	SFO	
Site I/UK, loamy sand	7.9	20	40% MWHC	1.3	4.3	1.3		chi^2: 6.4%	SFO	
Site D/UK, sandy loam	6.0	20	40% MWHC	3.6	12.0	3.6		chi^2: 10.8%	SFO	
Site G1/UK, sandy loam	7.1	20	40% MWHC	1.0	3.3	1.0		chi^2: 1.7%	SFO	
Manning/USA, sandy loam	7.7	20	40% MWHC	3.0	10.1	3.0		chi^2: 4.7%	SFO	
Site 1/UK, clay loam	7.8	20	40% MWHC	0.8	2.6	0.8		chi^2: 1.6%	SFO	
Site 7/UK, sandy loam	5.7	20	40% MWHC	2.4	8.1	2.4		chi^2: 2.4%	SFO	
Site 6/UK, sandy loam	7.1	20	40% MWHC	7.1	23.7	6.0		chi^2: 6.2%	SFO	
Site 9/UK, sandy loam	7.6	20	40% MWHC	3.9	12.9	3.9		chi^2: 4.9%	SFO	
Regent/ Canada, sandy clay loam	8.0	20	40% MWHC	1.6	5.2	1.6		chi^2: 4.2%	SFO	
Elstow/ Canada, sandy clay loam	5.9	20	40%	12.2	40.6	12.2		chi^2: 5.7%	SFO	
Ottobiano/Italy, loamy sand	5.4	20	40% MWHC	2.4	8.1	2.4		chi^2: 7.5%	SFO	
Greggio/Italy, clay loam	6.3	20	40% MWHC	4.4	14.6	4.4		chi^2: 9.7%	SFO	
Speyerer Wald, sandy loam	5.7	20	40% MWHC	2.8	9.2	2.8		chi^2: 6.3%	SFO	
Aggregated DT_{50}		**Coefficient of variation (%)**				**93**		No pH-dependency according to the		

(n = 20)	**Geometric mean (d)**	**3.3**	Kendall test
	90. percentile (d)	**11.5**	

Table 5.4-9: Summary of aerobic degradation rates for metabolite 7-OH-XDE-742

Soil type	**pH (H_2O)**	**T (°C)**	**Moisture**	**DT_{50} / DT_{90} (d)**	**f.f.**	**DT_{50} (d) 20 °C, pF2**		**Fit (%)**	**Kinetic**	**Reference**
Charentilly, sandy clay loam	6.2	20	40 % MWHC	38 / 126.2	-	33		chi^2: 28.3	SFO (Top Down)	Yoder, 2006a/ Jackson (2011)
Borstel, sand	5.7	20	40 % MWHC	79/ 262	-	79	71.1	chi^2: 1.9	SFO (Top Down)	Yoder, 2006a/ Jackson (2011)
Borstel, loamy sand	6.8	20	40% MWHC	72/ 239	-	64		chi^2: 15	SFO (Top Down)	Yoder, 2007a/ Jackson (2011)
Bruch West, sandy loam	7.9	20	40 % MWHC	4.4/ 14.6	-	4.4	12.2	chi^2: 15	SFO (Top Down)	Yoder, 2006a/ Jackson (2011)
Bruch west, loamy sand	6.1	20	40% MWHC	34/ 122.9	-	34		chi^2: 14.3	SFO (Top Down)	Yoder, 2007a/ Jackson (2011)
Aggregated DT_{50} (n = 3)		**Coefficient of variation (%)**				**77**		No pH-dependency according to the Kendall test		
		Geomean (d)				**30**				
		90th percentile (d)				**63.5**				

Table 5.4-10: Summary of aerobic degradation rates for metabolite 5-OH-XDE-742

Soil type	**pH (H_2O)**	**T (°C)**	**Moisture**	**DT_{50}/ DT_{90} (d)**	**f.f.**	**DT_{50} (d) 20 °C, pF2**		**Fit (%)**	**Kinetic**	**Reference**
LUFA 3A, sandy loam	7.8	20	40 % MWHC	3.4/ 11.29	0.490	2.7	3.4	chi^2: 12.8	SFO-SFO	Yoder, 2006a/ Jackson (2011)
LUFA 3A, sandy clay loam	8.0	20	40% MWHC	5.3/ 17.6	0.353	4.4		chi^2: 5.8	SFO-SFO	Yoder 2007a/ Jackson (2011)
Bruch West, sandy loam	7.9	20	40 % MWHC	2.7/ 8.9	0.278	2.4		chi^2: 14.3	SFO-SFO	Yoder, 2006a/ Jackson (2011)
Aggregated DT_{50} (n=2)		**Geometric mean**				**3.1**				
Formation Fraction from a.s. → 5-OH		**Arithmetic mean**			**0.374**					

Table 5.4-11: Summary of aerobic degradation rates for metabolite 6-Cl-7-OH-XDE-742

Soil type	**pH (H_2O)**	**T (°C)**	**Moisture**	**DT_{50}/ DT_{90} (d)**	**f.f.**	**DT_{50} (d) 20 °C, pF2**	**Fit**	**Kinetic**	**Reference**
Charentilly, sandy clay loam*	6.2	20	40 % MWHC	28/ 92.96	-	24.2	chi^2: 8.9	SFO (Top down)	Yoder, 2006a/ Jackson (2011)
Charentilly, clay loam*	5.6	20	40 % MWHC	53	-	44.7	chi^2: 34.8	SFO (Top down)	
Borstel, loamy sand*	5.7	20	40 % MWHC	53/ 176	-	47.3	chi^2: 16.6	SFO (Top down)	
Bruch West, sandy loam*	7.9	20	40 % MWHC	18/ 60	-	16.2	chi^2: 5.7	SFO (Top down)	
LUFA 3A sandy clay loam**	7.5	20	40% MWHC	9.9/ 33	-	8.2	chi^2: 6.6	SFO	Yoder, 2006b/ Jackson (2011)
Bruch West, loamy sand**	6.2	20	40% MWHC	22/ 73	-	22	chi^2: 15.7	SFO	
Borstel loamy sand**	5.5	20	40% MWHC	16/ 55	-	14	chi^2: 10.4	SFO	
Charentilly loam**	5.6	20	40% MWHC	3.6/ 12	-	3	chi^2: 8.9	SFO	
Aggregated DT_{50} (n = 8)		**Coefficient of variation (%)**				**72**	No pH-dependency according to the Kendall test		
		Geomean (d)				**(16.8)**			
		Geomean (d) of parent applied studies (LoEP), n=4				**30**			
		90th percentile (d)				**45.5**			

* metabolite formed in parent study, **metabolite applied as starting material

Table 5.4-12: Summary of aerobic degradation rates for metabolite Pyridine sulfonamide

Soil type	pH (H_2O)	T (°C)	Moisture	DT_{50} (d)	DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	Fit	Kinetic	Reference
Bruch west, loamy sand*	6.8	20	40% MWHC	93.4	310.4	(93.4)	r^2: 1.0	Top Down/ SFO	Yoder (2007a)
Charentilly, loam*	6.2	20	40% MWHC	183	607	(154)	r^2: 0.524	Top Down/ SFO	
Bruch West, sandy loam**	5.4	20	40% MWHC	143	475	143	chi^2: 2.2%	SFO	Wendelburg & Stephon (2008)
LUFA 3a, clay loam**	7.5	20	40% MWHC	66	220	51	chi^2: 5.3%	SFO	
Charentilly, clay loam**	5.4	20	40% MWHC	130	431	109	chi^2: 5.1%	SFO	
Borstel, loamy sand**	5.5	20	40% MWHC	60	199	57	chi^2: 3.2%	SFO	
Aggregated DT_{50} (n = 5)		**Coefficient of variation (%)**				**46**	No pH-dependency according to the Kendall test		
		Geomean (d)				**(93.1)**			
		Geomean (d) of metabolite applied studies (LoEP), n=4				**82.0**			
		90th percentile (d)				**149.6**			

* metabolite formed in parent study, **metabolite applied as starting material

Table 5.4-13: Summary of aerobic degradation rates for metabolite PSA (Sulfonic acid)

Soil type	**pH (H_2O)**	**T (°C)**	**Moisture**	**DT_{50}/ DT_{90} (d)**	**f.f.**	**DT_{50} (d) 20 °C pF2/10kPa**	**Fit**	**Kinetic**	**Reference**
Charentilly, sandy clay loam	6.2	20	40 %	40.7	-	(35.5)*	0.981	SFO	Yoder (2006a)
Aggregated DT_{50}		**default**				**300**	EU agreed endpoint for PECgw		

*based on only 3 data points, insufficient to be reliable. (<10% AR, reached max.5.9%AR in this 1 soil)

Table 5.4-14: Summary of aerobic degradation rates for metabolite 5,7-diOH-XDE-742

Soil type	pH (H_2O)	T (°C)	Moisture	DT_{50} (d)	DT_{90} (d	DT_{50} (d) 20 °C pF2/10kPa	Fit	Kinetic	Reference
Borstel, loamy sand	6.8	20	40% MWHC	0.19	15.3	-	chi^2: 3.6%	FOMC α: 0.382 β: 0.037	Rutherford, Meitel (2006)/ Jackson (2011)
				4.6	-	4.5		SFO (FOMC DT_{90}/ 3.32)	
Limburgerhof, loamy sand	7.1	20	40% MWHC	0.37	8.0	-	chi^2: 2.5%	FOMC α: 0.584 β: 0.163	
				2.47	-	2.4		SFO (FOMC DT_{90}/ 3.32)	
Charentilly, loam	6.1	20	40% MWHC	0.10	8.9	-	chi^2: 5.9%	FOMC α: 0.371 β: 0.018	
				2.68	-	2.7		SFO (FOMC DT_{90}/ 3.32)	
Speyer LUFA 3A, sandy clay loam	7.9	20	40% MWHC	0.14	2.9	-	chi^2: 6.2%	FOMC α: 0.605 β: 0.067	
				0.87	-	0.9		SFO (FOMC DT_{90}/ 3.32)	
Aggregated DT_{50} (n = 4)		**Coefficient of variation (%)**				**56**	No pH-dependency according to the Kendall test		
		Geomean (d)				**2.3**			
		90th percentile (d)				**4.0**			

5.4.1.2 Field studies

Pinoxaden

The field dissipation rates of Pinoxaden und its metabolites M2 (NOA407854) and M3 (NOA447204) were evaluated during EU assessment. No additional studies have been performed. At some locations field dissipation studies are fulfilling ctgb criteria, so that DT_{50} values can be used for PEC_{GW} modeling. The respective DT_{50} values for metabolite M2 (NOA407854) are summarized in Table 5.4-15. In the PRAPeR Meeting 101 it was concluded that the field data cannot be used in FOCUS modelling for the parent and metabolite M3 (NOA447204).

Table 5.4-15: Field degradation studies of metabolite M2 (NOA407854) fulfilling ctgb criteria (applicable for PEC_{GW})

Soil / location	pH (KCl)	Depth (cm)	DT_{50} (d)	DT_{90} (d)	DT_{50} (d) 20 °C, pF2	Fit χ^2	Method of calculation	Reference
spring application								
Rignano Scalo, Italy, silt loam	7.02	0-30	1.74	5.77	0.85	11.1	SFO	Tribolet, 2003a
Rignano Scalo, Italy, silt loam	7.10	0-30	2.24	7.43	2.04	5.41	SFO	Tribolet, 2003b
Bagnarola di Budrio, Italy, silty clay loam	7.29	0-30	7.30	24.20	14.8	10.5	SFO	Tribolet, 2003d
Tamarite de litera, Spain, silt loam	7.30	0-30	3.44	11.40	2.84	15.5	SFO	Tribolet, 2003e
Tamarite de litera, Spain, loam	7.54	0-30	1.43	4.74	0.85	6.71	SFO	Tribolet, 2003f
Alcala de Guadaria, Spain, loamy sand	7.59	0-30	8.22	27.30	7.24	9.78	SFO	Tribolet, 2003g
Rohlstorf, Germany, clay loam	7.00	0-30	2.43	8.06	2.37	2.21	SFO	Stolze, 2003a substudy 4
autumn application								
Rohlstorf, Germany, clay loam	7.00	0-30	-	-	0.99	13.0	SFO	Stolze, 2003a substudy 2
Stein, Switzerland, clay loam	7.18	0-30	1.60	5.33	1.30	0.95	SFO	Sandmeier, 2001
Coefficient of variation (%)					125			
Geometric Mean (d)					**2.23**			
90th percentile (d)					8.8			

The DT_{50} values of Pinoxaden do not show any pH dependency.

Pyroxsulam

No field studies submitted, none required.

5.4.2 Adsorption/desorption

Pinoxaden

No new studies have been submitted regarding adsorption/desorption in soil of Pinoxaden. The exposure modeling is based on the EU K_{Foc} values as summarized in Table 5.4-16. However, new studies (Robinson, 2012c+d, Völkel, 2012c+d) on the adsorption/desorption in soil of the Pinoxaden metabolites M11, M52, M54 and M55 has been submitted. A detailed evaluation of these studies is presented in Appendix 2.

Table 5.4-16: K_F, K_{Foc} and 1/n (Freundlich exponent) values for Pinoxaden

Soil Type	**OC (%)**	**pH (Ca Cl_2)**	**K_F (mL g^{-1})**	**K_{Foc} (mL g^{-1})**	**1/n (-)**	**Reference**
Borstel (Germany)	1.0	5.1	1.73	172.7	0.990	Adam, 2002 (EFSA Journal 2013;11(8): 3269)
Marsillargues (France)	1.4	7.3	4.4	323.4	1.025	
Gartenacker (CH)	2.4	7.2	2.9	121.2	1.029	
18 Acres (UK)	2.5	5.8	4.6	179.7	1.054	
Plaza (USA)	1.2	7.0	4.903	403	1.081	Spare, 2003a (EFSA Journal 2013;11(8): 3269)
Northwood (USA)	3.0	6.4	13.409	453	0.889	
Ephrata (USA)	0.35	6.7	1.041	299	1.019	
Minto (Canada)	3.2	7.5	10.954	337	0.969	
Larned (USA)	1.0	5.6	8.897	852	0.938	
Arithmetic mean (n=9)				352	0.999	
Median (n=9)				**323**	**1.03**	

The K_{Foc}/K_F values of Pinoxaden do not show any pH dependency.

Table 5.4-17: K_F, K_{Foc} and 1/n (Freundlich exponent) values for metabolite M2 (NOA407854)

Soil Type	**OC (%)**	**pH (Ca Cl_2)**	**K_F (mL g^{-1})**	**K_{Foc} (mL g^{-1})**	**1/n (-)**	**Reference (EFSA Journal 2013; 11(8):3269)**
Birkenheide (Germany)	0.9	6.0	0.4669	51.9	0.9717	Hein, 2003a
Plaza (USA)	1.2	7.7	0.06	5.2	1.019	Spare, 2002
Northwood (USA)	3.0	6.8	0.18	6.0	0.976	
Ephrata (USA)	0.3	7.0	0.098	23	1.153	
Minto (Canada)	3.2	7.8	0.14	4.2	0.988	
Larned (USA)	1.0	6.4	0.28	27	0.975	
18 Acres (UK)	2.9	5.9	0.4908	16.9	0.9022	Hein, 2003b
Wisborough Green (UK)	2.91	4.8	0.3233	11.1	0.9886	
Maine (USA)	2.6	5.0	0.1431	5.5	0.9642	
Wisborough Green (UK)	2.53	4.8	0.1	4.0	0.89	Kuet and Dick, 2003
Borstel (Germany)	1.4	4.9	0	0	1	
18 Acres (UK)	2.94	5.9	0.32	11	0.77	
Gartenacker (CH)	2.3	7.1	0	0	1	
Marsillargues (France)	0.58	7.8	0	0	1	
Welver-Borgeln	2.02	6.7	0.1931	9.6	0.9266	Fent, 2004
Pappelacker	1.14	6.7	0	0	1	
Arithmetic mean (n=9)				12	0.978	
Median (n=9)			**0.18**	**6**	**1**	

Table 5.4-18: K_F, K_{Foc} and 1/n (Freundlich exponent) values for metabolite M3 (NOA447204)

Soil Type	**OC (%)**	**pH ($CaCl_2$)**	**K_F (mL g^{-1})**	**K_{Foc} (mL g^{-1})**	**1/n (-)**	**Reference (EFSA Journal 2013; 11(8):3269)**
Borstel (Germany)	1.0	5.1	0.38	37.8	1.046	Adam, 2003
Marsillargues (France)	1.4	7.9	0.59	43.5	1.070	
Gartenacker (CH)	2.4	7.2	0.62	26.2	1.028	
Plaza (USA)	1.2	7.0	0.280	23	0.904	Spare, 2003b
Northwood (USA)	3.0	6.4	0.764	26	0.914	
Ephrata (USA)	0.35	6.7	0.121	35	0.916	
Minto (Canada)	3.2	7.5	0.856	26	0.900	
Larned (USA)	1.0	5.6	0.500	48	0.915	
Arithmetic mean (n=8)				33	0.962	
Median (n=8)				**30.6**	**0.916**	

Table 5.4-19: K_F, K_{Foc} and 1/n (Freundlich exponent) values for metabolite M11 (SYN504574)

Soil Type	**OC (%)**	**pH (H_2O)**	**K_F (mL g^{-1})**	**K_{Foc} (mL g^{-1})**	**1/n (-)**	**Reference**
Gartenacker, silt loam	1.71	7.52	0.206	12.0	0.97	Robinson, 2012c
18 Acres, sandy clay loam	3.09	6.35	0.351	11.4	0.98	
Marsillargues, silty clay loam	0.83	8.08	0.117	14.1	0.99	
Arithmetic mean (n=3)				12.5	0.98	

Table 5.4-20: K_F, K_{Foc} and 1/n (Freundlich exponent) values for metabolite M52 (SYN546105)

Soil Type	OC (%)	pH (H_2O)	K_F (mL g^{-1})	K_{Foc} (mL g^{-1})	1/n (-)	Reference
Gartenacker, silt loam	1.96	7.46	1.060	54.1	0.97	Völkel, 2012c
18 Acres, sandy clay loam	2.88	6.95	2.360	81.9	0.96	
Marsillargues, silty clay loam	1.05	7.95	2.836	270.1	1.00	
Arithmetic mean (n=3)				135.4	0.977	

Table 5.4-21: K_F, K_{Foc} and 1/n (Freundlich exponent) values for metabolite M54 (SYN546106)

Soil Type	OC (%)	pH (H_2O)	K_F (mL g^{-1})	K_{Foc} (mL g^{-1})	1/n (-)	Reference
Gartenacker, silt loam	1.96	7.46	0.267	13.6	0.93	Völkel, 2012d
18 Acres, sandy clay loam	2.88	6.95	0.321	11.1	1.03	
Marsillargues, silty clay loam	1.05	7.95	0.310	29.5	1.00	
Arithmetic mean (n=3)				18.1	0.987	

Table 5.4-22: K_F, K_{Foc} and 1/n (Freundlich exponent) values for metabolite M55 (SYN546107)

Soil Type	OC (%)	pH (H_2O)	K_F (mL g^{-1})	K_{Foc} (mL g^{-1})	1/n (-)	Reference
Gartenacker, silt loam	1.71	7.52	0.195	11.4	0.98	Robinson, 2012d
18 Acres, sandy clay loam	3.09	6.35	0.153	5.0	0.96	
Marsillargues, silty clay loam	0.83	8.08	0.143	17.3	1.05	
Arithmetic mean (n=3)				11.2	0.997	

Pyroxsulam

No new studies have been submitted regarding adsorption/desorption in soil of Pyroxsulam and its soil metabolites. The exposure modeling of Pyroxsulam is based on the EU K_{Foc} values as summarized in Table 5.4-23.

Table 5.4-23: K_f, K_{foc} and 1/n (Freundlich exponent) values for Pyroxsulam

Soil/ Soil Type	**OC (%)**	**pH (-)**	**K_f (mL g^{-1})**	**K_{foc} (mL g^{-1})**	**1/n (-)**	**Reference**
M641, Charentilly, France, Silty loam	0.9	6.2	0.48	53.3	1.0	Smith J.K. (2004)
M642, Baden-Würtemberg, Sandy loam	2.5	7.8	0.25	10.0	0.95	
M644, LUFA 5 M, Rheinland Pfalz, Loamy Sand	0.8	7.7	0.19	23.8	0.94	
M645, Lincolnshire, GB, Loamy Sand	1.3	7.8	0.33	25.4	1.25	
M646, Derbyshire, GB, Loamy Sand	2.7	5.9	1.03	38.1	0.93	
M649, Herts, GB, Sandy Clay Loam	3.8	7.6	0.27	7.1	0.98	
M650, Essex GB, Silty Loamy Sand	3.7	5.4	1.55	41.9	0.96	
M660, Schifferstadt, Speyerer Wald, Loamy Sand	1.0	6.3	0.24	24.0	0.90	
M661, Borstel, Silty Sand	1.3	5.7	0.69	53.1	1.03	
M662, Bruch West, Loamy Sand	2.5	7.9	0.16	6.4	0.93	
Arithmetic mean				**28.3**	**0.99**	
A pH dependency was also assumed for EU approval. Proposed end points for modelling as suggested for EU approval: **<pH 7: K_{foc}: 42, 1/n: 0.96;** **>pH 7: K_{foc}: 15, 1/n: 1.01**						

The K_{Foc}/K_F values of Pyroxsulam do show pH dependency that is summarized in Table 5.4-24.

Table 5.4-24: pH-dependency of K_{Foc} values of Pyroxsulam

pH dependency (K_{Foc})	Yes Statistical evaluation according to Kendall test: Kendall-τ: -0.539 p-value: 0.039 (< significance level of 0.05)
pH dependency (K_F)	Yes Statistical evaluation according to Kendall test: Kendall-τ: -0.629 p-value: 0.015 (< significance level of 0.05)

Table 5.4-25: K_f, K_{foc} and 1/n (Freundlich exponent) values for metabolite 7-OH-XDE-742

Soil/ Soil Type	OC (%)	pH (-)	K_d	K_{oc}	1/n (-)	Reference
Charentilly, clay loam	1.0	6.3	0.877	88	-	Smith-Drake J.K. (2006)
LUFA 3A, sandy loam	2.5	7.8	0.823	33	-	
Borstel, silty sand	1.3	5.7	1.408	108	-	
Bruch West, loamy sand	2.5	7.9	0.502	20	-	
Arithmetic mean				**62.3**	**1.0 (default)**	
For EU approval a pH dependency was suggested. Proposed end points for modelling as suggested for EU approval: **< pH 7: Koc= 98, 1/n: 1.0;** **> pH 7: Koc =27, 1/n: 1.0**						

Table 5.4-26: K_f, K_{foc} and 1/n (Freundlich exponent) values for metabolite 5-OH-XDE-742

Soil/ Soil Type	OC (%)	pH (-)	K_d	K_{oc}	1/n (-)	Reference
M630, Charentilly, clay loam	1.0	6.3	0.156	16	-	Smith-Drake J.K. (2006)
M642, Speyer LUFA 3A, Sandy Loam	2.5	7.8	0.073	3	-	
M661, Borstel, Silty Sand	1.3	5.7	0.322	22	-	
M662, Bruch West, Loamy Sand	2.5	7.9	0.053	2	-	
Arithmetic mean				**11**	**1.0 (default)**	
For EU approval a pH dependency was suggested. Proposed end points for modelling as suggested for EU approval: **< pH 7: Koc= 19, 1/n: 1.0;** **> pH 7: Koc =2.5, 1/n: 1.0**						

Table 5.4-27: K_f, K_{foc} and 1/n (Freundlich exponent) values for metabolite 6-Cl-7-OH-XDE-742

Soil/ Soil Type	**OC (%)**	**pH (-)**	**K_d**	**K_{oc}**	**1/n (-)**	**Reference**
M630, Charentilly, clay loam	1.0	6.3	0.473	47	-	Smith-Drake J.K. (2006)
M642, Speyer LUFA 3A, Sandy Loam	2.5	7.8	0.404	16	-	
M661, Borstel, Silty Sand	1.3	5.7	1.057	81	-	
M662, Bruch West, Loamy Sand	2.5	7.9	0.350	14	-	
Arithmetic mean				**39.5**	**1.0 (default)**	
For EU approval a pH dependency was suggested. Proposed end points for modelling as suggested for EU approval: **< pH 7: Koc= 64, 1/n: 1.0;** **> pH 7: Koc =15, 1/n: 1.0**						

Table 5.4-28: K_f, K_{foc} and 1/n (Freundlich exponent) values for metabolite 5,7-di-OH-XDE-742

Soil/ Soil Type	**OC (%)**	**pH (-)**	**K_d**	**K_{oc}**	**1/n (-)**	**Reference**
M630, Charentilly, clay loam	1.0	6.3	5.572	557	-	Smith-Drake J.K. (2006)
M642, Speyer LUFA 3A, Sandy Loam	2.5	7.8	1.333	53	-	
M661, Borstel, Silty Sand	1.3	5.7	5.923	456	-	
M662, Bruch West, Loamy Sand	2.5	7.9	1.396	56	-	
Arithmetic mean				**280.5**	**1.0 (default)**	
For EU approval a pH dependency was suggested. Proposed end points for modelling as suggested for EU approval: **< pH 7: Koc= 507, 1/n: 1.0;** **> pH 7: Koc =55, 1/n: 1.0**						

Table 5.4-29: K_f, K_{foc} and 1/n (Freundlich exponent) values for metabolite Pyridine Sulfonamide

Soil/ Soil Type	OC (%)	pH (-)	K_f	K_{foc}	1/n (-)	Reference
M726, Bruch West, Sandy Loam	0.6	5.4	0.97	161.7	0.93	Yoder (2007)
M727, LUFA 3A, Clay Loam	1.9	7.5	0.45	23.7	0.85	
M728, Charentilly, Clay Loam	1.0	5.4	0.41	41.0	0.80	
M729, Borstel, Loamy Sand	1.1	5.5	0.41	37.3	0.80	
Arithmetic mean				**65.9**	**0.845**	
No pH dependency was suggested for EU approval.						

Table 5.4-30: K_f, K_{foc} and 1/n (Freundlich exponent) values for metabolite XDE-742 Pyridine Sulfonic Acid (PSA)

Soil/ Soil Type	OC (%)	pH (-)	K_d	K_{oc}	1/n (-)	Reference
M630, Charentilly, clay loam	1.0	6.3	<LOD	<LOD	-	Smith-Drake J.K. (2006)
M642, Speyer LUFA 3A, Sandy Loam	2.5	7.8	<LOD	<LOD	-	
M661, Borstel, Silty Sand	1.3	5.7	<LOD	<LOD	-	
M662, Bruch West, Loamy Sand	2.5	7.9	<LOD	<LOD	-	
Default				**1.0**	**1.0**	

5.4.3 Rate of degradation in water and sediment

Pinoxaden

No new water/sediment study has been submitted. The exposure modeling is based on the results of the water/sediment study of Pinoxaden (Adam, 2003) reviewed in the DAR. The DT_{50} values were recalculated by Hardy and Patterson (2010) reviewed in Addendum 2 (01/2012).

The DT_{50} values of the water/sediment study are summarized in Table 5.4-31.

Table 5.4-31: Degradation in water/sediment of Pinoxaden and its metabolites M2 and M3

Water/sediment system	**$DegT_{50}$ / $DegT_{90}$ whole system**	**Method of calculation, Fit χ^2**	**$DissT_{50}$/ $DissT_{90}$ water**	**Method of calculation, Fit χ^2**	**$DissT_{50}$/ $DissT_{90}$ sed.**	**Method of calculation, Fit χ^2**	**Reference**
River	0.28/0.95	SFO, 3.7	0.26/0.87	SFO, 3.4			EFSA Journal 2013;11(8): 3269
Pond	0.28/0.93	SFO, 1.7	0.28/0.92	SFO, 1.7			
Geometric mean DT50 (n=2)	**0.28**						
Metabolite M2 (NOA407854)							
River	193/640	SFO, 7.7	317/>1000	SFO, 4.4			EFSA Journal 2013;11(8): 3269
Pond	515/>1000	SFO, 2.5	117/390	SFO, 9.5			
Geometric mean DT50 (n=2)	**315**						
Metabolite M3 (NOA447204)							
River	37.7/125	SFO, 0.77	41.8/139	SFO, 0.91			EFSA Journal 2013;11(8): 3269
Pond	34.1/113	SFO, 8.6	31.8/106	SFO, 6.3			
Geometric mean DT50 (n=2)	**35.9**						

Pyroxsulam

No new water/sediment study has been submitted. The exposure modeling is based on the results of the water/sediment study of Pyroxsulam (Yoder, 2006) reviewed in the DAR.

The DT_{50} values of the water/sediment study are summarized in Table 5.4-32.

Table 5.4-32: Degradation in water/sediment of Pyroxsulam and its metabolites 7-OH-XDE-742 and ATSA

Water/sediment system	**$DegT_{50}$/ $DegT_{90}$ whole system**	**Method of calculation, Fit**	**$DissT_{50}$/ $DissT_{90}$ water**	**Method of calculation, Fit**	**$DissT_{50}$/ $DissT_{90}$ sed.**	**Method of calculation, Fit**	**Reference**
River Roding, UK	23.6 / 78.3	SFO, chi^2: 2.2%	20.6/ 68.3	SFO, chi^2: 1.8%	14.4/ 47.8**	n.a. **	Yoder R.N. et al (2006)
Haut Languedoc, France	11.9 / 39.5	SFO; chi^2: 13.5%	10.6/ 35.2	SFO, chi^2: 14.7%	20.6/ 68.5***	SFO, chi^2: 42%	
n.a. = not applicable **two data points only *** only four data points							
Geometric mean DT_{50} (n=2)	**16.8**						
Metabolite 7-OH-XDE-742							
River Roding, UK	15.8 / 52.4	SFO, top down, chi^2: 6.2%	17.9/ 59.3	SFO, top down, chi^2: 8.9%	9.7	SFO, top down, chi^2: 1.1%	Yoder R.N. et al (2006)
Haut Languedoc, France	42.4 / 140.9	SFO, top down, r^2 0.913	50.5/ 167.9	SFO, top down, chi^2: 8.2%	n.d.	n.d.	
n.d. = not determinable							
Geometric mean DT_{50} (n=2)	**25.9**						
Metabolite XDE-742-ATSA							
River Roding, UK	34.7 / 115.1**	n.a.**	n.d.	n.d.	n.d.	n.d.	Yoder R.N. et al (2006)
Haut Languedoc, France	71.4 / 237.2**	n.a.**	n.d.	n.d.	n.d.	n.d.	
n.a. = not applicable, two data points only n.d. = not determinable **two data points only							
Geometric mean DT_{50} (n=2)	**49.8**						

5.5 Estimation of concentrations in soil (PEC_{soil}) (KIIIA1 9.4)

PEC_{soil} calculations are based on the recommendations of the FOCUS workgroup on degradation kinetics. A soil bulk density of 1.5 g/cm^3, a soil depth of 5 cm and a tillage depth of 20 cm (arable crop)/5 cm (permanent crops) were assumed. The PEC_{soil} calculations were performed with ESCAPE 2.0 based on the input parameters as presented in tables below.

Table 5.5-1: Application related input parameters for PEC_{Soil} calculations

Plant protection product:	AVOXA
Use No.:	A
Crop:	Winter cereals
Application rate:	Pinoxaden: 60 g a.s./ha Pyroxsulam: 15 g a.s./ha AVOXA: 1895 g/ha*
Number of applications/ interval:	1
Crop interception:	25 %

*Based on the maximum application of 1800 mL AVOXA/ha with a specific density of 1.053 g/mL.

Table 5.5-2: Substance related input parameters for PEC_{soil} calculation

Active substance	DT_{50}	Molecular weight (g/mol)	Molar correction factor (-)	Maximum occurrence in soil (%)
Pinoxaden	1.05 d (SFO, Maximum, laboratory studies, see Table 5.4-1)	400.5	-	-
Metabolite M2 (NOA407854)	57.8 d (SFO, Maximum, laboratory studies, see Table 5.4-2)	316.4	0.790	90%
Metabolite M3 (NOA447204)	387 d (SFO, Maximum, laboratory studies, acidic soils, see Table 5.4-3)	332.4	0.830	31%
Pyroxsulam	16.7 d (SFO, Maximum, laboratory studies, see Table 5.4-8)	434.36	-	-
Metabolite 7-OH	71.1 d (SFO, Maximum, laboratory studies, see Table 5.4-9)	420.33	0.968	76.5% (anaerobic soil study)
Metabolite 5-OH	3.4 d (SFO, Maximum, laboratory studie, see Table 5.4-10)	420.33	0.968	24.1%
Metabolite 6-Cl-7-OH	47.3 d (SFO, Maximum, laboratory studies, see Table 5.4-11)	454.77	1.047	26.2%
Metabolite 5,7-di-OH	4.5 d (SFO, Maximum, laboratory studies, see Table 5.4-14)	406.30	0.935	27.3% (anaerobic soil study)
Metabolite Pyridine Sulfonamide	154 d (SFO, 1 value, laboratory studies, see Table 5.4-12)	256.20	0.590	13.2%
Metabolite PSA	35.5 d (SFO, Maximum, laboratory studies, see Table 5.4-13)	257.19	0.592	5.9%

Due to the fast degradation of Pinoxaden in soil (DT_{90} < 365 d, laboratory data) the accumulation potential of Pinoxaden does not need to be considered.

Due to the fast degradation of Pyroxsulam and its soil metabolites (except Pyridine Sulfonamide) in soil (DT_{90} <365 d, SFO, laboratory data), their accumulation potential does not need to be considered. However, due to the slow soil degradation of soil metabolite Pyridine sulfonamide (DT_{90} > 365 d, SFO, laboratory data), the accumulation potential does need to be considered. Thus, for this metabolite an accumulated soil concentration (PEC_{accu}) is used for risk assessment that comprises background concentration in soil (PEC_{bkgd}) considering a tillage depth of 20 cm (arable crop) or 5 cm (permanent crops) and the maximum annual soil concentration PEC_{act} for a soil depth of 5 cm.

Additional PECact values were calculated for the product AVOXA.

The PEC_{soil} values of Pinoxaden and Pyroxsulam, their soil metabolites and the product AVOXA are presented in Table 5.5-3.

Table 5.5-3: Results of PEC_{soil} calculation for application of AVOXA in winter cereals (soil bulk density 1.5 g/cm^{-3}, soil depth 5 cm) according to use No. A

active substance/ preparation	soil relevant application rate (g/ha)	PEC_{act} (mg/kg)	PEC_{twa} 21 d (mg/kg)	tillage depth (cm)	PEC_{bkgd} (mg/kg)	PEC_{accu} = PEC_{act} + PEC_{bkgd} (mg/kg)
Pinoxaden	45.0	0.0599	-	-	-	-
Metabolite M2 (NOA407854)	32.0	0.0427	-	-	-	-
Metabolite M3 (NOA447204)	11.6	0.0155	-	-	-	-
Pyroxsulam	11.25	0.0150	-	-	-	-
Metabolite 7-OH	8.3	0.0111	-	-	-	-
Metabolite 5-OH	2.6	0.0035	-	-	-	-
Metabolite 6-Cl-7-OH	3.1	0.0041	-	-	-	-
Metabolite 5,7-di-OH	2.9	0.0039	-	-	-	-
Metabolite Pyridine Sulfonamide	0.9	0.0012	-	20	0.0001	0.0013
Metabolite PSA	0.4	0.0005	-	-	-	-
AVOXA	1421.25	1.8950	-	-	-	-

5.6 Estimation of concentrations in surface water and sediment (PECsw/PECsed) (KIIIA1 9.7)

PEC_{sw} and PEC_{sed} calculations are provided according to the recommendations of the FOCUS working group on surface water scenarios in a stepwise approach considering the pathways drainage and runoff.

The relevant input parameters used for PEC calculation are summarized in the tables below.

Table 5.6-1: Input parameters for Pinoxaden and its metabolites M2 and M3 for $PEC_{sw/sed}$ calculations (STEP 1 + 2)

Parameter	Endpoint used for $PEC_{sw/sed}$ calculation	Values in accordance to EU endpoint in LoEP	Remarks
Active substance	**Pinoxaden**		
Molecular weight (g/mol)	400.5	yes	
Water solubility (mg/L)	200	yes	
K_{Foc} (mL g^{-1})	323	yes	Median
DT_{50},soil (d)	0.34	yes	Geomean (Laboratory data)
DT_{50},water (d)	0.28	yes	Geomean of whole system
DT_{50},sed (d)	1000	yes	Default value
DT_{50},whole system (d)	0.28	yes	Geomean of whole system
Metabolite	**M2 (NOA 407854)**		
Molecular weight (g/mol)	316.4	yes	
Water solubility (mg/L)	380000	yes	
K_{Foc} (mL g^{-1})	6	yes	Median
DT_{50},soil (d)	2.23	yes	Geomean (field data)
DT_{50},water (d)	315	yes	Geomean of whole system
DT_{50},sed (d)	1000	yes	Default value
DT_{50},whole system (d)	315	yes	Geomean of whole system
Max. occurrence water/sediment [%]	100	yes	Default value
Max. occurrence soil [%]	100	yes	Default value
Metabolite	**M3 (NOA 447204)**		
Molecular weight (g/mol)	332.4	yes	
Water solubility (mg/L)	370	yes	
K_{Foc} (mL g^{-1})	30.6	yes	Median
DT_{50},soil (d)	208	yes	Geomean (Laboratory data, acidic soils)
DT_{50},water (d)	35.9	yes	Geomean of whole system
DT_{50},sed (d)	1000	yes	Default value
DT_{50},whole system (d)	35.9	yes	Geomean of whole system
Max. occurrence water/sediment [%]	100	yes	Default value
Max. occurrence soil [%]	100	yes	Default value

Table 5.6-2: Input parameters for Pyroxsulam for $PEC_{sw/sed}$ calculations according to the EU assessment (EFSA Journal 2013; 11(4): 3182)

Parameter	Endpoint used for $PEC_{sw/sed}$ calculation	Values in accordance to EU endpoint in LoEP	Remarks
Active substance	Pyroxsulam		
Molecular weight (g/mol)	434	yes	
Saturated vapour pressure (Pa)	1×10^{-7}	yes	
Water solubility (mg/L)	3200	yes	
Diffusion coefficient in water (m^2/d)	not required for Step 1+2/ 4.3×10^{-5}	yes	default
Diffusion coefficient in air (m^2/d)	not required for Step 1+2/ 0.43	yes	default
K_{Foc} (mL g^{-1})	15	yes	Average from soils with pH > 7, n = 5, see Table 5.4-23
Freundlich Exponent 1/n	not required for Step 1+2/ 1.01	yes	Average from soils with pH > 7, n = 5, see Table 5.4-23
Plant Uptake	not required for Step 1+2/ 0.5	yes	FOCUS default for systemic compounds
Wash-Off factor from Crop	not required for Step 1+2/ 0.05 mm^{-1} (MACRO) 0.50 cm^{-1}(PRZM)	yes	default
DT_{50},soil (d)	3.3	yes	Geomean (SFO, pF2, 20°C) Laboratory data (see Table 5.4-8)
DT_{50},water (d)	24	yes	Longest whole system value, n = 2, see Table 5.4-32
DT_{50},sed (d)	1000	yes	default value
DT_{50},whole system (d)	24	yes	Longest whole system value, n = 2, see Table 5.4-32

Table 5.6-3: FOCUS Step 1 and Step 2 input parameters for the metabolites of Pyroxsulam for $PEC_{sw/sed}$ calculations according to the EU assessment (EFSA Journal 2013; 11(4): 3182)

Metabolite:	5-OH	7-OH	6-Cl-7-OH	Sulfon-amide	5,7-diOH	ATSA
Molecular weight:	420	420	455	256	406	338
Koc (L/kg):	2.5	27	15	66	55	1
DT50 soil (d):	3.1	30	30	82	2.3	1000
DT50 water (d):	1000	42	1000	1000	1000	71
DT50 sediment (d):	1000	1000	1000	1000	1000	1000
Max % in soil:	24	14	26	13	27*	0.1
Max % in water/sediment:	0.1	58	0.1	0.1	0.1	13

* anaerobic soil study

Table 5.6-4: Input parameters related to application for $PEC_{sw/sed}$ calculations

Plant protection product	AVOXA
Use No.	A (worst case)
Crop	Winter cereals
Application rate (g as/ha)	Pinoxaden: 60 g a.s./ha Pyroxsulam: 15 g a.s./ha
Number of applications/interval	1
Season of application (step 2)	autumn (Oct-Feb), spring (Mar-May)
Crop interception (step 2)	minimal crop cover (25%)
Application timing (step 3)	15.02. (spring application)
Application method (step 3)	ground spray, CAM 2

Results of FOCUS SW calculations for the worst-case application scenario of AVOXA are summarized in the tables below.

Table 5.6-5: Maximum FOCUS Step 1 and Step 2 PEC_{sw} and PEC_{sed} of Pinoxaden for the application of AVOXA in winter cereals according to use No. A

Pinoxaden	**FOCUS Step 1**	**PECsw (µg/L)**	**PECsed (µg/kg)**
		14.531	45.154
	FOCUS Step 2	**PECsw (µg/L)**	**PECsed (µg/kg)**
	North Europe (Oct-Feb)	0.552	0.830
	North Europe (Mar-May)	0.552	0.830

Table 5.6-6: Maximum FOCUS Step 1 and Step 2 PEC_{sw} and PEC_{sed} of Pinoxaden metabolite M2 (NOA 407854) for the application in winter cereals

Metabolite M2 (NOA 407854)	**FOCUS Step 1**	**PECsw (µg/L)**	**PECsed (µg/kg)**
		16.111	0.964
	FOCUS Step 2	**PECsw (µg/L)**	**PECsed (µg/kg)**
	North Europe (Oct-Feb)	2.125	0.127
	North Europe (Mar-May)	1.108	0.066

Table 5.6-7: Maximum FOCUS Step 1 and Step 2 PEC_{sw} and PEC_{sed} of Pinoxaden metabolite M3 (NOA 447204) for the application in winter cereals

Metabolite M3 (NOA 447204)	**FOCUS Step 1**	**PECsw (µg/L)**	**PECsed (µg/kg)**
		16.407	4.924
	FOCUS Step 2	**PECsw (µg/L)**	**PECsed (µg/kg)**
	North Europe (Oct-Feb)	6.316	1.930
	North Europe (Mar-May)	2.775	0.847

Table 5.6-8: Maximum FOCUS Step 1 and Step 2 PEC_{sw} and PEC_{sed} of Pyroxsulam for the application of AVOXA in winter cereals according to use No. A

Pyroxsulam	**FOCUS Step 1**	**PECsw (µg/L)**	**PECsed (µg/kg)**
		5.04	0.74
	FOCUS Step 2	**PECsw (µg/L)**	**PECsed (µg/kg)**
	North Europe (Oct-Feb)	1.18	0.18
	North Europe (Mar-May)	0.54	0.08

Table 5.6-9: Global maximum FOCUS Step 3 PEC_{sw} values for Pyroxsulam for the application of AVOXA in winter cereals at 15 g/ha – spring application (15.02.)

FOCUS STEP 3 Scenario	**Water Body**	**PEC_{sw} global max (µg/L)**
D1	ditch	2.007
D1	stream	1.254
D2	ditch	1.836
D2	stream	1.231
D3	ditch	0.095
D4	pond	0.003
D4	stream	0.074
D5	pond	0.003
D5	stream	0.061
D6	ditch	0.098
R1	pond	0.004
R1	stream	0.189
R3	stream	0.204
R4	stream	0.131

Table 5.6-10: Maximum FOCUS Step 1 and Step 2 PEC_{sw} and PEC_{sed} for metabolites of Pyroxsulam for the application of AVOXA in winter cereals according to EU assessment (single application of 18.75 g/ha), (EFSA Journal 2013; 11(4): 3182)

Metabolite	**PECsw (µg/L)**		**PECsed (µg/kg)**	
	Step 1	**Step 2 North (Oct-Feb)**	**Step 1**	**Step 2 North (Oct-Feb)**
5-OH-XDE-742	1.45	0.22	0.04	0.01
7-OH-XDE-742	0.91	0.37	0.24	0.10
6-Cl-7-OH-XDE-742	1.67	0.57	0.25	0.09
Pyridine Sulfonamide	0.44	0.16	0.29	0.11
5,7-diOH-XDE-742	1.47	0.17	0.81	0.09
ATSA	0.02	0.02	< 0.01	< 0.01

5.7 Risk assessment ground water (KIIIA1 9.6)

5.7.1 Predicted environmental concentration in groundwater (PEC_{GW}) calculation for active substances and metabolites (Tier 1 and 2)

Groundwater contamination by direct leaching of the active substance and its metabolites, degradation or reaction products through soil is generally assessed by groundwater model calculations.

Table 5.7-1: Application related input parameters for PEC_{GW} modelling

Plant protection product	AVOXA
Use No.	A and B
Application rate (g as/ha)	Pinoxaden: A: 59.9 B: 45.0 Pyroxsulam: (A: 15.0) (B: 11.3) 18.75 (worst case, according to EU assessment)
Crop (crop rotation)	winter cereals
Relative application date(s)	d 106 (equivalent to 15.02. Hamburg scenario)
Interception (%)	25 %
Soil effective application rate (g as/ha)	Pinoxaden: A: 45.0 B: 33.75 Pyroxsulam: (A: 11.25) (B: 8.5) 14.06 (worst case, according to EU assessment)
Soil moisture	100 % FC
Q10-factor	2.58
Moisture exponent	0.7
Plant uptake factor	0
Simulation period (years)	26

Pinoxaden

The applicant has submitted new studies on DT_{50} in soil and k_{oc} for the lysimeter metabolites M11, M52, M54 and M55 and a new ground water risk assessment for this metabolites. This calculation is requested as confirmatory data in the context of the relevance assessment for the metabolites and has not been peer reviewed by MSs yet. ZRMS presents this assessment in this report, but will not anticipate the outcome of the peer review. In the opinion of zRMS it is more appropriate to use realistic input data instead of combinations of default worst case parameters as done in the EFSA Journal 2013;11(8):3269.

In the EFSA Journal 2013;11(8):3269 the PECgw is presented where the lysimeter metabolites which were found >0.1 µg/L were modelled as 'MetX' in which three separate runs were performed to simulate low, medium and high formation fraction of these metabolites. In the simulation a combination of worst case parameters were considered. For the authorization of AVOXA the modelling is not appropriate because some input data have changed. The GAP changed from two

applications to a single application, for metabolite M3 the field DT_{50} was used and for Pinoxaden and for all metabolites the plant uptake factor was set to 0.5.

The PEC of Pinoxaden and its metabolites in ground water have been assessed with standard FOCUS scenarios to obtain outputs from the FOCUS PELMO. The FOCUS calculation was performed by zRMS and is based on Ford (2013).

In the EFSA Journal 2013;11(8):3269 a pH dependency of DT_{50} values of metabolite M3 (NOA 447204) was considered in the PEC_{GW} calculation. Therefore, two simulation runs with the relevant FOCUS scenarios and DT_{50} (acidic and neutral/alkaline) were performed by zRMS. In FOCUS PELMO it is not possible to simulate metabolites in a single simulation when the sum of the formation fractions is greater than one. Therefore the metabolites M11, M54 and M55 were modelled in separate simulations.

In Ford (2013) the plant uptake factor for metabolite M3 was set to 0.5. This was not accepted by zRMS and the plant uptake factor for metabolite M3 was set to 0. This assumption is in line with the outcome of the PRAPeR-Meeting 101. The conclusion was that a plant uptake factor of 0 should be used in modelling.

Table 5.7-2: Input parameters related to Pinoxaden for PEC_{GW} modelling

Parameter	Endpoint used for PEC_{GW} calculation	Values in accordance to EU endpoint in LoEP	Remarks/Reference
Molecular weight (g/mol)	400.5	yes	
DT_{50} in soil (d)	0.34	yes	Geometric mean (lab.)
K_{Foc}	323	yes	Median
1/n	1.03	yes	Median

Table 5.7-3: Input parameters related to metabolites of Pinoxaden for PEC_{GW} modelling

Parameter	Endpoint used for PEC_{GW} calculation	Values in accordance to EU endpoint in LoEP	Remarks/Reference
Metabolite	**M2 (NOA 407854)**		
Molecular weight (g/mol)	316.4	yes	
Formation fraction	1.0	yes	from parent
DT_{50} in soil (d)	2.23	yes	Geometric mean (field)
K_{Foc}	6.0	yes	Median
1/n	1.0	yes	Median
Metabolite	**M3 (NOA 447204)**		
Molecular weight (g/mol)	332.4	yes	
Formation fraction	1.0	yes	from M2
DT_{50} in soil (d)	acidic soil: 208 neutral/alkaline soils: 67.4	yes	Geometric mean (lab.)
K_{Foc}	31	yes	Median
1/n	0.92	yes	Median

Metabolite	**M11 (SYN 504574)**		
Molecular weight (g/mol)	362.4	not stated	
Formation fraction	acidic soil: 1.0 neutral/alkaline soils: 0.49	not stated	from M3
DT_{50} in soil (d)	9.7*	not stated	Geometric mean (lab.)
K_{Foc}	12.5	not stated	Arithmetic mean
1/n	0.98	not stated	Arithmetic mean
Metabolite	**M52 (SYN546105)**		
Molecular weight (g/mol)	360.3	not stated	
Formation fraction	1.0**	not stated	from M2
DT_{50} in soil (d)	8.4	not stated	Geometric mean (lab.)
K_{Foc}	135.4	not stated	Arithmetic mean
1/n	0.977	not stated	Arithmetic mean
Metabolite	**M54 (SYN546106)**		
Molecular weight (g/mol)	362.4	not stated	
Formation fraction	acidic soil: 1.0 neutral/alkaline soils: 0.6	not stated	from M3
DT_{50} in soil (d)	7.5	not stated	Geometric mean (lab.)
K_{Foc}	18.1	not stated	Arithmetic mean
1/n	0.987	not stated	Arithmetic mean
Metabolite	**M55 (SYN546107)**		
Molecular weight (g/mol)	376.4	not stated	
Formation fraction	acidic soil: 0.2 neutral/alkaline soils: 0.12	not stated	from M3
DT_{50} in soil (d)	106	not stated	Max (lab.)
K_{Foc}	11.2	not stated	Arithmetic mean
1/n	0.997	not stated	Arithmetic mean
Metabolite	**M56 (SYN546108)*** **		
Molecular weight (g/mol)	360.3	yes	
Formation fraction	0.25	yes	from M3 (default)
DT_{50} in soil (d)	200	yes	default
K_{Foc}	0	yes	default
1/n	1	yes	default

*used by applicant for derivation of formation fractions for M11; zRMS recommends the use of 11.9 d
**used by zRMS because field DT_{50} is considered for M2 instead of ff=0.09 derived by applicant
***For metabolite M56 no additional studies (DT_{50} / K_{FOC} values) were submitted by the applicant because these studies are still on-going. However, in the EFSA Journal 2013;11(8):3269 a groundwater assessment of the lysimeter metabolites was considered with default values and modeled

as 'Met X'. For the authorization of AVOXA the conservative combination of input values for 'Met X' were used by zRMS.

Table 5.7-4: PEC_{GW} at 1 m soil depth for Pinoxaden and its metabolites for the application of AVOXA in winter cereals (use group A)

Crop/ Group/ use No.	Scenario		80th percentile PEC_{GW} at 1 m soil depth (µg L^{-1}) groundwater model: FOCUS PELMO 5.5.3							
	Name	pH-H_2O (1st horizon)	Pinoxaden	Metabolite						
				M2	M3	M11	M52	M54	M55	M56
winter cereals / group A	Châteaudun	8.0	<0.001	<0.001	1.767	0.262	<0.001	0.210	1.375	5.653
	Hamburg	6.4	<0.001	0.016	9.695	0.893	0.026	0.584	1.288	1.895
	Jokioinen	6.2	<0.001	0.009	10.413	1.123	0.020	0.698	1.582	3.485
	Kremsmünster	7.7	<0.001	0.002	2.696	0.367	0.004	0.299	1.039	2.698
	Okehampton	5.8	<0.001	0.016	6.645	0.521	0.015	0.367	0.640	0.975
	Piacenza	7.0	<0.001	0.004	1.995	0.277	0.003	0.228	1.254	3.914
	Porto	4.9	<0.001	0.003	4.606	0.466	0.002	0.315	0.841	1.434
	Sevilla	7.3	<0.001	<0.001	0.252	0.066	<0.001	0.050	0.648	2.905
	Thiva	7.7	<0.001	<0.001	0.454	0.088	<0.001	0.068	1.065	4.673

Scenario pH-value < 7.0: DT_{50}=208 d used for M3, Scenario pH-value ≥ 7.0: DT_{50}=67.4 d used for M3 according to EFSA Journal 2013;11(8):3269

Table 5.7-5: PEC_{GW} at 1 m soil depth for Pinoxaden and its metabolites for the application of AVOXA in winter cereals (use group B)

Crop/ Group/ use No.	Scenario		80th percentile PEC_{GW} at 1 m soil depth (µg L^{-1}) groundwater model: FOCUS PELMO 5.5.3							
	Name	pH-H_2O (1st horizon)	Pinoxaden	Metabolite						
				M2	M3	M11	M52	M54	M55	M56
winter cereals / group B	Châteaudun	8.0	<0.001	<0.001	1.287	0.194	<0.001	0.155	1.028	4.236
	Hamburg	6.4	<0.001	0.012	7.199	0.670	0.019	0.439	0.975	1.434
	Jokioinen	6.2	<0.001	0.007	7.679	0.844	0.015	0.528	1.196	2.638
	Kremsmünster	7.7	<0.001	0.001	1.989	0.273	0.003	0.223	0.781	2.031
	Okehampton	5.8	<0.001	0.012	4.956	0.392	0.012	0.276	0.485	0.739
	Piacenza	7.0	<0.001	0.003	1.481	0.207	0.002	0.170	0.940	2.935
	Porto	4.9	<0.001	0.002	3.395	0.352	0.001	0.238	0.635	1.084
	Sevilla	7.3	<0.001	<0.001	0.180	0.049	<0.001	0.037	0.485	2.176
	Thiva	7.7	<0.001	<0.001	0.328	0.065	<0.001	0.050	0.797	3.502

Scenario pH-value < 7.0: DT_{50}=208 d used for M3, Scenario pH-value ≥ 7.0: DT_{50}=67.4 d used for M3 according to EFSA Journal 2013;11(8):3269

According to the PEC_{GW} modelling with FOCUS PELMO 5.5.3 a groundwater contamination of the active substance Pinoxaden at a concentration of ≥ 0.1 µg/L is not expected for all FOCUS groundwater scenarios.

For the metabolites M2 and M52 a groundwater concentration of ≥ 0.1 µg/L can be excluded in all of the FOCUS groundwater scenarios.

For the metabolites M3, M11, M54, M55 and M56 a groundwater concentration of ≥ 0.1 µg/L cannot be excluded in all of the FOCUS groundwater scenarios.

In addition to the tier 1 PEC_{GW} modelling a higher tier leaching assessment using experimental data from lysimeter studies for the active substance Pinoxaden is performed.

Pyroxsulam

The PEC of Pyroxsulam and its metabolites in ground water have been assessed with standard FOCUS scenarios to obtain outputs from the FOCUS PELMO. The FOCUS calculation was taken from the EU assessment (see EFSA Journal 2013; 11(4): 3182).

Due to pH dependency of K_{Foc} of Pyroxsulam and its metabolites 7-OH, 5-OH, 6-Cl-7-OH and 5,7-di-OH two simulation runs with the relevant FOCUS scenarios were performed by RMS in the EU assessment. According to the EFSA Journal 2013;11(4):3182 all soil metabolites were modelled separately as direct applications to soil after correcting for the maximum percent observed in soil and molecular weight, except for 5-OH (the only metabolite which give reliable formation fractions). A single application of 18.75 g a.s./ha was assumed to be applied to winter cereals and a crop interception of 25% was considered.

Table 5.7-6: Input parameters related to Pyroxsulam for PEC_{GW} modelling

Parameter	Endpoint used for PEC_{GW} calculation	Values in accordance to EU endpoint in LoEP	Remarks/Reference
Molecular weight (g/mol)	434.4	yes	
DT_{50} in soil (d)	3.3	yes	Geometric mean
K_{Foc}	15 (pH >7) 42 (pH <7)	yes	Arithmetic mean
1/n	1.01 (pH >7) 0.96 (pH <7)	yes	Arithmetic mean
Plant uptake factor	0.5	yes	default

Table 5.7-7: Input parameters related to metabolites of Pyroxsulam for PEC_{GW} modelling

Parameter	Endpoint used for PEC_{GW} calculation	Values in accordance to EU endpoint in LoEP	Remarks/Reference
Metabolite	**5-OH-XDE-742**		
Molecular weight (g/mol)	420.3	yes	
Formation fraction	0.374	yes	Arithmetic mean
DT_{50} in soil (d)	3.1	yes	Geometric mean
K_{Foc}	2.5 (pH >7) 19 (pH <7)	yes	Arithmetic mean
1/n	1	yes	default
Plant uptake factor	0	yes	default
Metabolite	**7-OH-XDE-742**		
Molecular weight (g/mol)	420.3	yes	

Formation fraction	-	yes	
DT_{50} in soil (d)	30	yes	Geometric mean
K_{Foc}	27 (pH >7) 98 (pH <7)	yes	Arithmetic mean
1/n	1	yes	default
Plant uptake factor	0	yes	default
Max. % in soil	13.7	yes	From aerobic soil studies
Soil deposition (g a.s./ha)	1.86	yes	Input as direct application to soil.
Metabolite	**6-Cl-7-OH-XDE-742**		
Molecular weight (g/mol)	454.8	yes	
Formation fraction	-	yes	
DT_{50} in soil (d)	30	yes	Geometric mean
K_{Foc}	15 (pH >7) 64 (pH <7)	yes	Arithmetic mean
1/n	1	yes	default
Plant uptake factor	0	yes	default
Max. % in soil	26.2	yes	From aerobic soil studies
Soil deposition (g a.s./ha)	3.86	yes	Input as direct application to soil.
Metabolite	**5,7-diOH-XDE-742**		
Molecular weight (g/mol)	406.3	yes	
Formation fraction	-	yes	
DT_{50} in soil (d)	2.3	yes	Geometric mean
K_{Foc}	55 (pH >7) 507 (pH <7)	yes	Arithmetic mean
1/n	1	yes	default
Plant uptake factor	0	yes	default
Max. % in soil	27.3	yes	From aerobic soil studies
Soil deposition (g a.s./ha)	3.59	yes	Input as direct application to soil.
Metabolite	**Pyridine sulfonamide**		
Molecular weight (g/mol)	256.2	yes	
Formation fraction	-	yes	
DT_{50} in soil (d)	82	yes	Geometric mean from direct application to soil.
K_{Foc}	66	yes	Arithmetic mean
1/n	0.85	yes	Arithmetic mean

Plant uptake factor	0	yes	default
Max. % in soil	13.2	yes	From aerobic soil studies
Soil deposition (g a.s./ha)	1.09	yes	Input as direct application to soil.
Metabolite	**PSA**		
Molecular weight (g/mol)	257.2	yes	
Formation fraction	-	yes	
DT_{50} in soil (d)	300	yes	worst case value
K_{Foc}	1	yes	worst case value
1/n	1	yes	worst case value
Plant uptake factor	0	yes	default
Max. % in soil	5.9	yes	From aerobic soil studies
Soil deposition (g a.s./ha)	0.49	yes	Input as direct application to soil.

Due to pH dependent adsorption of Pyroxsulam and its soil metabolites, simulations of the more alkaline FOCUS scenarios Chateaudun, Kremsmünster, Piacenza, Sevilla and Thiva were performed using the K_{foc} and 1/n values for soil pH ≥7 and simulations of the more acidic FOCUS scenarios Hamburg, Jokoinen, Okehampton and Porto were performed using the K_{foc} and 1/n values for soil pH <7.

Table 5.7-8: PEC_{GW} at 1 m soil depth for Pyroxsulam and its metabolites in winter cereals according to EU assessment (see EFSA Journal 2013;11(4):3182)

Crop/ Group/ use No.	**Scenario**		**80th percentile PEC_{GW} at 1 m soil depth (µg L^{-1}) groundwater model: FOCUS PELMO 4.4.3**					
	Name	**pH-H_2O (1st horizon)**	**Pyroxsulam**	**Metabolite**				
				5-OH	**7-OH**	**6-Cl-7-OH**	**5,7-di-OH**	**PSA**
winter cereals / group A / 1 x 18.75 g a.s./ha / application 1st February	**Châteaudun**	8.0	<0.001	<0.001	0.022	0.086	<0.001	0.332
	Hamburg	6.4	<0.001	0.001	0.006	0.040	<0.001	0.238
	Jokioinen	6.2	<0.001	<0.001	0.004	0.026	<0.001	0.353
	Kremsmünster	7.7	<0.001	0.003	0.057	0.185	<0.001	0.174
	Okehampton	5.8	<0.001	0.001	0.009	0.043	<0.001	0.129
	Piacenza	7.0	0.022	<0.001	0.035	0.136	<0.001	0.233
	Porto	4.9	<0.001	0.004	0.007	0.030	<0.001	0.122
	Sevilla	7.3	<0.001	<0.001	0.002	0.009	<0.001	0.165
	Thiva	7.7	<0.001	<0.001	0.007	0.024	<0.001	0.270

Crop/ Group/ use No.	Scenario		80th percentile PEC_{GW} at 1 m soil depth (µg L^{-1}) groundwater model: FOCUS PELMO 4.4.3	
	Name	pH-H_2O (1st horizon)	Metabolite	
			Pyridine sulfonamide	
winter cereals / group A / 1 x 18.75 g a.s./ha / application 1st February	Châteaudun	8.0	<0.001	
	Hamburg	6.4	0.003	
	Jokioinen	6.2	0.001	
	Kremsmünster	7.7	0.002	
	Okehampton	5.8	0.004	
	Piacenza	7.0	0.002	
	Porto	4.9	0.002	
	Sevilla	7.3	<0.001	
	Thiva	7.7	<0.001	

According to the PEC_{GW} modelling with FOCUS PELMO a groundwater contamination of the active substance Pyroxsulam at a concentration of ≥ 0.1 µg/L is not expected for the FOCUS groundwater scenarios.

For the metabolites 5-OH, 7-OH, 5,7-di-OH and Pyridine sulfonamide a groundwater concentration of ≥ 0.1 µg/L can be excluded in the FOCUS groundwater scenarios.

For the metabolites 6-Cl-7-OH and PSA a groundwater concentration of ≥ 0.1 µg/L cannot be excluded in the FOCUS groundwater scenarios.

5.7.2 Higher tier leaching assessment (Tier 3)

Pionxaden

In case of the active substance Pinoxaden exposure assessment is based additionally on results of a lysimeter study.

active substance:	Pinoxaden
author:	Fent, G.
report:	Leaching of NOA 407855 and its major metabolites in two outdoors lysimeters
study date:	29/01/2004
study code:	NOV15
reference:	see DAR (Volume 3, chapter B.8.2.4) for a detailed description of the study

author:	Berdat und Nicollier
report:	NOA 407855: Analysis of Yearly Composite Leachate from a Lysimeter Study Conducted in the Facility “Staatliche Lehr- und Forschungsanstalt für Landschaft Weinbau und Gartenbau (SLFA), Neustadt, Germany
study date:	23/02/2004

study code:	03GN07
reference:	see DAR (Volume 3, chapter B.8.2.4) for a detailed description of the study

The experimental data on the leaching behaviour of the active substance Pinoxaden show that Pinoxaden and its metabolite M2 (NOA 407854) are not expected to penetrate into groundwater at concentrations of ≥ 0.1µg/L in the intended for uses in winter cereals.

For the metabolites of the Pinoxaden the following concentrations of >0.1µg/L in groundwater cannot be excluded:

M3: 0.218 µg/L

M11: 0.263 µg/L

M52: 0.150 µg/L

M54: 0.173 µg/L

M55: 0.161 µg/L

M56: 0.307 µg/L

5.7.3 Summary of risk assessment for ground water

Results of modelling with FOCUS PELMO 5.5.3 show that the active substance Pinoxaden is not expected to penetrate into groundwater at concentrations of ≥ 0.1 µg/L in the intended uses in winter cereals.

For the metabolites M2 and M52 a groundwater concentration of ≥ 0.1 µg/L can be excluded in all of the FOCUS groundwater scenarios.

For the metabolites M3, M11, M54, M55 and M56 a groundwater concentration of ≥ 0.1 µg/L cannot be excluded in all of the FOCUS groundwater scenarios.

In addition to the PECgw modelling experimental data from lysimeter studies studies are used to assess the leaching behaviour of the active substance Pinoxaden and its metabolites. For the metabolites M3, M11, M52, M54, M55 and M56 of Pinoxaden concentrations of >0.1µg/L in groundwater cannot be excluded.

An assessment of the metabolites M3, M11, M52, M54, M55 and M56 of Pinoxaden regarding their relevance for groundwater is necessary. For the assessment of relevance please refer to Section 8.

Results of modelling show that the active substance Pyroxsulam is not expected to penetrate into groundwater at concentrations of ≥ 0.1 µg/L in the intended uses in winter cereals.

For the metabolites 5-OH, 7-OH, 5,7-di-OH and Pyridine sulfonamide a groundwater concentration of ≥ 0.1 µg/L can be excluded in the FOCUS groundwater scenarios.

For the metabolites 6-Cl-7-OH and PSA a groundwater concentration of ≥ 0.1 µg/L cannot be excluded in the FOCUS groundwater scenarios.

An assessment of metabolites of Pyroxsulam regarding their relevance for groundwater is necessary. For the assessment of relevance for the metabolites 6-Cl-7-OH and PSA please refer to Section 8.

5.8 Potential of active substance for aerial transport

The vapour pressure at 20 °C of the active substance Pinoxaden is $< 10^{-5}$ Pa. Hence the active substance Pinoxaden is regarded as non-volatile. Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance Pinoxaden due to volatilization with subsequent deposition does not need to be considered.

The vapour pressure at 20 °C of the active substance Pyroxsulam is $< 10^{-5}$ Pa. Hence the active substance Pyroxsulam is regarded as non-volatile. Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance Pyroxsulam due to volatilization with subsequent deposition does not need to be considered.

Appendix 1 List of data submitted in support of the evaluation

Table A 1: List of data submitted in support of the evaluation

Annex point/ reference No	Author(s)	Year	Title Source (where different from company) Report-No. GLP or GEP status (where relevant), Published or not Authority registration No	Data protection claimed	Owner	How considered in dRR Study-Status/Usage*
OECD: KIIA 7.2.3	Robinson	2012a	Pinoxaden - Rate of Degradation of Metabolite SYN504574 (M11) under Aerobic Laboratory Conditions, in Three Soils, at 20 °C. Report No: 115 18 023 Task No: TK0021704	Y	Syngenta	1)
OECD: KIIA 7.2.3	Völkel	2012a	Pinoxaden - Rate of Degradation of Metabolite SYN546105 (M52) under Aerobic Laboratory Conditions, in Three Soils, at 20 °C. Report No: 115 20 023 Task No: TK0021706	Y	Syngenta	1)
OECD: KIIA 7.2.3	Völkel	2012b	Pinoxaden - Rate of Degradation of Metabolite SYN546106 (M54) under Aerobic Laboratory Conditions, in Three Soils, at 20 °C. Report No: 115 19 023 Task No: TK0021705	Y	Syngenta	1)
OECD: KIIA 7.2.3	Robinson	2012b	Pinoxaden - Rate of Degradation of Metabolite SYN546107 (M55) under Aerobic Laboratory Conditions, in Three Soils, at 20 °C. Report No: 115 21 023 Task No: TK0021707	Y	Syngenta	1)
OECD: KIIA 7.4.2	Robinson	2012c	Pinoxaden - Adsorption/Desorption Properties of Metabolite SYN504574 (M11) in Three Soils. Report No: 115 17 013 Task No: TK0021697	Y	Syngenta	1)
OECD: KIIA 7.4.2	Völkel	2012c	Pinoxaden - Adsorption/Desorption properties of Metabolite	Y	Syngenta	1)

			SYN546105 (M52) in Three Soils. Report No: 115 19 013 Task No: TK0021701			
OECD: KIIA 7.4.2	Völkel	2012d	Pinoxaden - Adsorption/Desorption properties of Metabolite SYN546106 (M54) in Three Soils. Report No: 115 18 013 Task No: TK0021700	Y	Syngenta	1)
OECD: KIIA 7.4.2	Robinson	2012d	Pinoxaden - Adsorption/Desorption properties of Metabolite SYN546107 (M55) in Three Soils. Report No: 115 20 013 Task No: TK0021702	Y	Syngenta	1)
OECD: IIIA 9.6.1	Ford	2013	A European Leaching Assessment for Parent and Metabolites M2, M3, M11, M52, M54 and M55 using the FOCUS PEARL 4.4.4 and FOCUS PELMO 5.5.3 Groundwater Scenarios Following Application to Cereals. Report No: SYN/30/02-01 Syngenta File No: NOA407855_10263	Y	Syngenta	1)

*

1) accepted (study valid and considered for evaluation)
2) not accepted (study not valid and not considered for evaluation)
3) not considered (study not relevant for evaluation)
4) not submitted but necessary (study not submitted by applicant but necessary for evaluation)
5) supplemental (additional information, alone not sufficient to fulfil a data requirement, considered for evaluation)

Appendix 2 Detailed evaluation of studies relied upon

The following studies have not previously been submitted for EU review and are provided in support of this assessment.

KIIA 7 Fate and Behaviour in the Environment – Pinoxaden

KIIA 7.2.3 Robinson, 2012a

Reference:	KIIA 7.2.3
Author:	Robinson, N.
Report:	Pinoxaden - Rate of Degradation of Metabolite SYN504574 (M11) under Aerobic Laboratory Conditions, in Three Soils, at 20 °C.
Date:	17.04.2012
Guideline(s):	Yes (OECD 307)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Test Material:	SYN504574 (M11)
Lot/Batch #:	MES 151/2
Purity:	96%
Stability of test compound:	Stable, determined within study
Application vehicle:	Water
Soils:	Three soils were used for the study, soils which were chosen to represent arable farming conditions in respect of soil texture and pH.

Table A 2: Physical and Chemical Properties of the soils used

Name	Gartenacker	18 Acres	Marsillargues
Particle size (% w/w):			
Clay (<2 µm)	10.61	24.06	35.76
Silt (50-2 µm)	55.30	28.06	59.45
Sand (2000-50 µm)	34.09	47.88	4.78
Texture (USDA)	Silt loam	Sandy clay loam	Silty clay loam
Soil Taxonomy (USDA)	Entisols Fluvents	Alfisols Aqualf	Entisols Aquents
pH (water)	7.53	6.10	8.08
pH (0.01M $CaCl_2$)	7.21	5.68	7.55
Organic matter (%) *	3.69	4.34	1.43
Organic carbon (%)	2.14	2.52	0.83
Nitrogen content (%)	0.24	0.25	0.11
C/N ratio *	8.92	9.00	7.55
CEC (meq/100 g soil)	13.86	21.10	17.55
Moisture at pF 2.0 (w/w %)	39.0	26.8	22.7
Biomass (mg carbon/kg soil), value in brackets (in % of organic carbon content of the soil)			
Initial (start of study)	354 (1.7%)	526 (2.1%)	269 (3.2%)
Final (end of study)	388 (1.8%)	469 (1.9%)	213 (2.6%)

Note: Parameters were determined by AgroLab AG, 6037 Root, Switzerland (non-GLP), with the exception of moisture at pF 2.0 (determined by Syngenta) and biomass (determined at IES Ltd).

*: Organic matter (OM) and C/N ratio were calculated as follows: %OM = 1.724 × % organic carbon
C/N ratio = % organic carbon / % nitrogen content

Results and discussions

SYN504574 (M11) rapidly degraded in all three soils. The mean initial amounts of 103.4%, 101.7% and 96.1% of the applied amount decreased to levels of 0.0%, 5.8% and 0.0% in Gartenacker, 18 Acres and Marsillargues, respectively, at the end of the incubation period (i.e. 90 days).

The degradation rate of the parent was determined using non-linear regression and a single first-order kinetics model (SFO, CAKE, version 1.3). SFO kinetics describes the degradation of SYN504574 (M11) with a Chi-square (χ^2) value lower than 15 in all cases.

Table A 3: Summary of Half-lives ($DegT_{50}$) and $DegT_{90}$ Values

Soil	SFO				
	$DegT_{50}$ [days]	**$DegT_{90}$ [days]**	**χ^2**	**R^2**	**Prob > t**
Gartenacker	7.6	25.2	6.1	0.9916	2.569E-011
18 Acres	13.0	43.3	9.8	0.9674	9.002E-014
Marsillargues	9.2	30.7	3.5	0.9949	1.353E-012

Conclusion

The rate of degradation of SYN504574 (M11) was investigated in three soils, Gartenacker, 18 Acres and Marsillargues, respectively. The corresponding half-lives calculated by using single first-order kinetics were 7.6, 13.0 and 9.2 days, respectively.

Comments of zRMS

Study is acceptable and used in evaluation. For soil 18 Acres the DFOP (slow phase) DT_{50} of 23.8 days (Chi^2=1.9) was chosen by zRMS instead of SFO kinetic because the visuell fit was clearly better.

KIIA 7.2.3 Völkel, 2012a

Reference:	KIIA 7.2.3
Author:	Völkel, W.
Report:	Pinoxaden - Rate of Degradation of Metabolite SYN546105 (M52) under Aerobic Laboratory Conditions, in Three Soils, at 20 °C.
Date:	24.04.2012
Guideline(s):	Yes (OECD 307)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Test Material:	SYN546105 (M52)
Lot/Batch #:	MES 217/2
Purity:	97%
Stability of test compound:	Stable, determined within study
Application vehicle:	Water
Soils:	Three soils were used for the study, soils which were chosen to represent arable farming conditions in respect of soil texture and pH.

Table A 4: Physical and Chemical Properties of the soils used

Name	Gartenacker	18 Acres	Marsillargues
Particle size (% w/w):			
Clay (<2 µm)	10.61	23.50	35.66
Silt (50-2 µm)	55.30	28.42	57.78
Sand (2000-50 µm)	34.09	48.08	6.56
Texture (USDA)	Silt loam	Loam	Silty clay loam
Soil Taxonomy (USDA)	Entisols Fluvents	Alfisols Aqualf	Entisols Aquents
pH (water)	7.53	6.49	8.19
pH (0.01M $CaCl_2$)	7.21	6.14	7.60
Organic matter (%) *	3.69	3.88	1.72
Organic carbon (%)	2.14	2.25	1.00
Nitrogen content	0.24	0.25	0.12
C/N ratio *	8.92	9.00	8.33
CEC (meq/100 g soil)	13.86	21.08	18.32
Moisture at pF 2.0 (w/w %)	39.0	26.8	22.7
Biomass (mg carbon/kg soil) and in % of organic carbon content of the soil (values in brackets)			
Initial (start of study)	434 (2.0%)	473 (2.1%)	350 (3.5%)
Final (end of study)	294 (1.4%)	300 (1.3%)	295 (3.0%)

Note: Parameters were determined by AgroLab AG, 6037 Root, Switzerland (non-GLP), with the exception of moisture at pF 2.0 (for 18 Acres soil determined by IES, for Gartenacker and Marsillargues soil provided by the sponsor) and biomass (determined at IES Ltd).

*: Organic matter (OM) and C/N ratio were calculated as follows:
%OM = 1.724 × % organic carbon
C/N ratio = % organic carbon / % nitrogen content

**: Not sampled to a soil depth of 20 cm as stated in the Study Plan.

Results and discussions

SYN546105 (M52) degraded rapidly in all three soils. The mean initial amounts of 91.4%, 91.2% and 98.6% decreased to levels of 6.8%, 6.4% and 12.0% of the applied amount in Gartenacker, 18 Acres and Marsillargues soil, respectively, at the end of the incubation period.

The rate of degradation of SYN546105 (M52) in soil incubated under aerobic conditions was calculated (CAKE, version 1.3) using hockey-stick (HS) and double-first-order in parallel (DFOP) kinetics, based on the FOCUS Kinetics Guidance on estimating persistence and degradation kinetics from Environmental Fate Studies.

Table A 5: Details of the Kinetic Evaluation

Gartenacker

Model	M_0	Parameter	Prob > t[a)]	CI includes zero?[a)]	DT_{50}	DT_{90}	χ^2-error
SFO	79.6	k= 0.3312	0.00024		2.1	7.0	28.3
DFOP		k_1 = k_2 = g =	b)				
HS	91.4	k_1 = 0.8716 k_2 = 0.07735 t_b = 1.265	6.219E-09 1.404E-05 3.318E-07		0.8	16.8	2.74
FOMC	91.32	α = 0.4702 β = 0.211		no no	0.7	28.1	6.2
Conclusion: • SFO, FOMC and HS statistically and visually acceptable • HS with smallest χ^2-error and less residual deviations at the end of sampling period, so HS chosen							

a) In order to assess the fitted degradation rates as statistically acceptable Prob > t (i.e. the p-value) should be < 0.05. Since both FOMC parameters α and β are shape parameters rather than degradation rates, the confidence interval (CI) is used for validation: to be statistically acceptable the confidence interval should not include zero.
b) Fitting failed

18 Acres

Model	M_0	Parameter	Prob > t[a)]	CI includes zero?[a)]	DT_{50}	DT_{90}	χ^2-error
SFO	83	0.3383	0.05678		2.0	6.8	23
DFOP	91.34	k_1 = 1.148 k_2 = 0.0667 g = 0.682	1.198E-07 8.513E-06 2.123E-11		1.0	17.4	3.8
HS	83	k_1 = 0.338 k_2 = 0.071 t_b = 127.4	b)		2.0	6.8	27.7
FOMC	91.28	α = 0.6471 β = 0.5494		no no	1.0	18.7	5.9
Conclusion: • SFO visually and statistically not acceptable • FOMC and DFOP statistically and visually acceptable • DFOP smaller χ^2-error than FOMC, so DFOP chosen							

a) In order to assess the fitted degradation rates as statistically acceptable Prob > t (i.e. the p-value) should be < 0.05. Since both FOMC parameters α and β are shape parameters rather than degradation rates, the confidence interval (CI) is used for validation: to be statistically acceptable the confidence interval should not include zero.
b) Calculation failed

Marsillargues

Model	M_0	Parameter	Prob > t[a)]	CI includes zero?[a)]	DT_{50}	DT_{90}	χ^2-error
SFO	80.69	k= 0.186	0.0004		3.7	12.4	25.7
DFOP	98.6	k_1 = 1.793 k_2 = 0.055 g = 0.5744	6.98E-07 1.263E-07 4.416E-12		1.0	26.3	2.7
HS	98.58	k_1 = 0.6952 k_2 = 0.055 t_b = 1.332	1.188E-10 7.008E-08 1.969E-09		1.0	26.3	2.5
FOMC	98.48	α = 0.3768 β = 0.2088		no no	1.1	93.6	6.4
Conclusion: • SFO visually not acceptable, systematic residual deviations at the end of sampling period • DFOP, HS and FOMC statistically and visually acceptable • HS provides smallest χ^2-error, so HS chosen							

a) In order to assess the fitted degradation rates as statistically acceptable Prob > t (i.e. the p-value) should be < 0.05. Since both FOMC parameters α and β are shape parameters rather than degradation rates, the confidence interval (CI) is used for validation: to be statistically acceptable the confidence interval should not include zero.

Table A 6: Estimation of modeling endpoints to FOCUS Kinetic Guideline

Soil	Flowchart steps according to FOCUS [4]			
	10 % initially measured concentration reached within experimental period?	Statistically and visually acceptable model; see, tables below	DT_{50}	DT_{90}
Gartenacker	yes	FOMC	**8.5** = 28.1/3.32	28.1
18 Acres	yes	FOMC	**5.6** = 18.7/3.32	18.7
Marsillargues	no	HS	**12.6** = ln2/0.055	26.3

Conclusion

The rate of degradation of SYN546105 (M52) was investigated in three soils, Gartenacker, 18 Acres and Marsillargues, respectively. The best fit DT_{50} values for modeling endpoints were 8.5, 5.6 and 12.6 days, respectively.

Comments of zRMS

Study is acceptable and used in evaluation.

KIIA 7.2.3 Völkel, 2012b

Reference:	KIIA 7.2.3
Author:	Völkel, W.
Report:	Pinoxaden - Rate of Degradation of Metabolite SYN546106 (M54) under Aerobic Laboratory Conditions, in Three Soils, at 20 °C.
Date:	24.04.2012
Guideline(s):	Yes (OECD 307)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Test Material:	SYN546106 (M54)
Lot/Batch #:	MES 207/1
Purity:	98%
Stability of test compound:	Stable, determined within study
Application vehicle:	Water
Soils:	Three soils were used for the study, soils which were chosen to represent arable farming conditions in respect of soil texture and pH.

Table A 7: Physical and Chemical Properties of the soils used

Name	Gartenacker	18 Acres	Marsillargues
Particle size (% w/w):			
Clay (<2 µm)	10.61	24.06	35.76
Silt (50-2 µm)	55.30	28.06	59.45
Sand (2000-50 µm)	34.09	47.88	4.78
Texture (USDA)	Silt loam	Loam	Silty clay loam
Soil Taxonomy (USDA)	Entisols Fluvents	Alfisols Aqualf	Entisols Aquents
pH (water)	7.53	6.10	8.08
pH (0.01M $CaCl_2$)	7.21	5.68	7.55
Organic matter (%) *	3.69	4.34	1.43
Organic carbon (%)	2.14	2.52	0.83
Nitrogen content	0.24	0.25	0.11
C/N ratio *	8.92	10.08	7.55
CEC (meq/100 g soil)	13.86	21.10	17.55
Moisture at pF 2.0 (w/w %)	39.0	26.8	22.7
Biomass (mg carbon/kg soil), value in brackets (in % of organic carbon content of the soil)			
Initial (start of study)	354 (1.7%)	526 (2.1%)	269 (3.2%)
Final (end of study)	375 (1.8%)	294 (1.2%)	270 (3.3%)

Note: Parameters were determined by AgroLab AG, 6037 Root, Switzerland (non-GLP), with the exception of moisture at pF 2.0 (for 18 Acres soil determined by IES Ltd, for Gartenacker and Marsillargues soil provided by the sponsor) and biomass (determined at IES Ltd.).

*: Organic matter (OM) and C/N ratio were calculated as follows:
%OM = 1.724 × % organic carbon
C/N ratio = % organic carbon / % nitrogen content

**: Not sampled to a soil depth of 20 cm as stated in the Study Plan.

Results and discussions

SYN546106 (M54) rapidly degraded in all three soils. The mean initial amounts of 99.7%, 92.6% and 99.3% of the applied amount decreased to levels of 4.8% in Gartenacker, and below the Limit of Quantification (LOQ) for 18 Acres and Marsillargues, respectively, at the end of the incubation period (i.e. 28, 61 and 61 days).

The rate of degradation of SYN546106 (M54) in soil incubated under aerobic conditions was calculated (Cake, version 1.3) using Single First-Order (SFO) kinetics, based on the FOCUS Kinetics Guidance on estimating persistence and degradation kinetics from Environmental Fate Studies.

Table A 8: Summary of Half-lives ($DegT_{50}$) and $DegT_{90}$ Values

Soil	SFO				
	Half-life [days]	**$DegT_{90}$ [days]**	**χ^2**	**R^2**	**Prob > t**
Gartenacker	4.9	16.4	5.4	0.9909	9.91×10^{-12}
18 Acres	9.3	30.8	5.5	0.9893	3.02×10^{-10}
Marsillargues	9.2	30.6	8.8	0.9885	1.52×10^{-08}

SFO: Single First-order kinetics

Conclusion

The rate of degradation of SYN546106 (M54) under aerobic conditions was investigated in three soils, Gartenacker, 18 Acres and Marsillargues. The corresponding half-lives calculated by using single first-order kinetics were 4.9, 9.3 and 9.2 days, respectively.

Comments of zRMS

Study is acceptable and used in evaluation.

KIIA 7.2.3 Robinson, 2012b

Reference:	KIIA 7.2.3
Author:	Robinson, N.
Report:	Pinoxaden - Rate of Degradation of Metabolite SYN546107 (M55) under Aerobic Laboratory Conditions, in Three Soils, at 20 °C.
Date:	24.04.2012
Guideline(s):	Yes (OECD 307)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Test Material:	SYN546107 (M55)
Lot/Batch #:	MES 219/1
Purity:	97%
Stability of test compound:	Stable, determined within study
Application vehicle:	Water
Soils:	Three soils were used for the study, soils which were chosen to represent arable farming conditions in respect of soil texture and pH.

Table A 9: Physical and Chemical Properties of the soils used

Name	Gartenacker	18 Acres	Marsillargues
Particle size (% w/w):			
Clay (<2 µm)	10.61	23.50	35.66
Silt (50-2 µm)	55.30	28.42	57.78
Sand (2000-50 µm)	34.09	48.08	6.56
Texture (USDA)	Silt loam	Sandy clay loam	Silty clay loam
Soil Taxonomy (USDA)	Entisols Fluvents	Alfisols Aqualf	Entisols Aquents
pH (water)	7.53	6.49	8.19
pH (0.01M $CaCl_2$)	7.21	6.14	7.60
Organic matter (%) *	3.69	3.88	1.72
Organic carbon (%)	2.14	2.25	1.00
Nitrogen content (%)	0.24	0.25	0.12
C/N ratio *	8.92	9.00	8.33
CEC (meq/100 g soil)	13.86	21.08	18.32
Moisture at pF 2.0 (w/w %)	39.0	29.8	22.7
Biomass (mg carbon/kg soil), value in brackets (in % of organic carbon content of the soil)			
Initial (start of study)	332 (1.6%)	358 (1.6%)	269 (2.7%)
Final (end of study)	249 (1.2%)	310 (1.4%)	276 (2.8%)

Notes: Parameters were determined by AgroLab AG, 6037 Root, Switzerland (non-GLP), with the exception of moisture at pF 2.0 (determined by Syngenta) and biomass (determined at IES Ltd).

*: Organic matter (OM) and C/N ratio were calculated as follows:
%OM = 1.724 × % organic carbon
C/N ratio = % organic carbon / % nitrogen content
For Marsillargues soil the depth of soil sampled was 3-10 cm rather than 0-20 cm as stated in the study plan.
For 18 Acres soil the depth of soil sampled was 5-20 cm rather than 0-20 cm as stated in the study plan

Results and discussions

SYN546107 (M55) degraded rapidly in Gartenacker and Marsillargues soils, but more slowly in 18 Acres soil.

In Gartenacker and Marsillargues soils, the mean initial amounts of 94.6% and 107.7% of applied amount decreased to levels of 0.8% and 0.0%, respectively, after 60 days of incubation.

In 18 Acres soil, the mean initial amount of 98.8% of applied amount decreased to a level of 36.8% after 120 days of incubation.

The degradation rate of the parent was determined using non-linear regression and a single first-order kinetics model (SFO, CAKE, version 1.3). SFO kinetics describes the degradation of SYN546107 (M55) with a Chi-square ($\chi 2$) value lower than 15% in all cases.

Table A 10: Summary of Half-lives ($DegT_{50}$) and $DegT_{90}$ Values

Soil	SFO				
	$DegT_{50}$ [days]	$DegT_{90}$ [days]	χ^2	R^2	Prob > t
Gartenacker	9.6	31.9	7.1	0.9769	2.124E-08
18 Acres	86.3	286.8	5.8	0.9354	4.828E-08
Marsillargues	5.3	17.5	8.6	0.973	5.104E-08

Table A 11: Estimation of modeling endpoints to FOCUS Kinetic Guideline

Soil	Flowchart steps according to FOCUS				
	SFO visually and statistically acceptable?	10 % initially measured concentration reached within experimental period?	Statistically and visually acceptable model; see, tables below	DT_{50}	DT_{90}
Gartenacker	yes	n.a.	SFO	9.6	31.9
18 Acres	no	no	DFOP	105.7 = ln2/0.00656	351.0 =ln10/0.00656
Marsillargues	yes	n.a.	SFO	5.3	18.4

*18 Acres: DFOP slow phase (k_2=0.00656)

Conclusion

The rate of degradation of SYN546107 (M55) was investigated in three soils, Gartenacker, 18 Acres and Marsillargues, respectively. The corresponding half-lives were 9.6, 105.7 and 5.3 days, respectively.

Comments of zRMS

Study is acceptable and used in evaluation.

KIIA 7.4.2 Robinson, 2012c

Reference:	KIIA 7.4.2
Author:	Robinson, N.
Report:	Pinoxaden - Adsorption/Desorption Properties of Metabolite SYN504574 (M11) in Three Soils.
Date:	20.04.2012
Guideline(s):	Yes (OECD 106)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Test Material:	SYN504574 (M11)
Lot/Batch #:	MES 151/2
Purity:	96%
Stability of test compound:	Stable, determined within study
Application vehicle:	0.01M $CaCl_2$
Soils:	Three soils were used for the study, soils which were chosen to represent arable farming conditions in respect of soil texture and pH.

Table A 12: Physical and Chemical Properties of the soils used

Name	Gartenacker	18 Acres	Marsillargues
Particle size (% w/w):			
Clay (<2 µm)	10.24	25.53	35.76
Silt (50-2 µm)	53.78	28.50	59.45
Sand (2000-50 µm)	35.98	45.97	4.78
Texture (USDA)	Silt loam	Sandy clay loam	Silty clay loam
Soil Taxonomy (USDA)	Entisols Fluvents	Alfisols Aqualf	Entisols Aquents
pH (water)	7.52	6.35	8.08
pH (0.01M $CaCl_2$)	7.13	5.96	7.55
Organic matter (%) *	2.95	5.33	1.43
Organic carbon (%)	1.71	3.09	0.83
Nitrogen content	0.21	0.25	0.11
C/N ratio *	8.14	12.36	7.55
CEC (meq/100 g soil)	13.9	20.99	17.55
Moisture content of air-dried soil (g/100g)	0.98	2.59	2.22

Note: Parameters were determined by AgroLab GmbH, CH-6037 Root, Switzerland (non-GLP).
*: %OM and C/N ratio were calculated as follows:
%OM = 1.724 × % organic carbon
C/N ratio = % organic carbon / % nitrogen content

Results and discussions

Kd values after the adsorption step ranged from 0.187 – 0.246 for Gartenacker, 0.338 – 0.398 for 18 Acres and 0.104 – 0.140 mL/g for Marsillargues soil, with corresponding KOC values of 10.9 – 14.4, 10.9 – 12.9 and 12.5 – 16.9 mL/g respectively. The corresponding 1/n values ranged from 0.97 to 0.99. The Freundlich coefficients (KF) calculated for the adsorption step were observed to be 0.206, 0.351 and 0.117, with corresponding KFOC values of 12.0, 11.4 and 14.1 for Gartenacker, 18 Acres and Marsillargues soil, respectively. The adsorption constants KF (mean values) were correlated to organic carbon (r2=0.9999) and weakly correlated to pH (r2=0.3047) of the soils.

Kd values after the desorption step were found to be 0.3579 – 0.5477 for Gartenacker, 0.4767 – 0.6311 for 18 Acres and 0.2824 – 0.4710 mL/g for Marsillargues soil, with corresponding KOC values of 20.9 – 32.0, 15.4 – 22.9 and 34.0 – 56.7 mL/g respectively. The Freundlich coefficients (KF) calculated for the desorption step were observed to be 0.352, 0.480 and 0.278, with corresponding KFOC values of 19.6, 15.5 and 33.5 for Gartenacker, 18 Acres and Marsillargues soil, respectively. The results are summarised in Table A 13.

Table A 13: Soil adsorption constants for SYN504574 (M11) in 3 Soils

Parameter	Gartenacker	18 Acres	Marsillargues
Texture	Silt loam	sandy clay loam	silty clay loam
pH (0.01M $CaCl_2$)	7.13	5.96	7.55
%OC	1.71	3.09	1.05
Adsorption			
K_F	0.206	0.351	0.117
K_{FOC}	12	11.4	14.1
Mean K_{FOC}	12.5		
1/n	0.97	0.98	0.99
r^2	0.997	0.999	0.996
Kd (mean)	0.221	0.374	0.120
K_{OC} (mean)	12.9	12.1	14.5
Desorption			
K_F	0.352	0.480	0.278
K_{FOC}	19.6	15.5	33.5
1/n	0.91	0.93	0.92
r^2	0.999	0.999	0.996
Kd (mean)	0.468	0.605	0.373
K_{OC} (mean)	27.4	19.6	44.9

Conclusion

SYN504574 (M11) adsorbed to all soils with a mean K_{FOC} value of **12.5 mL/g** and mean slope (1/n) of 0.98. Using the McCall Classification scale to assess a chemical's potential mobility in soil (based on its K_{FOC}), SYN504574 (M11) can be classified as having a "very high" potential mobility in Gartenacker, 18 Acres and Marsillargues soil.

Comments of zRMS

Study is acceptable and used in evaluation.

KIIA 7.4.2 Völkel, 2012c

Reference:	KIIA 7.4.2
Author:	Völkel, W.
Report:	Pinoxaden - Adsorption/Desorption properties of Metabolite SYN546105 (M52) in Three Soils.
Date:	24.04.2012
Guideline(s):	Yes (OECD 106)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Test Material:	SYN546105 (M52)
Appearance:	White solid
Lot/Batch #:	MES 217/2
Purity:	97%
Stability of test compound:	Stable, determined within study
Application vehicle:	0.01M $CaCl_2$
Soils:	Three soils were used for the study, soils which were chosen to represent arable farming conditions in respect of soil texture and pH.

Table A 14: Physical and Chemical Properties of the soils used

Name	Gartenacker	18 Acres	Marsillargues
Particle size (% w/w): [b]			
Clay (<2 µm)	10.1	24.4	36.4
Silt (50-2 µm)	56.6	27.6	59.2
Sand (2000-50 µm)	33.4	48.0	4.4
Texture (USDA) [b]	Silt loam	Sandy clay loam	Silty clay loam
Soil Taxonomy (USDA)	Entisols Fluvents [a]	Alfisols Aqualf [a]	Entisols Aquents [b]
pH (water) [b]	7.46	6.95	7.95
pH (0.01 M $CaCl_2$) [b]	7.10	5.58	7.46
Organic matter (%) [c]	3.38	4.97	1.81
Organic carbon (%) [b]	1.96	2.88	1.05
Nitrogen content [b]	0.22	0.29	0.13
C/N ratio [c]	8.91	9.93	8.08
CEC (meq/100 g soil) [b]	11.45	20.48	16.83
Moisture content of air-dried soil (g/100 g soil) [c]	1.11	2.10	2.24

[a] Parameters provided by the sponsor.
[b] Parameters determined by AgroLab GmbH, 6037 Root, Switzerland (non-GLP).
[c] Parameters determined by IES Ltd.
%OM and C/N ratio were calculated as follows:
%OM = 1.724 × % organic carbon
C/N ratio = % organic carbon / % nitrogen content

Results and discussions

Table A 15: Soil adsorption constants for SYN546105 (M52) in 3 Soils

Parameter		Gartenacker	18 Acres	Marsillargues
Texture		Silt loam	sandy clay loam	silty clay loam
pH (0.01 M $CaCl_2$)		7.10	5.58	7.46
%OC		1.96	2.88	1.05
Adsorption				
K_F	(mL/g)	1.060	2.360	2.836
K_{Foc}	(mL/g)	54.1	81.9	270.1
Mean K_{Foc}	(mL/g)	135.4		
1/n		0.97	0.96	1.00
Mean 1/n		0.98		
r^2		0.972	0.997	0.999
K_d (mean)	(mL/g)	1.193	2.729	2.815
K_{oc} (mean)	(mL/g)	60.9	94.7	268.1
Desorption				
K_F	(mL/g)	1.139	2.212	3.987
K_{Foc}	(mL/g)	58.1	76.8	379.8
Mean K_{Foc}	(mL/g)	171.5		
1/n		0.96	0.94	0.95
Mean 1/n		0.95		

Parameter		Gartenacker	18 Acres	Marsillargues
r^2		0.999	1.000	0.998
K_d (mean)	(mL/g)	1.319	2.811	5.019
K_{oc} (mean)	(mL/g)	67.3	97.6	478.0

Conclusion

SYN546105 (M52) adsorbed to all three soils with a mean K_{Foc} value of **135.4 mL/g** and mean slope (1/n) of 0.98. Mean K_{Foc} value and mean slope (1/n) for desorption of SYN546105 (M52) from all three soils were 171.5 and 0.95, respectively.

Using the McCall Classification scale to assess a chemical's potential mobility in soil, SYN546105 (M52) can be classified as having a "high" potential mobility in Gartenacker and 18 Acres soil and a "medium" potential mobility in Marsillargues soil.

Comments of zRMS

Study is acceptable and used in evaluation.

KIIA 7.4.2 Völkel, 2012d

Reference:	KIIA 7.4.2
Author:	Völkel, W.
Report:	Pinoxaden - Adsorption/Desorption properties of Metabolite SYN546106 (M54) in Three Soils.
Date:	26.04.2012
Guideline(s):	Yes (OECD 106)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Test Material:	SYN546106 (M54)
Lot/Batch #:	MES 207/1
Purity:	98%
Stability of test compound:	Stable, determined within study
Application vehicle:	0.01M $CaCl_2$
Soils:	Three soils were used for the study, soils which were chosen to represent arable farming conditions in respect of soil texture and pH.

Table A 16: Physical and Chemical Properties of the soils used

Name	Gartenacker	18 Acres	Marsillargues
Particle size (% w/w): [b]			
Clay (<2 µm)	10.1	24.4	36.4
Silt (50-2 µm)	56.6	27.6	59.2
Sand (2000-50 µm)	33.4	48.0	4.4
Texture (USDA) [b]	Silt loam	Sandy clay loam	Silty clay loam
Soil Taxonomy (USDA)	Entisols Fluvents [a]	Alfisols Aqualf [a]	Entisols Aquents [b]
pH (water) [b]	7.46	6.95	7.95
pH (0.01 M $CaCl_2$) [b]	7.10	5.58	7.46
Organic matter (%) [c]	3.38	4.97	1.81
Organic carbon (%) [b]	1.96	2.88	1.05
Nitrogen content [b]	0.22	0.29	0.13
C/N ratio [c]	8.91	9.93	8.08
CEC (meq/100 g soil) [b]	11.45	20.48	16.83
Moisture content of air-dried soil (g/100 g soil) [c]	1.11	2.10	2.24

[a] Parameters provided by the sponsor.
[b] Parameters determined by AgroLab GmbH, 6037 Root, Switzerland (non-GLP).
[c] Parameters determined by IES Ltd.
%OM and C/N ratio were calculated as follows:
%OM = 1.724 × % organic carbon
C/N ratio = % organic carbon / % nitrogen content

Results and discussions

K_d values after the adsorption step ranged from 0.260 – 0.377 for Gartenacker, 0.195 – 0.407 for 18 Acres and 0.239 – 0.397 mL/g for Marsillargues soil, with corresponding K_{oc} values of 13.3 – 19.2, 6.8 – 14.1 and 22.8 – 37.8 mL/g respectively. The Freundlich coefficients (K_F) calculated for the adsorption step were observed to be 0.267, 0.321 and 0.310, with corresponding K_{Foc} values of 13.6, 11.1 and 29.5 for Gartenacker, 18 Acres and Marsillargues soil, respectively.

K_d values after the desorption step ranged from 0.127 – 0.291 for Gartenacker, 0.188 – 0.329 for 18 Acres and 0.177 – 0.501 mL/g for Marsillargues soil, with corresponding K_{oc} values of 6.5 – 14.9, 6.5 – 11.4 and 16.8 – 47.7 mL/g respectively. The Freundlich coefficients (K_F) calculated for the desorption step were observed to be 0.358, 0.358 and 0.521, with corresponding K_{Foc} values of 18.3, 12.4 and 49.6 for Gartenacker, 18 Acres and Marsillargues soil, respectively. The results are summarized in Table A 17.

Table A 17: Soil adsorption constants for SYN546106 (M54) in 3 Soils

Parameter	Gartenacker	18 Acres	Marsillargues
Texture	Silt loam	sandy clay loam	silty clay loam
pH (0.01 M $CaCl_2$)	7.10	5.58	7.46
%OC	1.96	2.88	1.05
Adsorption			
K_F	0.267	0.321	0.310
K_{Foc}	13.6	11.1	29.5
1/n	0.93	1.03	1.00
r^2	0.9962	0.9729	0.9858
K_d (mean)	0.321	0.310	0.319
K_{oc} (mean)	16.4	10.8	30.4

Desorption			
K_F	0.358	0.358	0.521
K_{Foc}	18.3	12.4	49.6
1/n	1.20	1.17	1.16
r^2	0.9981	0.9952	0.9848
K_d (mean)	0.212	0.249	0.331
K_{oc} (mean)	10.8	8.6	31.5

Conclusion

SYN546106 (M54) adsorbed to all soils with a mean K_{Foc} value of **18.1 mL/g** and mean slope (1/n) of 0.99. SYN546106 (M54) desorbed from all soils with a mean K_{Foc} value of 26.8 mL/g and mean slope (1/n) of 1.18.

Using the McCall Classification scale to assess a chemical's potential mobility in soil (based on its KFoc), SYN546106 (M54) can be classified as having a "very high" potential mobility in all three soils.

Comments of zRMS

Study is acceptable and used in evaluation.

KIIA 7.4.2 Robinson, 2012d

Reference:	KIIA 7.4.2
Author:	Robinson, N.
Report:	Pinoxaden - Adsorption/Desorption properties of Metabolite SYN546107 (M55) in Three Soils.
Date:	20.04.2012
Guideline(s):	Yes (OECD 106)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Test Material:	SYN546107 (M55)
Purity:	97%
Stability of test compound:	Stable, determined within study
Application vehicle:	0.01M $CaCl_2$
Soils:	Three soils were used for the study, soils which were chosen to represent arable farming conditions in respect of soil texture and pH.

Table A 18: Physical and Chemical Properties of the soils used

Name	Gartenacker	18 Acres	Marsillargues
Particle size (% w/w):			
Clay (<2 µm)	10.24	25.53	35.76
Silt (50-2 µm)	53.78	28.50	59.45
Sand (2000-50 µm)	35.98	45.97	4.78
Texture (USDA)	Silt loam	Sandy clay loam	Silty clay loam
Soil Taxonomy (USDA)	Entisols Fluvents	Alfisols Aqualf	Entisols Aquents
pH (water)	7.52	6.35	8.08
pH (0.01M $CaCl_2$)	7.13	5.96	7.55
Organic matter (%) *	2.95	5.33	1.43

Organic carbon (%)	1.71	3.09	0.83
Nitrogen content	0.21	0.25	0.11
C/N ratio*	8.14	12.36	7.55
CEC (meq/100 g soil)	13.9	20.99	17.55
Moisture content of air-dried soil (g/100g)	0.98	2.59	2.22

Note: Parameters were determined by AgroLab GmbH, CH-6037 Root, Switzerland (non-GLP).
*: %OM and C/N ratio were calculated as follows at IES:
%OM = 1.724× % organic carbon, C/N ratio = % organic carbon / % nitrogen content

Results and discussions

Table A 19: Soil adsorption constants for SYN546107 (M55) in 3 Soils

Parameter	Gartenacker	18 Acres	Marsillargues
Texture	Silt loam	sandy clay loam	silty clay loam
pH (0.01M $CaCl_2$)	7.13	5.96	7.55
%OC	1.71	3.09	0.83
Adsorption			
K_F	0.195	0.153	0.143
K_{FOC}	11.4	5.0	17.3
Mean K_{FOC}	11.2		
1/n	0.98	0.96	1.05
r^2	0.9885	0.9775	0.9938
Kd (mean)	0.209	0.178	0.127
K_{OC} (mean)	12.2	5.8	15.3
Desorption			
K_F	0.289	0.292	0.375
K_{FOC}	16.9	9.4	45.2
1/n	0.97	1.15	0.98
r^2	0.990	0.961	0.996
Kd (mean)	0.329	0.199	0.400
K_{OC} (mean)	19.2	6.4	48.1

Conclusion

SYN546107 (M55) adsorbed to all soils with a mean K_{FOC} value of **11.2 mL/g** and mean slope (1/n) of 1.00.

To assess a chemical`s potential mobility in soil (based on its K_{FOC}), SYN546107 (M55) can be classified as having a “very high” potential mobility in Gartenacker, 18 Acres and Marsillargues soils.

Comments of zRMS

Study is acceptable and used in evaluation.

KIIIA1 9 Fate and Behaviour in the Environment – Plant protection product

Appendix 3 Additional information provided by the applicant (e.g. detailed modelling data)

Reference:	KIIIA 9.10.01
Author:	De la Fuente, K.
Report:	Cloquintocet-mexyl (co-formulant in A-12303) Document I, Part 5 Fate and Behaviour in the Environment. Syngenta File No. NOA407855/0469
Date:	07.10.2003

Summary

Cloquintocet-mexyl degrades very rapidly by de-esterification (by micro-organisms and at least partly by chemical processes). The half-life periods of the parent compound is found to be between 0.2 days and 2.4 days. The so formed acid metabolite CGA153433 declines by subsequent immobilisation under formation of non-extractable residues bound to soil. Thereafter, these components start to decrease, whereas mineralisation yielding ^{14}C-carbon dioxide increases in parallel.

Aquatic metabolism is characterised by a very fast dissipation of the parent compound and subsequent immobilisation forming sediment-bound residues. Microbial processes and direct photolysis are important degradation mechanisms contributing to the fast dissipation in natural aquatic systems.

Laboratory experiments indicate that cloquintocet-mexyl is strongly adsorbed by soils and sediments, the average K_{OC}-values being 12850 ± 4991 ml/g. The metabolite CGA 153433 is characterised as little mobile with average K_{OC}-values of 1772 ± 951 ml/g.

The fast and extensive degradation of cloquintocet-mexyl, the strong adsorption and fast immobilisation, as well as the low volatility lead to the conclusion that the risk of cloquintocet-mexyl to be translocated to non-target areas - including groundwater and surface water- is negligible. A monitoring field study corroborates these conclusions.

The acid metabolite CGA153433 is slightly more persistent and mobile and a study shows that the trace levels will be found in field drains under normal useage conditions. However, the mean residue between applications is always <0.1µg/litre.

Comments of zRMS

The plant protection product AVOXA contains, in addition to the active substances Pinoxaden and Pyroxsulam, the herbicide safener Cloquintocet-mexyl at 8.33 g/L. No exposure assessment for this safener following standard EU requirements is available. Additional data on Cloquintocet-mexyl has been submitted by the applicant, which has not been evaluated by zRMS.

A review programme for safeners is planned under Commission Regulation (EC) 1107/2009. The work program for this review, which is expected to include cloquintocet, should actually be adopted until 14 December 2014, but is still pending.

Appendix 4 Table of Intended Uses justification and GAP tables

PPP (product name/code)	**AVOXA / A19786A**	**Formulation type:**	**EC**
active substance 1	**pinoxaden**	**Conc. of as 1:**	**33.3 g/L**
active substance 2	**pyroxsulam**	**Conc. of as 2:**	**8.33 g/La**
safener	**cloquintocet-mexyl**	**Conc. of safener:**	**8.33 g/L**
Applicant:	**Syngenta Agro GmbH**	**professional use**	**X**
Zone(s):	**central EU**	**non professional use**	
Verified by MS:	**no**		

Crop and/ or situation (a)	Member state(s)	Product code	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	water L/ha min max	kg as/ha min max		
Winter Wheat	C-EU : AT, BE, CZ, DE, LU, NL, PL, SK	A19786A	F	Apera only	EC	as 1) 33.3 g/L as 2) 8.33 g/L safener 8.33 g/L	Foliar Spray	BBCH 10-32 (spring application only)	a) 1 b) 1	-	a) 1.35 b) 1.35	100-300	as 1) 45 g/ha as 2) 11.3 g/ha safener 11.3 g/ha	nr	

Crop and/ or situation (a)	Member state(s)	Product code	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	water L/ha min max	kg as/ha min max		
Winter Wheat	C-EU : AT, BE, CZ, DE, LU, NL, PL, SK	A19786A	F	Apera, Alopecurus, lolium, other grasses and dicots	EC	as 1) 33.3 g/L as 2) 8.33 g/L safener 8.33 g/L	Foliar Spray	BBCH 10-32 (spring application only)	a) 1 b) 1	-	a) 1.8 b) 1.8	100-300	as 1) 59.9 g/ha as 2) 15 g/ha safener 15 g/ha	nr	
Winter Rye	C-EU : AT, BE, CZ, DE, LU, NL, PL, SK	A19786A	F	Apera only	EC	as 1) 33.3 g/L as 2) 8.33 g/L safener 8.33 g/L	Foliar Spray	BBCH 10-32 (spring application only)	a) 1 b) 1	-	a) 1.35 b) 1.35	100-300	as 1) 45 g/ha as 2) 11.3 g/ha safener 11.3 g/ha	nr	
Winter Rye	C-EU : AT, BE, CZ, DE, LU, NL, PL, SK	A19786A	F	Apera, Alopecurus, lolium, other grasses and dicots	EC	as 1) 33.3 g/L as 2) 8.33 g/L safener 8.33 g/L	Foliar Spray	BBCH 10-32 (spring application only)	a) 1 b) 1	-	a) 1.8 b) 1.8	100-300	as 1) 59.9 g/ha as 2) 15 g/ha safener 15 g/ha	nr	
Winter Triticale	C-EU : AT, BE, CZ, DE, LU, NL, PL, SK	A19786A	F	Apera only	EC	as 1) 33.3 g/L as 2) 8.33 g/L safener 8.33 g/L	Foliar Spray	BBCH 10-32 (spring application only)	a) 1 b) 1	-	a) 1.35 b) 1.35	100-300	as 1) 45 g/ha as 2) 11.3 g/ha safener 11.3 g/ha	nr	

Crop and/ or situation (a)	Member state(s)	Product code	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	water L/ha min max	kg as/ha min max		
Winter Triticale	C-EU : AT, BE, CZ, DE, LU, NL, PL, SK	A19786A	F	Apera, Alopecurus, lolium, other grasses and dicots	EC	as 1) 33.3 g/L as 2) 8.33 g/L safener 8.33 g/L	Foliar Spray	BBCH 10-32 (spring application only)	a) 1 b) 1	-	a) 1.8 b) 1.8	100-300	as 1) 59.9 g/ha as 2) 15 g/ha safener 15 g/ha	nr	

Remarks:

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

REGISTRATION REPORT
Part B

Section 5 Environmental Fate
Detailed summary of the risk assessment

Product code:	**AVOXA / A19786A**		
Active Substances:	**Pinoxaden**	**33.3**	**g/L**
	Pyroxsulam	**8.33**	**g/L**

Central Zone
Zonal Rapporteur Member State: Germany

NATIONAL ADDENDUM – Germany

Applicant: **Syngenta**
Submission date: **28/03/2014**
MS Finalisation date: January 2018

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Sec 5 FATE AND BEHAVIOUR IN THE ENVIRONMENT (KIIIA 9)

The exposure assessment of the plant protection product AVOXA in its intended uses in winter cereals is documented in detail in the core assessment of the plant protection product AVOXA dated from July 2017 performed by Germany.

This document comprises the risk assessment for groundwater and the exposure assessment of surface water and soil for authorization of the plant protection product AVOXA in Germany according to uses listed in Appendix 3.

Regarding PECgw relevant risk mitigation measures, if necessary, are documented in this document. PECsoil, PECsw are used for risk assessment to derive specific risk mitigation measures if necessary (see National addendum Germany, part B, section 6 and part A).

5.1 General Information on the formulation

Table 5.1-1: General information on the formulation AVOXA

Code	008178-00/00		
Plant protection product	AVOXA		
Applicant	Syngenta		
Date of application	28/03/2014		
Formulation type (WP, EC, SC, …; density)	EC		
Active substances (as)	Pinoxaden	Pyroxsulam	Cloquintocet-mexyl (safener)
Concentration of as (g/L)	33.3	8.33	8.33

Data pool/task force	-
Letter of access/cross reference	For Pyroxsulam, a letter of access from Dow AgroSciences is submitted.

5.2 Proposed use pattern

The intended uses in Germany classified according the soil effective application rate (cumulative, disregarding degradation in soil) is presented in Table 5.2-1. Full details of the proposed uses that will be assessed is included in Appendix 3.

The intended uses in Germany (use No. 00-001, 00-002) are covered by the core assessment performed by Germany.

Table 5.2-1: Classification of intended uses in Germany for AVOXA

Group/ use No*	Crop/growth stage	Application method Drift scenario	Number of applications, Minimum application interval, application time, interception	Application rate, cumulative (g as/ha)	Soil effective application rate (g as/ha)
A/ 00-001	winter wheat, winter triticale, winter rye BBCH 10-32	spraying / field crops	1 x, spring (15.02.) 1. 25 %	Pinoxaden 1 x 59.9 Pyroxsulam 1 x 15	Pinoxaden 1 x 45 Pyroxsulam 1 x 11.25
B/ 00-002**	winter wheat, winter triticale, winter rye BBCH 10-32	spraying / field crops	1 x, spring (15.02.) 1. 25 %	Pinoxaden 1 x 45 Pyroxsulam 1 x 11.3	Pinoxaden 1 x 33.75 Pyroxsulam 1 x 8.5

* For administrative purposes, each intended use of a plant protection product in Germany is assigned with an individual use number from the German Federal Office of Consumer Protection and Food Safety (BVL). A complete list of the individual GAPs in Germany together with their assigned use numbers is given in Appendix 3 of this Addendum.

** please note that in agreement with BVL only use no. 00-001 was assessed in a risk envelope approach

5.3 Information on the active substances

5.3.1 Pinoxaden

Please refer to the core assessment (~~July 2017~~January 2018), part B, section 5, chapter 5.3.1

5.3.2 Pyroxsulam

Please refer to the core assessment (January 2018~~July 2017~~), part B, section 5, chapter 5.3.2

5.4 Summary on input parameters for environmental exposure assessment

5.4.1 Rate of degradation in soil

5.4.1.1 Laboratory studies

Pinoxaden

The DT_{50} values of Pinoxaden listed in the core assessment, part B, section 5, point 5.4.1 were analysed according to Holdt et al. 2011 (Holdt et al: Recommendations for simulations to predict environmental concentrations of active substances of plant protection products and their metabolites in groundwater (PEC_{GW}) in the National assessment for authorization in Germany, Texte Umweltbundesamt 56, 2011).

The statistical results for Pinoxaden according to the program INPUT DECISION 3.3 are listed in the following table.

Table 5.4-1: Statistical values according to INPUT DECISION 3.3 for Pinoxaden for PEC_{GW} modelling

Does the active substance dissociate?	No	
Correlation DT_{50} and pH	-	not significant
Coefficient of variation	72 %	sufficiently low
DT_{50} for PEC_{GW} (d)	0.34	Geometric mean

The DT_{50} values of the metabolites M2, M3, M11, M52, M54 and M55 of Pinoxaden listed in the core assessment, part B, section 5, point 5.4.1 were analysed according to Holdt et al. 2011 (Holdt et al: Recommendations for simulations to predict environmental concentrations of active substances of plant protection products and their metabolites in groundwater (PEC_{GW}) in the National assessment for authorization in Germany, Texte Umweltbundesamt 56, 2011).

For the statistical results for the metabolites according to the program INPUT DECISION 3.3 please refer to the core assessment, part B, section 5, point 5.4.1.

For metabolite M55 the coefficient of variation is to high (>100 %), therefore the 10^{th}/ 90^{th} percentile of the DT_{50} values is used for PEC_{GW}.

Table 5.4-2: Statistical values according to INPUT DECISION 3.3 for the metabolite M55 for PEC_{GW} modelling

Does the active substance dissociate?	No	
Correlation DT_{50} and pH	-	not significant
Coefficient of variation	141 %	too high
DT_{50} for PEC_{GW} (d)	6.2/ 86.5	10^{th} / 90^{th} percentile

Pyroxsulam

The DT_{50} values of Pyroxsulam listed in the core assessment, part B, section 5, point 5.4.1.1 were analysed according to Holdt et al. 2011 (Holdt et al: Recommendations for simulations to predict environmental concentrations of active substances of plant protection products and their metabolites in groundwater (PEC_{GW}) in the National assessment for authorization in Germany, Texte Umweltbundesamt 56, 2011).

The statistical results for Pyroxsulam according to the program INPUT DECISION 3.3 are listed in the following table.

Table 5.4-3: Statistical values according to INPUT DECISION 3.3 for Pyroxsulam for PEC_{GW} modelling

Does the active substance dissociate?	Yes (pK_a = 4.67)	
Correlation DT_{50} and pH	Kendall-τ: -.0320 p-value: 0.058	not significant
Coefficient of variation	94 %	sufficiently low (≤ 100%)
DT_{50} for PEC_{GW} (d)	3.3	Geometric mean

The DT_{50} values of the metabolite 7-OH, 6-Cl-7-OH, 5,7-di-OH and Pyridine Sulfonamide of Pyroxsulam listed in the core assessment , part B, section 5, point 5.4.1.1 were analysed according to Holdt et al. 2011 (Holdt et al: Recommendations for simulations to predict environmental concentrations of active substances of plant protection products and their metabolites in groundwater (PEC_{GW}) in the National assessment for authorization in Germany, Texte Umweltbundesamt 56, 2011).

The statistical results for the metabolites 7-OH, 6-Cl-7-OH, 5,7-di-OH and Pyridine Sulfonamide according to the program INPUT DECISION 3.3 are listed in the following table.

Table 5.4-4: Statistic values according to INPUT DECISION 3.3 for 7-OH-XDE-742 for PEC_{GW} modelling

Does the active substance dissociate ?	Yes	
correlation DT_{50} and pH	Kendall-τ:-0.60 p-value: 0.221	not significant
coefficient of variation	68%	sufficiently low (≤ 100%)
DT_{50} for PEC_{GW} (d)	30	Geometric mean

Table 5.4-5: Statistic values according to INPUT DECISION 3.3 for 6-Cl-7-OH-XDE-742 for PEC_{GW} modelling

Does the active substance dissociate ?	Yes	
correlation DT_{50} and pH	Kendall-τ: -0.667 p-value: 0.308	not significant
coefficient of variation	73	sufficiently low (≤ 100%)
DT_{50} for PEC_{GW} (d)	30	Geometric mean

Table 5.4-6: Statistic values according to INPUT DECISION 3.3 for 5,7-di-OH-XDE-742 for PEC_{GW} modelling

Does the active substance dissociate ?	Yes	
correlation DT_{50} and pH	Kendall-τ: -0.667 p-value: 0.308	not significant
coefficient of variation	56 %	sufficiently low (≤ 100%)
DT_{50} for PEC_{GW} (d)	2.3	Geometric mean

Table 5.4-7: Statistic values according to INPUT DECISION 3.3 for Pyridine Sulfonamide for PEC_{GW} modelling

Does the active substance dissociate ?	Yes	
correlation DT_{50} and pH	Kendall-τ: -0.913 p-value: 0.149	not significant
coefficient of variation	49%	sufficiently low (≤ 100%)
DT_{50} for PEC_{GW} (d)	82	Geometric mean (n=4)

5.4.1.2 Field studies

Pinoxaden

Field studies of metabolite M2 of Pinoxaden as evaluated in the EU review are presented in the core assessment, part B, section 5, chapter 5.4.1.2.

For metabolite M2 the coefficient of variation is to high (>100 %), therefore the 10^{th}/ 90^{th} percentile of the DT_{50} values is used for PEC_{GW}.

Table 5.4-8: Statistical values according to INPUT DECISION 3.3 for the metabolite M2 (NOA407854) for PEC_{GW} modelling

Does the active substance dissociate?	No	
Correlation DT_{50} and pH	-	not significant
Coefficient of variation	125 %	too high
DT_{50} for PEC_{GW} (d)	0.9/ 8.8	10^{th} / 90^{th} percentile

Pyroxsulam

Please refer to the core assessment (January 2018~~July 2017~~), part B, section 5, point 5.4.1.2.

5.4.2 Adsorption/desorption

Pinoxaden

Please refer to the core assessment (January 2018~~July 2017~~), part B, section 5, point 5.4.2.

The K_{Foc} values were analysed according to Holdt et al. 2011 (Holdt et al: Recommendations for simulations to predict environmental concentrations of active substances of plant protection products and their metabolites in groundwater (PEC_{GW}) in the National assessment for authorization in Germany, Texte Umweltbundesamt 56, 2011).

Table 5.4-9: K_F, K_{Foc} and 1/n (Freundlich exponent) values for Pinoxaden

Soil Type	OC (%)	pH (Ca Cl_2)	K_F (mL g^{-1})	K_{Foc} (mL g^{-1})	1/n (-)	Reference
Borstel (Germany)	1.0	5.1	1.73	172.7	0.990	Adam, 2002 (EFSA Journal 2013;11(8): 3269)
Marsillargues (France)	1.4	7.3	4.4	323.4	1.025	
Gartenacker (CH)	2.4	7.2	2.9	121.2	1.029	
18 Acres (UK)	2.5	5.8	4.6	179.7	1.054	
Plaza (USA)	1.2	7.0	4.903	403	1.081	Spare, 2003a (EFSA Journal 2013;11(8): 3269)
Northwood (USA)	3.0	6.4	13.409	453	0.889	
Ephrata (USA)	0.35	6.7	1.041	299	1.019	
Minto (Canada)	3.2	7.5	10.954	337	0.969	
Larned (USA)	1.0	5.6	8.897	852	0.938	
Arithmetic mean (n=9)				352	0.999	
Median (n=9)				323	1.03	LoEP

Table 5.4-10: Statistical values according to INPUT DECISION 3.3 for Pinoxaden for PEC_{GW} modelling

Does the active substance dissociate?	no	
Correlation K_F and oc	Kendall-τ: 0.479 p-value: 0.047	significantly positive (p-value < significance level)
Coefficient of variation K_{Foc}	65 %	not relevant
Correlation K_F and pH	Kendall-τ: 0.111 p-value: 0.754	not significant (p-value > significance level)
Correlation K_F and other soil parameters (clay, CEC)	-	not relevant
K_{Foc} for PEC_{GW}	352	arithmetic mean all soils, n= 9
1/n PEC_{GW}	0.999	arithmetic mean all soils, n=9

Table 5.4-11: K_F, K_{Foc} and 1/n (Freundlich exponent) values for metabolite M2 (NOA407854)

Soil Type	OC (%)	pH ($CaCl_2$)	K_F (mL g^{-1})	K_{Foc} (mL g^{-1})	1/n (-)	Reference (EFSA Journal 2013; 11(8):3269)
Birkenheide (Germany)	0.9	6.0	0.4669	51.9	0.9717	Hein, 2003a
Plaza (USA)	1.2	7.7	0.06	5.2	1.019	Spare, 2002
Northwood (USA)	3.0	6.8	0.18	6.0	0.976	
Ephrata (USA)	0.3	7.0	0.098	23	1.153	
Minto (Canada)	3.2	7.8	0.14	4.2	0.988	
Larned (USA)	1.0	6.4	0.28	27	0.975	
18 Acres (UK)	2.9	5.9	0.4908	16.9	0.9022	Hein, 2003b
Wisborough Green (UK)	2.91	4.8	0.3233	11.1	0.9886	
Maine (USA)	2.6	5.0	0.1431	5.5	0.9642	
Wisborough Green (UK)	2.53	4.8	0.1	4.0	0.89	Kuet and Dick, 2003
Borstel (Germany)	1.4	4.9	0	0	1	
18 Acres (UK)	2.94	5.9	0.32	11	0.77	
Gartenacker (CH)	2.3	7.1	0	0	1	
Marsillargues (France)	0.58	7.8	0	0	1	
Welver-Borgeln	2.02	6.7	0.1931	9.6	0.9266	Fent, 2004
Pappelacker	1.14	6.7	0	0	1	
Arithmetic mean (n=9)				12	0.978	
Median (n=9)			0.18	6	1	LoEP

Table 5.4-12: Statistical values according to INPUT DECISION 3.3 for metabolite M2 (NOA407854) for PEC_{GW} modelling

Does the active substance dissociate?	no	
Correlation K_F and oc	Kendall-τ: 0.251 p-value: 0.101	not positive significant (p-value > significance level)
Coefficient of variation K_{Foc}	120 %	too high (> 60%)
Correlation K_F and pH	Kendall-τ: -0.298 p-value: 0.132	not significant (p-value > significance level)
Correlation K_F and other soil parameters (clay, CEC)	Kendall-τ: 0.407 p-value: 0.018	positive significant (p-value < significance level)
K_F for PEC_{GW}	Calculated from CEC: 1.: 0.15 2.: 0.13 3.: 0.08 4.-6.: 0.07	Hamburg scenario with K_F-values specific for soil horizons, n=16
1/n PEC_{GW}	0.978	arithmetic mean all soils, n=16

Table 5.4-13: K_F, K_{Foc} and 1/n (Freundlich exponent) values for metabolite M3 (NOA447204)

Soil Type	**OC (%)**	**pH (Ca Cl_2)**	**K_F (mL g^{-1})**	**K_{Foc} (mL g^{-1})**	**1/n (-)**	**Reference (EFSA Journal 2013; 11(8):3269)**
Borstel (Germany)	1.0	5.1	0.38	37.8	1.046	Adam, 2003
Marsillargues (France)	1.4	7.9	0.59	43.5	1.070	
Gartenacker (CH)	2.4	7.2	0.62	26.2	1.028	
Plaza (USA)	1.2	7.0	0.280	23	0.904	Spare, 2003b
Northwood (USA)	3.0	6.4	0.764	26	0.914	
Ephrata (USA)	0.35	6.7	0.121	35	0.916	
Minto (Canada)	3.2	7.5	0.856	26	0.900	
Larned (USA)	1.0	5.6	0.500	48	0.915	
Arithmetic mean (n=8)				33	0.962	
Median (n=8)				30.6	0.916	LoEP

Table 5.4-14: Statistical values according to INPUT DECISION 3.3 for metabolite M3 (NOA447204) for PEC_{GW} modelling

Does the active substance dissociate?	no	
Correlation K_F and oc	Kendall-τ: 0.837 p-value: 0.003	significantly positive (p-value < significance level)
Coefficient of variation K_{Foc}	29 %	sufficiently low (≤ 60%)
Correlation K_F and pH	Kendall-τ: 0.286 p-value: 0.386	not positive significant (p-value > significance level)
Correlation K_F and other soil parameters (clay, CEC)	-	not relevant
K_{Foc} for PEC_{GW}	33	arithmetic mean all soils, n=8
1/n PEC_{GW}	0.962	arithmetic mean all soils, n=8

Table 5.4-15: K_F, K_{Foc} and 1/n (Freundlich exponent) values for metabolite M11 (SYN504574)

Soil Type	**OC (%)**	**pH (H_2O)**	**K_F (mL g^{-1})**	**K_{Foc} (mL g^{-1})**	**1/n (-)**	**Reference**
Gartenacker, silt loam	1.71	7.52	0.206	12.0	0.97	Robinson, 2012c
18 Acres, sandy clay loam	3.09	6.35	0.351	11.4	0.98	
Marsillargues, silty clay loam	0.83	8.08	0.117	14.1	0.99	
Arithmetic mean (n=3)				12.5	0.98	

Table 5.4-16: Statistical values according to INPUT DECISION 3.3 for metabolite M11 (SYN504574) for PEC_{GW} modelling

Does the active substance dissociate?	no	
Correlation K_F and oc	Kendall-τ: 1.000 p-value: 0.500	not positive significant (p-value > significance level)
Coefficient of variation K_{Foc}	11 %	sufficiently low (≤ 60%)
Correlation K_F and pH	Kendall-τ: -1.000 p-value: 1.000	not significant (p-value > significance level)
Correlation K_F and other soil parameters (clay, CEC)	-	not significant
K_{Foc} for PEC_{GW}	12.5	arithmetic mean all soils, n= 3
1/n PEC_{GW}	0.98	arithmetic mean all soils, n= 3

Table 5.4-17: K_F, K_{Foc} and 1/n (Freundlich exponent) values for metabolite M52 (SYN546105)

Soil Type	OC (%)	pH (H_2O)	K_F (mL g^{-1})	K_{Foc} (mL g^{-1})	1/n (-)	Reference
Gartenacker, silt loam	1.96	7.46	1.060	54.1	0.97	Völkel, 2012c
18 Acres, sandy clay loam	2.88	6.95	2.360	81.9	0.96	
Marsillargues, silty clay loam	1.05	7.95	2.836	270.1	1.00	
Arithmetic mean (n=3)				135.4	0.977	

Table 5.4-18: Statistical values according to INPUT DECISION 3.3 for metabolite M52 (SYN546105) for PEC_{GW} modelling

Does the active substance dissociate?	no	
Correlation K_F and oc	Kendall-τ:-0.333 p-value: 0.500	not positive significant (p-value > significance level)
Coefficient of variation K_{Foc}	87 %	too high (> 60%)
Correlation K_F and pH	Kendall-τ: 0.333 p-value: 1.000	not significant (p-value > significance level)
Correlation K_F and other soil parameters (clay, CEC)	-	not significant
K_F for PEC_{GW}	1.-3.: 2.09 4.-6.: 0	Hamburg scenario with K_F-values specific for soil horizons, n= 3
1/n PEC_{GW}	0.977	arithmetic mean all soils, n= 3

Table 5.4-19: K_F, K_{Foc} and 1/n (Freundlich exponent) values for metabolite M54 (SYN546106)

Soil Type	OC (%)	pH (H_2O)	K_F (mL g^{-1})	K_{Foc} (mL g^{-1})	1/n (-)	Reference
Gartenacker, silt loam	1.96	7.46	0.267	13.6	0.93	Völkel, 2012d
18 Acres, sandy clay loam	2.88	6.95	0.321	11.1	1.03	
Marsillargues, silty clay loam	1.05	7.95	0.310	29.5	1.00	
Arithmetic mean (n=3)				18.1	0.987	

Table 5.4-20: Statistical values according to INPUT DECISION 3.3 for metabolite M54 (SYN546106) for PEC_{GW} modelling

Does the active substance dissociate?	no	
Correlation K_F and oc	Kendall-τ: 1.000 p-value: 0.500	not significant (p-value > significance level)
Coefficient of variation K_{Foc}	55 %	sufficiently low (≤ 60%)
Correlation K_F and pH	Kendall-τ: 0.333 p-value: 1.000	not significant (p-value > significance level)
Correlation K_F and other soil parameters (clay, CEC)	-	not significant
K_{Foc} for PEC_{GW}	18.1	arithmetic mean all soils, n=3
1/n PEC_{GW}	0.987	arithmetic mean all soils, n=3

Table 5.4-21: K_F, K_{Foc} and 1/n (Freundlich exponent) values for metabolite M55 (SYN546107)

Soil Type	**OC (%)**	**pH (H_2O)**	**K_F (mL g^{-1})**	**K_{Foc} (mL g^{-1})**	**1/n (-)**	**Reference**
Gartenacker, silt loam	1.71	7.52	0.195	11.4	0.98	Robinson, 2012d
18 Acres, sandy clay loam	3.09	6.35	0.153	5.0	0.96	
Marsillargues, silty clay loam	0.83	8.08	0.143	17.3	1.05	
Arithmetic mean (n=3)				11.2	0.997	

Table 5.4-22: Statistical values according to INPUT DECISION 3.3 for metabolite M55 (SYN546107) for PEC_{GW} modelling

Does the active substance dissociate?	no	
Correlation K_F and oc	Kendall-τ: 0.333 p-value: 0.500	not positive significant (p-value > significance level)
Coefficient of variation K_{Foc}	56 %	sufficiently low (≤ 60%)
Correlation K_F and pH	Kendall-τ: -0.333 p-value: 1.000	not significant (p-value > significance level)
Correlation K_F and other soil parameters (clay, CEC)	-	not significant
K_{Foc} for PEC_{GW}	11.2	arithmetic mean all soils, n=3
1/n PEC_{GW}	0.997	arithmetic mean all soils, n=3

Pyroxsulam

Please refer to the core assessment (January 2018~~July 2017~~), part B, section 5, point 5.4.2.

In the core assessment K_{Foc} values from the EU assessment were considered.

The K_{Foc} values of Pyroxsulam and its metabolites 7-OH, 6-Cl-7-OH, 5-OH, 5,7-di-OH and Pyridine Sulfonamide listed in the core assessment were analysed according to Holdt et al. 2011 (Holdt et al: Recommendations for simulations to predict environmental concentrations of active substances of plant protection products and their metabolites in groundwater (PEC_{GW}) in the National assessment for authorization in Germany, Texte Umweltbundesamt 56, 2011).

Table 5.4-23: Statistic values according to INPUT DECISION 3.3 for the Pyroxsulam for PEC_{GW} modelling

Does the active substance dissociate ?	yes, pKs = 4.67	
correlation K_{foc} and pH	Kendall-τ: -0.539 p-value: 0.039	negativ significant → use pH tool of FOCUS PELMO 5.5.3
correlation K_f and pH	Kendall-τ: -0.629 p-value: 0.015	negativ significant (expected for acid)
correlation K_f and oc	Kendall-τ: 0.296 p-value: 0.140	not significant
coefficient of variation K_{foc}	63%	too high (> 60%)
coefficient of variation Kf	87%	sufficiently low (≤ 100%)
Correlation K_f and other soil parameters (clay, CEC)		not relevant
K_{foc}/K_f for PEC_{GW}	Two simulations of the scenarios Hamburg and Kremsmünster using the pH-tool of FOCUS PELMO 5.5.3 with two of the measured K_{foc} values of the active substance	
1/n PECgw	0.987	arithmetic mean all soils

Table 5.4-24: Statistic values according to INPUT DECISION 3.3 for the metabolite 7-OH-XDE-742 for PEC_{GW} modelling

Does the active substance dissociate ?	yes, pKs = 4.67	
correlation K_{foc} and pH	Kendall-τ: -1.000 p-value: 0.089	not significant
correlation K_f and pH	Kendall-τ:-1.000 p-value: 0.089	not significant
correlation K_f and oc	Kendall-τ: -0.548 p-value: 0.235	not significant
coefficient of variation K_{foc}	68%	too high (> 60%)
coefficient of variation Kf	42%	sufficiently low (≤ 100%)
Correlation K_f and other soil parameters (clay, CEC)	Clay: Kendall-τ: 0.000	not significant

	p-value: 1.000 CEC: Kendall-τ: -0.333 p-value: 0.367	
K_{foc}/K_f for PEC_{GW}	K_f-values specific for soil horizons: K_f = 0.90 (arithmetic mean) for the 1.-3. horizon of the scenario Hamburg and all soil horizons of the scenario Kremsmünster, Kf =0 for the 4.-6. horizon of the scenario Hamburg	
1/n PECgw	1.0	default

Table 5.4-25: Statistic values according to INPUT DECISION 3.3 for the metabolite 6-Cl-7-OH-XDE-742 for PEC_{GW} modelling

Does the active substance dissociate ?	yes, pKs = 4.67	
correlation K_{foc} and pH	Kendall-τ: -1.000 p-value: 0.089	not significant
correlation K_f and pH	Kendall-τ:-1.000 p-value: 0.089	not significant
correlation K_f and oc	Kendall-τ: -0.548 p-value: 0.235	not significant
coefficient of variation K_{foc}	79%	too high (> 60%)
coefficient of variation Kf	58%	sufficiently low (≤ 100%)
Correlation K_f and other soil parameters (clay, CEC)	Clay: Kendall-τ: 0.000 p-value: 1.000 CEC: Kendall-τ: -0.333 p-value: 0.367	not significant
K_{foc}/K_f for PEC_{GW}	K_f-values specific for soil horizons: K_f = 0.57 (arithmetic mean) for the 1.-3. horizon of the scenario Hamburg and all soil horizons of the scenario Kremsmünster, Kf =0 for the 4.-6. horizon of the scenario Hamburg	
1/n PECgw	1.0	default

Table 5.4-26: Statistic values according to INPUT DECISION 3.3 for the metabolite 5-OH-XDE-742 for PEC_{GW} modelling

Does the active substance dissociate ?	yes, pKs =4.67	
correlation K_{foc} and pH	Kendall-τ: -1.000 p-value: 0.089	not significant
correlation K_f and pH	Kendall-τ:-1.000 p-value: 0.089	not significant
correlation K_f and oc	Kendall-τ: -0.548 p-value: 0.235	not significant
coefficient of variation K_{foc}	99%	too high (> 60%)
coefficient of variation Kf	80%	sufficiently low (≤ 100%)
Correlation K_f and other soil parameters (clay, CEC)	Clay: Kendall-τ: 0.000 p-value: 1.000 CEC: Kendall-τ: -0.333 p-value: 0.367	not significant
K_{foc}/K_f for PEC_{GW}	K_f-values specific for soil horizons: K_f = 0.15 (arithmetic mean) for the 1.-3. horizon of the scenario Hamburg and all soil horizons of the scenario Kremsmünster, Kf =0 for the 4.-6. horizon of the scenario Hamburg	
1/n PECgw	1.0	default

Table 5.4-27: Statistic values according to INPUT DECISION 3.3 for the metabolite 5,7-di-OH-XDE-742 for PEC_{GW} modelling

Does the active substance dissociate ?	yes, pKs =4.67	
correlation K_{foc} and pH	Kendall-τ: -0.333 p-value:0.734	not significant
correlation K_f and pH	Kendall-τ: -0.667 p-value:0.308	not significant
correlation K_f and oc	Kendall-τ: -0.548 p-value: 0.235	not significant
coefficient of variation K_{foc}	94%	too high (> 60%)
coefficient of variation Kf	71%	sufficiently low (≤ 100%)
Correlation K_f and other soil parameters (clay, CEC)	Clay: Kendall-τ: -0.333 p-value: 0.734 CEC: Kendall-τ: -0.667 p-value:0.154	not significant

K_{foc}/K_f for PEC_{GW}	K_f-values specific for soil horizons: K_f = 3.56 (arithmetic mean) for the 1.-3. horizon of the scenario Hamburg and all soil horizons of the scenario Kremsmünster, Kf =0 for the 4.-6. horizon of the scenario Hamburg	
1/n PECgw	1.0	default

Table 5.4-28: Statistic values according to INPUT DECISION 3.3 for the metabolite Pyridine Sulfonamide for PEC_{GW} modelling

Does the active substance dissociate ?	yes, pKs =4.67	
correlation K_{foc} and pH	Kendall-τ:-0.913 p-value:0.149	not significant
correlation K_f and pH	Kendall-τ: 0.000 p-value: 1.000	not significant
correlation K_f and oc	Kendall-τ: -0.183 p-value: 0.500	not significant
coefficient of variation K_{foc}	97	too high (> 60%)
coefficient of variation Kf	48%	sufficiently low (≤ 100%)
Correlation K_f and other soil parameters (clay, CEC)	Clay: Kendall-τ: 0.183 p-value: 1.000 CEC: Kendall-τ: -0.183 p-value:0.500	not significant
K_{foc}/K_f for PEC_{GW}	K_f-values specific for soil horizons: K_f = 0.56 (arithmetic mean) for the 1.-3. horizon of the scenario Hamburg and all soil horizons of the scenario Kremsmünster, Kf =0 for the 4.-6. horizon of the scenario Hamburg	
1/n PECgw	0.845	arithmetic mean all soils n= 4

5.4.3 Rate of degradation in water/sediment

Pinoxaden

Please refer to the core assessment (January 2018~~July 2017~~), part B, section 5, point 5.4.3.

Accumulation of active substance and relevant metabolites in the sediment

active substance	Pinoxaden
accumulation potential in sediment	no ($DT_{90,whole\ system}$ < 1 year, see core assessment, part B, section 5, chapter 5.4.3)
accumulation factor (SFO) $\mathbf{f_{accu} = e^{-kt}/(1 - e^{-kt})}$	-
Metabolite	M2 (NOA407854)
accumulation potential in sediment	yes ($DT_{90,whole\ system}$ > 1 year, see core assessment, part B, section 5, chapter 5.4.3)
accumulation factor (SFO) $\mathbf{faccu = e^{-kt}/(1 - e^{-kt})}$	1.576 based on $DT_{50,\ whole\ system}$ = 515 d (maximum, see core assessment, part B, section 5, chapter 5.4.3), t = 365 d

Pyroxsulam

Please refer to the core assessment (January 2018~~July 2017~~), part B, section 5, point 5.4.3.

Accumulation of active substance and relevant metabolites in the sediment

active substance	Pyroxsulam
accumulation potential in sediment	no ($DT_{90,whole\ system}$ < 1 year, see core assessment, part B, section 5, chapter 5.4.3)
accumulation factor (SFO) $\mathbf{f_{accu} = e^{-kt}/(1 - e^{-kt})}$	-

5.5 Estimation of concentrations in soil (KIIIA1 9.4)

Results of PECsoil calculation for AVOXA according to EU assessment considering 5 cm soil depth are given in the core assessment (January 2018~~July 2017~~), part B, section 5, chapter 5.5.

For German exposure assessment the applied soil depth is based on experimental data (Fent, Löffler, Kubiak: Ermittlung der Eindringtiefe und Konzentrationsverteilung gesprühter Pflanzenschutzmittel-wirkstoffe in den Boden zur Berechnung des PEC-Boden. Abschlussbericht zum Forschungsvorhaben FKZ 360 03 018, UBA, Berlin 1999). Generally for active substances with a K_{Foc} < 500 a soil depth of 2.5 cm is applied whereas for active substances with a K_{Foc} > 500 a soil depth of 1 cm is applied. As soil bulk density 1.5 g cm^{-3} is assumed.

Due to the fast degradation of the active substance Pinoxaden in soil (DT_{90} < 365 d, Kinetic, laboratory data) the accumulation potential of Pinoxaden does not need to be considered.

Due to the fast degradation of Pyroxsulam and its soil metabolites (except Pyridine Sulfonamide) in soil (DT_{90} <365 d, SFO, laboratory data), their accumulation potential does not need to be considered. However, due to the slow soil degradation of soil metabolite Pyridine sulfonamide (DT_{90} > 365 d, SFO, laboratory data), the accumulation potential does need to be considered. Thus, for this metabolite an accumulated soil concentration (PEC_{accu}) is used for risk assessment that comprises background concentration in soil (PEC_{accu}) considering a tillage depth of 20 cm (arable crop) or 5 cm (permanent crops) and the maximum annual soil concentration PEC_{act} considering the relevant soil depth of 2.5 cm or 1.0 cm, respectively.

The PEC_{soil} calculations were performed with ESCAPE 2.0 based on the input parameters as presented in Table 5.5-1.

Table 5.5-1: Input parameters for AVOXA for PEC_{soil} calculation

Active substance	DT_{50}	Molecular weight (g/mol)	Molar correction factor (-)	Maximum occurrence in soil (%)
Pinoxaden	0.8 d (SFO, 90th Percentile, laboratory study)	400.5	-	-
Metabolite M2 (NOA407854)	48.4 d (SFO, 90th Percentile, laboratory study)	316.4	0.790	90%
Metabolite M3 (NOA447204)	346 d (SFO, 90th Percentile, laboratory study)	332.4	0.830	31%
Pyroxsulam	11.5 d (SFO, 90th percentile, laboratory studies)	434.36	-	-
Metabolite 7-OH-XDE-742	63.5 d (SFO, 90th percentile, laboratory studies)	420.33	0.968	76.5% (anaerobic soil study)
Metabolite 5-OH-XDE-742	3.4 d (SFO, Maximum, laboratory studies)	420.33	0.968	24.1%
Metabolite 6-Cl-7-OH-XDE-742	45.5 d (SFO, 90th percentile, laboratory studies)	454.77	1.047	26.2%
Metabolite 5,7-diOH-XDE-742	4.0 d (SFO, 90th percentile, laboratory studies)	406.30	0.935	27.3% (anaerobic soil study)

Metabolite Pyridine Sulfonamide	149.6 d (SFO, 90th percentile, laboratory studies)	256.20	0.590	13.2%
Metabolite PSA	35.5 d (SFO, 1 value, laboratory studies)	257.19	0.592	5.9%

Additional $PEC_{soil,act}$ was calculated for the formulation AVOXA for a soil depth of 2.5 cm. No short-term and long-term PEC_{soil} were calculated since $PEC_{soil,act}$ is considered sufficient for German risk assessment.

The calculated PEC_{soil} used for German risk assessment for Pinoxaden and Pyroxsulam as well as for the formulation AVOXA are summarized in Table 5.5-2.

Table 5.5-2: Results of PEC_{soil} calculation for the intended use in winter cereals used for German risk assessment

plant protection product:		AVOXA				
use:		00-001				
Number of applications/intervall		1				
application rate:		Pinoxaden: 60 g a.s./ha Pyroxsulam: 15 g a.s./ha AVOXA: 1895 g/ha[a)]				
crop interception:		25 %				
active substance/ formulation	**soil relevant application rate (g/ha)**	**$soil\ depth_{act}$ (cm)**	**PEC_{act} (mg/kg)**	**tillage depth (cm)**	**PEC_{bkgd} (mg/kg)**	**$PEC_{accu} = PEC_{act} + PEC_{bkgd}$ (mg/kg)**
Pinoxaden	45.0	2.5	0.1198	-	-	-
Metabolite M2 (NOA407854)	32.0	2.5	0.0853	-	-	-
Metabolite M3 (NOA447204)	11.6	2.5	0.0309	-	-	-
Pyroxsulam	11.25	2.5	0.0300	-	-	-
Metabolite 7-OH	8.3	2.5	0.0221	-	-	-
Metabolite 5-OH	2.6	2.5	0.0069	-	-	-
Metabolite 6-Cl-7-OH	3.1	2.5	0.0083	-	-	-
Metabolite 5,7-di-OH	2.9	2.5	0.0077	-	-	-
Metabolite Pyridine Sulfonamide	0.9	2.5	0.0024	20	0.0001	0.0025
Metabolite PSA	0.4	2.5	0.0011	-	-	-
AVOXA	1421.25	2.5	3.7900	-	-	-

[a)] Based on the maximum application of 1800 mL AVOXA/ha with a specific density of 1.053 g/mL.

5.6 Estimation of concentrations in surface water and sediment (KIIIA1 9.7)

Results of PECsw calculation of Pinoxaden and Pyroxsulam for the intended uses of AVOXA in winter cereals using FOCUS Surface Water are given in the core assessment (January 2018~~July 2017~~), part B, section 5, chapter 5.6.

For authorization in Germany, exposure assessment of surface water considers the two routes of entry (i) spraydrift and volatilisation with subsequent deposition and (ii) run-off, drainage separately in order to allow risk mitigation measures separately for each entry route.

Surface water exposure via spray drift and volatilization with subsequent deposition is estimated with the model EVA 3. Surface water exposure via surface run-off and drainage is estimated using the model EXPOSIT 3.0.

The German surface water exposure assessment is outlined in the following chapters.

5.6.1 PEC_{SW} after exposure by spraydrift and volatilization with subsequent deposition

The calculation of concentrations in surface water is based on spray drift data by Rautmann and Ganzelmeier.

The vapour pressure at 20 °C of the active substance Pinoxaden is $< 10^{-5}$ Pa. Hence the active substance Pinoxaden is regarded as non-volatile. Therefore exposure of surface water by the active substance Pinoxaden due to volatilization with subsequent deposition does not need to be considered.

The vapour pressure at 20 °C of the active substance Pyroxsulam is $< 10^{-5}$ Pa. Hence the active substance Pyroxsulam is regarded as non-volatile. Therefore exposure of surface water by the active substance Pyroxsulam due to volatilization with subsequent deposition does not need to be considered.

The calculation of PECsw after exposure via spray drift and volatilization with subsequent deposition is performed using the model EVA 3. For a single application, the exposure assessment via spray drift is based on the application rate in conjunction with the 90th percentile of the drift values. For multiple applications, lower percentiles of the drift values for each application are applied, resulting in an overall 90th percentile of drift probabilities. Only one volatilization event following the last use of pesticide is generally considered.

The endpoints used for modelling of surface water exposure via spray drift and volatilization with subsequent deposition with EVA 3 are summarized below.

Table 5.6-1: Endpoints of Pinoxaden used for the PEC_{SW} calculations with EVA 3

Parameter	Pinoxaden	Reference
Vapour pressure at 20 °C (Pa)	2.0×10^{-7}	EU endpoint
Solubility in water at 25 °C (mg/L)	200	EU endpoint
$DissT_{50}$ water (d)	0.28	SFO (worst case), EU endpoint
$DegT_{50}$ water/sediment study, total system (d)	0.28	SFO (worst case), EU endpoint

Table 5.6-2: Endpoints of Pyroxsulam used for the PEC_{SW} calculations with EVA 3

Parameter	Pyroxsulam	Reference
Vapour pressure at 20 °C (Pa)	$<1 \times 10^{-7}$	EU endpoint
Solubility in water at 25 °C (mg/L)	3200	EU endpoint
$DissT_{50}$ water (d)	21	SFO (worst case), EU endpoint
$DegT_{50}$ water/sediment study, total system (d)	24	SFO (worst case), EU endpoint

The calculated PECsw values after exposure via spray drift for Pinoxaden and Pyroxsulam for the intended use of AVOXA in winter cereals according to use No. 00-001 are presented in the National Addendum Germany, part B, section 6, chapter 6.5 considering the following input parameters related to the application.

Table 5.6-3: Input parameters for AVOXA used for PEC_{SW} calculations with EVA 3

Use No.:	00-001
Number of applications/ interval:	1
Application rate: **(g a.s./ha)**	Pinoxaden: 59.9 Pyroxsulam: 15.0
Drift scenario:	Arable crops

5.6.2 PEC_{SW} after exposure by surface run-off and drainage

The concentration of the active substance Pinoxaden and Pyroxsulam in adjacent ditch due to surface runoff and drainage is calculated using the model EXPOSIT 3.01.

The substance specific input parameters used for modelling surface water exposure via run-off and drainage in an adjacent ditch with EXPOSIT 3.01 are summarized in chapter 5.7.2 of this document.

The calculated PEC_{SW} in an adjacent ditch due to surface run-off and drainage for the active substance Pinoxaden and Pyroxsulam for the intended use of AVOXA in winter cereals according to use No. 00-001 are presented in the National Addendum Germany, part B, section 6, chapter 6.5 considering the following input parameters related to the application.

Table 5.6-4: Input parameters related to the application for PEC_{sw} calculations with Exposit 3.01

Use No.:	00-001
Number of applications/ interval:	1
Application rate **(g a.s./ha)**	Pinoxaden: 59.9 Pyroxsulam: 15.0
Crop interception:	25 %

5.7 Risk assessment for groundwater (KIIIA1 9.6)

Results of the PECgw calculation of Pinoxaden and Pyroxsulam for the intended uses of AVOXA in winter cereals according to EU assessment using FOCUS PELMO are given in the core assessment (January 2018~~July 2017~~), part B, section 5, chapter 5.7.

For authorization in Germany, risk assessment for groundwater considers two pathways, (i) direct leaching of the active substance into the groundwater after soil passage and (ii) surface run-off and drainage of the active substance into an adjacent ditch with subsequent bank filtration into the groundwater.

Direct leaching after soil passage is assessed following the recommendations of the publication of Holdt et al. 2011 (Holdt et al: Recommendations for simulations to predict environmental concentrations of active substances of plant protection products and their metabolites in groundwater (PEC_{GW}) in the National assessment for authorization in Germany, Texte Umweltbundesamt 56, 2011) for tier 1 and tier 2 risk assessment. According to Hold et al, 2011, endpoints for groundwater modelling are derived with the program INPUT DECISION 3.3 and subsequent simulations are performed for the groundwater scenarios "Hamburg" or with the scenarios "Hamburg" and "Kremsmünster" of FOCUS PELMO.

In tier 3 risk assessment, results of experimental studies (lysimeter studies and/or field leaching studies) can also be considered in German groundwater risk assessment.

Surface run-off and drainage into an adjacent ditch with subsequent bank filtration into the groundwater are estimated using the model EXPOSIT 3.

The German risk assessment for groundwater is given in the following chapters.

5.7.1 Direct leaching into groundwater

5.7.1.1 PEC_{GW} modelling

The worst case scenario used for PECgw modelling is summarized in Table 5.7-1. It covers the intended uses of AVOXA in winter cereals according to Table 5.2-1 (see also Appendix 3).

Table 5.7-1: Input parameters related to application for PEC_{GW} modelling with FOCUS PELMO 5.5.3

Use evaluated	A/00-001
Application rate	Pinoxaden: 59.9 g a.s./ha Pyroxsulam: 15 g a.s./ha
Crop (crop rotation)	winter cereals
Date(s) of application(s)	15.02.
Interception (%)	25 %
Soil effective application rate	Pinoxaden: 0.045 kg as/ha Pyroxsulam: 0.0113 kg a.s./ha
Soil moisture	100 % FC
Q10-factor	2.58
Moisture exponent	0.7
Plant uptake	0
Simulation period (years)	26

Pinoxaden

For PECgw modelling please refer to the core assessment (January 2018~~July 2017~~), part B, section 5, chapter 5.7.1.

In addition to the PECgw modelling experimental data from lysimeter studies studies are used to assess the leaching behaviour of the active substance Pinoxaden and its metabolites.

Pyroxsulam

The endpoints used for groundwater modelling for Pyroxsulam and its metabolites 5-OH, 7-OH, 6-Cl-7-OH, 5,7-di-OH, Pyridine Sulfonamide and PSA according to INPUT DECISION 3.3 are summarized inTable 5.7-2.

Table 5.7-2: Input parameters related to Pyroxsulam and its metabolites for PEC_{GW} modelling

Parent	**Pyroxsulam**	**Remarks/Reference to core assessment, part B, section 5**
Molecular weight (g/mol)	434.4	
DT_{50} in soil (d)	3.3	Geometric mean (laboratory data)
K_{Foc}	Two simulations of the scenarios Hamburg and Kremsmünster using the pH tool of FOCUS PELMO 5.5.3 with to of the measured K_{foc} values of the active substance 1. Kfoc: 24 at pH 6.3 2. Kfoc: 10 at pH 7.8 pKa: 4.67	
1/n	0.987	Arithmetic mean (all soils)
Plant uptake factor	0	default
Metabolite	**5-OH-XDE-742**	
Molecular weight (g/mol)	420.3	
Formation fraction	0.374	Arithmetic mean
DT_{50} in soil (d)	3.1	Geometric mean
K_{Foc}	K_f-values specific for soil horizons: K_f = 0.15 (arithmetic mean) for the 1.-3. horizon of the scenario Hamburg and all soil horizons of the scenario Kremsmünster, K_f =0 for the 4.-6. horizon of the scenario Hamburg	
1/n	1.0	default
Plant uptake factor	0	default
Metabolite	**7-OH-XDE-742**	
Molecular weight (g/mol)	420.3	
Formation fraction	-	
DT_{50} in soil (d)	30	Geometric mean
K_{Foc}	K_f-values specific for soil horizons: K_f = 0.90 (arithmetic mean) for the 1.-3. horizon of the scenario Hamburg and all soil horizons of the scenario Kremsmünster, Kf =0 for the 4.-6. horizon of the scenario Hamburg	
1/n	1.0	default

Plant uptake factor	0	default
Max. % in soil	13.7	From aerobic soil studies
Soil deposition (g a.s./ha)	1.5	Input as direct application to soil.
Metabolite	**6-Cl-7-OH-XDE-742**	
Molecular weight (g/mol)	454.8	
Formation fraction	-	
DT_{50} in soil (d)	30	Geometric mean
K_{Foc}	K_f-values specific for soil horizons: K_f = 0.57 (arithmetic mean) for the 1.-3. horizon of the scenario Hamburg and all soil horizons of the scenario Kremsmünster, Kf =0 for the 4.-6. horizon of the scenario Hamburg	
1/n	1.0	default
Plant uptake factor	0	default
Max. % in soil	26.2	From aerobic soil studies
Soil deposition (g a.s./ha)	3.1	Input as direct application to soil.
Metabolite	**5,7-diOH-XDE-742**	
Molecular weight (g/mol)	406.3	
Formation fraction	-	
DT_{50} in soil (d)	2.3	Geometric mean
K_{Foc}	K_f-values specific for soil horizons: K_f = 3.56 (arithmetic mean) for the 1.-3. horizon of the scenario Hamburg and all soil horizons of the scenario Kremsmünster, Kf =0 for the 4.-6. horizon of the scenario Hamburg	
1/n	1.0	default
Plant uptake factor	0	default
Max. % in soil	27.3	From aerobic soil studies
Soil deposition (g a.s./ha)	2.9	Input as direct application to soil.
Metabolite	**Pyridine sulfonamide**	
Molecular weight (g/mol)	256.2	
Formation fraction	-	
DT_{50} in soil (d)	82	Geometric mean
K_{Foc}	K_f-values specific for soil horizons: K_f = 0.56 (arithmetic mean) for the 1.-3. horizon of the scenario Hamburg and all soil horizons of the scenario Kremsmünster, Kf =0 for the 4.-6. horizon of the scenario Hamburg	
1/n	0.85	default
Plant uptake factor	0	default
Max. % in soil	13.2	From aerobic soil studies
Soil deposition (g a.s./ha)	0.9	Input as direct application to soil.

Metabolite	**PSA**	
Molecular weight (g/mol)	257.2	
Formation fraction	-	
DT_{50} in soil (d)	300	Conservative default (EU endpoint)
K_{Foc}	1.0	Worst case default (EU endpoint)
1/n	1.0	default
Plant uptake factor	0	default
Max. % in soil	5.9	From aerobic soil studies
Soil deposition (g a.s./ha)	0.4	Input as direct application to soil.

The results of the groundwater simulation are presented in Table 5.7-3.

Table 5.7-3: PEC_{GW} at 1 m soil depth of Pyroxsulam and its metabolites considered relevant for German exposure assessment

Use No.	Scenario	80th Percentile PEC_{GW} at 1 m soil depth (µg L^{-1}) modeled by FOCUS PELMO 5.5.3				
		Pyroxsulam	Metabolite			
			5-OH	7-OH	6-Cl-7-OH	5,7-di-OH
A/ 00-001	Hamburg	<0.001	<0.001	0.008	0.047	<0.001
	Kremsmünster	0.001	<0.001	0.005	0.029	<0.001
		Metabolite				
		Pyridine sulfonamide	PSA			
	Hamburg	0.006	**0.200**			
	Kremsmünster	0.003	**0.142**			

According to the results of the groundwater simulation with FOCUS-PELMO 5.5.3, a groundwater contamination of the active substance Pyroxsulam in concentrations ≥ 0.1 µg/L is not expected for the intended use in winter cereals.

For the metabolites 5-OH, 7-OH, 6-Cl-7-OH, 5,7-di-OH and Pyridine Sulfonamide of Pyroxsulam a groundwater concentrations ≥ 0.1 µg/L can be excluded for the application in winter cereals according to the results of the groundwater simulation with FOCUS-PELMO 5.5.3.

For the metabolite PSA of Pyroxsulam a groundwater concentrations ≥ 0.1 µg/L cannot be excluded for the application in winter cereals according to the results of the groundwater simulation with FOCUS-PELMO 5.5.3.

5.7.1.2 Experimental data to the leaching behaviour

Pinoxaden

In case of the active substance Pinoxaden exposure assessment is based additionally on results of a lysimeter study. The study by Fent (2004, Report No. NOV15) and Berdat and Nicollier (2004, Report No. 03GN07) is described in detail in DAR, Volume 3, chapter B.8.2.4.

The experimental data on the leaching behaviour of the active substance Pinoxaden show that the active substance Pinoxaden and its metabolite M2 (NOA 407854) are not expected to penetrate into groundwater at concentrations of ≥ 0.1µg/L in the intended uses of AVOXA in winter cereals.

For the metabolites of Pinoxaden the following concentrations of >0.1µg/L in groundwater cannot be excluded:

M3: 0.218 µg/L

M11: 0.263 µg/L

M52: 0.150 µg/L

M54: 0.173 µg/L

M55: 0.161 µg/L

M56: 0.307 µg/L

Pyroxsulam

No lysimeter study for Pyroxsulam available.

5.7.1.3 Summary on risk assessment for groundwater after direct leaching

Results of modelling with FOCUS PELMO 5.5.3 / lysimeter study show that the active substance Pinoxaden is not expected to penetrate into groundwater at concentrations of ≥ 0.1µg/L in the intended of AVOXA uses in winter cereals according to use No.00-001.

For the metabolite M2 (NOA 407854) concentrations of ≥ 0.1µg/L in groundwater can be excluded. For the metabolites M3, M11, M52, M54, M55 and M56 concentrations of ≥ 0.1µg/L in groundwater cannot be excluded.

An assessment of the metabolites M3, M11, M52, M54, M55 and M56 of Pinoxaden regarding their relevance for groundwater is necessary. For the assessment of relevance please refer to Section 8.

Results of modelling with FOCUS PELMO 5.5.3 show that the active substance Pyroxsulam is not expected to penetrate into groundwater at concentrations of ≥ 0.1µg/L in the intended of AVOXA uses in winter cereals according to use No. 00-001.

For the metabolites 5-OH, 7-OH, 6-Cl-7-OH, 5,7-di-OH and Pyridine Sulfonamide of Pyroxsulam a groundwater concentrations ≥ 0.1 µg/L can be excluded.

For the metabolite PSA of Pyroxsulam a groundwater concentrations ≥ 0.1 µg/L cannot be excluded.

An assessment of the metabolite PSA of Pyroxsulam regarding its relevance for groundwater is necessary. For the assessment of relevance for the metabolite PSA please refer to Section 8.

Consequences for authorization:

An assessment of the metabolites M3, M11, M52, M54, M55 and M56 of Pinoxaden regarding their relevance for groundwater is necessary. For the assessment of relevance please refer to Section 8. The authorisation of the plant protection product AVOXA in Germany according to use No. 00-001 is subject to the outcome of the assessment of the relevance of metabolite M3, M11, M52, M54, M55 and M56 of Pinoxaden by BfR.

An assessment of the metabolite PSA of Pyroxsulam regarding its relevance for groundwater is necessary. For the assessment of relevance please refer to Section 8.

5.7.2 Ground water contamination by bank filtration due to surface water exposure via run-off and drainage

Pinoxaden

The input parameters for Pinoxaden used for modelling surface water exposure via run-off and drainage in an adjacent ditch with subsequent bank filtration into the groundwater with EXPOSIT 3.0 are summarized in Table 5.7-4.

Table 5.7-4: Input parameters for Pinoxaden used for PEC_{GW} calculations with EXPOSIT 3.01

Parameter	Pinoxaden	Reference
$K_{Foc, Runoff}$	352	arithm. mean (see core assessment, section 5, chapter 5.4.2)
$K_{Foc, mobility class}$	352	arithm. mean (see core assessment, section 5, chapter 5.4.2)
DT_{50} soil (d)	0.8	90th Percentile, laboratory study (see core assessment, section 5, chapter 5.4.1.1)
Solubility in water (mg/L)	200	EU endpoint
Mobility class	3	default
Reduction by bank filtration	90 %	default

The calculated PECgw for Pinoxaden after surface run-off and drainage with subsequent bank filtration are summarized in Table 5.7-5.

Table 5.7-5: PEC_{gw} for Pinoxaden after surface run-off and drainage with subsequent bank filtration (modelled with EXPOSIT 3.01)

Active substance		**Pinoxaden**			
Use No.	**application rate interception**	**PECgw due to**			
		run-off		**drainage**	
		vegetated buffer strip (m)	**bank filtrate (µg/L)**	**Time of application**	**bank filtrate (µg/L)**
A / 00-001	1x 59.9 g a.s./ha, 25 %	0	<0.001	spring/summer	<0.001
		5	-		
		10	-	autumn/winter/ early spring	<0.001
		20	-		
required labelling		none			

According modelling with EXPOSIT 3.01, groundwater contamination at concentrations ≥ 0.1 µg/L by the active substance Pinoxaden due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

Metabolites of Pinoxaden

The soil metabolites of Pinoxaden (see core assessment, part B, section 5, point 5.3.1.3) are formed >10 % in soil. Therefore potential ground water contamination due to bank filtration via surface water exposure by run-off and drainage needs to be assessed using EXPOSIT 3.01.

The input parameter for the model EXPOSIT 3.01 are summarized in Table 5.7-6.

Table 5.7-6: Input parameter for soil metabolites of Pinoxaden for EXPOSIT 3.01

Parameter	**Metabolite M2 (NOA407854)**	**Metabolite M3 (NOA447204)**	**Reference**
Molecular weight (g/mol)	316.4	332.4	EU endpoint
Correction factor molecular weight	0.790	0.830	EU endpoint
Maximum occurrence in soil (%)	90 %	31 %	EU endpoint
$K_{Foc, Runoff}$	12	33	arithm. mean (see chapter 5.4.2)
$K_{Foc, mobility\ class}$	12	33	arithm. mean (see chapter 5.4.2)
DT_{50} soil (d)	48.4	346	90th Percentile, laboratory study (see core assessment, section 5, chapter 5.4.1.1)
Solubility in water (mg/L)	380000	370	EU endpoint
Mobility class	2	2	default
Reduction by bank filtration	75 %	75 %	default

The calculated PECgw for the soil metabolites of Pinoxaden after surface run-off and drainage with subsequent bank filtration are summarized in Table 5.7-7.

Table 5.7-7: PEC_{gw} for soil metabolite M2 of Pinoxaden after surface run-off and drainage with subsequent bank filtration (modelled with EXPOSIT 3.01)

Metabolite		**M2 (NOA407854)**			
Use No.	**application rate interception**	**PECgw due to**			
		run-off		**drainage**	
		vegetated buffer strip (m)	**bank filtrate (µg/L)**	**Time of application**	**bank filtrate (µg/L)**
A / 00-001	1x 42.6 g a.s./ha, 25 %	0	0.003	spring/summer	0.002
		5	-		
		10	-	autumn/winter/ early spring	0.006
		20	-		
required labelling		none			

Table 5.7-8: PEC_{gw} for soil metabolite M3 of Pinoxaden after surface run-off and drainage with subsequent bank filtration (modelled with EXPOSIT 3.01)

Metabolite		**M3 (NOA447204)**			
Use No.	**application rate interception**	**PECgw due to**			
		run-off		**drainage**	
		vegetated buffer strip (m)	**bank filtrate (µg/L)**	**Time of application**	**bank filtrate (µg/L)**
A / 00-001	1x 15.4 g a.s./ha, 25 %	0	0.001	spring/summer	0.001
		5	-		
		10	-	autumn/winter/ early spring	0.002
		20	-		
required labelling		none			

According to modelling with EXPOSIT 3, groundwater contamination at concentrations ≥ 0.1 µg/L by the soil metabolites M2 and M3 of Pinoxaden due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

Pyroxsulam

The input parameters for Pyroxsulam used for modelling surface water exposure via run-off and drainage in an adjacent ditch with subsequent bank filtration into the groundwater with EXPOSIT 3.0 are summarized in Table 5.7-9.

Table 5.7-9: Input parameters for Pyroxsulam used for PEC_{GW} calculations with EXPOSIT 3.01

Parameter	**Pyroxsulam**	**Reference**
Molecular weight	434.36	See core assessment, Part B, section 5.3.2.2
$K_{Foc, Runoff}$	28	arithm. mean (see core assessment, section 5, chapter 5.4.2)
$K_{Foc, mobility\ class}$	7	10th percentile (see core assessment, section 5, chapter 5.4.2)
DT_{50} soil (d)	11.5	90th percentile (see core assessment, section 5, chapter 5.4.1.1)
Solubility in water (mg/L)	3200 (at pH 7)	See core assessment, Part B, section 5.3.2.2
Mobility class	4	default
Reduction by bank filtration	100%	default

As the reduction by bank filtration is assumed to be 100 % for Pyroxsulam, no calculation is necessary.

According modelling with EXPOSIT 3.01, groundwater contamination at concentrations ≥ 0.1 µg/L by the active substance Pyroxsulam due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

Metabolites of Pyroxsulam

The soil metabolites of Pyroxsulam (see core assessment, part B, section 5, point 5.3.2.3) are formed >10 % in soil. Therefore potential ground water contamination due to bank filtration via surface water exposure by run-off and drainage needs to be assessed using EXPOSIT 3.01.

The input parameter for soil metabolite 7-OH-XDE-742 for the model EXPOSIT 3.01 are summarized in Table 5.7-10.

Table 5.7-10: Input parameter for soil metabolites 7-OH-XDE-742 of Pyroxsulam for EXPOSIT 3.01

Parameter	**Metabolite 7-OH-XDE-742**	**Reference**
Molecular weight (g/mol)	420.33	EU endpoint
Correction factor molecular weight	0.968	EU endpoint
Maximum occurrence in soil (%)	76.5	See core assessment, Part B, section 5.3.2.3
$K_{Foc, Runoff}$	62.3	arithm. mean (see core assessment, section 5, chapter 5.4.2)
$K_{Foc, mobility\ class}$	24	10th percentile (see core assessment, section 5, chapter 5.4.2)
DT_{50} soil (d)	63.5	90th percentile (see core assessment, section 5, chapter 5.4.1.1)
Solubility in water (mg/L)	3200 (at pH7)	See core assessment, Part B, section 5.3.2.2
Mobility class	3	default
Reduction by bank filtration	90 %	default

The calculated PECgw for the soil metabolite 7-OH-XDE-742 of Pyroxsulam after surface run-off and drainage with subsequent bank filtration are summarized in Table 5.7-11.

Table 5.7-11: PEC_{gw} for soil metabolite 7-OH-XDE-742 of Pyroxsulam after surface run-off and drainage with subsequent bank filtration (modelled with EXPOSIT 3.01)

Metabolite		**7-OH-XDE-742**			
Use No.	**application rate interception**	**PECgw due to**			
		run-off		**drainage**	
		vegetated buffer strip (m)	**bank filtrate (µg/L)**	**time of application**	**bank filtrate (µg/L)**
A/ 00-001	11.1 g a.s./ha 25 %	0	<0.001	spring/summer	<0.001
		5	-		
		10	-	autumn/winter/ early spring	0.001
		20	-		
Required labelling		none			

The input parameter for soil metabolite 5-OH-XDE-742 for the model EXPOSIT 3.01 are summarized in Table 5.7-12.

Table 5.7-12: Input parameter for soil metabolites 5-OH-XDE-742 of Pyroxsulam for EXPOSIT 3.01

Parameter	Metabolite 5-OH-XDE-742	Reference
Molecular weight (g/mol)	420.33	EU endpoint
Correction factor molecular weight	0.968	EU endpoint
Maximum occurrence in soil (%)	24.1	See core assessment, Part B, section 5.3.2.3
$K_{Foc, Runoff}$	11	arithm. mean (see core assessment, section 5, chapter 5.4.2)
$K_{Foc, mobility class}$	2	10th percentile (see core assessment, section 5, chapter 5.4.2)
DT_{50} soil (d)	3.4	Maximum (see core assessment, section 5, chapter 5.4.1.1)
Solubility in water (mg/L)	3200 (at pH7)	See core assessment, Part B, section 5.3.2.2
Mobility class	4	default
Reduction by bank filtration	100 %	default

As the reduction by bank filtration is assumed to be 100 % for metabolite 5-OH-XDE-742, no calculation is necessary.

The input parameter for soil metabolite 6-Cl-7-OH-XDE-742 for the model EXPOSIT 3.01 are summarized in Table 5.7-13.

Table 5.7-13: Input parameter for soil metabolites 6-Cl-7-OH-XDE-742 of Pyroxsulam for EXPOSIT 3.01

Parameter	Metabolite 6-Cl-7-OH-XDE-742	Reference
Molecular weight (g/mol)	454.77	EU endpoint
Correction factor molecular weight	1.047	EU endpoint
Maximum occurrence in soil (%)	26.2	See core assessment, Part B, section 5.3.2.3
$K_{Foc, Runoff}$	40	arithm. mean (see core assessment, section 5, chapter 5.4.2)
$K_{Foc, mobility class}$	15	10th percentile (see core assessment, section 5, chapter 5.4.2)
DT_{50} soil (d)	45.5	90th percentile (see core assessment, section 5, chapter 5.4.1.1)
Solubility in water (mg/L)	3200 (at pH7)	See core assessment, Part B, section 5.3.2.2
Mobility class	2	default
Reduction by bank filtration	75 %	default

The calculated PECgw for the soil metabolite 6-Cl-7-OH-XDE-742 of Pyroxsulam after surface run-off and drainage with subsequent bank filtration are summarized in Table 5.7-14.

Table 5.7-14: PEC_{gw} for soil metabolite 6-Cl-7-OH-XDE-742 of Pyroxsulam after surface run-off and drainage with subsequent bank filtration (modelled with EXPOSIT 3.01)

Metabolite		**6-Cl-7-OH-XDE-742**			
Use No.	**application rate interception**	**PECgw due to**			
		run-off		**drainage**	
		vegetated buffer strip (m)	**bank filtrate (µg/L)**	**time of application**	**bank filtrate (µg/L)**
A/ 00-001	4.1 g a.s./ha 25 %	0	<0.001	spring/summer	<0.001
		5	-		
		10	-	autumn/winter/ early spring	0.001
		20	-		
Required labelling		none			

The input parameter for soil metabolite 5,7-diOH-XDE-742 for the model EXPOSIT 3.01 are summarized in Table 5.7-15.

Table 5.7-15: Input parameter for soil metabolite 5,7-diOH-XDE-742 of Pyroxsulam for EXPOSIT 3.01

Parameter	**Metabolite 5,7-diOH-XDE-742**	**Reference**
Molecular weight (g/mol)	406.3	EU endpoint
Correction factor molecular weight	0.935	EU endpoint
Maximum occurrence in soil (%)	27.3	See core assessment, Part B, section 5.3.2.3
$K_{Foc, Runoff}$	280	arithm. mean (see core assessment, section 5, chapter 5.4.2)
$K_{Foc, mobility\ class}$	54	10th percentile (see core assessment, section 5, chapter 5.4.2)
DT_{50} soil (d)	4	90th percentile (see core assessment, section 5, chapter 5.4.1.1)
Solubility in water (mg/L)	3200 (at pH7)	See core assessment, Part B, section 5.3.2.2
Mobility class	4	default
Reduction by bank filtration	100 %	default

As the reduction by bank filtration is assumed to be 100 % for metabolite 5,7-diOH-XDE-742, no calculation is necessary.

According to modelling with EXPOSIT 3, groundwater contamination at concentrations ≥ 0.1 µg/L by the soil metabolites 5-OH, 7-OH, 6-Cl-7-OH and 5,7-di-OH of Pyroxsulam due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

Consequences for authorization:

None

Appendix 1 List of data submitted in support of the evaluation

No additional data for national assessment submitted.

Appendix 2 Detailed evaluation of studies relied upon

Appendix 3 Table of Intended Uses in Germany (according to BVL 16.10.2017)

PPP (product name/code) **AVOXA / A19786A** **Formulation type:** **EC**
active substance 1 **Pinoxaden** **Conc. of as 1:** **33.3 g/L**
active substance 2 **Pyroxsulam** **Conc. of as 2:** **8.33 g/L**

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**			**Application rate**			**PHI** (days)	**Remarks:** e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
00-001	DE	Winter cereals (soft wheat, rye, triticale)	F	*Alopecurus myosuroides* ALOMY *bromegrass* BROSS *galium aparine* GALAP	spraying	After emergence BBCH 10 – 32 spring	a) 1 b) 1	a) 1.8 L/ha b) 1.8 L/ha	a) as 1: 59.9 g/ha as 2: 15 g/ha b) as 1: 59.9 g/ha as 2: 15 g/ha	200-400	XF *	Also includes safener at 15 g cloquintocet-mexyl/ha
00-002	DE	Winter cereals (soft wheat, rye, triticale)	F	*Apera* spica-venti APESV *Lolium ssp.* LOLSS *annual dicotyledonous weeds* TTTDS	spraying	After emergence BBCH 10 – 32 spring	a) 1 b) 1	a) 1.35 L/ha b) 1.35 L/ha	a) as 1: 45 g/ha as 2: 11.3 g/ha b) as 1: 45 g/ha as 2: 11.3 g/ha	200-400	XF *	Also includes safener at 15 g cloquintocet-mexyl/ha

* XF: The PHI is covered by the conditions of use and/or the vegetation period remaining between the application of the plant protection product and the use of the product (e. g. harvest) or the setting of a PHI in days is not required resp.

REGISTRATION REPORT
Part B

Section 6: Ecotoxicological studies
Detailed summary of the risk assessment

Product code: A19786A (AVOXA)
Active Substance: 33.3 g/L Pinoxaden
8.33 g/L Pyroxsulam
Safener: 8.33 g/L Cloquintocet-mexyl

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Syngenta
Date: Jan. 2018

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Sec 6 ECOTOXICOLOGICAL STUDIES (MIIIA 10)

This document reviews the ecotoxicological studies for the product A19786A (AVOXA) containing the active substances Pinoxaden and Pyroxsulam as well as cloquintocet-mexyl as safener.

At the date of submission pinoxaden was currently evaluated for approval under Reg. (EC) No 1107/2009 (repealing Directive 91/414/EEC) and was provisionally authorized according to legislation 2005/459/EC and 2012/191/EU. Since July 1st 2016 pinoxaden is approved under Reg. (EC) No 1107/2009 and fulfils the criteria according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2.

Pyroxsulam is currently approved under Reg. (EC) No 1107/2009 (repealing Directive 91/414/EEC) and fulfils the criteria according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2.

The safener cloquintocet-mexyl has already been evaluated and approved under national registration across the EU in formulations and mixture containing the active substances clodinafop, pinoxaden, and pyroxsulam. Safeners and synergists are in scope of REG 1107/2009 and similar data requirements as known for active substances were actually supposed to be defined for safeners and synergists by a review programme planned under Commission Regulation (EC) 1107/2009 until the 14th December 2014. However, these data requirements are not available yet and it is not legally allowed – by now – to request missing data if not submitted. Against this backdrop, information on cloquintocet-mexyl was considered for the risk assessment were available. We provide these data within the CA. Data were partly made available by the applicant in a summarizing report on cloquintocet-mexyl (Lefebvre, B., 07.10.2003, Report No. ERA7148) and partly taken from previous EU assessments (e.g. old DAR of Clodinafop-propargyl). Thus no new endpoints for cloquintocet-mexyl were considered but previously submitted and evaluated endpoints.

A19786A (AVOXA) was not the representative formulation considered in the EU review process as part of the approval of pinoxaden and pyroxsulam.

The studies with the relevant endpoints for each non-target organism group were agreed during EU review process and are used for the risk assessment. Reference is made to the following documents, if not otherwise labelled with an asterisk:

Pinoxaden: EFSA Conclusion/LoEP: EFSA Journal 2013;11(8):3269

Pyroxsulam: EFSA Conclusion/LoEP: EFSA Journal 2013;11(4):3182

Full details of toxicity studies are provided in the respective EU DAR and their respective addenda. The applicant provides further studies with the formulation A19786A (AVOXA). Detailed study summaries for the studies performed with the formulated product A19786A (AVOXA) and for other new studies are presented in Appendix 2.

6.1 GAP and overall conclusions

6.1.1 Table of intended uses

Table 6.1-1: GAP and overall conclusions

Intended use	F/G	Timing (months, BBCH)	Max number appl. (interval in days)	Application per treatment		Overall conclusions						
				kg/ha max	Rate/season [kg a.s./ha] max	Birds	Aquatic organisms	Mammals	Bees	Non-target arthropods	Soil organisms	Non-target plants
Winter Wheat	F	BBCH 10-32 (spring application only)	1	1.35	pinoxaden 45 g/ha pyroxsulam 11.3 g/ha safener 11.3 g/ha		"X1"					
Winter Wheat	F	BBCH 10-32 (spring application only)	1	1.8	pinoxaden 59.9 g/ha pyroxsulam 15 g/ha safener 15 g/ha		"X1"			"X2"		
Winter Rye	F	BBCH 10-32 (spring application only)	1	1.35	pinoxaden 45 g/ha pyroxsulam 11.3 g/ha safener 11.3 g/ha		"X1"					
Winter Rye	F	BBCH 10-32 (spring application only)	1	1.8	pinoxaden 59.9 g/ha pyroxsulam 15 g/ha safener 15 g/ha		"X1"			"X2"		

Intended use	F/G	Timing (months, BBCH)	Max number appl. (interval in days)	Application per treatment		Overall conclusions						
				kg/ha max	Rate/season [kg a.s./ha] max	Birds	Aquatic organisms	Mammals	Bees	Non-target arthropods	Soil organisms	Non-target plants
Winter Triticale	F	BBCH 10-32 (spring application only)	1	1.35	pinoxaden 45 g/ha pyroxsulam 11.3 g/ha safener 11.3 g/ha		"X1"					
Winter Triticale	F	BBCH 10-32 (spring application only)	1	1.8	pinoxaden 59.9 g/ha pyroxsulam 15 g/ha safener 15 g/ha		"X1"			"X2"		

F: Field use; G: Glasshouse use

Remarks:
- Safe use identified
- Further refinement and/or risk mitigation measures are needed
- No safe use identified and considered possible

Explanations:

The colours in the Table 6-1 are intended to reflect the outcome of the assessments including the available and valid refinement steps and risk mitigations measures.

Remarks "X1": Not all scenarios pass at FOCUS step 3 due to risk for aquatic higher planst from exposure to pyroxsulam indication that risk mitigation (buffer strip and/or drift reducing technique) has to be implemented to achieve and acceptable risk for the respective scenarios.

Remarks "X2": Please note that there is an in-field risk identified. It should be evaluated on member state level, if risk mitigations can be used to manage the risk in the respective member state.

6.1.2 Grouping of intended uses for risk assessment

The following table lists the grouping of the intended uses in order to perform a risk envelope approach.

Table 6.1-2: Critical use pattern of A19786A (AVOXA)

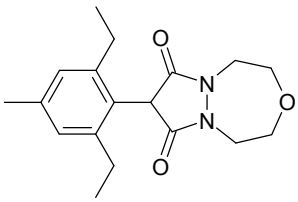
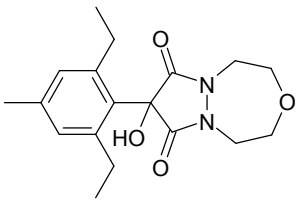
Group*	Crop/growth stage	Application method / Drift scenario	Number of applications, Minimum application interval, interception, application time (season)	Application rate, cumulative (g as/ha)
A*	winter wheat, winter triticale, winter rye BBCH 10-32	spraying / field crops	1 x 1.8 L/ha, spring 1. 25 %	Pinoxaden 1 x 59.9 Pyroxsulam 1 x 15
B	winter wheat, winter triticale, winter rye BBCH 10-32	spraying / field crops	1 x 1.35 L/ha, spring 1. 25 %	Pinoxaden 1 x 45 Pyroxsulam 1 x 11.3

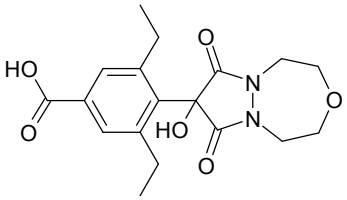
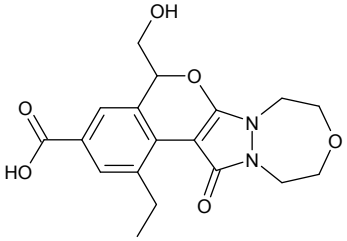
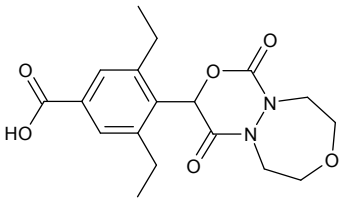
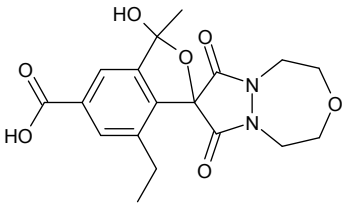
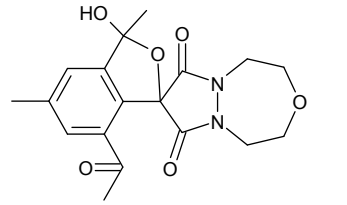
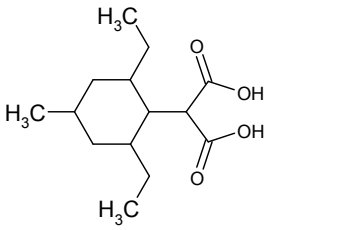
*Group A covers all intended uses in winter cereals in the central zone. Lower applications rates are also intended for use in cereals (see Group B).

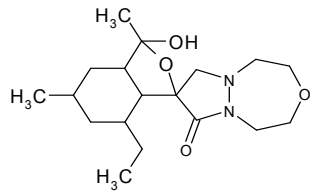
6.1.3 Consideration of metabolites

The metabolites which require an ecotoxicological assessment according to the endpoint list are given below.

Table 6.1-3: Metabolites of pinoxaden potentially relevant for exposure assessment (> 10 % of as or > 5 % of as in 2 sequential measurements or > 5 % of a.s. and maximum of formation not yet reached at the end of the study)

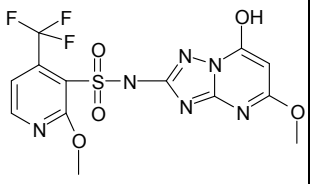
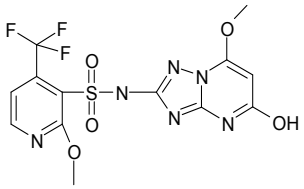
Metabolite	Structural formula/ Molecular mass	occurrence in compartments (Max. at day)	Status of Relevance (EFSA Journal 2013;11(8): 3269)
M2 (NOA 407854) (CSAA468548)	 316.4 g/mol	Soil: max. 90% after 3 d Water: max. 88.8% after 3 d Sediment: max. 29.6% after 35 d Soil-Photolysis: 78.7 % after 9 h	Aquatic organisms: Water: not relevant Sediment: not relevant Terrestrial organisms: not relevant Groundwater: relevant (Step 2/Step 3-4)[1)]
M3 (NOA 447204) (CSAA783052)	 332.37 g/mol	Soil: max. 31% after 120 d Soil-Photolysis: 15.3 % after 6 d Lysimeter leachate: 0.218 µg/L	Aquatic organisms: Water: not relevant Sediment: not relevant Terrestrial organisms: not relevant Groundwater: relevant (Step 2/Step 3-4)[1)]

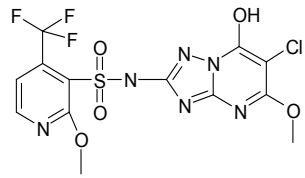
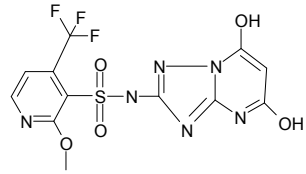
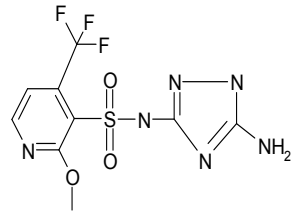
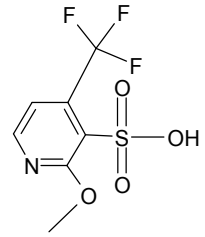
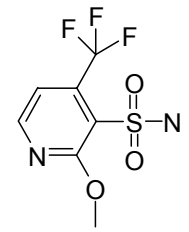
M11 (SYN 504574) (CSCC204395)	 362.36 g/mol	Lysimeter leachate: 0.263 µg/L	Aquatic organisms: Water: not applicable Sediment: not applicable Terrestrial organisms: not applicable Groundwater: relevant (Step 2/Step 3-4)[1)]
M52 (SYN546105) (CSCD704931)	 360.34 g/mol	Lysimeter leachate: 0.150 µg/L	Aquatic organisms: Water: not applicable Sediment: not applicable Terrestrial organisms: not applicable Groundwater: relevant (Step 2/Step 3-4)[1)]
M54 (SYN546106) (CSCD704932)	 362.4 g/mol	Lysimeter leachate: 0.173 µg/L	Aquatic organisms: Water: not applicable Sediment: not applicable Terrestrial organisms: not applicable Groundwater: relevant (Step 2/Step 3-4)[1)]
M55 (SYN546107) (CSCD704933)	 376.4 g/mol	Lysimeter leachate: 0.161 µg/L	Aquatic organisms: Water: not applicable Sediment: not applicable Terrestrial organisms: not applicable Groundwater: relevant (Step 2/Step 3-4)[1)]
M56 (SYN546108)	 360.34 g/mol	Lysimeter leachate: 0.307 µg/L	Aquatic organisms: Water: not applicable Sediment: not applicable Terrestrial organisms: not applicable Groundwater: relevant (Step 2/Step 3-4)[1)]
NOA 440626		Photolysis in water: max. 18.3 % after 23 d	Aquatic organisms: Water: not assessed Sediment: not assessed Terrestrial organisms: not applicable Groundwater: not applicable

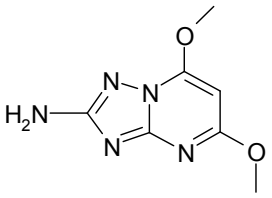
SYN515622	 346 g/mol	Soil-Photolysis: 20.4% after day 6	Aquatic organisms: Water: not applicable Sediment: not applicable Terrestrial organisms: not assessed Groundwater: not assessed

[1)] According to Guidance Document on the assessment of the relevance of metabolites in groundwater of substances regulated under council directive 91/414/EEC (SANCO/221/2000 –rev.10- final - 25 February 2003)

Table 6.1-4: Metabolites of pyroxsulam potentially relevant for exposure assessment (> 10 % of as or > 5 % of as in 2 sequential measurements or > 5 % of a.s. and maximum of formation not yet reached at the end of the study)

Metabolite	**Structural formula/ Molecular weight**	**occurrence in compartments (Max. at day)**	**Status of Relevance (SANCO/12099/2012rev1-03/10/2013)**
7-OH (7-OH-XDE-742)	 420.33 g/mol	Soil, aerobic: max. 13.7 % after 3 d (20°C) soil, anaerobic: 76.5% after 58 d → after 30 d, oxygen probably leaked in the anaerobic soil system, thus the amount of 7-OH formed in the anaerobic soil study will be considered in risk assessment also under aerobic conditions water/sediment-system: water: max. 32.7 % after 17d sediment: max. 25.8 % after 17d total system: max. 58.4 % after 17d	Aquatic organism: Water: not relevant Sediment: not relevant Terrestrial organism: not relevant Groundwater: not relevant (Step 3-4)[1)]
5-OH (5-OH-XDE-742)	 420.33 g/mol	Soil, aerobic: max. 24.1 % after 3 d (20°C)	Aquatic organism: Water: not relevant Sediment: not relevant Terrestrial organism: not relevant Groundwater: not relevant (Step 2)[1)]

6-Cl (6-Cl-7-OH-XDE-742)	 454.77 g/mol	<u>Soil, aerobic:</u> max. 26.2 % after 7 d (20°C)	Aquatic organism: Water: not relevant Sediment: not relevant Terrestrial organism: not relevant Groundwater: not relevant* (Step 3-4)[1)]
5,7-di-OH-XDE-742	 406.30	<u>Soil, anaerobic:</u> max. 27.3 % after 126 d → after 30 d, oxygen probably leaked in the anaerobic soil system, thus the amount of 5,7-di-OH formed in the anaerobic soil study will be considered in risk assessment also under aerobic conditions	Aquatic organism: Water: not relevant Sediment: not relevant Terrestrial organism: not assessed Groundwater: not relevant (Step 2)[1)]
XDE-742-ATSA	 338.27	<u>water/sediment-system:</u> water: 9.6, 7.8 and 8.7% after 54, 75 and 101 d (3x >5 %) Sediment: 5.3 % after 75 d (1x >5 %)	Aquatic organism: Water: not relevant Sediment: not relevant Terrestrial organism: not applicable Groundwater: not applicable
PSA (XDE-742 sulfonic acid) = Pyridin-sulfonic acid) = 2-methoxy-4-(trifluoromethyl)pyridine-3-sulfonic acid (IUPAC) = 2-methoxy-4-(trifluoromethyl)pyridine-3-sulfonamide	 257.19	<u>soil, aerobic:</u> max. 5.8 & 5.9 % max. after 21 & 29 d (2 x successively >5%) <u>aqueous photolysis</u> max. 79.2 % after 3.8 d	Aquatic organism: Water: not relevant Sediment: not relevant Terrestrial organism: not assessed Groundwater: not relevant* (Step 3-4)[1)]
XDE-742 Sulfonamide = Pyridine Sulfonamide =XDE-742 unsubstituted Sulfonamide Metabolite	 256.20	<u>soil, aerobic:</u> max. 13.2% after 29 d	Aquatic organism: Water: not relevant Sediment: not relevant Terrestrial organism: not relevant Groundwater: not relevant (Step 2)[1)]

742-ADTP	 195.18	Metabolite of aqueous photolysis max. 39.8 % after 3.8 d	Aquatic organism: Water: not relevant Sediment: not relevant Terrestrial organism: not applicable Groundwater: not applicable

[1)] According to Guidance Document on the assessment of the relevance of metabolites in groundwater of substances regulated under council directive 91/414/EEC (SANCO/221/2000 –rev.10- final - 25 February 2003)
* refers to EFSA Supporting publication 2017:EN-1168

6.2 Effects on birds (MIIIA 10.1, KPC 10.1, KPC 10.1.1)

Table 6.2-1: Endpoints used for risk assessment for birds

Species	Substance	Exposure System	Results	Reference	Internal code
Colinus virginianus	pinoxaden (NOA 407855)	Acute toxicity	LD_{50} > 2250 mg/kg bw	[redacted] 31.07.2003 97-01	51227
Colinus virginianus	pinoxaden metabolite NOA 407854 (M2)	Reproductive toxicity	NOEC = 27.8 mg/kg bw/d	[redacted] 08.09.2003 101-01	51236
Colinus virginianus	pyroxsulam	Acute toxicity	LD_{50} >2000 mg/kg bw	EFSA, DAR 2008. [redacted] (2003) 11W0298/035027	66090
Anas platyrhynchos	pyroxsulam	Reproductive toxicity	NOEL 46.3 mg/kg bw/d	EFSA, DAR 2008. [redacted] (2005) 12550.4116	66093
Colinus virginianus	Cloquintocet-mexyl (Safener)	Acute toxicity	LD_{50} > 2000 mg/kg bw	[redacted] 30.03.1990 CBG 471/89310	34009
Colinus virginianus	Cloquintocet-mexyl (safener)	Reproductive toxicity	NOEC: 51.72 mg/kg bw/d (= 500 ppm)	[redacted] 09.11.1993 CBG 548/549/931369	34014

6.2.1 Justification for new endpoints

Not necessary.

6.2.2 Risk assessment (MIIIA 10.1.1, MIIIA 10.1.2) for spray applications

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438).

For risk assessment purposes, a risk envelope approach was used. Hence, intended use group A covers the risk for birds from all intended uses (see Table 6.1-2).

Exposure to standard generic focal species was estimated according to the Guidance Document on Risk Assessment for Birds and Mammals (EFSA Journal 2009; 7(12): 1438)

$$DDD = \sum_i \frac{PD_i \times FIR_{total}}{bw} \times RUD \times AR \times PT$$

$$= \sum_i \frac{FIR_i}{bw} \times RUD \times AR \times PT$$

where:

DDD = Daily dietary dose (mg/kg bw/day)
PDi = composition of diet obtained from treated area
FIRi = Food intake rate of indicator species i (g fresh weight/d)
bw = Body weight (g)
RUD = Residue per unit dose, bases on an application rate of 1 kg a.s./ha and assuming broadcast seedling
AR = Application rate (kg/ha)
PT = Proportion of diet obtained in the treated area (0…1)

In a first approach, it is assumed that birds do not avoid contaminated food items, that they feed exclusively in the treated area and on a single food type. Factors PT and PD are therefore equal to 1.

The risk assessment procedure follows a stepwise approach. A first screening step involves standard scenarios and default values for the exposure estimate, representing a "reasonable worst case". If a risk is indicated in the screening step, then one or several refinement steps (Tier 1, Tier2) may follow. According to the Guidance Document, no further assessment is required if all uses are safe in the screening step.

Mixture toxicity

According to Appendix B to the Guidance Document on the Risk assessment for birds and mammals (EFSA, 1438/2009), the basic concept of the risk assessment is that animals are exposed to residues of the active substances in the environment. Thus, the assessment for A19786A (AVOXA) does not evaluate the formulation toxicity as such, but the effects of an exposure to a mixture of active substances in the environment, resulting from the use of the formulation. Toxicity studies for birds with formulated products are typically not available. For the assessment of acute effects, a surrogate LD_{50} is calculated. Sublethal effects and effects on reproduction are assessed on a case-by-case basis. A model often used to estimate the toxicity of mixtures is the assumption of dose/concentration additivity of toxicity (Finney approach of concentration additivity of toxicity; Finney 1948 and 1971).

The following formula is used to derive a surrogate LD_{50} for the mixture of active substances with known toxicity assuming dose additivity:

$$LD_{50}(mix) = \left(\sum_i \frac{X(a.s._i)}{LC_{50}(a.s._i)} \right)^{-1}$$

where:

X(a.s. *i*)= fraction of active substance (i) in the mixture expressed as:

X(pinoxaden) = 33.3 g pinoxaden /kg / (33.3 g pinoxaden /kg + 8.33 g pyroxsulam/kg + 8.33 g cloquintocet-mexyl/kg)

X(pyroxsulam) = 8.33 g pyroxsulam /kg / (33.3 g pinoxaden /kg + 8.33 g pyroxsulam/kg + 8.33 g cloquintocet-mexyl/kg)

X(cloquintocet-mexyl) = 8.33 g cloquintocet-mexyl /kg / (33.3 g pinoxaden /kg + 8.33 g pyroxsulam/kg + 8.33 g cloquintocet-mexyl/kg)

LD_{50}(a.s. *i*) = acute toxicity value for active substance (*i*)

This results in LD50(mix) of 2160 mg/kg bw when considering cloquintocet-mexyl as a contributor to overall toxicity, and a LD50mix of 2195 mg/kg bw when only considering the to active substances pinoxaden and pyroxsulam.

Because of the direct proportionality of the calculated TER to the LD_{50}, it is possible to calculate a TER(mix) with the following formula:

$$\mathrm{TER(mix)} = \left(\sum_i \frac{1}{\mathrm{TER(a.s._i)}} \right)^{-1}$$

where:

$TER_{(a.s.i)}$= calculated TER for the active substance *i*

TERmix is considered in the risk assessment.

6.2.2.1 Screening assessment

In the screening step, the risk to indicator bird species from an exposure to A19786A (AVOXA) is assessed. These indicators are considered to have highest exposure in a specific crop at a particular time due to their size and feeding habits and represent a worst case scenario.

To estimate the daily dietary doses, following equations were used:

Daily dietary dose (DDD):

$DDD_{\text{single application}}$ = application rate [kg a.s./ha] × shortcut value[1]

[1] see section 4.1 of EFSA/2009/1438

Toxicity exposure ratio (acute):

$$\mathrm{TER_A} = \frac{\mathrm{LD_{50}\ (mg/kg\,bw/day)}}{\mathrm{Acute\,DDD\,(mg/kg\,bw/day)}}$$

The results of the acute and reproductive screening risk assessments are summarized in the following tables.

Table 6.2-2: Acute screening assessment for birds

Intended use [g/ha]	Indicator species	Endpoint [mg/kg bw]	SV	MAF_{90}	DDD	TER
pinoxaden						
Intended use Group A (59.9 g a.s./ha)	Small omnivorous bird	2250	158.8	1	9.512	236.5
pyroxsulam						
Intended use Group A (15 g a.s./ha)	Small omnivorous bird	2000	158.8	1	2.382	839.6
cloquintocet-mexyl (safener)						
Intended use Group A (15 g a.s./ha)	Small omnivorous bird	2000	158.8	1	2.382	839.6
A19786A (AVOXA), combined toxicity considering pinoxaden, pyroxsulam and cloquintocet-mexyl based on the above presented formula: TERmix = 1/(1/236.5+1/839.6+1/839.6) = 151.3						

SV: shortcut value; MAF_{90}: multiple application factor (90th percentile); DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 6.2-3: Reproductive screening assessment for birds

Intended use [g/ha]	Indicator species	Endpoint [mg/kg bw/d]	SV	MAF_m x twa	DDD	TER
pinoxaden						
Intended use Group A (59.9 g a.s./ha)	Small omnivorous bird	27.8	64.8	0.53	2.057	13.5
pyroxsulam						
Intended use Group A (15 g a.s./ha)	Small omnivorous bird	46.3	64.8	0.53	0.515	89.9
cloquintocet-mexyl						
Intended use Group A (15 g a.s./ha)	Small omnivorous bird	51.72	64.8	0.53	0.515	100.4
A19786A (AVOXA), combined toxicity A19786A (AVOXA), combined toxicity considering pinoxaden, pyroxsulam and cloquintocet-mexyl based on the above presented formula: TERmix = 1/(1/13.5+1/89.9+1/100.4) = 10.4						10.4

SV: shortcut value; MAF_{90}: multiple application factor (90th percentile); DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

According to EFSA/2009/1438, the calculation of a combined toxicity is not applicable to the risk assessment of reproductive effects. Due to differences in evaluated endpoints and the dependency of the derived NOEL of the test design, any calculated TER_{mix} value can only be used for illustrating purposes. Hence, in the case of an unacceptable TER_{mix}, it has to be discussed if the results of the toxicity studies present any evidence for a possible concentration additivity of the effects and risks. Since here the TERmix

approach indicates an acceptable risk even with some margin of safety, an overall acceptable risk is concluded.

6.2.2.2 Tier 1 risk assessment

Not triggered.

6.2.2.3 Higher tier risk assessment

Not triggered.

6.2.2.4 Drinking water exposure

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals (see below), no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/kg).

A comparison of the relevant endpoints with the effective application rates for pinoxaden and pyroxsulam as well as cloquintocet-mexyl is presented below.

Table 6.2-4: Application rate to endpoint ratios for birds exposed to pinoxaden, pyroxsulam and cloquintocet-mexyl

Intended use	**Exposure Scenario**	**Effective application rate*** **[g a.s./ha]***	**Koc** **[L/kg]**	**LD_{50}/NOEL** **[mg a.s./kg bw]**	**Ratio Application Rate : endpoint**
pinoxaden					
Intended use group A	Acute	59.9	323	2250	0.03
	Long-term			27.8	2.16
pyroxsulam					
Intended use group A	Acute	15	15	2000	<0.01
	Long-term			46.3	0.32
cloquintocet-mexyl					
Intended use group A	Acute	15	12850	2000	<0.01
	Long-term			51.72	0.29

* effective application rate = application rate multiplied by mean MAF

Leaf scenario

Since A19786A (AVOXA) is not intended to be applied on leafy vegetables forming heads or other water collecting structures, the leaf scenario does not have to be considered.

Puddle scenario

As presented above no specific calculation is needed.

6.2.2.5 Effects of secondary poisoning (MIIIA 10.1.9)

The EFSA birds and mammals guidance document (EFSA Journal 2009; 7(12): 1438) states that a log $K_{ow} \geq 3$ is used to indicate that there might be a potential for bioaccumulation (see chapter 5.6 "Bioaccumulation and food chain behaviour"). Since the log K_{ow} value of pyroxsulam is < 3 (-1.01 at pH=7), this active substances is deemed to have a negligible potential to bioaccumulate in animal tissues. No formal risk assessment from secondary poisoning is therefore required for pyroxsulam.

The log K_{ow} value of pinoxaden is 3.2, thus formally a risk assessment from secondary poisoning would be required for pinoxaden. Yet in accordance with the applicant's argumentation and the EFSA conclusion on pinoxaden (EFSA Journal 2013;11(8):3269), the zRMS DE considers the potential for bioaccumulation as low due to the fast degradation in water, sediment (water/sediment studies), plant and soil and indication of low bioaccumulation potential from ADME studies.

Since the log K_{ow} value of cloquintocet-mexyl is 5.2, a formal a risk assessment from secondary poisoning is conducted for cloquintocet-mexyl.

The assessment of the risk for bird through secondary poisoning is based on the evaluation of an earthworm eating birds (100 g bw, food intake rate, FIR = 104.6 g fresh weight /d). The calculation is performed for the worst case intended use group A with the maximal soil relevant amount of the formulation A19786A (AVOXA).

Risk assessment for earthworm-eating birds via secondary poisoning

Dry soil approach

Table 6.2-5: Assessment of the risk for earthworm eating birds from an exposure to cloquintocet-mexyl through secondary poisoning for the intended use group A

Parameter	**cloquintocet-mexyl**	**comments**
PEC_{soil} (twa = 21 d) [mg/kg soil]	0.011	1 × 15 g/ha, interception 0%, soil layer depth 5 cm, DT50 = 10 d, twa interval = 21 d
K_{ow}	158489	log Pow = 5.2
K_{oc}	12850	
F_{oc}	0.02	default
BCF_{worm}	7.404	BCF-worm/soil = (PEC-worm,ww / PEC-soil,dw) = (0.84 + 0.012 × Pow) / (foc × Koc)
PEC_{worm}	0.078	PEC-worm = PEC-soil × BCF-worm
Daily dietary dose (mg/kg bw/d)	0.082	DDD = PEC-worm × 1.05
NOEL (mg/kg bw/d)	51.72	*Colinus virginianus*
TER_{lt}	631.5	≥ 5, acceptable risk

TER values shown in bold fall below the relevant trigger.

Risk assessment for fish-eating birds via secondary poisoning

No FOCUS calculations were available for cloquintocet-mexyl. However, accumulation in aquatic non-target organisms was considered to be low (see 6.5.2.4) thus no quantitative assessment is deemed necessary here.

6.2.3 Biomagnification in terrestrial food chains

Not relevant.

6.2.4 Risk assessment (MIIIA 10.1.3, MIIIA 10.1.4, MIIIA 10.1.5) for baits, pellets, granules, prills or treated seed

Not relevant.

6.2.5 Overall conclusions

Dietary risk assessment

Based on the screening assessment step, the calculated TER values for the acute and long-term risk resulting from an exposure of birds to pinoxaden, pyroxsulam and cloquintocet-mexyl (oral exposure and exposure via drinking water and secondary poisoning) according to the GAP of the formulation A19786A (AVOXA) achieve the acceptability criteria TER ≥ 10 resp. TER ≥ 5, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. for acute effects. The results of the assessment indicate an acceptable acute and long-term risk for birds due to the intended use of A19786A (AVOXA) in cereals according to the label.

Risk assessment for exposure via drinking water

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER were necessary for the intended uses of the product A19786A (AVOXA) in cereals. Hence, it can be concluded that the risk for birds due to the intended use of A19786A (AVOXA) in cereals according to the label is acceptable.

Risk assessment for exposure via secondary poisoning

Based on the calculation of the risk arising from secondary poisoning , the calculated TER values for birds exposed to the safener cloquintocet-mexyl according to the GAP of the formulation A19786A (AVOXA) achieve the acceptability criteria TER ≥ 5, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. for long-term effects.

6.3 Effects on Terrestrial Vertebrates Other Than Birds (MIIIA 10.3, KPC 10.1, KPC 10.1.2)

Table 6.3-1: EU agreed endpoints and new endpoints

Species	Substance	Exposure System	Results	Reference	Internal code
Rat	pinoxaden (NOA 407855)	Acute toxicity	LD_{50} > 5000 mg/kg bw	[redacted] 20001076 10.08.2000	86020
Rat	pinoxaden metabolite NOA 447204 (M3, soil)	Acute toxicity	LD_{50} = 1098 mg/kg bw	BfR-report	
Rat	pinoxaden metabolite SYN 502836 (M6)	Acute toxicity	LD_{50} > 2000 mg/kg bw	BfR-report State: 07.06.2007	
Rat	pinoxaden metabolite SYN 505887 (M10)	Acute toxicity	LD_{50} > 2000 mg/kg bw	BfR-report State: 07.06.2007	
Rat	pinoxaden (NOA 407855)	Multi-generation, gavage	NOAEL Parental = 50 mg/kg bw/d Repro = 500 mg/kg bw/d Offspring = 250 mg/kg bw/d	EFSA Journal 2013;11(8):3269	
Rabbit	pinoxaden (NOA 407855)	Developmental	NOAEL Maternal = 10 mg/kg bw/d **pups = 30 mg/kg bw/d**	EFSA Journal 2013;11(8):3269	
Rat	pyroxsulam	Acute toxicity	LD_{50} > 2000 mg/kg bw	EFSA Journal 2013;11(4):3182	75588
Rat	pyroxsulam	Reproductive toxicity	NOEL 1000 mg/kg bw/d	[redacted] (2005) 041012	75592
Rat	pyroxsulam	short-term study, used for the derivation of the ADI	NOEL: 89 mg/kg bw/day	EFSA Journal 2013;11(4):3182	
Rat	cloquintocet-mexyl (CGA 185072)	Acute toxicity	LD_{50} > 2000 mg/kg bw	BfR-report	
Rat	Cloquintocet-mexyl (CGA 185072)	Reproductive toxicity	NOAEL Parental = 350 mg/kg bw/d Repro = 722 mg/kg bw/d Offspring = 350 mg/kg bw/d	BfR-report	

Rat	Cloquintocet-mexyl (CGA 185072)	Developmental	NOAEL Maternal, development = 60 mg/kg bw/d	BfR-report	
Rat	A19786A	Acute	LD_{50} > 2000 mg/kg bw *	[redacted] 06.02.2013 12/343-001P	85995

*endpoints provided by BfR

6.3.1 Justification for new endpoints

A new studies with the preparation was submitted. The study is valid and suitable for the risk assessment.

6.3.2 Risk assessment (MIIIA 10.3.1) for spray applications

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438). Please see 6.2.2 for detailed information on the estimation of daily intake rates and the assessment of mixture toxicity.

For risk assessment purposes, a risk envelope approach was used. Hence, intended use group A covers the risk for mammals for all intended uses according to the GAP (see Table 6.1-2).

Please note, that the applicant was suggesting to use the NOEL of 1000 mg/kg bw/day from the reproduction study with pyroxsulam for the long-term risk assessment. We disagree with this approach and use the NOEL of 89 mg/kg bw/day instead. Even though this NOEL was derived from a short-term study it was considered as relevant endpoint for the derivation of the ADI during active substance approval (see EFSA Journal 2013;11(4):3182). This endpoint is also listed in the list of endpoints as relevant for the environmental risk assessment and has thus been used for the risk assessment presented below.

Based on the formula presented in chapter 6.2.2. the LD50(mix) was calculated to be 3333 mg/kg bw when considering the available individual toxicity of pinoxaden, pyroxsulam and cloquintocet-mexyl. If the information on the safener is not acknowledged, this results in a LD50(mix) of 3846 mg/kg bw. The measured LD50 for AVOXA is ≥ 2000 mg/kg bw, i.e. represents the worst-case in terms of the risk assessment. Even though the possibility to compare the measured and calculated LD50(mix) is limited as no definite LD50 was measured, the results correspond and give no indication of synergism.

TERmix is considered in the risk assessment presented below.

6.3.2.1 Screening assessment

For the estimation of Daily dietary doses (DDD) and the calculation of TER values, please see 6.2.2.1.

The results of the acute and reproductive screening risk assessments are summarized in the following tables.

Table 6.3-2: Acute screening assessment for mammals

Intended use	**Indicator species**	**Endpoint**	**SV**	**MAF_{90}**	**DDD**	**TER**

		[mg/kg bw/d]			[mg/kg bw/d]	
pinoxaden						
Intended use Group A (59.9 g a.s./ha)	Small herbivorous mammal	5000	118.4	1	7.092	705
pyroxsulam						
Intended use Group A (15 g a.s./ha)	Small herbivorous mammal	2000	118.4	1	1.776	1126
cloquintocet-mexyl						
Intended use Group A (15 g a.s./ha)	Small herbivorous mammal	2000	118.4	1	1.766	1126
A19786A (AVOXA)						
Intended use Group A (89.9 g a.s./ha)	Small herbivorous mammal	(>)2000	118.4	1	213.12	(>)9.4*
A19786A (AVOXA), combined toxicity considering pinoxaden, pyroxsulam and cloquintocet-mexyl based on the above presented formula: TERmix = 1/(1/705+1/1126+1/1126) = 313						

SV: shortcut value; MAF_{90}: multiple application factor (90th percentile); DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

*considered acceptable since the screening step is a) conservative, b) the endpoint is conservative since the LD50 value is considered to be larger as 2000 mg/kg bw/d (based on the calculated LD50mix of 3333 mg/kg bw the TER value would be 15.6), and c) the respectively conservative TERmix calculation does not indicate any risk either.

Table 6.3-3: Reproductive screening assessment for mammals

Intended use [g/ha]	Indicator species	Endpoint [mg/kg bw/d]	SV	MAF_m x twa	DDD [mg/kg bw/d]	TER
pinoxaden						
Intended use Group A (59.9 g a.s./ha)	Small herbivorous mammal	30	48.3	0.53	1.533	19.6
pyroxsulam						
Intended use Group A (15 g a.s./ha)	Small herbivorous mammal	89	48.3	0.53	0.384	231.8
cloquintocet-mexyl						
Intended use Group A (15 g a.s./ha)	Small herbivorous mammal	60	48.3	0.53	0.384	156.3
A19786A (AVOXA), combined toxicity considering pinoxaden, pyroxsulam and cloquintocet-mexyl based on the above presented formula: TERmix = 1/(1/19.6+1/231.8+1/156.3) = 16.2						

SV: shortcut value; MAF_m: multiple application factor (mean); DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

According to EFSA/2009/1438, the calculation of a combined toxicity is not applicable to the risk assessment for reproductive effect. Due to differences in evaluated endpoints and the dependency of the

derived NOEL of the test design, any calculated TER_{mix} value can only be used for illustrating purposes. Hence, in the case of an unacceptable TER_{mix}, it has to be discussed if the results of the toxicity studies present any evidence for a possible concentration additivity of the effects and risks. Since here the TERmix indicates no risk with a reasonable margin of safety, an overall acceptable risk is concluded.

6.3.2.2 Tier-1 risk assessment

Not triggered.

6.3.2.3 Higher tier risk assessment

Not triggered.

6.3.2.4 Drinking water exposure

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals (see below), no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/kg).

A comparison of the relevant endpoints with the effective application rates for pinoxaden, pyroxsulam and cloquintocet-mexyl is presented below.

Table 6.3-4: Application rate to endpoint ratios for mammals exposed to pinoxaden, pyroxsulam and cloquintocet-mexyl

Intended use	Exposure Scenario	Effective application rate* [g a.s./ha]*	Koc [L/kg]	LD_{50}/NOEL [mg a.s./kg bw]	Ratio Application Rate : endpoint
pinoxaden					
Intended use group A	Acute	59.9	323	5000	0.01
	Long-term			30	2.00
pyroxsulam					
Intended use group A	Acute	15	15	2000	<0.01
	Long-term			89	0.17
cloquintocet-mexyl					
Intended use group A	Acute	15	12850	2000	<0.01
	Long-term			60	0.25

* effective application rate = application rate multiplied by mean MAF

Puddle scenario

As presented above no specific calculation is needed.

6.3.2.5 Effects of secondary poisoning (MIIIA 10.3.2.3)

The EFSA birds and mammals guidance document (EFSA Journal 2009; 7(12): 1438) states that a log $K_{ow} \geq 3$ is used to indicate that there might be a potential for bioaccumulation (see chapter 5.6 "Bioaccumulation and food chain behaviour"). Since the log K_{ow} value of pyroxsulam is < 3 (-1.01 at pH=7), this active substances is deemed to have a negligible potential to bioaccumulate in animal tissues. No formal risk assessment from secondary poisoning is therefore required for pyroxsulam.

The log K_{ow} value of pinoxaden is 3.2, thus formally a risk assessment from secondary poisoning would be required for pinoxaden. Yet in accordance with the applicant's argumentation and the EFSA conclusion on pinoxaden (EFSA Journal 2013;11(8):3269), the zRMS DE considers the potential for bioaccumulation as low due to the fast degradation in water, sediment (water/sediment studies), plant and soil and indication of low bioaccumulation potential from ADME studies.

Since the log K_{ow} value of cloquintocet-mexyl is 5.2, a formal a risk assessment from secondary poisoning is conducted for cloquintocet-mexyl.

The assessment of the risk to mammals exposed to A19786A (AVOXA) through secondary poisoning is based on the evaluation of an earthworm eating mammal (10 g bw, food intake rate, FIR = 12.8 g fresh weight/d). The calculation is performed for the worst case intended use group A with the maximal soil relevant amount of the formulation.

Risk assessment for earthworm-eating mammals via secondary poisoning

Dry soil approach

Table 6.3-5: Assessment of the risk for earthworm eating mammals from an exposure to cloquintocet-mexyl through secondary poisoning for the intended use group A

Parameter	**Cloquintocet-mexyl**	**comments**
PEC_{soil} (twa = 21 d) [mg/kg soil]	0.011	1 × 15 g/ha, interception 0%, soil layer depth 5 cm, DT50 = 10 d, twa interval = 21 d
K_{ow}	158489	log Pow = 5.2
K_{oc}	12850	
F_{oc}	0.02	Default
BCF_{worm}	7.404	$BCF_{worm} = (PEC_{worm}/PEC_{soil})$ $= (0.84 + 0.012 \times K_{ow})/ f_{oc} \times K_{oc}$
PEC_{worm}	0.078	$PEC_{worm} = PEC_{soil} \times BCF$
Daily dietary dose (mg/kg bw/d)	0.100	$DDD = PEC_{worm} \times 1.05$
NOEL (mg/kg bw/d)	60	rat
TER_{lt}	601	

TER values shown in bold fall below the relevant trigger.

Risk assessment for fish-eating mammal via secondary poisoning

No FOCUS calculations were available for cloquintocet-mexyl. However, accumulation in aquatic non-target organisms was considered to be low (see 6.5.2.4) thus no quantitative assessment is deemed necessary here.

6.3.3 Biomagnification in terrestrial food chains

Not relevant.

6.3.4 Risk assessment (MIIIA 10.3.1) for baits, pellets, granules, prills or treated seed

Not relevant.

6.3.5 Overall conclusions

Dietary risk assessment

Based on the screening assessment step, the calculated TER values for the acute and long-term risk resulting from an exposure of mammals to pinoxaden, pyroxsulam and cloquintocet-mexyl (oral exposure and exposure via drinking water and secondary poisoning) according to the GAP of the formulation A19786A (AVOXA) achieve the acceptability criteria TER ≥ 10 resp. TER ≥ 5, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. for acute effects. The results of the assessment indicate an acceptable acute and long-term risk for mammals due to the intended use of A19786A (AVOXA) in cereals according to the label.

Risk assessment for exposure via drinking water

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER were necessary for the intended uses of the product A19786A (AVOXA) in cereals. Hence, it can be concluded that the risk for mammals due to the intended use of A19786A (AVOXA) in cereals according to the label is acceptable.

Risk assessment for exposure via secondary poisoning

Based on the calculation of the risk arising from secondary poisoning , the calculated TER values for mammals exposed to the safener cloquintocet-mexyl according to the GAP of the formulation A19786A (AVOXA) achieve the acceptability criteria TER ≥ 5, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. for long-term effects.

6.4 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KPC 10.1.3)

Not yet considered since there is no guideline available for the risk assessment of amphibians available yet.

6.5 Effects on aquatic organisms (MIIIA 10.2, KPC 10.2, KPC 10.2.1)

Table 6.5-1: Endpoints used for risk assessment for aquatic organisms for pinoxaden and its relevant metabolites

Species	Substance	Exposure System	Results [mg a.s./L]	Reference	Internal code
Fish					
Oncorhynchus mykiss	pinoxaden (NOA 407855)	96 h, flow-through	LC_{50} = 10.3 mg/L mm	[redacted] 22.12.2000 2001806	51151
Oncorhynchus mykiss	pinoxaden metabolite NOA 407854 (M2)	96 h, static	LC_{50} > 100 mg/L nom.	[redacted] 19.04.1999 991505	51174
Oncorhynchus mykiss	pinoxaden metabolite NOA 447204 (M3)	96 h, static	LC_{50} > 120 mg/L nom.	[redacted] 09.11.2001 2011580	51175
Oncorhynchus mykiss	Pinoxaden (NOA 407855)	28 d, flow-through	NOEC = 3.2 mg/L real (behaviour)	[redacted] 27.10.2000 2001509 *	51157
Pimephales promelas	pinoxaden metabolite NOA 407854 (M2)	28 d, flow-through	NOEC ≥ 1 mg/L nom.	[redacted] 21.10.2003 BL7550/B	51177
Aquatic invertebrates					
Crassostrea virginica	pinoxaden (NOA 407855)	96 h, flow-through	LC_{50} (96 h) >0.88 mg/L EC_{50} (96 h) = 0.40 mg/L **	Palmer, S., Kendall, T. and Krueger, H. 27.10.2003 528A-122A	51204
Daphnia magna	pinoxaden (NOA 407855)	48 h, flow-through	EC_{50} = 52 mg/L real	Knauer, K. 05.02.2003 2011581	51193
Americamysis bahia	pinoxaden	48 h, flow-through	LC_{50} = 8.3 mg a.s./L_{mm}	EFSA Journal 2013;11(8):3269	
Daphnia magna	pinoxaden metabolite NOA 407854 (M2)	48 h, stat.	EC_{50} > 100 mg/L nom.	Grade, R. 04.02.2000 991504	51196
Daphnia magna	pinoxaden metabolite NOA 447204 (M3)	48 h, stat.	EC_{50} > 120 mg/L nom.	Wallace, S.J. 26.11.2001 BL7157/B	51197
Daphnia magna	pinoxaden metabolite NOA 407854 (M2)	21 d, semi	NOEC = 6.25 mg/L nom.	Bätscher, R. 19.01.2004 848337	51254
Sediment dwelling organisms					
none					
Aquatic plants					

Skeletonema costatum	pinoxaden (NOA 407855)	72 h, 96 h (LoEP)	EbC50 = 0.81 mg/L mm ErC50 = 0.98 mg/L mm NOErC = 0.52 mg/L mm Biomass: EbC50 : 0.9086 mg/L initialy measured Growth rate: ErC50 : 1.3244 mg/L initialy measured	Swarbrick R.H., Maynard S.J. 23.12.2002 02-0271/D; BL7448/B	51261
Pseudokirchneriella subcapitata	pinoxaden metabolite NOA 407854 (M2)	72 h	EbC_{50} > 100 mg/L nom. ErC_{50} > 100 mg/L nom. NOErC = 100 mg/L nom.	Grade, R. 24.02.2000 991503	51263
Pseudokirchneriella subcapitata	pinoxaden metabolite NOA 447204 (M3)	72 h	EbC_{50} > 89,9 mg/L nom. NOEbC = 15 mg/L nom.	Wallace, S.J. 23.11.2001 BL7158/B	51264
Lemna gibba	pinoxaden (NOA 407855)	7 d, static	LoEP: EbC50: 3.5 mg/L initially measured Conversion to mean measured: EbC_{50} = 1.14 mg/L mm ErC_{50} = 1.72 mg/L mm NOErC = 0.23 mg/L mm	Grade, R. 26.09.2002 2011599	51265
Phragmites australis	pinoxaden (NOA 407855)	20 d, static	LoEP: ErC50: 8.5 mg/L nom. Conversion to mean measured: EC_{50} = 0.71 mg/L mm NOEC = 0.17 mg/L mm	Knauer, K. 09.09.2002 2001794	51267
Lemna gibba	pinoxaden metabolite NOA 407854 (M2)	7 d, static	EbC_{50} = 10.6 mg/L nom. ErC_{50} = 14.6 mg/L nom. NOErC = 4 mg/L nom.	Grade, R. 24.02.2000 991533	51272

			LoEP: EbC50: 10.6 mg/L nom.		
Lemna gibba	pinoxaden metabolite NOA 447204 (M3)	7 d, static	LoEP: EbC50 > 100 mg/L nom Conversion to mean measured: EbC_{50} > 23.09 mg/L mm. ErC_{50} > 23.09 mg/L mm NOEbC = 9.92 mg/L mm NOErC = 4.25 mg/L mm	Grade, R 07.01.2003 2021657.	51274

* Endpoint not listed in the LoEP, yet reported in the DAR of pinoxaden

** please note: the LOEP indicated the endpoint after 48 h, yet the test duration (inline with testguidline) was 96 h (as correctly reported in the DAR and thus used here)

Table 6.5-2: Endpoints used for risk assessment for aquatic organisms for pyroxsulam and its relevant metabolites

Species	Substance	Exposure System	Results [mg a.s./L]	Reference	Internal code
Fish					
Oncorhynchus mykiss	pyroxsulam	96 h, static	LC_{50} > 87 mg/L mm	[redacted] 19.12.2003 12F0298/0350031	64803
Oncorhynchus mykiss	7-OH-XDE-742 (pyroxsulam metabolite)	96 h, static	LC_{50} > 120 mg/L mm	[redacted] 05.04.2006 050165	64942
Oncorhynchus mykiss	XDE-742-ATSA (pyroxsulam metabolite)	96 h, static	LC_{50} > 119 mg/L mm	[redacted] 15.03.2006 061010	64943
Oncorhynchus mykiss	pyridine sulfonamide = XDE-742 sulfonamide	96 h, static	LC_{50} > 8.7 mg/L mm (modelled)	EFSA Journal 2013;11(4):3182	
Pimephales promelas	pyroxsulam	35 d, flow-through	NOEC: 10.1 mg/L nom.	[redacted] 03.08.2005 051007	65114
Aquatic invertebrates					
Daphnia magna	pyroxsulam	48 h, stat	EC_{50} > 100 mg/L nom.	Marino, T.A., McClymont, E.L., Najar, J.R.	65115

				22.12.2004 041022 J52	
Daphnia magna	7-OH-XDE-742 (pyroxsulam metabolite)	48 h, stat	EC_{50} > 99 mg/L nom.	Sayers, L.E. 14.03.2006 050164	64944
Daphnia magna	XDE-742-ATSA (pyroxsulam metabolite)	48 h, stat	EC_{50} > 121 mg/L mm	Marino, T.A., Arnold, B.H., Najar, J.R., Sushynski, J.M. 15.03.2006 061005	64945
Daphnia magna	pyridine sulfonamide (pyroxsulam metabolite)	48 h, stat	EC_{50} : 10.0 mg/L nom. (modelled)	EFSA Journal 2013;11(4):3182	
Daphnia magna	pyroxsulam	21 d, stat	NOEC: 10.4 mg/L nom.	Marino, T.A., McClymont, E.L, Najar, J.R. 31.01.2005 041023	65116
Sediment dwelling organisms					
Chironimus riparius	pyroxsulam	28 d, static (spiked water)	NOEC: 100 mg/L nom.	Henry, K.S.; McClymont, E.L. and Najar, J.R. 03.01.2005 041061	65134
Chironimus riparius	7-OH (pyroxsulam-metabolite)	28 d, static (spiked water)	EC_{50} > 120 mg/L nom NOEC: 30 mg/L nom	Putt, A.E. 15.05.2006 050166	64955
Chironimus riparius	pyridine sulfonamide (pyroxsulam metabolite)	28 d, static (spiked water)	NOEC: 10.0 mg/L nom. (modelled)	EFSA Journal 2013;11(4):3182	
Algae					
Pseudokirchneriella subcapitata	pyroxsulam	3 d, static	E_bC_{50}: 0.111 mg/L mm NOE_bC: 0.0261 mg/L mm E_rC_{50}: 0.924 mg/L mm NOE_rC: 0.055 mg/L mm	Hancock, G.A., McClymont, E.L., Staley, J.L. 23.12.2004 041054 J52	65117
Anabaena flos-aquae	pyroxsulam	4 d, static	E_rC_{50} = 41 mg a.s./L $_{mm}$ E_bC_{50} = 22 mg a.s./L $_{mm}$	EFSA Journal 2013;11(4):3182	
Skeletonema costatum	pyroxsulam	4 d, static	E_rC_{50} = 59.0 mg a.s./L $_{mm}$ E_bC_{50} = 14.4 mg a.s./L $_{mm}$	EFSA Journal 2013;11(4):3182	

Navicula pelliculosa	pyroxsulam	4 d, static	E_rC_{50} = 6.9 mg a.s./L $_{mm}$ E_bC_{50} = 5.8 mg a.s./L $_{mm}$	EFSA Journal 2013;11(4):3182	
Pseudokirchneriella subcapitata	7-OH-XDE-742	3 d, static	E_rC_{50} = 65 mg a.s./L $_{mm}$ E_bC_{50} = 50 mg a.s./L $_{mm}$	EFSA Journal 2013;11(4):3182	
Pseudokirchneriella subcapitata	ATSA	3 d, static	E_rC_{50} = 42.8 mg a.s./L $_{mm}$ E_bC_{50} = 16.8 mg a.s./L $_{mm}$	EFSA Journal 2013;11(4):3182	
Pseudokirchneriella subcapitata	pyridine sulfinic acid	3 d, static	E_rC_{50} > 97 mg a.s./L $_{mm}$ E_bC_{50} > 97 mg a.s./L $_{mm}$	EFSA Journal 2013;11(4):3182	
Pseudokirchneriella subcapitata	5-OH-XDE-742	3 d, static	E_rC_{50} > 80 mg a.s./L $_{mm}$ E_bC_{50} = 57 mg a.s./L $_{mm}$	EFSA Journal 2013;11(4):3182	
Pseudokirchneriella subcapitata	6-Cl-7-OH – XDE-742	3 d, static	E_rC_{50} = 85 mg a.s./L $_{mm}$ E_bC_{50} = 69 mg a.s./L $_{mm}$	EFSA Journal 2013;11(4):3182	
Pseudokirchneriella subcapitata	ADTP	3 d, static	E_rC_{50} > 92 mg a.s./L $_{mm}$ E_bC_{50} > 92 mg a.s./L $_{mm}$	EFSA Journal 2013;11(4):3182	
Pseudokirchneriella subcapitata	5,7-Di-OHXDE-742	3 d, static	E_rC_{50} = 60 mg a.s./L $_{mm}$ E_bC_{50} = 56 mg a.s./L $_{mm}$	EFSA Journal 2013;11(4):3182	
Pseudokirchneriella subcapitata	pyridine sulfonamide	3 d, static	E_rC_{50} > 114 mg a.s./L $_{mm}$ E_bC_{50} > 114 mg a.s./L $_{mm}$	EFSA Journal 2013;11(4):3182	
Aquatic higher plants #					
Lemna gibba	pyroxsulam	7 d, semistatic	EC_{50} = 0.00257 mg a.s./L $_{mm}$ frond number	EFSA Journal 2013;11(4):3182	
Lemna gibba	7-OH-XDE-742	7 d, semistatic	E_rC_{50} = 4 mg a.s./L $_{mm}$ E_bC_{50} = 2.1 mg a.s./L $_{mm}$	EFSA Journal 2013;11(4):3182	
Lemna gibba	5-OH-XDE-742	7 d, semistatic	E_rC_{50} = 7.4 mg a.s./L $_{mm}$ E_bC_{50} = 6.6 mg a.s./L $_{mm}$	EFSA Journal 2013;11(4):3182	

Lemna gibba	6-Cl-7-OHXDE-742	7 d, semistatic	E_rC_{50} = 46 mg a.s./L $_{mm}$ E_bC_{50} = 35 mg a.s./L $_{mm}$	EFSA Journal 2013;11(4):3182	
Lemna gibba	ATSA	7 d, semistatic	$E_{r,b}C_{50}$ > 120 mg/L mm	EFSA Journal 2013;11(4):3182	
Lemna gibba	pyridine sulfinic acid	7 d, semistatic	$E_{r,b}C_{50}$ > 110 mg/L mm	EFSA Journal 2013;11(4):3182	
Lemna gibba	ADTP	7 d, semistatic	$E_{r,b}C_{50}$ > 93 mg/L mm	EFSA Journal 2013;11(4):3182	
Lemna gibba	5,7-Di-OH - XDE-742	7 d, semistatic	$E_{r,b}C_{50}$ > 95 mg/L mm	EFSA Journal 2013;11(4):3182	
Lemna gibba	Pyridine sulfonamide	7 d, semistatic	$E_{r,b}C_{50}$ > 114 mg/L mm	EFSA Journal 2013;11(4):3182	

Table 6.5-3: Endpoints used for risk assessment for aquatic organisms for cloquintocet-mexyl (safener) and its relevant metabolites

Species	Substance	Exposure System	Results [mg a.s./L]	Reference	Internal code
Fish					
Oncorhynchus mykiss	cloquintocet-mexyl (CGA 185072)	96 h, flow-through	LC_{50} > 0.97 mg/L mm NOEC = 0.97 mg/L	[redacted] 30.04.1998 108A-196	51258
Lepomis macrochirus	cloquintocet-mexyl-metabolite CGA 153433 T	96 h, stat.	LC_{50} = 82.6 mg/L mm	[redacted] 18.09.1992 928052	33990
Oncorhynchus mykiss	cloquintocet-mexyl (CGA 185072)	21 d, flow-through	NOEC = 1.26 mg/L mm	[redacted] 19.10.1990 901114	34000
Aquatic invertebrates					
Daphnia magna	cloquintocet-mexyl (CGA 185072)	48 h, flow-through	EC_{50} > 0.82 mg/L mm	Palmer, S.J., Krueger, H.O. 30.04.1998 108A-195	51241
Daphnia magna	cloquintocet-mexyl (CGA 185072)	21 d, semistatic	NOEC = 0.002 mg/L mm	Vial, A. 02.07.1990 881743	33974
Daphnia magna	cloquintocet-mexyl (CGA 185072)	21 d, semistatic	NOEC = 0.437 mg/L mm	Bätscher, R. 2003 847407 *	
Sediment dwelling organisms					

Chironimus riparius	cloquintocet-mexyl (safener)	28 d, stat	NOEC = 8 mg/L nom EC_5 = 0.078 mg/L nom. (mortality) EC_{10} = 0.418 mg/L nom. (mortality)	Grade, R. 03.12.1998 981535	38798
Aquatic plants					
Scenedesmus subspicatus	cloquintocet-mexyl (CGA 185072)	4 d, static	EbC_{50} = 0.63 mg/L nom. NOEbC = 0.22 mg/L nom.	Grade, R. 14.01.1993 928205	33948
Microcystis aeruginosa	cloquintocet-mexyl metabolite CGA 153433 T	5 d, static	EbC_{50} = 1.9 mg/L nom. NOEC = 1.3 mg/L nom.	Grade, R. 11.01.1993 928207	33964
Lemna gibba	Cloquintocet-mexyl (CGA 185072)	14 d, semi-static	EC_{50} > 0.42 mg/L nom. NOEC = 0.42 mg/L nom.	Hoberg, J.R. 23.07.1993 93-6-4831	33962
Lemna gibba	Cloquintocet-mexyl-Metabolit CGA 153433 T	14 d, semi-static	EbC_{50} > 10 mg/L nom. NOEC = 10 mg/L nom.	Hoberg, J.R. 10.11.1993 93-6-4836	33966

*study unvalidated since only the summary was available

Table 6.5-4: Endpoints used for risk assessment for aquatic organismsfor A19786A (AVOXA)

Species	**Substance**	**Exposure System**	**Results [mg a.s./L]**	**Reference**	**Internal code**
Oncorhynchus mykiss	A19786A (AVOXA)	96 h, static	LC_{50} = 10.3 (nom), = 8.879 (mm)	[redacted] 13.03.2013 D62623; A19786A_10013 *	85993
Daphnia magna	A19786A (AVOXA)	48 h, static	EC_{50} = 4.4 (nom), = 3.78 mg/L (mm)	Liedtke, A. 12.04.2013 D62634; A19786A_10016 *	85992
Pseudokirchneriella subcapitata	Pinoxaden/Pyroxsulam/Cloquintocet-mexyl EC (A19786A)	72 h, static	E_rC_{50} = 1.7 (nom), = 0.989 (mm) E_yC_{50} = 1.1 (nom), = 0.640 (mm)	Liedtke, A. 19.03.2013 D62601; A19786A_10011 *	85987

Lemna gibba	A19786A (AVOXA)	7 d, semistatic	E_rC_{50} = 0.44 (nom), **= 0.1123 (mm)** E_yC_{50} = 0.24 (nom), = 0.0613 (mm) NOE_rC = 0.01276 µg/L (mm)	Liedtke, A. 27.03.2013 D62645; A19786A_10014 *	85988

* New study submitted

6.5.1 Justification for new endpoints

New studies with the preparation were submitted. The studies are valid and suitable for risk assessment. Study summaries are provided in Appendix 2.

In a few cases the RMS converted endpoints for pinoxaden that are listed based on "nominal" or "initially measured" concentrations in the list of endpoints to "mean measured" concentration to comply with the new aquatic guidance document (EFSA Journal 2013;11(7):3290) and EFSA technical report (EFSA Supporting publication 2015:EN-924).

6.5.2 Toxicity to exposure ratios for aquatic species (MIIIA 10.2.1)

The evaluation of the risk for aquatic and sediment-dwelling organisms was performed in accordance with the recommendations of the "Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters", as provided by EFSA (EFSA Journal 2013;11(7):3290).

The applicant has not provided FOCUS exposure calculations for the safener cloquintocet-mexyl as he is not obliged to do so. However, based on the available data is has to be assumed that the safener contribute significantly to the overall toxicity of the product (see mixture toxicity section below). Thus, the safener is also included in our considerations on mixture toxicity.

Mixture Toxicity

A model often used to estimate the toxicity of mixtures is the assumption of dose/concentration additivity of toxicity (Finney approach of concentration additivity of toxicity; Finney, D.J., 1948 and 1971).

Toxicity studies on acute and chronic effects of the active substances and A19786A (AVOXA) to aquatic organisms are available. For a more detailed assessment of mixture toxicity, a surrogate LC_{50} or EC_{50} can be calculated. However, reliable results can only be expected for combinations of EC_X values for the same biological endpoint. Moreover, the use of NOEC values, which are strongly depending on dose-spacing, would introduce additional bias in the calculations.

Calculated mixture toxicity

The default model of Concentration Addition (CA) is applied to calculate the toxicity of the formulated product (ECxmix-CA) based on the toxicity of the active substances using the following equation:

$$ECx_{mix-CA} = \left(\sum_{i=1}^{n} \frac{P_i}{ECx_i} \right)^{-1}$$

where:

n: number of mixture components

i: index from 1…n mixture components

P_i: the i^{th} component as a relative fraction of the mixture composition (note: Σ pi must be 1)

ECx_i: concentration of component i provoking x % effect (pragmatically, NOECi may be inserted, too).

For each endpoint, the calculated toxicity (ECx_{mix-CA}) for the various endpoints is compared to the measured toxicity of the formulation (ECx_{PPP}) as Model Deviation Ratio (MDR) as

$$MDR = \frac{ECx_{mix-CA}}{ECx_{PPP}}$$

Concentrations are both based on the sum of active substances, i.e. the above listed, measured product endpoints have been re-calculated to the sum of a.s. for this purpose.

The approach of the mixture risk assessment may be simplified if one active substance is driving the toxicity of the formulation. Relative Toxic Units ($\%TU_i$) as calculated for each active substance as

$$\%TU_i = \frac{TU_i}{\sum_{i=1}^{n} TU_i}$$

with TU_i being the concentration of substance i in the product divided by its ECx.

a) Mixture toxicity under consideration of the two a.s. pinoxaden and pyroxsulam

Table 6.5-5: Mixture toxicity under consideration of the two a.s. pinoxaden and pyroxsulam

Endpoint Active Substance	**ECx_i** **(mg a.s./L)**	**Concentration (C_i) in formulation** **(g a.s./L)**	**P_i**	**relative Toxic Unit (%TU)**	**ECx_{mix-CA}** **(mg /L)**	**ECx_{PPP}** **(mg sum of a.s./L)**	**MDR**
Fish, acute toxicity							

Pinoxaden *Oncorhynchus mykiss*	10.3	33.3	0.800	97.1	12.51	0.37	33.8
Pyroxsulam *Oncorhynchus mykiss*	87	8.33	0.200	2.9			
Invertebrates, acute toxicity							
Pinoxaden *Daphnia magna*	52	33.3	0.800	88.58	57.53	0.157	365.6
Pyroxsulam *Daphnia magna*	100	8.33	0.200	11.5			
Algal growth inhibition							
Pinoxaden *Skeletonema costatum*	0.98	33.3	0.800	79.0	0.97	0.041	23.5
Pyroxsulam *Pseudokirchneriella subcapitata*	0.924	8.33	0.200	21.0			
Aquatic higher plants							
Pinoxaden *Lemna gibba*	1.72	33.3	0.800	0.6	0.013	0.0047	2.7
Pyroxsulam *Lemna gibba*	0.00257	8.33	0.200	99.4			

Based on the toxic unit approach, pinoxaden seems to be driving the risk for fish wereas for aquatic high plants risk is driven by pyroxsulam and no driver is identified for algae and daphnia. However, the MDR values for fish, daphnia and algae are above the range of 0.2 to 5 for which concentration additivity (CA) can be assumed, thus apparent synergism is indicated. Only for L.gibba the comparision suggests that CA can be assumed with pyroxsulam driving the risk. Since, however, the above comparision does not take the safener cloquintocet-mexyl into account for which the available data show that is similarly toxic as the a.s. and which is present in the formulation to the same extent than pyroxsulam, the comparison has also been made under consideration of the both, the two a.s. and the safener.

b) Mixture toxicity under consideration of the two a.s. pinoxaden and pyroxsulam and the safener cloquintocet-mexyl. Given its low solubilty in water lowest known endpoints for cloquintocet-mexyl have been considered (including > values) as a concervative approach.

Table 6.5-6: Mixture toxicity under consideration of the two a.s. pinoxaden and pyroxsulam and the safener cloquintocet-mexyl.

Endpoint	**EC_{x_i}**	**Concentration (C_i) in formulation**	**P_i**	**relative Toxic Unit (%TU)**	**$EC_{x_{mix\text{-}CA}}$**	**$EC_{x_{PPP}}$**	**MDR**

Active Substance	**(mg a.s./L)**	**(g a.s./L)**			**(mg /L)**	**(mg sum of a.s./L)**	
Fish, acute toxicity							
Pinoxaden *Oncorhynchus mykiss*	10.3	33.3	0.667	27.1	4.19	0.444	9.45
Pyroxsulam *Oncorhynchus mykiss*	87	8.33	0.167	0.8			
Cloquintocet-mexyl *Oncorhynchus mykiss*	0.97	8.33	0.167	72.1			
Invertebrates, acute toxicity							
Pinoxaden *Daphnia magna*	52	33.3	0.667	5.9	4.59	0.19	24.3
Pyroxsulam *Daphnia magna*	100	8.33	0.167	0.8			
Cloquintocet-mexyl *Daphnia magna*	0.82	8.33	0.167	93.3			
Algal growth inhibition							
Pinoxaden *Skeletonema costatum*	0.98	33.3	0.667	60.44	0.89	0.049	18.0
Pyroxsulam *Pseudokirchneriella subcapitata*	0.924	8.33	0.167	16.04			
Cloquintocet-mexyl *Scenedesmus subspicatus*	0.63	8.33	0.167	23.52			
Aquatic higher plants							
Pinoxaden *Lemna gibba* *(Phragmites australis)*	1.72 (0.71)	33.3	0.667	0.6 (1.4)	0.015	0.0056	2.7
Pyroxsulam *Lemna gibba*	0.00257	8.33	0.167	98.8 (98, when considering *P.australis* for pinoxaden)			
Cloquintocet-mexyl *Lemna gibba*	0.42	8.33	0.167	0.6			

Even though the resulting MDR values are much lower when the contribution of cloquintocet-mexyl to the overall toxicity is considered, apparent synergism remains for all species except *L.gibba*. The co-formulants may contribute to these findings, however their impact is not further elucidated or discussed by the applicant. Thus, based on the available data for both the two active substances and the safener, assuming CA is only justified for aquatic higher plants (*L.gibba*). For fish, daphnia and algae, there is apparent synergism, meaning that for the acute risk assessment of these species the measured product toxicity would be crucial. At the same time it has to be considered that the observed (=measured) product toxicity for fish, daphnia and algae is much lower than the observed (=measured) product toxicity for aquatic higher plants, namely by an absolute factor of 79 for fish (7.9 when corrected for the different standard assessment factor), 35 for daphnia (3.5 when corrected for the assessment factor), and 9 for algae (same assessment factor). Therefore, even when considering the different assessment factors for fish and daphnia vs primary producers, aquatic higher plants give the lowest RAC and thus are the crucial scenario for the risk assessment as illustrated in the table below.

Table 6.5-7: Comparision of RACs derived from product endpoints of AVOXA

Group	**Fish acute**	**Invertebrates acute**	**Algae**	**Aquatic higher plant**
Test species	***Oncorhynchus mykiss***	***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Lemna gibba***
Product endpoint (µg product/L)*	LC_{50} 8800	EC_{50} 3780	E_rC_{50} 989	E_rC_{50} 112.3
AF	100	100	10	10
RAC (µg/L)	88	37.8	98.9	11.23

*please note that here not the sum of a.s. is considered but the product endpoint as given in table 6.5-4.

Further, the available data for *L.gibba* indicate that not only CA is given but also that the risk is driven by one of the actives substance, pyroxsulam, i.e. single substance assessment is justified. This also holds true, if for pinoxaden not *L.gibba* but the most sensitive available macrophyte endpoint (0.71 mg/L for *P.australis* is entered in the calculation (the relative TUs for pyroxsulam then shift from 98.8 % to 98%, the calculated $ECx_{mix\text{-}CA}$ shifts from 0.0152 mg/L to 0.0151 mg/L, the MDR remains 2.7; see table 6.5-6).

Based on these considerations and against the backdrop that the findings of aquatic higher plants being the crucial scenario fit to the herbicidal mode of action of the product, it can be concluded that the single substance risk assessment for pyroxsulam with *L.gibba* covers the acute risk for the product.

For the chronic risk assessment it is assumed that the influence of the formulation as such is reduced and that given their low DissT50 values the proportions of a.s. being simultaneously present shift significantly whereas the consideration of metabolites becomes more relevant. Thus for the chronic risk assessment the individual a.s. and their relevant metabolites are considered.

For the risk assessment a risk envelope approach was used: intended use group A covers the risk for aquatic organisms from all intended uses (see Table 6.1-2).

6.5.2.1 Toxicity to exposure ratio for the active substances

In the following table the TER values for each FOCUS scenario for each organisms group are given.

Table 6.5-8: Aquatic organisms: PEC_{sw} for pinoxaden and relevant ecotoxicological endpoints for each organism' group.

Scenario **FOCUS**	**PEC_{SW} global max** **[µg/L]**	**Fish acute** ***O. mykiss*** **LC_{50}** 10300 **[µg/L]**	**Fish prolonged** ***O. mykiss*** **NOEC** 3200 **[µg/L]**	**Invertebrates acute** ***C. virginica*** **EC_{50}** 400 **[µg/L]**	**Invertebrates prolonged** ***D. magna*** **NOEC** n.a. **[µg/L]**	**Algae** ***S. costatum*** **E_rC_{50}** 980 **[µg/L]**	**Sed. dweller prolonged** ***C. riparius*** **NOEC** n.a. **[µg/L]**	**Aquatic higher plant** ***P. australis*** **E_rC_{50}** 710 **[µg/L]**
Step 1								
	14.531	708.8	220.2	27.5	-	67.4	-	48.9
Step 2								
North Europe (Oct-Feb)	0.552	18659.4	5797.1	724.6	-	1775.4	-	1286.2
North Europe (Mar-May)	0.552	18659.4	5797.1	724.6	-	1775.4	-	1286.2
TER criterion		100	10	100	10	10	10	10

TER values shown in bold fall below the relevant trigger.

Table 6.5-9: Aquatic organisms: PEC_{sw} for pinoxaden metabolite M2 (NOA 407854) and relevant ecotoxicological endpoints for each organism' group.

Scenario **FOCUS**	**PEC_{SW} global max** **[µg/L]**	**Fish acute** ***O. mykiss*** **LC_{50}** 100000 **[µg/L]**	**Fish prolonged** ***P. promelas*** **NOEC** 1000 **[µg/L]**	**Invertebrates acute** ***D. magna*** **EC_{50}** 100000 **[µg/L]**	**Invertebrates prolonged** ***D. magna*** **NOEC** 6250 **[µg/L]**	**Algae** ***P. subcapitata*** **E_rC_{50}** 100000 **[µg/L]**	**Sed. dweller prolonged** ***C. riparius*** **NOEC** n.a. **[µg/L]**	**Aquatic higher plant** ***L. gibba*** **E_rC_{50}** 14600 **[µg/L]**
Step 1								
	16.111	6206.9	62.1	6206.9	387.9	6206.9	-	906.2
Step 2								
North Europe (Oct-Feb)	2.125	47058.8	470.6	47058.8	2941.2	47058.8	-	6870.6
North Europe (Mar-May)	1.108	90252.7	902.5	90252.7	5640.8	90252.7	-	13176.9
TER criterion		100	10	100	10	10	10	10

TER values shown in bold fall below the relevant trigger.

Table 6.5-10: Aquatic organisms: PEC_{sw} for pinoxaden metabolite M3 (NOA 447204) and relevant ecotoxicological endpoints for each organism' group.

Scenario	PEC_{SW} global max	Fish acute	Fish prolonged	Invertebrates acute	Invertebrates prolonged	Algae	Sed. dweller prolonged	Aquatic higher plant
		O. mykiss	*O. mykiss*	*D. magna*	*D. magna*	*P. subcapitata*	*C. riparius*	*L. gibba*
FOCUS		**LC_{50}**	**NOEC**	**EC_{50}**	**NOEC**	**E_bC_{50}**	**NOEC**	**E_rC_{50}**
		120000	n.a.	120000	n.a.	89900	n.a.	23090
	[µg/L]	**[µg/L]**	**[µg/L]**	**[µg/L]**	**[µg/L]**	**[µg/L]**	**[µg/L]**	**[µg/L]**
Step 1								
	16.407	7314	-	7314	-	5479.4	-	1407.3
Step 2								
North Europe (Oct-Feb)	6.316	18999.4	-	18999.4	-	14233.7	-	3655.8
North Europe (Mar-May)	2.775	43243.2	-	43243.2	-	32396.4	-	8320.7
TER criterion		100	10	100	10	10	10	10

TER values shown in bold fall below the relevant trigger.

Table 6.5-11: Aquatic organisms: PEC_{sw} for pyroxsulam and relevant ecotoxicological endpoints for each organism' group.

Scenario	PEC_{SW} global max	Fish acute	Fish prolonged	Invertebrates acute	Invertebrates prolonged	Algae	Sed. dweller prolonged	Aquatic higher plant

FOCUS		*O. mykiss* LC_{50} 87000 [µg/L]	*P. promelas* NOEC 10100 [µg/L]	*D. magna* EC_{50} 100000 [µg/L]	*D. magna* NOEC 10400 [µg/L]	*P. subcapitata* E_rC_{50} 924 [µg/L]	*C. riparius* NOEC 100000 [µg/L]	*L. gibba* EC_{50} 2.57 [µg/L]
Step 1								
	5.04	17261.9	2004	19841.3	2063.5	183.3	19841.3	**0.5**
Step 2								
North Europe (Oct-Feb)	1.18	73728.8	8559.3	84745.8	8813.6	783.1	84745.8	**2.2**
North Europe (Mar-May)	0.54	161111.1	18703.7	185185.2	19259.3	1711.1	185185.2	**4.8**
Step 3								
D1/ditch	2.007	43348.3	5032.4	49825.6	5181.9	460.4	49825.6	**1.3**
D1/stream	1.254	69378	8054.2	79744.8	8293.5	736.8	79744.8	**2**
D2/ditch	1.836	47385.6	5501.1	54466.2	5664.5	503.3	54466.2	**1.4**
D2/stream	1.231	70674.2	8204.7	81234.8	8448.4	750.6	81234.8	**2.1**
D3/ditch	0.095	915789.5	106315.8	1052631.6	109473.7	9726.3	1052631.6	27.1
D4/pond	0.003	29000000	3366666.7	33333333.3	3466666.7	308000	33333333.3	856.7
D4/stream	0.074	1175675.7	136486.5	1351351.4	140540.5	12486.5	1351351.4	34.7
D5/pond	0.003	29000000	3366666.7	33333333.3	3466666.7	308000	33333333.3	856.7
D5/stream	0.061	1426229.5	165573.8	1639344.3	170491.8	15147.5	1639344.3	42.1

D6/ditch	0.098	887755.1	103061.2	1020408.2	106122.4	9428.6	1020408.2	26.2
R1/pond	0.004	21750000	2525000	25000000	2600000	231000	25000000	642.5
R1/stream	0.189	460317.5	53439.2	529100.5	55026.5	4888.9	529100.5	13.6
R3/stream	0.204	426470.6	49509.8	490196.1	50980.4	4529.4	490196.1	12.6
R4/stream	0.131	664122.1	77099.2	763358.8	79389.3	7053.4	763358.8	19.6
TER criterion		100	10	100	10	10	10	10

TER values shown in bold fall below the relevant trigger.

The results indicate that risk mitigation measures may be needed due to an unacceptable risk for some scenarios for higher aquatic plants from exposure to pyroxsulam. It should be noted that the TER values for acute risk on fish, invertebrates and algae only have indicative character, as in the given case the product toxicity endpoints suggest that synergism is given. Given that aquatic higher plants have shown to be the most sensitive group and that for this group the CA concept is applicable with pyroxsulam being identified as the toxicity driver as explained above, the risk assessment for aquatic higher plants for the a.s. pyroxsulam accounts for the product (i.e. the mixture) and other species.

Please note that in principal ErC50s are selected in this Core Assessment but there are some uncertainties regarding the level of protection reached for primary producers. This is indicated for macrophytes in the aquatic Guidance Document (EFSA Journal 2013;11(7):3290) that recommends: "... a proper calibration between different tiers (higher and lower tier data) for macrophytes should be performed in the future". Such calibration should be extended to algae and shall be performed at EU level. Until relevant information on the level of protection reached is made available, it is recommended to address this uncertainty at each Member State level in the National Addendum if considered necessary, although it would be highly appreciated to have a harmonised approach in the Central zone.

Seemingly the crucial EC50 for *Lemna gibba* as cited in the list of endpoints is an EbC50, thus the issue might be irrelevant in this case.

6.5.2.2 Risk assessment for the product (based on drift only)

A risk assessment for the formulation based on PEC_{SW} values referring to spray drift data by Rautmann and Ganzelmeier can be used to derive suitable risk mitigation measures (as used in the national addendum). However, since pyroxsulam was identified to be driving the toxicity, single substance risk assessment is suitable to characterize the overall risk from the product (see tables above indicating that risk mitigation, e.g. vegetated buffer strips, may be needed for some sceanrios; for risk mitigation derived for Germany please refer to the national addendum).

6.5.2.3 Consideration of Metabolites

For the pinoxaden metabolites M2 (exhibiting pesticidal activity comparable to the parent) and M3 (quantitatively largest amount) please refer to the quantitative risk assessment presented above.

Metabolites of pyroxsulam were assessed in EFSA conclusion; EFSA Journal 2013;11(4):3182A. According to EFSA conclusion metabolites of pyroxsulam pose a low risk to aquatic organisms. Since during the peer review a higher application rate was considered as intended for A19786A, no quantitative risk assessment is deemed necessary to conclude an acceptable risk for aquatic organsims from exposure to pyroxsulam metabolites.

With respect to exposure of surface water bodies from groundwater via bank filtration also the pinoxaden metabolites M3, M11, M52, M54, M55 and M56, and the pyroxsulam metabolites 6-Cl-7-OH and PSA need to be considered, since for these metabolites of pinoxaden concentrations of >0.1µg/L in groundwater cannot be excluded. However, since a dilution factor of 10 is considered on the respective PECgw resulting in values below 0.1µg/L for related surface water exposure this would result in acceptable TER values even when considering the metabolites to be 10 times more toxic than the parent. The only exception is the pyroxsulam metabolite PSA when considering it to be 10 times more toxic than the parent towards *Lemna gibba*. However, from the available algae test there is no indication that PSA would actually be more toxic than the parent, thus the risk is considered as acceptable.

6.5.2.4 Accumulation in aquatic non-target organisms

Bioaccumulation of any of the active substances under natural conditions is not expected to occur and a study is not necessary to determine bioaccumulation in aquatic non-target organisms.

The same conclusion can be drawn for the safener cloquintocet-mexyl which has a log K_{ow} value of 5.20 at pH 7, yet shows rapid degradation to the polar metabolite cloquintocet acid and a BCF of 621 with depuration reaching the limit of dection after 10 d.

The the results of the assessment indicate an acceptable risk for aquatic organisms due to the intended use of A19786A (AVOXA) in cereals according to the label.

6.5.3 Overall conclusions

Based on the calculated concentrations of pinoxaden and its respective metabolites in surface water (PEC_{SW} FOCUS Step 1 + 2), the calculated TER values for the acute and long-term risk resulting from an exposure of aquatic organisms to pinoxaden according to the GAP of the formulation A19786A (AVOXA) achieve the acceptability criteria TER ≥ 100 and TER ≥ 10, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. for long-term effects. The results of the assessment indicate an acceptable risk for aquatic organisms due to the intended use of A19786A (AVOXA) in cereals according to the label.

Based on the calculated concentrations of pyroxsulam and its respective metabolites in surface water (PEC_{SW} FOCUS Step 1-3), the calculated TER values for the acute and long-term risk resulting from an exposure of aquatic organisms to pyroxsulam according to the GAP of the formulation A19786A (AVOXA) do not achieve the acceptability criteria TER ≥ 100 and TER ≥ 10, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. for long-term effects for all scenarios, hence risk mitigation such as buffer strips or drift reducing technique may have to be implemented. The results of the assessment indicate that an acceptable risk for aquatic organisms due to the intended use of A19786A (AVOXA) in cereals according to the label can be achieved, when risk mitigation is implemented.

6.6 Effects on bees (MIIIA 10.4, KPC 10.3.1)

Effects on bees of A19786A were not evaluated as part of the EU review of pinoxaden or pyroxsulam. Therefore all relevant data and assessments are provided here and are considered adequate.

Toxicity
Table 6.6-1 presents the results of laboratory bee toxicity studies with the formulation. Further details regarding the tests with the formulation are provided in chapter 10.4.2. For the sake of completeness the table also presents results of laboratory bee toxicity studies with the active substance.

Table 6.6-1: Results of laboratory bee toxicity studies

Test substance	Exposure route	LD_{50}	Reference
A19786A	oral 48 h	> 591 µg product/bee	Kling A., 2013 Report Number: S12-03713
	contact 48 h	> 406 µg product/bee	
pinoxaden tech.	oral 48 h	> 200 µg a.s./bee *	EFSA Scientific Report, 2013; 11(6): 3269 Conclusion on the peer review of the pesticide risk assessment of the active substance pinoxaden
	contact 48 h	> 100 µg a.s./bee *	
pyroxsulam tech.	oral 48 h	> 107.4 µg a.s./bee *	EFSA Scientific Report, 2013; 11(4): 3182

	contact 48 h	> 100 µg a.s./bee *	Conclusion on the peer review of the pesticide risk assessment of the active substance pyroxsulam

* EU agreed endpoint

Exposure
The recommended use pattern for A19786A includes application in cereals at a maximum application rate of up to 1.8 L product/ha. This maximum single application rate is equivalent to 1904 g product/ha.
Bees may be exposed to A19786A by direct spraying while bees are foraging on flowers and weeds, through contact with fresh or dried residues or by oral uptake of contaminated pollen, nectar and honey dew.

Hazard quotients
Table 6.6-2 presents the Hazard quotients for oral and contact exposure according to EPPO (2010) Environmental risk assessment scheme for plant protection products (Chapter 10: Honeybees (PP 3/10(3)). Bulletin OEPP/EPPO Bulletin 40: 323-331). The HQ-values were calculated as follows:

$$\text{Hazard Quotient} = \text{max. application rate [g product/ha]} / LD_{50} \text{ [µg product/bee]}$$

Table 6.6- 2: Hazard quotients for honeybees

Test substance	Max. single application rate [g product/ha]	Exposure route	LD_{50} [µg product/bee]	Hazard quotient (HQ)	HQ trigger
A19786A	1904	oral	> 591 µg	< 3.2	50
		contact	> 406 µg	< 4.7	

Risk assessment
Due to the results of laboratory tests A19786A is considered to be practically non-toxic to bees. All hazard quotients are clearly below the trigger of 50, indicating that the intended use poses a low risk to bees in the field. Bee brood testing is not required since the test item is not an IGR.

Overall conclusion
It is concluded that A19786A will not adversely affect bees or bee colonies when used as recommended. Label NB6641 is assigned to the product.

6.7 Effects on arthropods other than bees (MIIIA 10.5, KPC 10.3.2)

Table 6.7-1: Toxicity of the product A19786A (AVOXA) to non-target arthropods

Species	Substance	Exposure System	Results	Reference	Internal code
Typhlodromus pyri (protonymphs)	A19786A (AVOXA)	Extended laboratory test, bean leaves, 2D	LR_{50} = 1652 mL/ha	Fallowfield, L. 15.01.2013 SYN-12-43 *	85990

			ER_{50} > 1800 mL/ha (28.9 % effect)		
Aphidius rhopalosiphi (adults)	A19786A (AVOXA)	Extended laboratory test, barley seedlings, 3D	LR_{50} > 1000 mL/ha ER_{50} > 1000 mL/ha NOER = 1000 mL/ha	Stevens, J. 07.12.2012 SYN-12-44 *	85989

* New study submitted

6.7.1 Justification for new endpoints

New extended laboratory studies with the preparation were submitted. The studies are valid and generally suitable for the risk assessment. Study summaries are presented in Appendix 2. It has to be noted, that the test with *Aphidius rhopalosiphi* did not cover the intended field rate. For implications for the in-field risk assessment, please refer to chapter 6.7.2.1 below.

6.7.2 Risk assessment

The evaluation of the risk for non-target arthropods was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002), and in consideration of the recommendations of the guidance document ESCORT 2.

6.7.2.1 Risk assessment for in-field exposure

Exposure

The in-field exposure, given as predicted environmental rates, PER, for non-target arthropods resulting from the intended uses of A19786A (AVOXA) is calculated according to published agreement after ESCORT 2 workshop (Candolfi et al. 2001[1] -hereafter referred to as 'Guidance Document') using the following equation:

$$PER_{in-field} = \text{Application rate (g a.s./ha)} \times \text{MAF}$$

where:

MAF = generic multiple application factor used to take into account the potential build-up of applied substances between applications. This factor integrates number of applications, application interval and degradation kinetics of the active substance

Default MAF values for given numbers of applications are listed in the Guidance Document.

[1] Candolfi, M.P.; Barrett, K.L.; Campbell, P.; Forster, R.; Grandy, N.; Huet, M.C.; Lewis. G.; Oomen, P.A.; Schmuck, R.; Vogt, H. (2001): Guidance document on regulatory testing and risk assessment procedures for plant protection products with non-target arthropods. ESCORT2 Workshop European Standard Characteristics of Non-Target Arthropod Regulatory Testing. Wageningen, The Netherlands, 46 pp.

Table 6.7-2: Predicted in-field environmental rates (PER)

Intended use	Exposure	Single appl. rate [mL/ha]	MAF	$PER_{in-field}$ [mL/ha]
Group A	In-field	1800 mL/ha: 59.9 g pinoxaden/ha 15 g pyroxsulam/ha	1	1800 mL/ha: 59.9 g pinoxaden/ha 15 g pyroxsulam/ha
Group B	In-field	1350 mL/ha: 45 g pinoxaden/ha 11.3 g pyroxsulam/ha	1	1350 mL/ha: 45 g pinoxaden/ha 11.3 g pyroxsulam/ha

MAF: Multiple application factor; f_{drift}: Drift factor; f_{veg}: Vegetation distribution factor; PER: Predicted environmental rates

Tier 1 risk assessment for in-field exposure

Since only extended laboratory tests have been submitted for A19786A (AVOXA), the zRMS does not calculate Tier 1 HQ values which are appropriate for studies performed on glass plates.

Higher tier risk assessment for in-field exposure

At Higher Tier, a hazard quotient approach is not used for non-target arthropods. Instead, a trigger value for lethal or sublethal effects of 50 % is used.

The risk for non-target arthropods exposed in-field to A19786A (AVOXA) was assessed by comparing the environmental rate ($PER_{in-field}$) to the lowest lethal rate (LR_{50}) estimated in toxicity tests with non-target arthropods. With regard to extended laboratory tests and semi-field tests, lethal and sublethal effects of less than 50 % are considered acceptable, provided that the tests covered the appropriate field rate. This has, however, not been the case for the submitted extended laboratory test with *Aphidius rhopalosiphi* since only concentrations up to 1000 mL product/ha were tested. Thus strictly it cannot be concluded whether at PER in-field the risk is acceptable or not for *Aphidius rhopalosiphi.*

Based on the detected lethal effects on *Typhlodromus pyri,* there is a risk indicated for intended use group A, that represents the worst-case.

The results of the risk assessment are summarised in the following table.

Table 6.7-3: Risk assessment for non-target arthropods (Higher tier) for in-field exposure according to intended use group A

Intended use	Species	LR_{50}/ER_{50} [mL product/ha]	PER [mL product/ha]	Risk acceptable [yes/no]
Group A	*Typhlodromus pyri*	1652	1800	no
	Aphidius rhopalosiphi	>1000	1800	no (issue not finalized)
Group B	*Typhlodromus pyri*	1652	1350	yes
	Aphidius rhopalosiphi	>1000	1350	no (issue not finalized)

PER: Predicted environmental rates

The applicant did not present any further data, yet concluded an acceptable risk nevertheless. The zRMS consideres this to be insufficient, yet investigated options for a weight of evidence approach to back up the applicants conclusion at least for intended use group B, i.e. reviewing the existing data in order to see whether it is justified to base the risk assessment on the available endpoint for *Typhlodromus pyri.*

Based on the two provided extended laboratory studies with A19786A (AVOXA) there is some indication that *Typhlodromus pyri* may be more sensitive than *Aphidius rhopalosiphi* based on the respective NOER values. The data available from the EU peer review of the active substances further indicate that

a) pinoxaden is more toxic towards arthropods than pyroxsulam (based on the EU peer review data pinoxaden is ≥ 20 time more toxic towards *T.pyri* and ≥ 6 times more toxic towards *A.rhopalosiphi* than pyroxsulam) and

b) *Typhlodromus pyri* is more sensitive than *Aphidius rhopalosiphi* when exposed to pinoxaden (factor 3.4). Also, for pinoxaden two additional species have been tested: *Chrysoperla carnea* and *Aleochara bilineata*, both of which being less sensitive towards pinoxaden than *T.pyri*.

A19786A (AVOXA) contains four times more pinoxaden than pyroxsulam, i.e. pinoxaden is expected to be dominating the toxicity. This conclusion can be supported by adopting the mixture toxicity approach as presented in the chapter on aquatic risk assessment for the available data for pinoxaden and pyroxsulam. For illustration, a LR50mix-CA was calculated based on the EU peer review endpoint for *T.ypri* and *A.rhopalosiphi* and compared to the measured LR50 for AVOXA as shown in the table below.

Table 6.7-4: Comparision between calculated and measured LR50 for AVOXA for use in weight of evidence approach

Endpoint Active Substance	**EC_{xi}** **(mg a.s./L)**	**Concentration (C_i) in formulation** **(g a.s./L)**	**P_i**	**relative Toxic Unit (%TU)**	**$LR50_{mix-CA}$** **(mg /L)**	**$LR50_{PPP}$** **(mg sum of a.s./L)**	**MDR**
T.pyri							
Pinoxaden	1.81	33.3	0.800	98.8	2.24	68.77	0.03
Pyroxsulam	>37.5	8.33	0.200	1.2			
A.rhopalosiphi							
Pinoxaden	6.22	33.3	0.800	96.0	7.47	41.63	0.18
Pyroxsulam	>37.5	8.33	0.200	4.0			

The above calculation only have illustrative character, yet they give an indication that the measured LR50 is less severe than expected based on the toxicity data for the individual substances, i.e. the safener does not seem to enhance the toxicity towards the standard test species.

In a weight of evidence approach, it may thus be acceptable to base the risk assessment on the provided endpoint for *Typhlodromus pyri* from the product test with AVOXA without insisting on additional tests

with the product formulation as it is reasonable to assume that pinoxaden is the crucial a.s. for which it has been shown during the EU peer review that *T.pyri* was most sensitive.

Hence, at this level there is an acceptable risk concluded for intended use group B and an in-field risk identified for intended use group A and members states have to check whether this impedes the authorization at national level.

6.7.2.2 Risk assessment for off-field exposure

Exposure

Exposure of non-target arthropods living in non-target off-field areas to A19786A (AVOXA) will mainly be due to spray drift from field applications. Off-field predicted environmental rates (PER-values) were calculated from in-field PERs in conjunction with drift values published by the BBA (2000[2]) as shown in the following equation:

$$Off-field\ PER = \frac{Maximum\ in-field\ PER\ x \left(drift\ percentile \diagup 100 \right)}{vegetation\ distribution\ factor\ (vdf)}$$

where:

vdf = vegetation distribution factor used in combination with test results derived from 2-dimensional exposure set-ups

To account for interception and dilution by three-dimensional vegetation in off-crop areas, a vegetation distribution or dilution factor (vdf, see above) is incorporated into the equation when calculating off-field exposure in conjunction with toxicity endpoints derived from two-dimensional studies (e.g. glass plate or leaf discs). A vdf of 10 is recommended in the ESCORT 2 report when the off-field risk assessment is based on toxicity endpoints obtained in a test design with two-dimensional exposure but has been questioned. Germany considers a vdf of five as a more reliable value to extrapolate from a two dimensional exposure situation to the exposure situation in the field. The exposure estimation was based mainly on the 'Retention Area Index' (RAI) characterizing the total retention area of sprayed plant protection products in a canopy per base area. As a 'realistic worst case scenario, meadow canopies < 20 cm height was chosen (Koch and Weisser, 2004[3]; German Federal Environment Agency UBA, 2006[4]). The derived vdf of 5 agrees well with

[2] BBA (Biologische Bundesanstalt für Land- und Forstwirtschaft) (2000): Abdrifteckwerte für Flächen- und Raumkulturen sowie für den gewerblichen Gemüse-, Zierpflanzen- und Beerenobstanbau. Bundesanzeiger 100, 26. Mai 2000, Köln, pp. 9879.

[3] Koch H and Weisser P, 2004. Die Gesamtoberflaeche in Saumstrukturen als potentielle Retentionsflaeche fuer Driftpartikel, Retention Area Index (RAI). Nachrichtenblatt des Deutschen Pflanzenschutzdienstes, 56, 65-69.

[4] German Federal Environment Agency (UBA), 2006. Exposure calculation for arthropods in field border structures - selection of an appropriate 'vegetation distribution factor'. Parma.

field data by Koch et al. (2003)[5], who compared measured residues of plant protection products on two dimensional surfaces with the measured residues on meadows next to a treated area (factor of 4.4 to 6.5 between median spray residues on leaves when a standard nozzle was used for spray application). Even though the zRMS is in the opinion that a dilution factor of 5 more appropriated, the risk assessment procedure here considers both dilution factors of 5 and 10. For endpoints resulting from 3-dimensional studies, i.e. where spray treatment is applied onto whole plants, the vdf is not used.

Pinoxaden and pyroxsulam both have a vapour pressure of $< 10^{-5}$ Pa and are therefore classified as non-volatile. Hence, deposition following volatilization has not to be considered.

For the results of study with *T. pyri* exposed to A19786A (AVOXA), a vegetation distribution factor has to be considered (study conducted in 2D environment).

Regarding the results of the study with *A. rhopalosiphi* exposed to A19786A (AVOXA), the vegetation distribution factor does not have to be considered since it was conducted in 3D environment.

Table 6.7-5: Predicted off-field environmental rates (PER) for A19786A (AVOXA)

Intended use	Exposure	Single appl. rate [mL product/ha]	MAF	Drift scenario	f_{drift}	vdf	$PER_{off\text{-}field}$ [mL product/ha]
Group A	Off-field	1800	1	90th percentile	2.77 %	10 / 5 / 1	4.986 / 9.972 / 49.86
Group B	Off-field	1350	1	90th percentile	2.77 %	10 / 5 / 1	3.740 / 7.479 / 37.395

MAF: Multiple application factor; f_{drift}: Drift factor; vdf: Vegetation distribution factor; PER: Predicted environmental rates

Higher tier risk assessment for off-field exposure

According to ESCORT II , lethal and sublethal effects less than 50 % at the calculated deposition rates including the correction factor are considered acceptable. The correction factor can be lowered to 5 if higher tier tests with the more sensitive of the species affected in tier I and 'two additional species with different biology' were submitted (please refer to European Commission 2002)[6] Since here no additional species were tested, the CF of 10 is remained.

[5] Koch H, Weisser P and Landfried M, 2003. Effect of drift potential on drift exposure in terrestrial habitats. Nachrichtenblatt des Deutschen Pflanzenschutzdienstes, 55, 181-188.

[6] European Commission (2002): Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC: Directorate E - Food Safety: plant health, animal health and welfare, international questions; E1 - Plant health.

Additionally, the assessment of the risk to non-target arthropods due to an exposure to A19786A (AVOXA) was performed on basis of the calculation of toxicity-exposure ratios (TER values) according the following formula:

$$TER = \frac{L(E)R50\,(L\ product/ha)}{Off-field\ PER\,(L\ product/ha)}$$

The risk is considered acceptable if the values obtained are TER off-field > 10 when the ecotoxicological data resulted from tier 1 tests on glass plates or TER off-field > 5 if higher tier tests with the more sensitive of the species affected in tier I and 'two additional species with different biology' were submitted (please refer to European Commission, 2002)[7]. Since here no additional species were tested, the threshold of 10 is remained. The TER calculation is included as additional information since potential risk mitigation measures on national level (Germany) would be retrieved using this concept.

The results of the risk assessment are summarized in the following table.

Table 6.7-6: Risk assessment for non-target arthropods (Tier 2) for off-field exposure

Intended use	Species	LR_{50}/ER_{50} [mL product/ha]	$PER_{off-field}$ [mL product/ha]	$PER_{off-field}$ x correction factor [mL product/ha]	Risk acceptable [yes/no]	Additional info: TER
Group A	*Typhlodromus pyri*	1652	4.986 / 9.972	49.86 / 99.72	Yes	331 / 166
	Aphidius rhopalosiphi	>1000	49.86	498.6	Yes	20
Group B	*Typhlodromus pyri*	1652	3.740 / 7.479	37.4 / 74.79	Yes	442 / 221
	Aphidius rhopalosiphi	>1000	37.395	373.95	Yes	27

PER: Predicted environmental rates; TER: Toxicity to ecposure ratio. TER values shown in bold fall below the relevant trigger.

6.7.2.3 Risk mitigation measures

No risk mitigation needed.

[7] European Commission. 2002. Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC: Directorate E - Food Safety: plant health, animal health and welfare, international questions; E1 - Plant health.

6.7.3 Overall conclusions

In-field

Based on the calculated rates of A19786A (AVOXA) in in-field areas, the the risk resulting from an exposure of non-target arthropods to A19786A (AVOXA) according to the GAP of the formulation A19786A (AVOXA) only achieve the acceptability criteria of less than 50% effects (higher Tier), according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2 for intended use group B yet not for intended use group A. Thus at this stage the results of the assessment indicate an acceptable risk for intended use group B and an unacceptable risk for intended use group A for non-target arthropods due to the intended use of A19786A (AVOXA) in cereals according to the label.

It should be evaluated on member state level, if risk mitigations can be used to manage the risk in the respective member state. As a recommendation the Guidance Document on Terrestrial Ecotoxicology (draft working document SANCO/10329/2002 rev 2 final of 17 October 2002) suggests to modify the following use specifications to reduce the effects on non-target arthropods within cropped areas.

- application frequency and intervals
- timing of application (crop stage)
- unsprayed headlands

Off-field

Based on the calculated rates of A19786A (AVOXA) in off-field areas, the calculated HQ and TER values describing the risk resulting from an exposure of non-target arthropods to A19786A (AVOXA) according to the GAP of the formulation A19786A (AVOXA) achieve the acceptability criteria of less than 50% effects at calculated drift rates (higher Tier) and of TER ≥ 10, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for non-target arthropods due to the intended use of A19786A (AVOXA) in cereals according to the label.

6.8 Effects on non-target soil meso- and macrofauna (MIIIA 10.6, KPC 10.4, KPC 10.4.1, KPC 10.4.2)

Table 6.8-1: EU agreed endpoints and new endpoints for earthworms and other soil macro- and mesofauna

Species	Substance	Exposure System	Results	Reference	Internal code
Eisenia fetida	pinoxaden	acute	LC_{50} corr. > 500 mg a.s./kg soil dw	EFSA Journal 2013;11(8):3269	

Eisenia fetida	NOA 407854 (M2)	acute	LC_{50} > 1000 mg a.s./kg soil dw	EFSA Journal 2013;11(8):3269	
Eisenia fetida	NOA 447204 (M3)	acute	LC_{50} > 1000 mg a.s./kg soil dw	EFSA Journal 2013;11(8):3269	
Eisenia fetida	pyroxsulam	acute	LR_{50} > 10000 mg a.s./kg soil dw	EFSA Journal 2013;11(4):3182	
Eisenia foetida	7-OH metabolite of pyroxsulam	acute	LC_{50} > 1000 mg a.s./kg soil dw	EFSA Journal 2013;11(4):3182	
Eisenia fetida	5-OH metabolite of pyroxsulam	acute	LC_{50} > 1000 mg a.s./kg soil dw	EFSA Journal 2013;11(4):3182	
Eisenia fetida	6-Cl-7-OH metabolite of pyroxsulam	acute	LC_{50} > 1000 mg a.s./kg soil dw	EFSA Journal 2013;11(4):3182	
Eisenia fetida	Pyridine sulfonamide	acute	LC_{50} > 1000 mg a.s./kg soil dw	EFSA Journal 2013;11(4):3182	
Eisenia fetida	7-OH metabolite of pyroxsulam	chronic	NOEC = 0.068 mg/kg soil dw	EFSA Journal 2013;11(4):3182	
Eisenia fetida	5-OH metabolite of pyroxsulam	chronic	NOEC = 0.107 mg/kg soil dw	EFSA Journal 2013;11(4):3182	
Eisenia fetida	6-Cl-7-OH metabolite of pyroxsulam	chronic	NOEC = 0.130 mg/kg soil dw	EFSA Journal 2013;11(4):3182	
Eisenia fetida	Pyridine sulfonamide	chronic	NOEC = 0.038 mg/kg soil dw	EFSA Journal 2013;11(4):3182	
Folsomia candida	7-OH metabolite of pyroxsulam	chronic	NOEC = 0.068 mg/kg soil dw	EFSA Journal 2013;11(4):3182	
Folsomia candida	6-Cl-7-OH metabolite of pyroxsulam	chronic	NOEC = 0.136 mg/kg soil dw	EFSA Journal 2013;11(4):3182	
Folsomia candida	Pyridine sulfonamide	chronic	NOEC = 0.038 mg/kg soil dw	EFSA Journal 2013;11(4):3182	
Eisenia fetida	A19786A (AVOXA)	chronic	**EC_{10} = 191 mg/kg soil dw** NOEC = 309 mg/kg soil dw EC_{20} = 311 mg/kg soil dw	Friedrich, S. 28.02.2013 13 10 48 008 S	85999

**Corrected value derived by dividing the endpoint by a factor of 2 in accordance with the EPPO earthworm scheme 2002 (for substances with a log K_{ow} > 2 and 10% peat in the study).

* New study submitted

6.8.1 Justification for new endpoints

A new study with the preparation has been submitted. The study is valid and suitable for the risk assessment. The study summary is provided in Appendix 2.

6.8.2 Toxicity exposure ratios for earthworms and other soil macro- and mesofauna, TER_A and TER_{LT} (MIIIA 10.6.1)

The evaluation of the risk for earthworms and other soil macro-organisms was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

For the calculations of predicted environmental concentrations in soils (PEC soil), reference is made to the environmental fate section (Part B, Section 5) of this submission.

For risk assessment purposes, a risk envelope approach was used. Hence, intended use group A covers the risk for earthworms and other soil macro- and mesofauna for all intended uses of the GAP (see Table 6.1-2).

The acute risk for earthworms and other non-target soil macro- and mesofauna resulting from an exposure to A19786A (AVOXA), its containing active substances as well as their major soil degradation products was assessed by comparing the maximum PEC_{SOIL} with the 14-day LC_{50} value to generate acute TER values. The TER_A was calculated as follows:

$$TER_A = \frac{LC_{50}\ (mg/kg)}{PEC_{soil}\ (mg/kg)}$$

The chronic risk for earthworms, other non-target soil macro- and mesofauna and organic matter breakdown resulting from an exposure to A19786A (AVOXA), its containing active substances as well as their major soil degradation products was assessed by comparing the maximum PEC_{SOIL} with the NOEC value to generate chronic TER values. The TER_{LT} was calculated as follows:

$$TER_{LT} = \frac{NOEC\ (mg/kg)}{PEC_{soil}\ (mg/kg)}$$

The results of the risk assessment are summarized in the following table.

Table 6.8-2: TER values for earthworms and other soil macro- and mesofauna (Tier-1), use group A, 1 x 1.8 L product/ha, 25 % interception

Species	Test item	Time scale	Endpoint [mg/kg soil dw]	Max. PEC_{SOIL} [mg/kg soil dw]	TER
Eisenia fetida	pinoxaden	acute	500	0.0599	>> 100
	NOA 407854 (M2)	acute	1000	0.0427	>> 100
	NOA 447204 (M3)	acute	1000	0.0155	>> 100
	pyroxsulam	acute	10000	0.0150	>> 100
	Metabolite 7-OH	chronic	0.130	0.0111	6.1
	Metabolite 5-OH	chronic	0.107	0.0035	30.6
	Metabolite 6-Cl-7-OH	chronic	0.130	0.0041	31.7
	Pyridine sulfonamide	chronic	0.038	0.0013	29.2
	A19786A (AVOXA)	chronic	191	1.895	100.8

Folsomia candida	Metabolite 7-OH	chronic	0.068	0.0111	6.1
	Metabolite 6-Cl-7-OH	chronic	0.136	0.0041	33.2
	Pyridine sulfonamide	chronic	0.038	0.0013	29.2

TER values shown in bold fall below the relevant trigger.

6.8.3 Higher tier risk assessment

Not relevant.

6.8.4 Overall conclusions

Based on the predicted concentrations of A19786A (AVOXA)), its containing active substances as well as their major soil degradation products in soils, the TER values describing the acute and long-term risk for earthworms and other non-target soil organisms following exposure to A19786A (AVOXA) according to the GAP of the formulation A19786A (AVOXA) achieve the acceptability criteria TER ≥ 10 resp. TER ≥ 5 according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for soil organisms due to the intended use of A19786A (AVOXA) in cereals according to the label.

6.9 Effects on soil microbial activity (MIIIA 10.7, KPC 10.5)

Table 6.9-1: EU agreed endpoints and new endpoints for soil microorganisms

Substance	Test design	Results	Source	Internal code
pinoxaden (assumed also NOA 407854 (M2)	N-mineralisation	<25 % inhibition at 0.4 mg/kg soil dw after 28 d, equivalent to 300 g/ha	EFSA Journal 2013;11(8):3269	59104
	C-mineralisation			
NOA 447204 (pinoxaden metabolite M3)	N-mineralisation	<25 % inhibition at 0.066 mg/kg soil dw after 28 d , equivalent to 50 g/ha	EFSA Journal 2013;11(8):3269	71281
	C-mineralisation			
	N-mineralisation	< 25 % inhibition at 0.66 mg/kg soil dw after 28 d	Völkel, W. 2006 A39003 *	71283
	C-mineralisation			
pyroxsulam tested as GF-1274	N-mineralisation	< 25% effect at ≥ 0.125 mg a.s./kg soil dw after 28 d	EFSA Journal 2013;11(4):3182	
	C-mineralisation			
cloquintocet-mexyl	N-mineralisation	≤ 25 % effect at 0.27 mg /kg soil dw, equivalent to 200 g a.s/ha	Morgenroth, U. 1992 315360	71275
	C-mineralisation			
A19786A (AVOXA)	N-mineralisation	≤ 25 % effect at 12.64 mg /kg soil dw, equivalent to 9 L product/ha	Schulz, L. 29.01.2013 13 10 48 004 C/N **	85994
	C-mineralisation			

* Study not part of the list of endpoints, yet previously submitted for product assessments

**New study submitted

6.9.1 Justification for new endpoints

A new study with the preparation has been submitted. The study is valide and suitable for the use in risk assessment. A study summary is provided in Appendix 2.

6.9.2 Risk assessment

The evaluation of the risk for soil micro-organisms was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

Please refer to above for the predicted environmental concentrations in soil (PEC_{SOIL}) of A19786A (AVOXA)), its containing active substances as well as their major soil degradation products.

The results of the risk assessment are summarized in the following table.

Table 6.9-2: Risk assessment for effects on soil micro-organisms

Test substance	**Test concentration (adverse effects < 25%)** **[mg /kg]**	**PEC_{SOIL}** **[mg/kg]**	**Risk acceptable** **[yes/no]**
pinoxaden (assumed also NOA 407854 (M2))	0.4	0.0599 + 0.0427	Yes, MoS = 3.9
NOA 447204 (pinoxaden metabolite M3)	0.66 (0.066)*	0.0155	Yes, MoS > 10 (4)*
pyroxsulam tested as GF-1274	0.125	0.0150	Yes, MoS > 5
A19786A (AVOXA)	12.64	1.895	Yes, MoS > 5

*the values in () consider the LoEP endpoint

6.9.3 Overall conclusions

Based on the predicted concentrations of A19786A (AVOXA)), its containing active substances as well as their major soil degradation products in soils, the risk to soil microbial processes following exposure to A19786A (AVOXA) according to the GAP of the formulation A19786A (AVOXA) is considered to be acceptable according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2.

6.10 Effects on non-target plants (MIIIA 10.8, KPC 10.6)

6.10.1 Effects on non-target terrestrial plants (MIIIA 10.8.1)

Table 6.10-1: EU-agreed endpoints and new endpoints for non-target terrestrial plants

Species	Substance	Exposure System	Results	Reference	Internal code
Avena sativa (=most sensitive) *Lycopersicon esculentum (= second most sensitive)* In total 10 species tested, 4 monocots and 6 dicots (see study summary in Appendix 2)	A19786A (AVOXA)	Vegetative vigour 21 d	ER_{50} = 3.62 mL/ha (*Avena sativa*) ER_{50} = 26.99 mL/ha (*Lycopersicon esculentum*)	Bramby-Gunary, J. 16.10.2012 A19786A_10002, ACE-12-050 *	85997
Avena sativa	A19786A (AVOXA)	Vegetative vigour 21 d	ER_{50} = 61.14 mL/ha	Stefanut, M. 10.09.2013 A19786A_10056, ACE-13-080 *	85998
Allium cepa (= most sensitive) In total 10 species tested, 4 monocots and 6 dicots (see study summary in Appendix 2)	A19786A (AVOXA)	Seedling emergence 21 d	ER_{50} = 92.99 mL/ha	Bramby-Gunary, J. 16.10.2012 A19786A_10001, ACE-12-049 *	85996

* New study submitted

6.10.2 Justification for new endpoints

New studies with the preparation in dose-response design have been submitted. The studies are valid and generally suitable for risk assessment. Study summaries are provided in Appendix 2.

Please note: the vegetative vigour test by Bramby-Gunary (2012) in which 10 species were tested resulted in larger as 50 % effect on *Avena sativa* at the loweste tested concentration, thus the ER50 for biomass (dry weight) is based on an extrapolation. Since the ratio between ER50 biomass to ER50 height for *Avena sativa* was 42, whereas for the other species tested the ratio ranged between 2 and 6), the applicant carried out an additional vegetative vigour test with *Avena sativa* resulting in an ER50 of 61.14 mL/ha and suggested to consider the second most sensitive species *Lycopersicon esculentum* (ER50 = 26.99 mL/ha) of the first vegetative vigour test for the risk assessment. This is accompanied by an explanatory statement of the applicant argueing as to why the first results for *Avena sativa* depict a rather unusual pattern of response which is also not in line with the other poaceae. The RMS agrees, that the results of the first vegetative vigour test seems less plausible in light of the results for the other species and from the repeated

test with *Avena sativa*. However, there is no plausible explanation on what may have impaired the results for *Avena sativa* in the first test. The zRMS thus considers the test as relevant and will use the geomean of the ER50 biomass for *Avena sativa* from both available (and valid) vegetative vigour tests for the use in the risk assessement. The resulting geomean ER50 biomass for *Avena sativa* is 14.88 mL/ha, which is in the same range as the ER50 biomass for *Lycopersicon esculentum.*

6.10.2.1 Risk assessment

The risk assessment is based on the "Guidance Document on Terrestrial Ecotoxicology", (SANCO/10329/2002 rev.2 final, 2002). It is restricted to off-field situations, as non-target plants are non-crop plants located outside the treated area. Spray drift from the treated areas may lead to residues of a product in off-crop areas.

Exposure

Effects on non-target plants are of concern in the off-field environment, where they may be exposed to spray drift. The amount of spray drift reaching off-crop habitats is calculated using the 90th percentile estimates derived by the BBA (2000) from the spray-drift predictions of Ganzelmeier & Rautmann (2000). Any dilution over the 3-dimensional vegetation surface is accounted for in the study design. Therefore, in contrast to the assessment of risks to arthropods from standard laboratory tests, no vegetation distribution factor is considered here.

$PER_{off\text{-}field}$= Maximum $PER_{in\text{-}field}$ (including MAF) x %drift

Pinoxaden and pyroxsulam both have vapour pressures of < 10^{-5} Pa and are therefore classified as non-volatile. Hence, deposition following volatilization does not have to be considered.

For calculation of $PER_{in\text{-}field}$, please refer to 6.7.2.1.

Table 6.10-2: Predicted off-field environmental rates (PER) for A19786A (AVOXA)

Intended use	Exposure	Single appl. rate [mL/ha]	MAF	Drift scenario	f_{drift}	$PER_{off\text{-}field}$ [mL/ha]
Group A	Off-field	1800	1	90th percentile	2.77 %	49.86
Group B	Off-field	1350	1	90th percentile	2.77 %	37.395

MAF: Multiple application factor; f_{drift}: Drift factor; PER: Predicted environmental rates

Tier 1 assessment

The assessment of the risk to non-target plants due to an exposure to A19786A (AVOXA) is performed on basis of the calculation of toxicity-exposure ratios (TER values) according the following formula:

$$TER = \frac{ER50\,(L\ product/ha)}{Off-field\ PER\,(L\ product/ha)}$$

The results of the risk assessment are summarized in the following table. The considered relevant endpoint is the ER50 biomass (geomean) of 14.88 mL A19786A/ha derived for *Avena sativa* in vegetative vigour tests.

Table 6.10-3: Risk assessment for non-target terrestrial plants exposed to A19786A (AVOXA) for intended use groups A and B

Intended use	**ER_{50} [mL/ha]**	**PER [mL/ha]**	**TER**
Group A	Vegetative vigour: 14.88 (geomean)	49.86	0.3
Group B	Vegetative vigour: 14.88 (geomean)	37.395	0.4

The resulting TER values indicate a risk for off-crop non-target plants.

Risk mitigation measures

In order to reduce the amount of A19786A (AVOXA) reaching off-field areas, risk mitigation measures need to be implemented. These correspond to unsprayed in-field buffer strips of a given width and/or the usage of drift reducing nozzles.

The results of the risk assessment are summarized in the following table.

Table 6.10-4: Risk assessment for non-target terrestrial plants exposed to A19786A (AVOXA) under the implementation of different risk mitigation measures, corresponding to vegetated buffer strips and drift reduction technology for the intended use group A

Buffer strip [m]	**Drift [%]**	**$PER_{off\text{-}field}$ [mL/ha]**	**$PER_{off\text{-}field}$ No drift reduction [mL/ha]**	**$PER_{off\text{-}field}$ 50 % drift reduction [mL/ha]**	**$PER_{off\text{-}field}$ 75 % drift reduction [mL/ha]**	**$PER_{off\text{-}field}$ 90 % drift reduction [mL/ha]**
1	2.77	49.860	49.860	24.930	12.465	4.986
5	0.57	10.260	10.260	5.130	2.565	1.026
TER, relevant toxicity: ER_{50} geomean = 14.88 g/ha (*A. sativa*)						
1			**0.300**	**0.600**	**1.200**	**3.000**
5			**1.500**	**2.900**	5.800	14.500

TER values shown in bold fall below the relevant trigger. Please note that in the national addendum to derive national risk mitigation measures, Germany considers a TER trigger od 10 instead of 5.

Table 6.10-5: Risk assessment for non-target terrestrial plants exposed to A19786A (AVOXA) under the implementation of different risk mitigation measures, corresponding to vegetated buffer strips and drift reduction technology for the intended use group B

Buffer strip [m]	Drift [%]	$PER_{off\text{-}field}$ [mL/ha]	$PER_{off\text{-}field}$ No drift reduction [mL/ha]	$PER_{off\text{-}field}$ 50 % drift reduction [mL/ha]	$PER_{off\text{-}field}$ 75 % drift reduction [mL/ha]	$PER_{off\text{-}field}$ 90 % drift reduction [mL/ha]
1	2.77	37.395	37.395	18.698	9.349	3.740
5	0.57	7.695	7.695	3.848	1.924	0.770
TER, relevant toxicity: ER_{50} geomean = 14.88 g/ha (*A. sativa*)						
1			**0.400**	**0.800**	**1.600**	**4.000**
5			**1.900**	**3.900**	7.700	19.300

TER values shown in bold fall below the relevant trigger. Please note that in the national addendum to derive national risk mitigation measures, Germany considers a TER trigger od 10 instead of 5.

6.10.2.2 Higher tier risk assessment

Not relevant.

6.10.3 Overall conclusions

Based on the predicted rates of A19786A (AVOXA) in off-field areas and under consideration of risk mitigating measures such as buffer strip and/or drift reducing technique, the TER values describing the risk for non-target plants following exposure to A19786A (AVOXA) according to the GAP of the formulation A19786A (AVOXA) achieve the acceptability criteria TER ≥ 10 resp. ≥ 5 according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for non-target terrestrial plants due to the intended use of A19786A (AVOXA) in cereals according to the label.

6.11 Effects on other terrestrial organisms (flora and fauna) (KPC 10.7)

6.12 Monitoring data (KPC 10.8)

6.13 Available preliminary data (IIIA 10.9)

6.14 Other/special studies (IIIA 10.10)

The applicant provided a compendium on available ecotoxicological data for the safern cloquintocet-mexyl which found to be broadly consistent with the data already known by the zRMS from previous approval

procedure. Since no original studies were provided and there is no legal obligation to do so, no summaries were included in Appendix 2. Information has been considered for the assessment were applicable.

Appendix 1 List of data submitted in support of the evaluation

Table A 1: List of data submitted in support of the evaluation

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protect-tion claimed Y/N	Justification if data protection is claimed	Owner SYN = Syngenta
KIIIA1 10.2.2. 1 / 01	[redacted]	2013	Pinoxaden/Pyroxsulam/Cloquint ocet-mexyl EC (A19786A) - Acute Toxicity to Rainbow Trout (Oncorhynchus mykiss) in a 96-Hour Test Syngenta [redacted] GLP, not published Syngenta File No A19786A_10013	Y	N/A*	N/A	SYN
KIIIA1 10.2.2. 2 / 01	Liedtke A.	2013a	Pinoxaden/Pyroxsulam/cloquint ocet-mexyl EC (A19786A) - Acute Toxicity to Daphnia magna in a 48-Hour Immobilization Test Syngenta Harlan Laboratories Ltd., Itingen, Switzerland, D62634 GLP, not published Syngenta File No A19786A_10016	N	N/A*	N/A	SYN
KIIIA1 10.2.2. 3 / 01	Liedtke A.	2013 b	Pinoxaden/Pyroxsulam/Cloquint ocet-mexyl EC (A19786A) - Toxicity to Pseudokirchneriella subcapitata in a 96-Hour Algal Growth Inhibition Test Syngenta Harlan Laboratories Ltd., Itingen, Switzerland, D62601 GLP, not published Syngenta File No A19786A_10011	N	N/A*	N/A	SYN
KIIIA1 10.3.2. 1 / 01	[redacted]	2013	Pinoxaden/Pyroxsulam/Cloquint ocet-mexyl EC (A19786A) - Acute Oral Toxicity Study in the Rat (Up and Down Procedure) Syngenta [redacted] GLP, not published Syngenta File No A19786A_10005	Y	N/A*	N/A	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protect-tion claimed Y/N	Justification if data protection is claimed	Owner SYN = Syngenta
KIIIA1 10.4.2. 1 / 01	Kling A.	2013	Pinoxaden/Pyroxsulam/cloquint ocet-mexyl EC (A19786A) - Acute oral and contact toxicity to the honeybee Apis mellifera L. in the laboratory Syngenta Eurofins Agroscience Services EcoChem GmbH, N-Osch., Germany, S12-03713 GLP, not published Syngenta File No A19786A_10008	N	N/A*	N/A	SYN
KIIIA1 10.5.2 / 01	Stevens J.	2012	Pinoxaden/Pyroxsulam/Cloquint ocet-mexyl EC (A19786A) - A rate-response extended laboratory bioassay of the effects of fresh residues on the parasitic wasp Aphidius rhopalosiphi Syngenta Mambo-Tox Ltd., Southampton, United Kingdom, SYN-12-44 GLP, not published Syngenta File No A19786A_10003	N	N/A*	N/A	SYN
KIIIA1 10.5.2 / 02	Fallowfiel d L.	2013	Pinoxaden/Pyroxsulam/Cloquint ocet-mexyl EC (A19786A) - A rate-response extended laboratory bioassay of the effects of fresh residues on the predatory mite Typhlodromus pyri (Acari: Phytoseiidae) Syngenta Mambo-Tox Ltd., Southampton, United Kingdom, SYN-12-43 GLP, not published Syngenta File No A19786A_10004	N	N/A*	N/A	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protect-tion claimed Y/N	Justification if data protection is claimed	Owner SYN = Syngenta
KIIIA1 10.6.3 / 01	Friedrich S.	2013	Pinoxaden/Pyroxsulam/Cloquintocet-mexyl EC (A19786A) - Sublethal Toxicity to the Earthworm Eisenia fetida in Artificial Soil Syngenta BioChem Agrar, Gerichshain, Germany, 13 10 48 008 S GLP, not published Syngenta File No A19786A_10012	N	N/A*	N/A	SYN
KIIIA1 10.7.1 / 01	Schulz L.	2013	Pinoxaden/Pyroxsulam/Cloquintocet-mexyl EC (A19786A) - Effects on the activity of soil microflora (nitrogen and carbon transformation tests) Syngenta BioChem Agrar, Gerichshain, Germany, 13 10 48 004 C/N GLP, not published Syngenta File No A19786A_10007	N	N/A*	N/A	SYN
KIIIA1 10.8.1. 2 / 01	Bramby-Gunary J.	2012 b	Pinoxaden/Pyroxsulam/cloquintocet-mexyl EC (A19786A) - Evaluation of the Phytotoxicity to Non Target Terrestrial Plant Vegetative Vigour Test Syngenta AgroChemex Ltd, Manningtree, United Kingdom, Battelle UK Ltd., Ongar, United Kingdom, ACE-12-050 GLP, not published Syngenta File No A19786A_10002	N	N/A*	N/A	SYN
KIIIA1 10.8.1. 2 / 02	Stefanut M.	2013	Pinoxaden/Pyroxsulam/cloquintocet-mexyl EC (A19786A) - Evaluation of the Phytotoxicity to Avena sativa Plant Vegetative Vigour Test Syngenta AgroChemex Ltd, Manningtree, United Kingdom, ACE-13-080 GLP, not published Syngenta File No A19786A_10056	N	N/A*	N/A	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protect-tion claimed Y/N	Justification if data protection is claimed	Owner SYN = Syngenta
KIIIA1 10.8.1. 3 / 01	Bramby-Gunary J.	2012a	Pinoxaden/Pyroxsulam/cloquint ocet-mexyl EC (A19786A) - Evaluation of the Phytotoxicity to Non Target Terrestrial Plant Seedling Emergence and Seedling Growth Test Syngenta AgroChemex Ltd, Manningtree, United Kingdom, Battelle UK Ltd., Ongar, United Kingdom, ACE-12-049 GLP, not published Syngenta File No A19786A_10001	N	N/A*	N/A	SYN
KIIIA1 10.8.2. 1 / 01	Liedtke A.	2013c	Pinoxaden/Pyroxsulam/Cloquint ocet-mexyl EC (A19786A) - Toxicity to the Aquatic Higher Plant Lemna gibba in a 7-Day Growth Inhibition Test Syngenta Harlan Laboratories Ltd., Itingen, Switzerland, D62645 GLP, not published Syngenta File No A19786A_10014	N	N/A*	N/A	SYN
KIIIA1 10.10.1 / 01	Lefebvre B.	2003	NOA407855 - EU - Document I - Part 6 - Ecotoxicological studies Syngenta Crop Protection AG, Basel, Switzerland, ERA7148 Not GLP, not published Syngenta File No NOA407855/0470	N	N/A*	N/A	SYN

* Data protection is country specific; for the data protection claim, and justification of that claim, please refer to Part A, Appendix 3 for the relevant country

Table A 2: List of data relied on for the safener cloquintocet-mexyl

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.1.1	[redacted]	1990	Acute Oral Toxicity (LD50) of CGA 185072 to the Bobwhite Quail Report No.: CBG 471/89310 GLP/GEP (Y/N): Y Published (Y/N): N	Y	Syngenta Agro
KCP 10.1.1	[redacted]	1993	Bobwhite Quail Dietary Reproduction and Tolerance Studies Report No.: 548/549/931369 GLP/GEP (Y/N): Y Published (Y/N): N	Y	Syngenta Agro
KCP 10.1.1	BfR	2007	Risk assessment report for cloquintocet-mexyl. AL6-2501-4307712 / AL6-2501-4323353 / AL6-2501-4326043	Y	BfR-reprot 2007
KCP 10.1.2	[redacted]	1987	CGA 185072 - Acute oral toxicity in the rat. Report No.: 861143 GLP/GEP (Y/N): Y Published (Y/N): N	Y	BfR-report 2007
KCP 10.1.3	[redacted]	1998	CGA 185072: a 96-hour flow-through acute toxicity test with the Rainbow Trout (Oncorhynchus mykiss) Report No.: 108A-196 GLP/GEP (Y/N): Y Published (Y/N): N	Y	Syngenta Agro
KCP 10.1.3	[redacted]	1990	Report on the Prolonged Toxicity Test of CGA 185072 Technical to Rainbow Trout Report No.: 901114 GLP/GEP (Y/N): Y Published (Y/N): N	Y	Syngenta Agro
KCP 10.1.3	[redacted]	1992	Report on the Acute Toxicity Test of CGA 153433 Technical to Bluegill (Lepomis macrochirus) Report No.: 928052 GLP/GEP (Y/N): Y Published (Y/N): N	Y	Syngenta Agro
KCP 10.1.3	Palmer, S.J., Krueger, H.O.	1998	CGA 185072: a 48-hour flow-through acute toxicity test with the Cladoceran (Daphnia magna) Report No.: 108A-195 GLP/GEP (Y/N): Y Published (Y/N): N	N	Syngenta Agro
KCP 10.1.3	Vial, A.	1990	Report on the Reproduction Test of CGA 185072 to Daphnia (Daphnia magna Straus 1820) Report No.: 881743 GLP/GEP (Y/N): Y Published (Y/N): N	N	Syngenta Agro

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.1.3	Grade, R.	1998	Toxicity test of CGA 185072 tech. on sedimentdwelling Chironomus riparius (syn. Chironomus Thummi) under static conditions Report No.: 981535 GLP/GEP (Y/N): Y Published (Y/N): N	N	Syngenta Agro
KCP 10.1.3	Grade, R.	1993	Report on the Growth Inhibition Test of CGA 153433 Tech. to Blue Algae (Microcystis aeruginosa) Report No.: 928207 GLP/GEP (Y/N): Y Published (Y/N): N	N	Syngenta Agro
KCP 10.1.3	Grade, R.	1993	Report on the Growth Inhibition Test of CGA 185072 Tech. to Green Algae (Scenedesmus suspicatus) Report No.: 928208 GLP/GEP (Y/N): Y Published (Y/N): N	N	Syngenta Agro
KCP 10.1.3	Hoberg, J.R.	1993	Toxicity to Duckweed, Lemna gibba Report No.: 93-6-4836 GLP/GEP (Y/N): Y Published (Y/N): N	N	Syngenta Agro
KCP 10.1.3	Hoberg, J.R.	1993	Toxicity to Duckweed, Lemna gibba Report No.: 93-6-4831 GLP/GEP (Y/N): Y Published (Y/N): N	N	Syngenta Agro
KCP 10.5	Morgenroth, U.	1992	The Effects of CGA 185072 on Soil Respiration and Nitrification Report No.: 315360 GLP/GEP (Y/N): Y Published (Y/N): N	N	Syngenta Agro

Appendix 2 Detailed evaluation of the new studies

IIIA 10.1 Effects on birds

IIIA 10.1.3 Baits: Concentration of active substance in bait in mg/kg

IIIA 10.1.4 Pellets, granules, prills or treated seed

IIIA 10.1.4.1 Amount of active substance in or on each item

IIIA 10.1.4.2 Proportion of active substance LD_{50} per 100 items and per gram of items

IIIA 10.1.5 Size and shape of pellet, granule or prill

IIIA 10.1.6 Acute toxicity of the formulation

IIIA 10.1.7 Supervised cage or field trials

IIIA 10.1.8 Acceptance of bait, granules or treated seeds (palatability testing)

IIIA 10.2 Effects on aquatic organisms

IIIA 10.2.2 Acute toxicity (aquatic) of the preparation

IIIA 10.2.2.1 Fish acute toxicity LC_{50}, freshwater, cold-water species

Comments of zRMS:	The study is generally acceptable. However, the RMS points out that the product test is considered a tier 1 test that should be conducted under constant exposure and the analysed substance pinoxaden was not stable (was not found to be in the margin of +/- 20 % of nominal). Thus, in addition to the endpoints expressed based on nominal (more correctly it would be initial) concentrations, the RMS expressed the endpoints based on the measured average recovery of pinoxaden as "mean measured". This translates into the following value considered for the risk assessment: LC_{50} = 8.879 mg/L (mm) The RMS is aware that by doing so the measured dissipation of pinoxaden is projected to the other active ingredients, which presents a worst-case approach in this given case. The study summary was provided by the applicant.

Reference:	IIIA 10.2.2.1/01, Pinoxaden/Pyroxsulam/Cloquintocet-mexyl EC (A19786A) - Acute Toxicity Test to Rainbow Trout (Oncorhynchus mykiss) in a 96-Hour Test

Author(s), year:	[redacted] 2013
Report/Doc number:	Report Number D62623, Syngenta File No. A19786A_10013
Guidelines:	Yes, OECD Guidelines for Testing of Chemicals, Section 2 - Effects on Biotic Systems, Method 203: Fish, Acute Toxicity Test (1992) US EPA Ecological Effects Test Guidelines, OPPTS 850.1075: Fish Acute Toxicity Test, Freshwater and Marine (1996); Public draft Official Journal of the European Communities, Commission Regulation (EC) No 440/2008, Method C.1: Acute Toxicity for Fish (2008)
GLP:	Yes
Deviations:	No
Validity:	Yes

Executive Summary

The acute toxicity of A19786A to rainbow trout *Oncorhynchus mykiss* was determined under static conditions. Fish were exposed to a range of nominal concentrations of 0.70, 1.5, 3.2, 7.0 and 15 mg A19786A/L alongside a dilution water control. Based on nominal concentrations, the 96 hour LC_{50} was 10.3 mg A19786A/L with a 95% confidence interval of 7.0 to 15 mg A19786A/L.

Materials

Test material	A19786A	
	Pinoxaden/Pyroxsulam EC (033.3/008.33) & S: Cloquintocet-mexyl (008.33)	
Lot/Batch #:	SMU2AL001	
Actual content of active ingredients:	Pinoxaden:	3.20 % w/w corresponding to 33.7 g/L
	Pyroxsulam:	0.77 % w/w corresponding to 8.11 g/L
	Cloquintocet-mexyl:	0.77 % w/w corresponding to 8.11 g/L.
Description:	Brown clear liquid	
Stability of test compound:	Stable under standard conditions	
Reanalysis/expiry date:	31 March 2015	
Density:	1053 kg/m3	
Treatments		
Test concentrations:	Dilution water control and nominal concentrations of 0.70, 1.5, 3.2, 7.0 and 15 mg A19786A/L	
Solvent:	None	

Analysis of test concentrations:	Yes 0 and 96 hours (based on measurement of pinoxaden) using LC-MS/MS analysis, except for the highest nominal concentration 15 mg A19786A/L where the last sample was taken at 24 hours, as all fish were dead at this observation.
Test organisms	
Species:	Rainbow trout Oncorhynchus mykiss
Source:	[redacted]
Acclimatisation period:	one week
Treatment for disease:	Not reported
Weight and length of acclimatised fish at the start of the exposure period*:	Mean length: 4.25 cm (standard deviation 0.17 cm) Mean weight: 0.62 g (standard deviation 0.05 g)
Feeding:	None during test
Test design	
Test vessels:	Glass vessels (35 cm x 23 cm x 25 cm) containing 15 L of test medium
Test medium:	Reconstituted test water consisting of analytical grade salts dissolved in purified water to obtain 147 mg/L $CaCl2 \cdot 2H2O$, 61.5 mg/L $MgSO4 \cdot 7H2O$, 32.5 mg/L $NaHCO3$, 2.9 mg/L KCl
Replication:	None
No of fish per tank:	7
Exposure regime:	Static
Duration:	96 hours
Environmental conditions	
Test temperature:	13 - 14° C
pH:	7.1 – 7.4
Dissolved oxygen:	9.1 – 9.9 mg/L (≥ 88% saturation) gentle aeration provided
Hardness of dilution water:	125 mg/L as $CaCO3$
Lighting:	16 hours light (140 to 480 Lux) and 8 hours dark with 30 minute dawn and dusk transition period

* The measured fish were not introduced for the test

Study Design and Methods

Experimental dates: 05 November 2012 to 18 January 2013.

A concentrated stock solution with a nominal concentration of 100 mg A19786A/L was prepared by dissolving 0.4502 g of A19786A completely in 4.5 L of test water by intense stirring for 15 minutes at room temperature. Appropriate volumes of the stock were then made up to 15 L of dilution water in each test vessel and were intensively mixed to give the test concentrations. The control consisted of dilution water only.

At the start of the test seven fish were randomly allocated to each of the test concentrations and the dilution water control. The water temperature in the test vessels was maintained by a cooling device in each test vessel. Observations for mortalities and symptoms of toxicity were made at 3, 24, 48, 72 and 96 hours.

Daily measurements of the test solutions were undertaken throughout the 96 hour period for pH, temperature, dissolved oxygen concentration and appearance. Additionally, the water temperature was continuously recorded with a data logger.

The test concentrations were verified by chemical analysis of pinoxaden at 0 and 96 hours using an LC-MS/MS method. Samples for analysis were taken from the centre of the test solutions.

Results and Discussion

At the start of the test, the analytically determined concentrations of A19786A (based on measurements of the active ingredient pinoxaden) were in the range 94 to 104 % of the nominal values, 93% after day 1 and at the end of the test were in the range 72 to 79% (see table below). The limit of quantification in this study was 0.505 µg pinoxaden/L. Nominal formulation concentrations were used for the calculation and reporting of results.

Table 10.2.1.1-1: Analytical results

Nominal formulation concentrations (mg A19786A/L)	**% of nominal measured at 0 hours**	**% of nominal measured at 96 hours**
Control	n.a.	n.a.
0.70	104	73
1.5	104	72
3.2	95	75
7	94	79
15	97	93*

*: Performed after 24 hours due to 100% fish mortality.

n.a.: not applicable

The tabulated values of the samples represent rounded results obtained by calculation using the exact raw data

The median lethal concentration (LC_{50}) was defined as the concentration resulting in 50% mortality of the fish in the time period specified. The 24- , 48-, 72- and 96-hour LC_{50} could not be calculated by regression analysis due to the steep concentration-effect relationship. Instead, the LC_{50} values were determined as a geometric mean value of the two consecutive test concentrations with 0 and 100% mortality, and the corresponding 95% confidence limits as the test concentrations with 0 and 100% mortality. The NOEC (No Observed Effect Concentration) is defined as the highest tested concentration which did not produce an adverse effect when compared to the control and was determined directly from the raw data.

Mortalities were observed at nominal concentrations of 15 mg A19786A/L. Symptoms of toxicity observed were apathy and mainly bottom swimming and were observed at concentrations of 7.0 mg A19786A/L and above. No mortality or symptoms of toxicity were observed in the control. The mortality data and estimated LC_{50} values are shown in the table below:

Table 10.2.1.1-2: Effects of A19786A on the survival of *Oncorhynchus mykiss*

Nominal concentration (mg A19786A/L)	**Mortality observed (cumulative number of dead fish) (n = 7)**				
	3 hour	**24 hours**	**48 hours**	**72 hours**	**96 hours**
Dilution water control	0	0	0	0	0
0.7	0	0	0	0	0
1.5	0	0	0	0	0
3.2	0	0	0	0	0
7.0	0	0	0	0	0
15	0	7	7	7	7
LC_{50} mg A19786A/L	n.d.	10.3	10.3	10.3	10.3
95% confidence interval	n.d.	7.0 - 15	7.0 – 15	7.0 – 15	7.0 – 15
NOEC mg A19786A/L	n.d.	n.d.	n.d.	n.d.	7.0
LOEC mg A19786/L	n.d.	n.d.	n.d.	n.d.	15

n.d.: not determined

Validity Criteria

The validity criteria for the study were met:

- Control fish mortality ≤ 1 fish (0 observed)
- Oxygen concentration in the test media should not drop below 60% of air saturation during test (≥ 88 % observed)

Conclusions

Based on nominal concentrations, the 96-hour LC_{50} for A19786A to rainbow trout (*Oncorhynchus mykiss*) was 10.3 mg A19786A/L with a 95% confidence interval of 7.0 to 15 mg A19786A/L and the 96-hour NOEC was 7.0 mg A19786A/L.

([redacted] 2013)

IIIA 10.2.2.2 Acute toxicity (24 & 48 h) for Daphnia preferably Daphnia magna

Comments of zRMS:	The study is generally acceptable. However, the RMS points out that the product test is considered a tier 1 test that should be conducted under constant exposure and the analysed substance pinoxaden was not stable (was not found to be in the margin of +/- 20 % of nominal). Thus, in addition to the endpoints expressed based on nominal (more correctly it would be initial) concentrations, the RMS expressed the endpoints based on the measured average recovery of pinoxaden as "mean measured". This translates into the following value considered for the risk assessment: EC_{50} = 3.78 mg/L (mm) The RMS is aware that by doing so the measured dissipation of pinoxaden is projected to the other active ingredients, which presents a worst-case approach in this given case. The study summary was provided by the applicant.

Reference:	IIIA 10.2.2.2/01, Pinoxaden/Pyroxsulam/Cloquintocet-mexyl EC (A19786A) – Acute Toxicity to *Daphnia magna* in a 48-Hour Immobilization Test
Author(s), year:	Liedtke A., (2013)
Report/Doc number:	Report number D62634, Syngenta File No. A19786A_10016
Guidelines:	Yes, OECD 202 (2004) OPPTS 850.1010 (1996; Public Draft) 92/69/EEC, C.2 (1992)
GLP:	Yes
Deviations:	No
Validity:	Yes

Executive Summary

The acute toxicity of A19786A to *Daphnia magna* was determined under static conditions. Daphnids were exposed to a range of nominal formulation concentrations of 1.0, 2.2, 4.6, 10, 22 and 46 mg/L alongside a dilution water control. Based on nominal concentrations, the 24-hour and 48-hour EC_{50} values for A19786A to *Daphnia magna* were 9.7 and 4.5 mg /L and the 48-hour NOEC value was 0.1 mg/L.

Materials

Test Material	A19786A Pinoxaden/Pyroxsulam/Cloquintocet-mexyl EC
Lot/Batch #:	SMU2AL001
Actual content of active ingredients:	I. pinoxaden: 3.20% w/w corresponding to 33.7 g/L II. pyroxsulam: 0.77% w/w corresponding to 8.11 g/L III. cloquintocet-mexyl: 0.77% w/w corresponding to 8.11 g/L
Description:	Brown clear liquid
Stability of test compound:	Stable under standard conditions.
Reanalysis/Expiry date:	End of March 2015
Density:	1053 kg/m3
Treatments	
Test concentrations:	Dilution water control and nominal formulation concentrations of : 1.0, 2.2, 4.6, 10, 22 and 46 mg/L.
Solvent:	None
Positive control:	Potassium dichromate used twice a year
Analysis of test concentrations:	Yes 0 and 48 hours (based on measurement of the active ingredient pinoxaden) using LC-MS/MS analysis
Test organisms	
Species:	*Daphnia magna* Straus 1992, Clone 5
Age:	6 - 24 hours at start of test
Source:	Continuous laboratory cultures, originally obtained from University of Sheffield
Feeding:	None during test
Test design	
Test vessels:	250 mL glass beakers containing 125 mL covered by glass plates

Test medium:	ISO reconstituted water
Replication:	4 replicates of 5 daphnids
Exposure regime:	Static
Duration:	48 hours
Environmental conditions	
Test temperature:	21 °C
pH range:	7.7 – 8.0
Dissolved oxygen:	8.3 – 8.8 mg/L (no aeration).
Total hardness of dilution water:	150 mg/L CaCO3.
Lighting:	16 hours light (400 to 540 Lux) and 8 hours dark, with a 30 minute dawn/dusk period

Study Design and Methods

Experimental dates: 17th September 2012 to 18th January 2013

A stock solution with a nominal concentration of 100 mg A19786A /L was prepared by dissolving 0.1305 g of the test item into 1300 mL of dilution water using ultrasonic treatment for 15 minutes and intense stirring for 15 minutes at room temperature. This intensively mixed stock solution was used to prepare the test media of the two highest test concentrations. The test media of the lower test item concentrations were prepared as a dilution series from the highest test concentration of 46 mg/L. The control consisted of dilution water only. Test solutions were added to the test vessels and the Daphnia added without conscious bias.

The immobility of the daphnids was determined by visual observations after 24 and 48 hours of exposure. Organisms unable to swim within 15 seconds after gentle agitation of the test beaker were considered to be immobile.

The pH, temperature and dissolved oxygen were measured at the start and end of the test in each test concentration and the control.

The test concentrations were verified by chemical analysis of pinoxaden at 0 and 48 hours using LC-MS/MS.

Results and Discussion

At the start of the test, the analytically determined concentrations of the test item (based on the measured concentrations of the active ingredient pinoxaden) in the analyzed test media were between 85 and 100% of the nominal values. The last measurement at the nominal test concentrations of 22 and 46 mg/L (performed after 24 hours due to 100% daphnia immobility) resulted in 73 and 74% of the nominal value, respectively. At the lower concentrations of 1.0 to 10 mg/L, the measured values ranged from 72 to 79% of

nominal at the end of the test after 48 hours. The limit of quantification in this study was 0.505 µg pinoxaden/L. Nominal formulation concentrations were used for the calculation and reporting of results.

Table 10.2.1.3-1: Analytical results

Nominal concentrations of formulation (mg/L)	**% of nominal measured at 0 hours**	**% of nominal measured at 48 hours**
Control	<LOQ	<LOQ
1.0	100	79
2.2	96	77
4.6	88	75
10	87	72
22	86	73 (24 hours)
46	85	74 (24 hours)

<LOQ – less than the limit of quantification

The median effect concentration (EC50) was defined as the concentration resulting in 50% immobilisation of the Daphnia in the time period specified and was calculated using Weibull analysis at 24 and 48 hours. The NOEC (No Observed Effect Concentration) is defined as the highest tested concentration which did not produce an adverse effect when compared to the control and was determined by visual inspection of the data. There was no immobility observed in the dilution water control. Immobility data and estimated EC_{50} values are shown in the table below:

Table 10.2.1.3-2: Effects of A19786A on *Daphnia magna* following exposure for 48-hours in a static test

Nominal concentration of A19786A (mg/L)	**Immobilised daphnids after 24 hours**		**Immobilised daphnids after 48 hours**	
	Number	**%**	**Number**	**%**
Dilution water control	0	0	0	0
1.0	0	0	0	0
2.2	4	20	5	25
4.6	1 (2F)	5	8 (3A, 2F)	40
10	8 (8F)	40	20	100
22	20	100	20	100

Nominal concentration of A19786A	**Immobilised daphnids after 24 hours**		**Immobilised daphnids after 48 hours**	
46	20	100	20	100
EC_{50} mg A19786A /L	9.7		4.5	
95% Confidence limits	0.9-25		3.5-5.5	
NOEC	1.0		1.0	

A: daphnids trapped at the water surface

F: reduced swimming activity

Conclusions

The acute toxicity of A19786A to *Daphnia magna* was determined under static conditions. Daphnids were exposed to a range of nominal formulation concentrations of 1.0, 2.2, 4.6, 10, 22 and 46 mg/L alongside a dilution water control. Based on nominal concentrations, the 24-hour and 48-hour EC_{50} values for A19786A to *Daphnia magna* were 9.7 and 4.5 mg /L and the 48-hour NOEC value was 0.1 mg/L.

(Liedtke A., 2013)

IIIA 10.2.2.3 Effects on algal growth and growth rate

Comments of zRMS:	The study is generally acceptable. However, the RMS points out that the product test is considered a tier 1 test that should be conducted under constant exposure and the analysed substance pinoxaden was not stable (was not found to be in the margin of +/- 20 % of nominal). Thus, in addition to the endpoints expressed based on nominal (more correctly it would be initial) concentrations, the RMS expressed the endpoints based on the measured average recovery of pinoxaden (58.2 %) as "mean measured". This translates into the following values considered for the risk assessment: E_rC_{50} = 1.7 (nom) = 0.989 (mm) E_yC_{50} = 1.1 (nom)= 0.640 (mm) The RMS is aware that by doing so the measured dissipation of pinoxaden is projected to the other active ingredients, which presents a worst-case approach in this given case. The study summary was provided by the applicant.

Reference:	IIIA 10.2.2.3/01, Pinoxaden/Pyroxsulam/Cloquintocet-mexyl (A19786A) - Toxicity to Pseudokirchneriella subcapitata in a 96-hour Algal Growth Inhibition Test
Author(s), year:	Liedtke A, 2013
Report/Doc number:	Report Number D62601, Syngenta File No. A19786A_10011
Guidelines:	Yes, OECD Guidelines for Testing of Chemicals, Section 2 - Effects on Biotic Systems, Method 201: Freshwater Alga and Cyanobacteria, Growth Inhibition Test, 23 March 2006 (corrected 2011) Official Journal of the European Communities, Commission Regulation (EC) No 761/2009, Part C.3: Algal inhibition test (2009) US EPA Ecological Effects Test Guidelines, OPPTS 850.5400: Algal Toxicity, Tiers I and II, (1996)
GLP:	Yes
Deviations:	No
Validity:	Yes

Executive Summary

The toxicity of A19786A to the green alga Pseudokirchneriella subcapitata was determined. Algae were exposed to nominal concentrations of 0.10, 0.22, 0.46, 1.0, 2.2, 4.6 and 10 mg A19786A/L alongside a culture medium control.

Based on nominal concentrations the 72-hour E_rC_{50} was 1.7mg A19786A /L, and the E_yC_{50} and E_bC_{50} were 1.1 mg A19786A/L. The 96-hour E_rC_{50} was 2.0 mg A19786A/L, the E_yC_{50} was 1.3 mg A19786A/L and the E_bC_{50} was 1.2 mg A19786A/L.

Materials

Test Material	A19786A	
	Pinoxaden/Pyroxsulam EC (033.3/008.33) & S: Cloquintocet-mexyl (008.33)	
Lot/Batch #:	SMU2AL001	
Actual content of active ingredients:	Pinoxaden:	3.20 % w/w corresponding to 33.7 g/L
	Pyroxsulam:	0.77 % w/w corresponding to 8.11 g/L
	Cloquintocet-mexyl:	0.77 % w/w corresponding to 8.11 g/L
Description:	Brown clear liquid	
Stability of test compound:	Stable under standard conditions	
Reanalysis/expiry date:	31 March 2015	

Density:	1053 kg/m3
Treatments	
Test concentrations:	Culture medium control and nominal concentrations of 0.10, 0.22, 0.46, 1.0, 2.2, 4.6 and 10 mg A19786A/L
Solvent:	None
Positive control:	Potassium dichromate, separate study (September 2012, Study number D64298)
Analysis of test concentrations:	Yes, 0 and 96 hours (based on measurements of pinoxaden) using LC-MS/MS
Test organism	
Species:	*Pseudokirchneriella subcapitata*, strain 61.81 SAG
Source:	Laboratory culture, originally obtained from the Collection of Algal Cultures (SAG), Institute for Plant Physiology, University of Göttingen, 37073 Göttingen, Germany
Test design	
Test vessels:	50 mL Erlenmeyer flask covered with a glass dish, containing approximately 15 mL of medium
Test medium:	AAP algal medium according to OECD guideline 201
Replication:	Six vessels for the control and three vessels for each test concentration
Starting cell density:	0.5 × 104 cells/mL
Exposure regime:	Static
Aeration:	None
Duration:	96 hours
Environmental conditions	
Test temperature:	21 °C
pH:	test start: 7.7 to 7.8
	test end: 8.0 to 8.2
Lighting:	Continuous illumination at 5700 Lux (range: 5060 to 6160 Lux)

Study Design and Methods

Experimental dates: 21 September 2012 to 04 December 2012

A stock solution with a nominal concentration 100 mg A19786A/L was prepared by dissolving 100.43 mg of A19786A into 1000 mL of test medium using intense stirring for 15 minutes at room temperature. Appropriate volumes of the stock solution were diluted to give the test concentration series. The control consisted of culture medium only.

The test was started by inoculation of 5,000 algal cells per mL of test medium. Test solutions were continuously stirred using magnetic stirrers, and were held under continuous illumination.

Small volumes of all test concentrations and the control were taken from all test flasks after 24, 48, 72 and 96 hours of exposure. The algal biomass in these samples was determined using an electronic particle counter. In addition, after 96 hours exposure, a sample was taken from the control and from the test concentration of nominal 1.0 mg A19786A/L. The shape of the algal cells was examined microscopically in these samples. This test concentration was chosen, since at the higher nominal concentrations of 2.2 and 10 mg A19786A/L, the algal cell density was too low for a reliable examination.

The pH was measured at the start and at the end of the test in each test concentration and the control. The water temperature was measured daily in a flask incubated under the same conditions as the test flasks.

The test concentrations were verified by chemical analysis of pinoxaden at 0 and 96 hours, using LC-MS/MS.

Results and Discussion

At the start of the test, the analytically determined concentrations of A19786A/L (based on measurements of the active substance pinoxaden) were in the range 98 to 109 % of the nominal values and at the end of the test were in the range < LOQ to 78 % (see table below). The limit of quantification in this study was 0.500 µg pinoxaden/L. Nominal formulation concentrations were used for the calculation and reporting of results.

Table 10.2.2.3-1: Analytical results

Nominal concentrations (mg A19786A/L)	**% of nominal measured at 0 hours**	**% of nominal measured at 96 hours**
Control	n.a.	n.a.
0.1	98	n.a.
0.22	103	n.a.
0.46	106	16
1.0	109	32
2.2	105	67
4.6	101	72
10	107	78

n.a. = not applicable

The algal biomass was measured at 24, 48, 72 and 96 hours and the mean biomass, growth rate and yield calculated. The 72-hour and 96-hour EbC_{50}, EyC_{50} and ErC_{50} values (defined as the concentration resulting in 50% reduction of each parameter), and their 95% confidence intervals, were calculated by Probit analysis using linear maximum likelihood regression.

For determination of the LOEC (Lowest Observed Effect Concentration) and NOEC (No Observed Effect Concentration) values, a William's t-test or Welch t-test was used to identify significant differences in the calculated mean biomass, growth rate and yield at the test item treatments compared to the control.

There were no cell abnormalities, observed microscopically, in the control or 1.0 mg A19786A/L test culture at 96-hours.

Growth rates

The growth rate 0 to 72 hours and 0 to 96 hours were calculated for each replicate culture and the means are shown below, alongside the calculated EC_{50} values.

Table 10.2.2.3-2: Mean values at each concentration of A19786A for the growth rate at 72 and 96 hours for *Pseudokirchneriella subcapitata* and relevant endpoints

Nominal concentrations (mg A19786A/L)	**Mean growth rate (1/day) 0 – 72 hrs**	**Percentage inhibition**	**Mean growth rate (1/day) 0 – 96 hrs**	**Percentage inhibition**
Control	1.527	n.a.	1.383	n.a.
0.10	1.521	0.4	1.383	0.0
0.22	1.517	0.7	1.380	0.2
0.46	1.473#	3.5	1.360	1.7
1.0	1.373#	10.1	1.327#	4.1
2.2	0.350#	77.1	0.575#	58.4
4.6	0.124#	91.9	-0.037#	102.7
10	0.139#	90.9	0.100#	92.8
ErC50 mg A19786A/L	1.7		2.0	
(95% confidence limits)	1.5 - 1.8		1.9 - 2.1	
NOEC mg A19786A/L	0.22		0.46	
LOEC mg A19786A/L	0.46		1.0	

#: mean value statistically significantly lower than in the control (according to Welch t-test, one-sided smaller, $\alpha = 0.05$)

n.a. = not applicable

Yield

The yield 0 to 72 hours and 0 to 96 hours were calculated for each replicate culture and the means are shown below, alongside the calculated EC50 values.

Table 10.2.2.3-3: Mean values at each concentration of A19786A for the yield at 72 and 96 hours for *Pseudokirchneriella subcapitata* and relevant endpoints

Nominal concentrations (mg A19786A/L)	Mean yield (x 103 cells/mL) 0 – 72 hrs	Percentage inhibition	Mean yield (x 103 cells/mL) 0 – 96 hrs	Percentage inhibition
Control	54.5	n.a.	142.0	n.a.
0.10	53.4	2.0	142.9	-0.6
0.22	52.8	3.0	140.5	1.1
0.46	46.3#	15.0	129.5	8.8
1.0	34.1#	37.3	113.3#	20.2
2.2	1.0#	98.1	5.2#	96.3
4.6	0.3#	99.5	0.0#	100.0
10	0.3#	99.5	0.3#	99.8
EyC50 mg A19786A/L	1.1		1.3	
(95% confidence limits)	1.0 - 1.2		1.2 - 1.5	
NOEC mg A19786A/L	0.22		0.46	
LOEC mg A19786A/L	0.46		1.0	

#: mean value statistically significantly lower than in the control (according to Welch t-test, one-sided smaller, α = 0.05)

n.a. = not applicable

Biomass (area under the growth curve)

The areas under the growth curve for 0 to 72 hours and 0 to 96 hours were calculated for each replicate culture and the means are shown below, alongside the calculated EC_{50} values.

Table 10.2.2.3-4: Mean values at each concentration of A19786A for the biomass integral (area under the growth curve) at 72 and 96 hours for *Pseudokirchneriella subcapitata* and relevant endpoints

Nominal concentrations (mg A19786A/L)	Mean biomass integral (area, 103*day) 0 – 72 hrs	Percentage inhibition	Mean biomass integral (area, 103*day) 0 – 96 hrs	Percentage inhibition

Control	40.8	n.a.	139.1	n.a.
0.10	39.8	2.5	138.0	0.8
0.22	39.6	3.0	136.3	2.0
0.46	35.3#	13.6	123.2#	11.4
1.0	25.3#	38.0	99.0#	28.8
2.2	2.4#	94.2	5.5#	96.0
4.6	1.2#	97.1	1.3#	99.1
10	0.9#	97.7	1.3#	99.1
E_bC_{50} mg A19786A /L	1.1		1.2	
(95% confidence limits)	1.0 – 1.2		1.1 – 1.3	
NOEC mg A19786A/L	0.22		0.22	
LOEC mg A19786A/L	0.46		0.46	

#: mean value statistically significantly lower than in the control (according to Welch t-test, one-sided smaller, $\alpha = 0.05$)

n.a. = not applicable

Validity criteria

The algal biomass in the control increased by a factor of 98 over 72 hours (must be least 16). The mean coefficient of variation of the daily growth rates during 72 and 96 hours in the control cultures were 13 and 24%, respectively (must be ≤ 35%). The coefficient of variation of average specific growth rates in the replicates of the control after 72 and 96 hours was 0.6%, (must be <7%). Therefore, all validity criteria were met.

Conclusions

Based on nominal concentrations the 72-hour E_rC_{50} was 1.7mg A19786A /L, and the E_yC_{50} and E_bC_{50} were 1.1 mg A19786A/L. The 96-hour E_rC_{50} was 2.0 mg A19786A/L, the E_yC_{50} was 1.3 mg A19786A/L and the E_bC_{50} was 1.2 mg A19786A/L.

The LOEC at 72 hours, based on growth rate and yield was 0.46 mg A19786A /L and at 96 hours was 1.0 mg A19786A /L, and the corresponding NOECs were 0.22 mg A19786A /L and 0.46 mg A19786A /L, respectively. The LOEC at 72 and 96 hours, based on biomass integral was 0.46 mg A19786A /L, and the corresponding NOEC was 0.22 mg A19786A /L.

(Liedtke A, 2013)

IIIA 10.2.2.4 Marine or estuarine organisms acute toxicity LC_{50}/EC_{50}

IIIA 10.2.2.5 Marine sediment invertebrates, acute toxicity LC_{50}/EC_{50}

IIIA 10.2.3 Microcosm or mesocosm study

IIIA 10.2.4 Residue data in fish (long-term)

IIIA 10.2.5 Chronic fish toxicity data

IIIA 10.2.5.1 Chronic toxicity (28 day exposure) to juvenile fish.
Analytical data on concentrations in the test media

IIIA 10.2.5.2 Fish early life stage toxicity test.
Analytical data on concentrations in the test media

IIIA 10.2.5.3 Fish life cycle test.
Analytical data on concentrations in the test media

IIIA 10.2.6 Chronic toxicity to aquatic invertebrates

IIIA 10.2.6.1 Chronic toxicity in Daphnia magna (21-day).
Analytical data on concentrations in the test media

IIIA 10.2.6.2 Chronic toxicity for a representative species of aquatic insects.
Analytical data on concentrations in the test media

IIIA 10.2.6.3 Chronic toxicity for a representative species of aquatic gastropod molluscs.
Analytical data on concentrations in the test media

IIIA 10.2.7 Accumulation in aquatic non-target organisms.
Analytical data on concentrations in the test media

IIIA 10.3.2.1 Acute oral toxicity of the preparation

Comments of zRMS:	Study acceptable. A full summary should be provided in Section 3.

Reference:	IIIA 10.3.2.1/01, Pinoxaden / Pyroxsulam / Cloquintocet-mexyl EC (A19786A). Acute oral toxicity study in the rat (up and down procedure)
Author(s), year:	[redacted], 2013
Report/Doc number:	Report No. 12/343-001P, Syngenta File No. A19786A_10005
Guidelines:	Yes, OECD 425
GLP:	Yes
Deviations:	No

Validity:	Yes

Under the conditions of this study, the acute oral median lethal dose (LD_{50}) of the test item, Pinoxaden / Pyroxsulam / Cloquintocet-mexyl EC (A19786A), was greater than 2000 mg/kg bw (limit dose) in female CRL:(WI) rats. Full details are provided in the **dRR Part B Section 3**.

IIIA 10.3.2.2 Acceptance of bait, granules or treated seeds by terrestrial vertebrates (palatability test)

IIIA 10.3.3 Supervised cage or field trials or other appropriate studies

IIIA 10.4 Effects on bees

IIIA 10.4.1 Hazard quotients for bees

Refer to table 6.6-2.

IIIA 10.4.1.1 Oral exposure Q_{HO}

Refer to IIIA 10.4.1.

IIIA 10.4.1.2 Contact exposure Q_{HC}

Refer to IIIA 10.4.1.

IIIA 10.4.2 Acute toxicity of the formulation to bees

The following bee acute toxicity study performed on A19786A is provided in support of the assessment and has not been previously evaluated. Since no major deviations from the guideline were reported which could have influenced the results of the study only a brief summary and the endpoints are presented below.

Report:	**KIIIA1 10.4.2.1/01** Kling A, (2013), Pinoxaden/pyroxsulam/cloquintocet-mexyl EC (A19786A) – Acute Oral and Contact Toxicity to the Honeybee *Apis mellifera* L. in the Laboratory. Eurofins Agroscience Services EcoChem GmbH, Niefern-Öschelbronn, Germany, Report Number S12-03713
Document No:	A19786A_10008
Guidelines:	OECD 213 and 214
GLP	Yes

Executive Summary

The 48 hour contact LD_{50} for A19786A is 591 µg A19786A/L with confidence limits of 507-703 µg A19786A/L. Sublethal effects (affected, apathetic, cramped or moribund bees) were observed at all tested dose levels 4 hours after application. At the 24 and 48 hour assessments affected and apathetic bees were observed at dose levels ≥ 500 µg A19786A/bee.

The 48 hour oral LD_{50} for A19786A is >406 µg A19786A/L. Sublethal effects (affected or apathetic bees) were observed at all tested dose levels at the 4 hour assessment and at nominal dose levels ≥ 500 µg A19786A/bee at the 24 hour assessment. No remarkable effects were observed in surviving bees at the final assessment.

Materials and Methods
In a test under laboratory conditions A19786A was offered to worker honey bees (*Apis mellifera* L.) in oral and contact route. Treatments with the test substance, the control and the reference item (dimethoate) were carried out in five replicates containing 10 bees each.

Test species:	Worker honey bees *Apis mellifera*
Test substance:	A19786A Pinoxaden: 3.20% w/w corresponding to 33.7 g/L Pyroxsulam: 0.77% w/w corresponding to 8.11 g/L Cloquintocet-mexyl: 0.77% w/w corresponding to 8.11 g/L
Control:	oral: 50% w/v aqueous sucrose solution contact: mineral water
Toxic standard:	Perfekthion/BAS 152 11 I (nominally 400 g dimethoate/L; measured 411.7 g dimethoate/L) oral: 0.08, 0.11, 0.15 and 0.20 µg a.s./bee contact: 0.10, 0.13, 0.17 and 0.26 µg a.s./bee dissolved in mineral water
Doses:	oral (A19786A sucrose solution): 73.4, 121, 222, 325 and 406 µg product/bee (measured) contact (A19786A dissolved in mineral water): 62.5, 125, 250, 500 and 1000 µg product/bee
Bees per dose:	10
Replicates:	5

Oral toxicity study:
In a dose response, five replicates of 10 bees were fed with a sugar/water solution containing A19786A. The tested concentration was 73.4, 121, 222, 325 and 406 µg product/bee. An untreated sugar/water solution was used as water control. Dimethoate was used as toxic standard. The test was conducted at darkness and a temperature of 24.2 - 26.1 °C and humidity between 50 and 71%. Biological observations including mortality and behavioural changes were recorded at 4, 24 and 48 hours after dosing. Results are based on nominal concentrations of the product per bee.

Contact toxicity study:
In a dose response, five replicates of 10 bees were exposed to A19786A + mineral water, administered topically in a small droplet (2µL) to the thorax of each bee. The tested concentration was 62.5, 125, 250, 500 and 1000 µg product/bee. A group of bees treated with an equivalent volume of mineral water was used as water control. Dimethoate solved in mineral water was used as toxic standard. The test was conducted at darkness and a temperature of 24.2 - 26.1 °C and humidity between 50 and 71%. Biological observations, including mortality and behavioural changes were recorded at 4, 24 and 48 hours after application.

Findings
In the contact toxicity test sublethal effects (affected, apathetic, cramped or moribund bees) were observed at all tested dose levels 4 hours after application. At the 24 and 48 hour assessments affected and apathetic bees were observed at dose levels ≥ 500 µg A19786A/bee. In the oral toxicity test sublethal effects (affected or apathetic bees) were observed at all tested dose levels at the 4 hour assessment and at nominal dose levels ≥ 500 µg A19786A/bee at the 24 hour assessment. No remarkable effects were observed in surviving bees at the final assessment.
Mortality data for the test material and toxic standard are summarised in the Table below.

Table 10.4.2.1: Summary of acute toxicity of A19786A to the honeybee

Treatment	Exposure		LD_{50} values	95% confidence interval
	Route	Duration (hours)		
Test material (µg A19786A/bee)	Contact	24	605	528 – 703
		48	591	507 - 703
	Oral	24	> 406	n.d.
		48	> 406	n.d.
Toxic standard (µg dimethoate/bee)	Contact	24	0.17	0.15 – 0.19
	Oral	24	0.12	0.11 – 0.13

n.d. = not determined

The study is considered to be valid because:

- the mean mortality of the control in the oral and contact toxicity test was ≤ 10% (observed 2.0 and 0% after 48 hours in the oral and contact tests, respectively)
- the 24h LD_{50} of the reference item in the oral toxicity test was within the range of 0.10 to 0.35 µg active substance/bee (measured 0.12 µg dimethoate/bee)
- the 24h LD_{50} of the reference item in the contact toxicity test was within the range of 0.10 to 0.30 µg active substance /bee (measured 0.17 µg dimethoate/bee)

Conclusions
The 48 hour contact LD_{50} for A19786A is 591 µg product/L. Sublethal effects (affected, apathetic, cramped or moribund bees) were observed at all tested dose levels 4 hours after application. At the 24 and 48 hour assessments affected and apathetic bees were observed at dose levels ≥ 500 µg A19786A/bee.

The 48 hour oral LD_{50} for A19786A is >406 µg product/L. Sublethal effects (affected or apathetic bees) were observed at all tested dose levels at the 4 hour assessment and at nominal dose levels ≥ 500 µg A19786A/bee at the 24 hour assessment.

No remarkable effects were observed in surviving bees at the final assessment.

IIIA 10.4.2.1 Oral

Refer to IIIA 10.4.2.

IIIA 10.4.2.2 Contact

Refer to IIIA 10.4.2.

IIIA 10.4.3 Effects on bees of residues on crops

Not required.

IIIA 10.4.4 Cage tests

Not required.

IIIA 10.4.5 Field tests

Not required.

IIIA 10.4.6 Investigation into special effects

Not required.

IIIA 10.4.6.1 Larval toxicity

Not required since the test item is not an IGR.

IIIA 10.4.6.2 Long residual effects

Not required.

IIIA 10.4.6.3 Disorienting effects on bees

Not required.

IIIA 10.4.7 Tunnel tests

Not required.

MIIIA 10.5 Effects on arthropods other than bees

IIIA 10.5.1 Effects on sensitive species already tested, using artificial substrate

IIIA 10.5.2 Effects on non-target terrestrial arthropods in extended laboratory tests

Comments of zRMS:	The study is acceptable, i.e. valid and plausible. For use in the risk assessment, the following endpoints are derived: LR_{50} > 1000 mL/ha ER_{50} > 1000 mL/ha NOER = 1000 mL/ha The study summary was provided by the applicant.

Reference:	IIIA 10.5.2/01, Pinoxaden/Pyroxsulam/Cloquintocet-mexyl EC (A19786A) – A rate-response extended laboratory bioassay of the effects of fresh residues on the parasitic wasp *Aphidius rhopalosiphi* (Hymenoptera, Braconidae).
Author(s), year:	Stevens J, (2012)
Report/Doc number:	Report Number SYN-12-44, Syngenta file No. A19786A_10003
Guidelines:	Yes, Mead-Briggs et al. (2009). An extended laboratory test for evaluating the effects of plant protection products on the parasitic wasp, *Aphidius rhopalosiphi* (Hymenoptera, Braconidae). BioControl (DOI 10.2007/s10526-009-92607). Published online 5 December 2009. Springer.
GLP:	Yes
Deviations:	No
Validity:	Yes

Executive Summary

The 48-h LR_{50} for effects of A19786A on *Aphidius rhopalosiphi* under extended laboratory test conditions was determined to be >1000 mL A19786A/ha, the maximum rate tested.

The test item did not have adverse effects on the reproduction of the surviving wasps at treatment rates of up to and including 1000 mL A19786A/ha.

The no observed effect rate (NOER), defined as the highest rate tested that did not produce a statistically significant adverse effect relative to the control, was 1000 mL A19786A/ha.

Materials:

Test Material	A19786A	
	Pinoxaden/Pyroxsulam EC (033.3/008.33) & S :Cloquintocet-mexyl (008.33)	
Lot/Batch #:	SMU2AL001	
Actual content of active ingredients:	Pinoxaden:	3.20 % w/w corresponding to 33.7 g/L
	Pyroxsulam:	0.77 % w/w corresponding to 8.11 g/L
	Cloquintocet-mexyl:	0.77 % w/w corresponding to 8.11 g/L
Description:	Brown clear liquid	
Stability of test compound:	Stable under standard conditions	
Reanalysis/Expiry date:	31 March 2015	
Density:	1053 kg/m3	
Treatments		
Test rates:	62.5, 125, 250, 500 and 1000 mL A19786A/ha	

Control:	Purified water
Toxic standard:	Perfekthion BAS 152 11 I (nominally 400 g dimethoate/L, analysed 411.7 g dimethoate/L) in purified water, applied at a rate of 10 mL product per ha in 400 L water /ha
Spray volume rate:	400 L spray solution/ha
Application method:	Schachtner track sprayer (3 bar pressure, 80° flat fan nozzle)
Test organisms	
Species:	*Aphidius rhopalosiphi* De Stefani-Perez. (Hymenoptera, Braconidae)
Age:	Adults; female
Source:	Culture maintained at Test Facility on cereal aphids (Metopolophium dirhodum and Rhopalosiphum padi). Originally obtained from Katz Biotech AG, Baruth, Germany.
Feeding:	1:3 v/v solution of honey and water
Test design – Mortality phase	
Arenas:	Clear acrylic cylinders (8cm diameter, 20 cm high, tops covered with nylon netting) were placed over pots containing approximately 10 sprayed barley seedlings (Hordeum vulgare Westminster)
Replication:	6
No. of wasps/arena :	5
Test design - Fecundity phase	
Arenas:	Clear acrylic cylinders (9cm diameter, 20 cm high, tops covered with nylon netting) were placed over pots containing 15 barley seedlings (Hordeum vulgare Westminster). The untreated barley had been infested seven days previously with host aphids (>100 adults and nymphs of Metopolopium dirhodum and Rhopalosiphum padi).
Replication:	15 female wasps/treatment
No. of wasps/arena :	1
Duration of test:	Mortality assessment: 48 hours Fecundity assessment: 24 hours Observation of mummies developing: 10 days after adult removal
Environmental test conditions	
Temperature:	Mortality assessment phase: 21°C Fecundity assessment phase: 21°C – 22.8°C

Humidity:	Mortality assessment phase: 71% - 75% RH
Photoperiod:	Mortality assessment phase: 16 h photoperiod (1420 lux)
	Fecundity assessment phase: 16 h photoperiod (4698 lux)

Study Design and Methods

Experimental dates: 25 September 2012 to 26 November 2012

Treatments were applied to test plants (seedlings of barley - Hordeum vulgare var. Westminster) which, once dry, were placed within arenas. The wasps were introduced to these arenas and their behaviour and mortality were assessed 2, 24 and 48 h later.

To assess any sub-lethal effects, reproduction assessments were then carried out using surviving females from the control and from the test material treatment rates of 250, 500, and 1000 mL A19786A/ha. Wasps were confined individually over untreated aphid-infested barley plants for 24 hours, before being removed. The plants were left for a further 10 days before the number of aphid mummies that had developed on plants where wasps had been found alive after the 24-h oviposition period was recorded.

The percentage mortality, defined as the number of moribund and dead insects combined, was calculated over 48 hours. The corrected percentage mortality (taking into account any control treatment losses) was derived using Abbott's (1925) formula. Mortality in the individual test item treatments was compared to that in the control treatment using Fisher's Exact Test ($\alpha = 0.05$).

The numbers of mummies produced per female found alive after the 24-h parasitism period were analysed by one-way ANOVA ($\alpha = 0.05$) of the square root-transformed data. The percentage change in numbers of mummies produced in individual test item treatments, relative to the control, was also calculated using the equation:

$$(1-Rt/Rc)*100\%$$

where Rt and Rc are the absolute values for reproduction observed in the treatment and control groups, respectively.

Results and Discussion

Mortality and fecundity are summarised in the table below.

Table 10.5.2-1: Effects of fresh residues of A19786A on mortality and fecundity of *Aphidius rhopalosiphi*, when exposed under extended laboratory test conditions

Treatment (mL A19786A/ha)	Mean % mortality at 48 ha	Mean % corrected mortality at 48 h (M-value)b	Number females successfully assessed for reproductive capacity	Mean number mummies per surviving femalec	% Effect on reproduction compared to control (R-value)d
Control	0.0	-	13	13.8	-
62.5	0.0	0.0	n.d.	n.d.	n.d.
125	0.0	0.0	n.d.	n.d.	n.d.
250	0.0	0.0	14	15.3	-10.4

500	3.3	3.3	11	13.3	4.1
1000	0.0	0.0	15	14.9	-7.9
Toxic reference	93.3*	93.3	n.d.	n.d.	n.d.

a The results for the individual treatments were compared to the control using Fisher's Exact Test (α=0.05)

b Derived using Abbott's formula

c The results for the test item treatments were compared to the control by one-way ANOVA (α=0.05), but there were no significant differences

d Percentage effect on reproduction, relative to the control. A negative value indicates an increase relative to the control

* Significant differences from the control

n.d. Not determined

Validity criteria

The validity criteria for the control groups were met:

- Mean mortality in control ≤ 17% (observed 0%)
- Mortality in toxic reference ≤ 25 % at 2 hours (observed: 0%), ≥ 50% at 48 hours (observed 93.3%)
- Mean number of mummies per female in the control ≥ 5.0 with no more than two zero values (observed 13.8, no zero values)

Conclusions

The 48-h LR_{50} for effects of A19786A on *Aphidius rhopalosiphi* under extended laboratory test conditions was determined to be >1000 mL A19786A/ha, the maximum rate tested.

The test item did not have adverse effects on the reproduction of the surviving wasps at treatment rates of up to and including 1000 mL A19786A/ha.

The no observed effect rate (NOER), defined as the highest rate tested that did not produce a statistically significant adverse effect relative to the control, was 1000 mL A19786A/ha.

(Stevens J, 2012)

Comments of zRMS:	The study is acceptable, i.e. valid and plausible. For use in the risk assessment, the following endpoints are derived: LR_{50} = 1652 mL/ha ER_{50} > 1800 mL/ha (28.9 % effect) The study summary was provided by the applicant.

Reference:	IIIA 10.5.2/02, Pinoxaden/Pyroxsulam/Cloquintocet-mexyl EC (A19786A) – A rate-response extended laboratory bioassay of the effects of fresh residues on the predatory mite, Typhlodromus pyri (Acari: Phytoseiidae).

Author(s), year:	Fallowfield L, (2013)
Report/Doc number:	Report Number SYN-12-43, Syngenta file No. A19786A_10004
Guidelines:	Yes, Blümel et al. (2000). Laboratory residual contact test with the predatory mite *Typhlodromus pyri* Scheuten (Acari: Phytoseiidae) for regulatory testing of plant protection products.
GLP:	Yes
Deviations:	No
Validity:	Yes

Executive Summary

The 7-day LR_{50} for effects of A19786A on mortality of *Typhlodromus pyri* under extended laboratory test conditions was calculated to be 1652.0 mL A19786A/ha.

The test item did not have adverse effects on the reproduction of the surviving mites at treatment rates of up to and including 1800 mL A19786A/ha.

The no observed effect rate (NOER), defined as the highest rate tested that did not produce a statistically significant adverse effect relative to the control, was 450 mL A19786A/ha for mortality, and for reproduction was 1800 mL A19786A/ha.

Materials

Test Material	A19786A	
	Pinoxaden/pyroxsulam EC (033.3/008.33) & S: cloquintocet-mexyl (008.33)	
Lot/Batch #:	SMU2AL001	
Actual content of active ingredients:	Pinoxaden:	3.20 % w/w corresponding to 33.7 g/L
	Pyroxsulam:	0.77 % w/w corresponding to 8.11 g/L
	Cloquintocet-mexyl:	0.77 % w/w corresponding to 8.11 g/L
Description:	Clear brown liquid	
Stability of test compound:	Stable under standard conditions	
Reanalysis/Expiry date:	31 March 2015	
Density:	1053 kg/m3	
Treatments		
Test rates:	112.5, 225, 450, 900 and 1800 mL A19786A/ha	
Control:	Purified water	

Toxic standard:	BAS 152 11I Perfekthion (nominally 400 g dimethoate/L, analysed 411.7 g dimethoate/L) applied at a rate of 30 mL product per 200 L water/ ha (12 g a.i./ha)
Spray volume rate:	200 L spray solution/ha
Application method:	Laboratory track sprayer (3 bar pressure, 80° flat fan nozzle)
Test organisms	
Species:	*Typhlodromus pyri* Scheuten (Acari: Phytoseiidae)
Age:	Less than 24 h old protonymphs
Source:	Culture maintained at Test Facility, originally obtained (April 1995) from P.K. Nützlingszuchten, Welzheim, Germany, supplemented with mites from same source in 1996 and 1997
Feeding:	1:1 v/v mixture of almond (Prunus sp. var Butte) and apple (Malus sp. var. Red Delicious) pollen
Test design	
Arenas:	Leaf discs (taken from French bean plants, Phaseolus vulgaris var. The Prince) mounted on damp cotton wool with a ring of a sticky non-drying gel drawn around the edge to create a circular arena in which the mites were confined. The ring was approximately 4 cm in diameter, enclosing an area of ca. 12.5 cm2.
Replication:	3
No. of mites/arena :	20
Duration of test:	Mortality assessment: 0-7 days Fecundity assessment: 7-14 days
Environmental test conditions	
Temperature:	25 – 26 °C
Humidity:*	45 – 81 % RH
Photoperiod:	16 h photoperiod (730 – 1200 Lux)

*Minor fluctuations below the intended lower humidity threshold of 60% were for periods of >2 hours and were not considered to be deviations.

Study Design and Methods

Experimental dates: 05 November 2012 to 03 December 2012

Treatments were applied to the leaf discs and the bioassay initiated approximately 1 h later, once residues had dried. The leaf discs were placed onto damp cotton wool and a ring of a sticky non-drying gel drawn

around the edge of each to create circular arenas in which mites were confined. The survival of the mites was assessed over a 7-day period, by which time they were adult. The sex of the adult mites was determined, and where necessary males were moved between replicates to ensure a male to female ratio of 1:5 in each treatment, they were then left in situ so that their reproduction could be assessed over a further 7 days. Any eggs produced prior to 7 DAT were removed and discarded. For 7 days, the total egg production (numbers of eggs plus live and dead juvenile stages) was recorded for each unit. Assessments of ovipostion activities were carried out at 9, 11 and 14 DAT. Any eggs and nymphs present were recorded and then removed. In addition, the condition of the adult female and male mites in each arena was recorded on each date.

The numbers of any stuck, drowned or missing mites were added to the number of dead mites found in each treatment to derive the overall "mortality". The percentage mortality at each treatment rate was corrected for mortality in the control treatment using Abbott's formula (Abbott, 1925). Mortality in the individual test item treatments was compared to that in the control treatment using Fisher's Exact Test ($\alpha = 0.05$). The data for mite reproduction was analysed by one-way ANOVA ($\alpha = 0.05$).

The effect of treatments on mite fecundity relative to the control was calculated using the formula:

% change = [1-(Rt/Rc)] * 100

where Rt and Rc are the absolute values observed in the treatment and control groups respectively.

Results and Discussion

Mortality and fecundity are summarised in the table below. All values were calculated using the original raw data and were not based on rounded values.

Table 10.5.1-1: Effects of A19786A on mortality and fecundity of *Typhlodromus pyri,* when exposed under extended laboratory test conditions

Treatment (mL A19786A/ha)	Mean % mortality at 7 DAT[a)]	Mean corrected % mortality at 7 DAT[b)]	Mean eggs/female from 7 to 14 DAT [c)]	% Effect on reproduction compared to control[d)]
Control	12	-	6.8	-
112.5	10	0	7.0	-3.1
225	18	8	7.5	-10.0
450	22	11	6.0	11.4
900	28*	19	6.3	6.6
1800	62*	57	4.8	28.9
Toxic reference	100*	100	-	-

a) Results for mortality in individual treatments at 7 DAT were compared to that in the control by Fisher's Exact Test ($\alpha = 0.05$). Treatment means that differed significantly from the control are indicated with an asterisk (*).

b) Calculated using Abbott's formula

c) Results for reproduction over the assessment period were compared by one-way ANOVA ($\alpha = 0.05$). No treatment means differed significantly from the control.

d) Egg production, relative to the control. A negative value indicates an increase.

Validity Criteria

The validity criteria for the test were met:

- mortality in the control treatment over the initial 7 days should not exceed 20% (12% observed)
- mortality in the toxic reference treatment should be 50-100% (100% observed)
- the mean cumulative number of eggs produced from 7 to 14 days should be ≥ 4.0 per female in the control treatment (6.8 observed)

Conclusions

The 7-day LR_{50} for effects of A19786A on mortality of *Typhlodromus pyri* under extended laboratory test conditions was calculated to be 1652.0 mL A19786A/ha.

The test item did not have adverse effects on the reproduction of the surviving mites at treatment rates of up to and including 1800 mL A19786A/ha.

The no observed effect rate (NOER), defined as the highest rate tested that did not produce a statistically significant adverse effect relative to the control, was 450 mL A19786A/ha for mortality, and for reproduction was 1800 mL A19786A/ha.

(Fallowfield L, 2012)

IIIA 10.5.3 Effects on non-target terrestrial arthropods in semi-field tests

IIIA 10.5.4 Field tests on arthropods species

IIIA 10.6 Effects on earthworms and other soil macro-organisms

IIIA 10.6.2 Acute toxicity to earthworms

IIIA 10.6.3 Sublethal effects on earthworms

Comments of zRMS:	The study is acceptable. The RMS derived the following endpoints from the study, of which the EC10 will be used in the risk assessment: NOEC = 309 mg/kg soil dw EC10 = 191 mg/kg soil dw EC20 = 311 mg/kg soil dw.

	The study summary was provided by the applicant.

Reference:	IIIA 10.6.3/01, Pinoxaden/Pyroxsulam/Cloquintocet-mexyl EC (A19786A) - Sublethal Toxicity to the Earthworm Eisenia fetida in Artificial Soil
Author(s), year:	Friedrich S, (2013)
Report/Doc number:	Report Number 13 10 48 008 S, Syngenta file No. A19786A_10012
Guidelines:	Yes, OECD Guideline for testing of chemicals No. 222 (adopted 13 April 2004): Earthworm Reproduction Test (*Eisenia fetida/Eisenia andrei*)
GLP:	Yes
Deviations:	No
Validity:	Yes

Executive Summary

In a chronic toxicity test in which earthworms (Eisenia fetida) were exposed to A19786A the NOEC was determined to be 309 mg A19786A/kg soil dry weight based on reproduction. The EC50 based on reproduction was estimated to be 794 mg A19786A /kg soil dry weight, with 95% confidence limits of 686 – 918 mg A19786A /kg soil dry weight.

Materials:

Test Material	A19786A	
	Pinoxaden/Pyroxsulam EC (033.3/008.33) & S :Cloquintocet-mexyl (008.33)	
Lot/Batch #:	SMU2AL001	
Actual content of active ingredients:	Pinoxaden:	3.20 % w/w corresponding to 33.7 g/L
	Pyroxsulam:	0.77 % w/w corresponding to 8.11 g/L
	Cloquintocet-mexyl:	0.77 % w/w corresponding to 8.11 g/L
Description:	Brown clear liquid	
Stability of test compound:	Stable under standard conditions	
Reanalysis/Expiry date:	31 March 2015	
Density:	1053 kg/m3	
Treatments		

Test rates:	29, 53, 95, 171, 309, 556, 1000 and 1800 mg A19786A/kg soil d.w.
Control:	Untreated substrate, irrigated with deionised water
Toxic standard:	Nutdazim 50 FLOW (Carbendazim SC 500) was tested at concentrations of 5 and 10 mg product/kg soil dry weight (separate study - No.: R12 10 48 004 S dated 29 October 2012)
Test organisms	
Species:	*Eisenia fetida* (Savigny, 1826) [subspecies Eisenia andrei (Bouché, 1972)]
Age and weight range at test start:	Adult worms, approximately 3 months old with clitellum; 300 – 450 mg/worm
Source:	Reared in the test facility (original breeding animals purchased from W. Neudorff GmbH KG, An der Mühle 3, 31860 Emmerthal, Germany)
Feeding:	Air-dried and finely ground horse manure
Test design	
Vessels:	Plastic trays (16.5 × 12 × 6 cm) with a lid pervious to air and light.
Substrate:	Artificial soil comprising 10% sphagnum peat, 20 % kaolinite clay, 69.5 % industrial quartz sand (> 50% of the particles between 0.05 mm and 0.2 mm) and 0.5% calcium carbonate. 810 g wet weight soil, corresponding to 600 g dry weight, of artificial soil was added to each test vessel.
Replication:	8 for control, 4 for treatment
No. of worms/arena :	10
Duration of test:	8 weeks
Environmental test conditions	
Temperature:	18.1 – 21.5 °C
pH of soil*:	Test start: 6.17 – 6.22
	Test end: 5.82 – 6.09
Water content of soil*:	Test start: 34.9 - 35.1 % (equivalent to 55.7 - 56.0 % of water holding capacity)
	Test end: 34.2 - 34.9 % (equivalent to 54.5 - 55.7 % of water holding capacity)
Photoperiod:	16 hours light:8 hours dark , 540 Lux

*pooled replicates per treatment group

Study Design and Methods

Experimental dates: 23 November 2012 to 18 January 2013

Approximately 24 hours prior to test start, the artificial soil was prepared and deionised water was added to the dry components to adjust the water content to approximately 50% of its maximum water holding capacity (WHC). The worms were acclimatised in a separate batch of the untreated artificial substrate (mixed with horse manure) for approximately 24 hours before test start. On the day of the test start, the test item was introduced by dispersing the quantity of test item required to obtain the desired test concentration in the volume of water required to hydrate the soil to 40-60% of its WHC. The acclimatised test animals were weighed and randomly placed onto the test substrate (10 animals per test vessel). After approximately 30 minutes the test vessels were covered with perforated transparent lids.

One day after application, 5 g dried and ground horse manure was scattered on the soil surface of each test vessel. This was sprinkled with 5 mL deionised water. The feeding interval was weekly during the first four weeks of the test.

After four weeks, the adult worms were removed from the test vessels, and mortality and the body weight of the surviving worms were determined. After all of the adult worms had been removed, the soil in each vessel was mixed with 5 g horse manure. Four weeks later, the number of surviving juveniles and any morphological alterations were recorded. Behavioural and pathological symptoms were observed weekly.

The EC_{50} (number of juveniles) were calculated by Probit analysis using the maximum likelihood method. Confidence limits (95%) of the EC values were computed by normal approximation. Fisher`s Exact Binomial Test with Bonferroni Correction and the Williams-t-test were used to compare the control with the test item groups. For statistical evaluation of the biomass change, the changed mean fresh weight of surviving worms per replicate was used.

Results and Discussion

Mortality and fecundity are summarised in the table below.

Table 10.6.3-1: Effect of A19786A on mortality, growth and reproduction of *Eisenia fetida*

Endpoints	**Treatment groups (mg A19786A/kg soil dry weight)**								
	Control	**29**	**53**	**95**	**171**	**309**	**556**	**1000**	**1800**
Mean adult mortality at 28 days (%)	1.3	2.5	0.0	0.0	5.0	0.0	0.0	2.5	10.0
Mean % biomass change of adults from 0-28 days	30.8	30.2	32.1	29.3	28.2	31.0	32.3	27.0	22.1*

Mean number of juveniles after 8 weeks	111.5	112.0	125.5	99.3	105.8	88.5	71.5*	46.8*	24.3*
Coefficient of variation for reproduction (cv %)	18.8	27.6	10.5	27.8	18.9	22.8	20.3	39.5	69.8
% difference in reproduction relative to the control	-	-0.4	-12.6	11.0	5.2	20.6	35.9	58.1	78.3
LC_{50}	>1800 mg A19786A/kg soil d.w.								
EC_{50} (reproduction)	794 mg A19786A/kg soil d.w. (95% confidence limits 686 to 918 mg A19786A/kg soil d.w.)								
NOEC(mortality)	1800 mg A19786A/kg soil d.w.								
NOEC (biomass)	1000 mg A19786A/kg soil d.w.								
NOEC (reproduction)	309 mg A19786A/kg soil d.w.								

* Statistically significant compared to control (Williams-t-test, $p \leq 0.05$, one-sided smaller). Mortality not statistically significant compared to control (Fisher's Exact Binomial Test with Bonferroni Correction).

d.w.: dry weight (of artificial soil)

Negative values = increase, relative to control

Validity criteria

Validity criteria for the control group were met:

- Adult mortality after 4 weeks: ≤ 10% (being 1.3% after 4 weeks)
- Number of juveniles per replicate: ≥ 30 (being ≥ 86)
- Coefficient of variation for reproduction: ≤ 30% (being 18.8%)

Conclusions

In a chronic toxicity test in which earthworms (*Eisenia fetida*) were exposed to A19786A the NOEC was determined to be 309 mg A19786A/kg soil dry weight based on reproduction. The EC_{50} based on reproduction was estimated to be 794 mg A19786A /kg soil dry weight, with 95% confidence limits of 686 – 918 mg A19786A /kg soil dry weight.

(Friedrich S, 2013)

IIIA 10.6.4 Field tests (effects on earthworms)

IIIA 10.6.5 Residue content of earthworms

IIIA 10.6.6 Effects of other soil non-target macro-organisms

IIIA 10.6.7 Effects on organic matter breakdown

IIIA 10.7 Effects on soil microbial activity

IIIA 10.7.1 Laboratory test to investigate impact on soil microbial activity

Comments of zRMS:	The study is acceptable. The RMS derived the following endpoint from the study for use in the risk assessment: < 25 % effect at 12.64 mg A19786A/kg soil dw after 28 d The study summary was provided by the applicant.

Reference:	IIIA 10.7.1/01, Pinoxaden/Pyroxsulam/Cloquintocet-mexyl EC (A19786A) – Effects on the Activity of Soil Microflora (Nitrogen and Carbon Transformation Tests)
Author(s), year:	Schulz L, (2013)
Report/Doc number:	Report Number 13 10 48 004 C/N, Syngenta file No. A19786A_10007
Guidelines:	Yes, OECD Guideline 216: Soil Microorganisms, Nitrogen Transformation Test, January 2000 and OECD Guideline 217: Soil Microorganisms, Carbon Transformation Test, January 2000
GLP:	yes
Deviations:	No
Validity:	yes

Executive Summary

A19786A was applied to the soil at concentrations of 2.53 mg A19786A/kg dry soil and 12.64 mg A19786A/kg dry soil. No adverse effects are to be expected on either short-term microbial respiration or on the nitrification process and hence on soil fertility.

Materials:

Test Material A19786A

	Pinoxaden/Pyroxsulam EC (033.3/008.33) & S :Cloquintocet-mexyl (008.33)	
Lot/Batch #:	SMU2AL001	
Actual content of active ingredients:	Pinoxaden:	3.20 % w/w corresponding to 33.7 g/L
	Pyroxsulam:	0.77 % w/w corresponding to 8.11 g/L
	Cloquintocet-mexyl:	0.77 % w/w corresponding to 8.11 g/L
Description:	Brown clear liquid	
Stability of test compound:	Stable under standard conditions	
Reanalysis/Expiry date:	31 March 2015	
Density:	1053 kg/m3	
Treatments		
Test rates:	2.53 and 12.64 mg A19786A/kg soil d.w. equivalent to 1.8 L and 9 L A19786A/ha, respectively	
Control:	Deionised water only	
Toxic standard:	Dinoterb (purity 98.0 ± 0.5%) at concentrations of 6.8, 16.0 and 27.0 mg Dinoterb/kg (Separate study – BioChem project No: R 12 10 48 001 C/N, date 13.01 to 11.02.2012)	
Test design		
Soil:	Agricultural sandy loam soil, supplied by BioChem agrar GmbH	
Soil type:	Sandy loam: 10.7 % clay (< 0.002 mm), 35.3 % silt (0.002 - 0.050 mm) and 54.0 % sand (0.050 – 2.0 mm) (USDA classification)	
Test units:	Nitrogen transformation test: 200 g soil dry weight in 500 mL wide-mouthed glass flasks	
	Carbon transformation test: 1000 g soil dry weight in 4 L steel test vessels	
Replication:	Nitrogen transformation test: 3 replicates per treatment rate and control	
	Carbon transformation test: 3 replicates per treatment rate and control	
Sampling intervals :	Nitrogen transformation test: 3 hours, 7 days, 14 days and 28 days after application	
	Carbon transformation test: 3 hours, 7 days, 14 days and 28 days after application	
Duration of test:	28 days	
Environmental test conditions		

Temperature:	18.7 – 20.7 °C
pH of soil:	Nitrogen transformation test: 6.2 at test start, 6.3 at test end
	Carbon transformation test: 6.4 at test start, 6.3 at test end
Soil moisture content:	Nitrogen transformation test: 13.39 – 14.33 g/100 g soil d.w. (equivalent to 41.58 – 44.49 % of WHC)
	Carbon transformation test: 13.58 – 14.41 g/100 g soil d.w. (equivalent to 42.15 – 44.72 % of WHC)
Photoperiod:	Darkness

Study Design and Methods

Experimental dates: 09 November 2012 to 11 December 2012

Soil samples were treated with A19786A at two doses – 2.53 (low dose) and 12.64 mg A19786A/kg dry soil (high dose) relating to a soil depth of 5 cm and a soil density of 1.5 g/cm3. The test item was mixed with deionised water, which was added to the soil samples and mixed thoroughly. The soil moisture content of all samples was adjusted to 45 % of the WHC by adding deionised water and the samples incubated in the dark at a temperature of 18.7 – 20.7□C. The soil moisture content was checked weekly, and adjusted with purified water to maintain 40 – 50 % of the soil WHC.

Respiration and nitrification were determined for all treatments at 3 hours, 7, 14 and 28 days after treatment. In order to measure the short-term respiration of soil microbes, 100 g soil d.w. were taken from each treatment at each sampling occasion. The samples were amended with glucose and the evolved CO2 measured over a period of 12 hours. To determine the nitrification, the soil samples were amended with Lucerne meal after application and 10 g soil d.w. per replicate were taken at each sampling point. The samples were extracted with KCl, and analysed for nitrite-nitrogen, nitrate-nitrogen and ammonium-nitrogen.

Data of nitrate formation and O2 consumption were used to calculate the percentage deviation from the control on each sampling date which was then analysed statistically (2-sided Student-t-test at 5% significance level).

Results and Discussion

Table 10.7.1-1: Effects on Nitrogen Transformation in Soil after Treatment with A19786A

Days after application	Control		2.53 mg A19786A/kg soil dry weight equivalent to 1.8 L			12.64 mg A19786A/kg soil dry weight equivalent to 9 L		
	NO3-N [mg/kg soil d.w.]	CV [%]	NO3-N [mg/kg soil d.w.]	CV [%]	Deviation from control [%][1)]	NO3-N [mg/kg soil d w.]	CV [%]	Deviation from control [%][1)]

0	20.4	2.0	20.5	2.0	+0.5	20.1	1.6	-1.6
7	43.9	9.2	44.8	7.3	+2.0	46.5	5.9	+5.8
14	52.1	7.0	54.8	5.6	+5.1	57.5	1.1	+10.3
28	63.9	2.8	62.8	5.7	-1.7	59.7	5.8	-6.5

The calculations were performed with non-rounded values

CV [%] = Coefficient of Variation

1) based on NO3-nitrogen production; - = inhibition; + = stimulation

No statistically significant differences between the control and the test item treatments were calculated

Table 10.7.1-2: Effects on Carbon Transformation in Soil after Treatment with A19786A

Days after application	**Control**		**2.53 mg A19786A/kg soil dry weight equivalent to 1.8 L A19786A/ha**			**12.64 mg A19786A/kg soil dry weight equivalent to 9 L A19786A/ha**		
	O2 consumption [mg/kg soil d.w./h]	**CV [%]**	**O2 consumption [mg/kg soil d.w./h]**	**CV [%]**	**Deviation from control [%][1]**	**O2 consumption [mg/kg soil d.w./h]**	**CV [%]**	**Deviation from control [%][1]**
0	9.45	1.4	9.36	1.1	-0.9	9.02*	0.4	-4.5
7	9.13	1.2	8.96	2.8	-1.8	8.90	3.0	-2.4
14	9.26	1.4	9.01	1.5	-2.7	9.14	1.6	-1.3
28	8.57	0.3	8.50	1.7	-0.8	8.20*	1.1	-4.4

The calculations were performed with non-rounded values

CV [%] = Coefficient of Variation

1) based on O2 consumption; - = inhibition; + = stimulation

* statistically significantly different to control (Student-t-test for homogeneous variances, 2-sided, $p \leq 0.05$)

Validity Criteria

The validity criteria were fulfilled. The coefficients of variation in the control group in both the nitrogen and carbon transformation tests were ≤ 15% (maximum 9.2 and 1.4 %, respectively)

The results with the reference substance for both the nitrogen and carbon transformation tests demonstrated the sensitivity of the test system.

Conclusions

A19786A was applied to the soil at concentrations of 2.53 mg A19786A/kg dry soil and at 12.64 mg A19786A/kg dry soil. No adverse effects are to be expected on either short-term microbial respiration or on the nitrification process and hence on soil fertility.

(Schulz L, 2013)

IIIA 10.7.2 Further laboratory, glasshouse of field testing to investigate impact on soil microbial activity

III 10.8 Effects on non-target plants

III 10.8.1 Effects on non-target terrestrial plants

IIIA 10.8.1.1 Seed germination

IIIA 10.8.1.2 Vegetative vigour

Comments of zRMS:	The study is valid and generally acceptable. However, the results for the apparent most sensitive species *Avena sativa* are not entirely plausible. Effects larger than 50 % effect on *Avena sativa* apperead at the loweste tested concentration, thus the EC50 of 3.62 mL/ha based on dry weight is based on an extrapolation. This result for *Avena sativa* is not in line with the effects observed in height and survival for the same species in this test as the ratio between ER50 biomass to ER50 height is 42, whereas for the other species tested the ratio ranged between 2 and 6. Thus the applicant carried out an additional vegetative vigour test with *Avena sativa* resulting in an ER50 of 61.14 mL/ha (see study by Stefanut, 2013) and suggests to consider the second most sensitive species Lycopersicon esculentum (ER50 biomass = 26.99 mL/ha) of the first vegetative vigour test for the risk assessment as it is the most sensitive species when considering both EC50 biomass and EC50 height. The RMS agrees, that the results for *Avena sativa* seem less plausible in light of the results for the other species and the results from the additional test with *Avena sativa*. However, at the same time there is no plausible explanation on what could have impaired the results of this given test. Thus, in line with original study report, the RMS considers the following endpoints derived from this test as relevant:

	*Avena sativa (*most sensitive species overall and most sensitive monocot species among the species tested*):* $ER_{50\ biomass}$ = 3.62 mL A9786A/ha, $ER_{50\ height}$ = 150.64 ml A19786A/ha $NOER_{biomass,\ height}$ < 6 mL A9786A /ha *Lycopersicon esculentum (*second most sensitive species overall and most sensitive dicot species among the species tested*)*: $ER_{50\ biomass}$ = 26.99 mL A19786A/ha $ER_{50\ height}$ =130.79 ml A19786A/ha $NOER_{biomass,\ height}$ < 6 mL A9786A /ha For implications on the use in the risk assessment please refer to the respective chapter. The study summary was provided by the applicant.

Reference:	IIIA 10.8.1.2/01, Pinoxaden/Pyroxsulam/cloquintocet-mexyl EC (A19786A) - Evaluation of the Phytotoxicity to Non Target Terrestrial Plant Vegetative Vigour Test
Author(s), year:	Bramby-Gunary J (2012b)
Report/Doc number:	Report Number ACE-12-050, Syngenta file No. A19786A_10002
Guidelines:	Yes, OECD Guideline for the Testing of Chemicals. Guideline 227: Terrestrial Plant Test: Vegetative Vigour Test (July 2006)
GLP:	Yes
Deviations:	No
Validity:	Yes

Executive Summary

A single foliar application of A19786A, at rates up to 4375 mL A19786A per hectare resulted in ER_{50} values ranging from 3.62 to 417.52 mL A19786A/ha based on dry weight, and 85.28 - > 4375 mL A19786A/ha based on final height.

Avena sativa (oat) was the most sensitive species, with an ER_{50} of 3.62 and 150.64 mL A19786A/ha based on dry weight and final height, respectively, and a NOER value based on dry weight and final height of < 6.00 mL A19786A/ha.

Materials:

Test material	A19786A	
	Pinoxaden/Pyroxsulam EC (033.3/008.33) & S:Cloquintocet-mexyl (008.33)	
Lot/Batch #:	SMU2AL001	
Actual content of active ingredients:	Pinoxaden:	3.20% w/w corresponding to 33.7 g/L
	Pyroxsulam:	0.77% w/w corresponding to 8.11 g/L
	Cloquintocet-mexyl:	0.77% w/w corresponding to 8.11 g/L
Description:	Brown clear liquid	
Stability of test compound:	Stable under standard conditions.	
Reanalysis/expiry date:	31 March 2015	
Density:	1053 kg/m3	
Treatments		
Test concentrations:	6.00, 18.0, 54.0, 162, 486, 1458 and 4375 mL A19786A/ha	
Control:	Water only	
Spray volume:	200 L/ha +/- 10%	
Application method:	Mardrive cabinet track sprayer with SS8005E TeeJet flat fan nozzle	
Test organisms		
Species:	*Allium cepa* (onion)	
	Avena sativa (oat)	
	Lolium perenne (ryegrass)	
	Zea mays (maize)	
	Beta vulgaris (sugar beet)	
	Brassica napus (oilseed rape)	
	Daucus carota (carrot)	
	Glycine max (soybean)	
	Lactuca sativa (lettuce)	

	Lycopersicon esculentum (tomato)
Test soil:	Sandy loam mixed as follows: 20 litres of sterile loam + 10 litres of sand. The soil was determined to consist of 75% w/w sand (2.00 – 0.063mm), 8% silt w/w (0.063 – 0.002 mm), 17% w/w clay (<0.002 mm). The organic carbon content was 1.3% w/w. To obtain good plant health, 100 g slow release fertiliser was incorporated into 30 litres of soil mix.
Test design	
Test vessels:	Non-porous plastic pots (8 x 8 x 8 cm), placed in saucers filled with enough water to ensure that the pots were kept moist at all times
Sampling interval:	Plants were assessed at 7, 14 and 21 days after application for mortality and visual phytotoxicity. Biomass and height were assessed at test termination
Replication:	Five pots per treatments, 4 seedlings per pot (six for *Allium cepa* (onion))
Duration:	21 days after application of test substance
Environmental conditions	
Test temperature:	Mean: 18.9 °C, (Min: 13.9 °C, Max: 24.0 °C)
Humidity*:	Mean; 69.3 %, (Min: 40.7 %, Max: 90.9 %)
Soil pH:	7.4
Lighting:	Ambient lighting was supplemented by sodium vapour lamps giving at least a 16 hour day. The mean ambient light intensity for the study period was 13.1 kilo lux (Kl), and the maximum ambient light intensity was 51.0 Kl.

* The humidity fell below the range specified in the study plan on three occasions; however the plants were healthy and grew well. This minor deviation had no impact on the study.

Study Design and Methods

Experimental dates: 19 April 2012 to 29 May 2012

Young plants of four monocot species (*Allium cepa, Avena sativa, Lolium perenne and Zea mays*) and six dicot species (*Beta vulgaris, Brassica napus. Daucus carota, Glycine max, Lactuca sativa,* and *Lycopersicon esculentum*) were sprayed with a series of seven test concentrations of A19786A. Nominal test concentrations used in the definitive test for all test species ranged from 6.00 to 4375 mL A19786A/ha. The number of emerged seedlings, number of surviving seedlings, seedling height and weight were determined at test termination.

All the species were germinated in seed trays of Levingtons F1 compost and transplanted shortly after emergence at BBCH Growth Stage 10 into plastic pots (8 cm diameter and 8 cm deep), four seedlings per pot (six for *Allium cepa*). At the time of application seedlings had 2 to 4 open leaves.

Observations were made 7, 14 and 21 days after application (DAA) to document plant condition and mortality. Observations were made 21 DAA to document plant height. Plant condition was described by noting the presence or absence of possible signs of phytotoxicity such as necrosis, leaf wrinkle, chlorosis, lodging or stunting. Each plant was then assigned a numerical score that described the plant condition. This was a scale from 0 to 100% - a subjective or qualitative assessment that determines whether damage is absent (0%), slight (1 – 39%), moderate (40 – 69%), severe (70 – 99%) or all plants dead (100%). A score of 10 does not mean that 10% of the plant is showing the effect (e.g. chlorosis), merely that the severity of the effect (e.g. chlorosis) is very slight.

The growth of test plants was evaluated at the end of the test (21 DAA) by assessing height and biomass. Plant biomass was estimated by measuring the total dry weight of the shoots within each replicate. Plant height was measured from the surface of the soil to the tip of the tallest leaf. Dead or non-emerged seedlings were assigned a height of 0 cm. Plants were then clipped at soil level, the shoots of all living plants within a replicate were placed in a labelled paper bag and dried in an oven to a constant weight. Mean height and total replicate biomass were determined for each treatment group containing living seedlings at test termination.

Results and Discussion

Statistical analyses were used to evaluate effects of test substance application on plant height and biomass. Least Significant Difference (LSD) was used to establish the NOER by determining which treatment groups differed significantly ($p \leq 0.05$) from the control group. Effect rates (i.e. ER_{50}) and their confidence limits were determined using simple probit – maximum likelihood estimation method. Statistical analysis was not conducted for plant condition and visual phytotoxicity because those data are qualitative.

The mean 21-day survival for each of the ten test species is presented in the table below:

Table 10.8.1.2-1: Mean 21-day survival per pot after application of A19786A (expressed as %)

Species	**Rate: mL A19786A/ha**							
	Control	**6.0**	**18.0**	**54.0**	**162**	**486**	**1458**	**4375**
Monocots								
Allium cepa (onion)	100	100	100	100	100	100	100	100
Avena sativa (oat)	100	100	100	100	100	100	75	0
Lolium perenne (ryegrass)	100	100	100	100	100	50	0	0
Zea mays (maize)	100	100	100	100	100	45	0	0
Dicots								
Beta vulgaris (Sugar beet)	100	100	100	100	100	100	95	65

Species	Rate: mL A19786A/ha							
	Control	**6.0**	**18.0**	**54.0**	**162**	**486**	**1458**	**4375**
Brassica napus (oilseed rape)	100	100	100	100	100	85	25	0
Daucus carota (carrot)	100	100	100	100	100	100	100	100
Glycine max (soya bean)	100	100	100	100	100	70	55	45
Lactuca sativa (lettuce)	100	100	100	100	100	100	100	100
Lycopersicon esculentum (tomato)	100	100	100	100	100	100	95	95

The NOER and ER_{50} for each of the ten test species are presented in the table below:

Table 10.8.1.2-2: Effect Rates of A19786A on 21-Day Biomass and Height

Species	**Biomass (mL A19786A/ha)**			**Height (mL A19786A/ha)**		
	NOER	**ER_{50}**	**95% Confidence limits**	**NOER**	**ER_{50}**	**95% Confidence limits**
Monocots						
Allium cepa (onion)	6.00	417.52	342.22 – 515.07	18.0	> 4375	N/A*
Avena sativa (oat)	< 6.00	3.62	1.91 – 5.95	< 6.00	150.64	109.44 – 208.77
Lolium perenne (ryegrass)	18.0	71.12	64.95 – 77.95	18.0	182.91	167.73 – 199.73
Zea mays (maize)	18.0	82.15	74.46 – 90.75	54.0	167.77	155.50 – 181.06
Dicots						
Beta vulgaris (Sugar beet)	< 6.00	50.82	43.30 – 59.10	18.0	303.36	255.89 – 360.15
Brassica napus (oilseed rape)	18.0	125.21	114.71 – 136.51	18.0	273.80	248.86 – 301.85
Daucus carota (carrot)	18.0	126.45	110.00 – 144.86	6.00	301.47	250.51 – 364.17
Glycine max (soya bean)	6.00	124.52	110.45 – 140.04	< 6.00	85.28	73.29 – 98.73
Lactuca sativa (lettuce)	6.00	155.11	137.77 – 174.48	6.00	429.26	371.79 – 498.04
Lycopersicon esculentum (tomato)	< 6.00	26.99	21.11 – 33.67	< 6.00	130.79	101.04 – 167.97

* N/A; not applicable

Discussion

It is noted that in the above table the sensitivity of *Avena sativa* in the biomass assessment is out of line with the other species as seen in the height and survival assessments. For example the ratio of the biomass ER_{50} to the height ER_{50} is 42, whereas for all the other species this ratio is below 6. This effect is also seen

in the rate response, see the table below. In most species the rate response is rapid (moving from around 30% to 70% in 3 rate steps), whereas for *Avena* we see much the same effects at 5 rates (ranging from 27% to 40% between 6, 18, 54, 162 and 486 ml/ha).

This sensitivity is also out of line with other results for pinoxyden and pyroxsulam in previous vegetative vigour tests. For this reason this study on *Avena sativa* was repeated and the new study is summarised below.

Table 10.8.1.2-3: Mean Plant Dry Weight (g and as % of untreated)

Rate ml A19786A /ha	***Allium cepa* Onion**		***Avena sativa* Oat**		***Lolium perenne* Ryegrass**		***Zea mays* Maize**		***Beta vulgaris* Sugar beet**	
	weight	%	weight	%	weight	%	weight	%	weight	%
0 (water only)	0.344	N/A**	2.314	N/A**	1.540	N/A**	3.346	N/A**	2.416	N/A**
6.00	0.309	90	0.877*	38	1.428	93	3.058	91	2.146*	89
18.0	0.300*	87	0.917*	40	1.458	95	3.152	94	1.810*	75
54.0	0.214*	62	0.861*	37	1.142*	74	2.882*	86	0.731*	30
162	0.154*	45	0.811*	35	0.309*	20	1.000*	30	0.506*	21
486	0.151*	44	0.626*	27	0.141*	9	0.376*	11	0.374*	15
1458	0.140*	41	0.320*	14	0.000*	0	0.000*	0	0.389*	16
4375	0.129*	37	0.000*	0	0.000*	0	0.000*	0	0.248*	10

*Significantly different from the control. ** N/A = Not applicable

Validity criteria

The validity criteria for the test were met:

- The control plants did not exhibit any phytotoxic effects
- There was more than 90% survival in the control plants
- The environmental conditions were identical for all the tested species

Conclusions

A single foliar application of A19786A, at rates up to 4375 mL A19786A per hectare resulted in ER50 values ranging from 3.62 to 417.52 mL A19786A/ha based on dry weight, and 85.28 - > 4375 mL A19786A/ha based on final height.

Lycopersicon esculentum (tomato) was the most sensitive species, with an ER_{50} of 26.99 mL A19786A/ha and 130.79 mL A19786A/ha based on height. Thus the biomass endpoint for tomato is 7.5 times higher than for oat, whereas the height endpoint is lower.

(Bramby-Gunary J. 2012b)

Comments of zRMS:	The study is acceptable. The RMS derived the following endpoint from the study: *Avena sativa*: $ER_{50\ biomass}$ 61.14 mL A19786A/ha, $ER_{50\ height}$ = 210.26 mL A19786A/ha The study summary was provided by the applicant.

Reference:	IIIA 10.8.1.2/02, Pinoxaden/Pyroxsulam/cloquintocet-mexyl EC (A19786A) - Evaluation of the Phytotoxicity to Avena sativa Plant Vegetative Vigour Test
Author(s), year:	Stefanut M, (2013)
Report/Doc number:	Report Number ACE-13-080, Syngenta file No. A19786A_10056
Guidelines:	Yes, OECD Guideline for the Testing of Chemicals. Guideline 227: Terrestrial Plant Test: Vegetative Vigour Test (July 2006)
GLP:	yes
Deviations:	no
Validity:	yes

Executive Summary

Avena sativa was exposed to a water control and 7 test item concentrations of A19786A at rates up to 4375 ml A19786A/ha. The ER50 of *Avena sativa* to A19786A is 61.14 ml/ha based on dry weight, with a NOEC of 162 ml/ha.

Materials

Test material	A19786A pinoxaden/pyroxsulam/cloquintocet-mexyl
Lot/Batch #:	SMU2AL001
Actual content of active ingredients:	Pinoxaden: 3.20 % w/w corresponding to 33.7 g/L pyroxsulam: 0.77 % w/w corresponding to 8.11 g/L

	cloquintocet-mexyl: 0.77 % w/w corresponding to 8.11 g/L
Description:	Brown clear liquid
Stability of test compound:	Stable under standard conditions.
Reanalysis/expiry date:	March 2015
Density:	1053 kg/m3
Treatments	
Test concentrations:	6.0, 18.0, 54.0, 162, 486, 1458 and 4375 ml A19786A/ha
Control:	Water only
Spray volume:	200 L/ha ± 10 %
Application method:	Mardrive cabinet track sprayer with 8004E TeeJet flat fan nozzle
Test organisms	
Species:	*Avena sativa* (oat)
Test soil:	Sandy loam mixed as follows: 20 litres of sterile loam + 10 litres of sand. The soil was determined to consist of 62% w/w sand (2.00 – 0.063mm), 21% silt w/w (0.063 – 0.002 mm), 17% w/w clay (<0.002 mm). The organic matter content was not more than 1.5%. To obtain good plant health, 100g slow release fertiliser was incorporated into 30 litres of soil mix.
Test design	
Test vessels:	Non-porous plastic pots (8 x 8 x 8 cm)
Sampling interval:	Plants were assessed at 7, 14 and 21 days after application for mortality and visual phytotoxicity. Biomass and height were assessed at test termination
Replication:	Five pots per treatments, 4 plants per pot
Duration:	21 days after application of test substance
Environmental conditions	
Test temperature:	Mean: 22.5 °C (Min.: 16.3 °C, Max.: 27.9 °C)
Humidity:	Mean: 45.4 % (Min.: 17.5 %, Max.: 75.0 %)*
Soil pH:	7.4
Lighting:	Ambient lighting was supplemented by sodium vapour lamps giving at least a 16 hour day. The mean ambient light intensity for the study period was 15.1 kilo lux (Kl), and the maximum intensity was 60.3 Kl

* The humidity fell below the range specified in the study plan on a few of occasions however the plants were healthy and grew well. This minor deviation had no impact upon the study.

Study Design and Methods

Experimental dates: 05 April 2013 to 29 April 2013

Young plants of one monocotyledon species (*Avena sativa*) were sprayed with a series of seven test concentrations of A19786A. Nominal test concentrations used in the definitive test for all test species ranged from 6.0 to 4375 ml A19786A/ha. The number of surviving seedlings, seedling height and weight were determined at test termination.

All the species were germinated in seed trays of Levingtons F1 compost and transplanted shortly after emergence at BBCH Growth Stage 10 into plastic pots (8 cm diameter and 8 cm deep), four seedlings per pot.

Observations were made at 7, 14 and 21 days after application (DAA) for mortality and visual phytotoxicty expressed as a percentage of healthy untreated control plants. Plant condition was described by noting the presence or absence of possible signs of phytotoxicity. This was a scale from 0 to 100% - no phytotoxicity (0%), slight phytotoxicity (1 – 39%), moderate phytotoxicity (40 – 69%), severe phytotoxicity (70 – 99%) or all plants dead (100%). The growth of test plants was evaluated at the end of the test (21 DAA) by assessing height and dry weight (biomass). The height of all live plants above soil level to the top of the tallest leaf was recorded in cm at the final assessment. The height and dry weight of dead plants were not measured or weighed but were recorded as "0". Plant biomass was estimated by measuring the total dry weight of the shoots within each replicate. All plants in one treatment pot were cut at soil level and placed in a paper bag for drying. This procedure was repeated for all the treatment pots in the five replicates of a species. Dead plants were not harvested. Plants were dried in an oven for three days and the contents of each bag were weighed.

Results and Discussion

Statistical analysis was carried out by AgroChemex using Agriculture Research Manager (ARM) 8.0 software, purchased from Gylling Data Management, Inc. The descriptive statistics for calculating Analysis of Variance (AOV) Means using ARM 8.0 software were Least Significant Difference (LSD) with 5% significance level. Significant differences in mean final height and mean dry weight between treatments are indicated by an asterisk after the mean values ($p \leq 0.05$, LSD). 50% Effect Rate (ER50) values were calculated using audited mean values of final height and dry weight per treatment and ARM 8.0 software using simple probit – maximum likelihood estimation method with 95% confidence level. The estimation algorithms were provided courtesy of J. J. Hubert, University of Guelph. The No Observed Effect Rate (NOER) is the highest concentration at which no statistically significant adverse effect was observed ($p \leq 0.05$) when compared with the control.

The mean 21-day survival for each of the test species is presented in the table below:

Table 10.8.1.2-4: Mean 21-Day Survival per Pot Expressed as %

Species	Rate: ml A19786A/ha							
	Control	**6.0**	**18.0**	**54.0**	**162**	**486**	**1458**	**4375**
Avena sativa (oat)	100	100	100	100	100	20	0	0

The NOER and ER50 for the test species are presented in table below:

Table 10.8.1.2-5: Effect Rates of A19786A on 21-Day Dry Weight and Height

Species	Dry weight (ml A19786A/ha)			Height (ml A19786A/ha)		
	NOER	**ER_{50}**	**95% Confidence limits**	**NOER**	**ER_{50}**	**95% Confidence limits**
Avena sativa (oat)	162	61.14	48.54,77.55	162	210.26	192.62,230.02

Validity criteria

The validity criteria for the test were met:

- The control plants did not exhibit any phytotoxic effects
- There was more than 90% survival in the control plants
- The environmental conditions were identical for all the tested species

Conclusions

Avena sativa was exposed to a water control and 7 test item concentrations of A19786A at rates up to 4375 ml A19786A/ha. The ER50 of *Avena sativa* to A19786A is 61.14 ml/ha based on dry weight, with a NOEC of 162 ml/ha.

(Stefanut M., 2013)

IIIA 10.8.1.3 Seedling emergence

Comments of zRMS:	The study is acceptable. The RMS derived the following endpoint from the study for use in the risk assessment: *Allium cepa*: ER_{50} 92.99 mL A19786A/ha The study summary was provided by the applicant.

Reference:	IIIA 10.8.1.3/01, Pinoxaden/Pyroxsulam/cloquintocet-mexyl EC (A19786A) – Evaluation of the Phytotoxicity to Non Target Terrestrial Plant Seedling Emergence and Seedling Growth Test
Author(s), year:	Bramby-Gunary J (2012a)
Report/Doc number:	Report Number ACE-12-049, Syngenta file No. A19786A_10001
Guidelines:	Yes, OECD Guideline for the Testing of Chemicals, Volume 1, Number 2, April 1984, pp. 1 – 21 (21) Test No. 208 (3)
GLP:	Yes
Deviations:	No
Validity:	Yes

Executive Summary

A pre-emergent application of A19786A, at rates up to 4375 ml A19786A/ha resulted in ER50 values ranging from 92.99 to > 4375 ml A19786A/ha.

Allium cepa (onion) was the most sensitive species, with ER50 values based on dry weight, height and emergence of 92.99, 217.92 and > 4375 ml A19786A/ha, respectively, and a NOER based on dry weight, height and emergence of 6.00, 18.0 and 486 ml A19786A/ha, respectively.

Materials:

Test material	A19786A
	Pinoxaden/Pyroxsulam EC (033.3/008.33) & S:Cloquintocet-mexyl (008.33)
Lot/Batch #:	SMU2AL001
Actual content of active ingredients:	Pinoxaden: 3.20 % w/w corresponding to 33.7 g/L
	Pyroxsulam: 0.77 % w/w corresponding to 8.11 g/L
	Cloquintocet-mexyl: 0.77 % w/w corresponding to 8.11 g/L
Description:	Brown clear liquid
Stability of test compound:	Stable under standard conditions.
Reanalysis/expiry date:	31 March 2015
Density:	1053 kg/m3
Treatments	

Test concentrations:	Nominal Values: 0 (water only), 6.00, 18.0, 54.0, 162, 486, 1458 and 4375 ml A19786A/ha
Control:	Tap water
Spray volume:	200 L/ha ± 10%
Application method:	Mardrive Cabinet Track Sprayer with SS8005E TeeJet flat fan nozzle
Test organisms	
Species:	*Allium cepa* (onion)
	Avena sativa (oat)
	Lolium perenne (ryegrass)
	Zea mays (maize)
	Beta vulgaris (sugar beet)
	Brassica napus (oilseed rape)
	Daucus carota (carrot)
	Glycine max (soybean)
	Lactuca sativa (lettuce)
	Lycopersicon esculentum (tomato)
Test soil:	Sandy Loam soil mixed as follows: 20L of sterile loam + 10L of sand. Composition: Sand (2.00 – 0.063 mm) 75% w/w, Silt (0.063 – 0.002 mm) 8% w/w, Clay (<0.002 mm) 17% w/w. Organic Carbon content: 1.3% w/w
Test design	
Test vessels:	Non-porous plastic pots (8 x 8 x 8 cm), placed in saucers filled with enough water to ensure that the pots were kept moist at all times
Sampling interval:	Plants were assessed at 7, 14 and 21 days after 50% emergence in controls for emergence, mortality and visual phytotoxicity. Biomass and height were assessed at test termination.
Replication:	Five replicate pots per treatment for each plant species. Four seeds per pot (six for *Allium cepa* (onion)).
Duration:	21 days after 50% emergence in the controls
Environmental conditions	
Test temperature:	Mean 18.4 °C (Min: 13.6 °C, Max: 24.0 °C)
Humidity:	Mean 65.9 % (Min: 37.5 %, Max: 96.0 %)
Soil pH:	7.4

Lighting:	Ambient lighting was supplemented by sodium vapour lamps giving at least a 16 hour day. The mean ambient light intensity for the study period was 12.8 kilo lux (Kl), and the maximum intensity was 51.2 Kl.

Study Design and Methods

Experimental dates: 29 March 2012 to 24 May 2012

Planted seeds of four monocot species (*Allium cepa, Avena sativa, Zea mays* and *Lolium perenne*) and six dicot species (*Beta vulgaris, Brassica napus, Daucus carota, Glycine max, Lactuca sativa*, and *Lycopersicon esculentum*) were sprayed with a series of seven test concentrations of A19786A. Nominal test concentrations used in the definitive test for all test species ranged from 6.00 to 4375 ml A19786A per hectare. The number of emerged seedlings, number of surviving seedlings, seedling height and weight were determined at test termination.

Seeds were sown directly into plastic pots (8 cm diameter and 8 cm deep), 1- 2 cm deep, four seeds per pot (six for *Allium cepa*).

Observations were made 7, 14 and 21 days after 50% emergence in controls to document seedling emergence, mortality and visual phytotoxicity. Plant height was recorded at the final assessment. Plant condition was described by noting the presence or absence of possible signs of phytotoxicity such as chlorosis, leaf distortion and stunting. Each plant was then assigned a numerical score that described the plant condition. This was a scale from 0 to 100% - a subjective or qualitative assessment that determines whether damage is absent (0%), slight (1 – 39%), moderate (40 – 69%), severe (70 – 99%) or all plants dead (100%). A score of 10 does not mean that 10% of the plant is showing the effect (e.g. chlorosis), merely that the severity of the effect (e.g. chlorosis) is very slight.

The growth of emerged seedlings was evaluated at the end of the test by assessing the height and biomass of seedlings. Plant biomass was estimated by measuring the total dry weight of the shoots within each replicate. The height of all live plants above soil was recorded in cm at the final assessment. Dead or non-emerged seedlings were assigned a height of 0 cm. Seedlings were then clipped at soil level, the shoots of all living seedlings within a replicate were placed in a labelled paper bags, dried in an oven, and weighed as a group. Mean seedling height and replicate biomass were determined for each treatment group containing living seedlings at test termination.

Results and Discussion

Statistical analyses were used to evaluate effects of test substance application on plant emergence, height, and biomass. Least Significant Difference (LSD) was used to establish the NOER by determining which treatment groups differed significantly ($p \leq 0.05$) from the control group. Effect rates (i.e. ER50) and their confidence limits were determined using simple probit maximum likelyhood estimation method. Statistical analysis was not conducted for plant condition and visual phytotoxicity because those data are qualitative.

The NOER and ER50 for biomass, height and emergence for each of the ten test species are presented in table below:

Table 10.8.1.3-1: Effect Rates of A19786A on 21-Day Biomass, Height and Emergence

Species	**ER_{50} (ml A19786A/ha)**			**NOER (ml A19786A/ha)**		
	Dry weight	**Height**	**Emergence**	**Dry weight**	**Height**	**Emergence**
Monocots						
Allium cepa (onion)	92.99	217.92	> 4375	6.00	18.0	486
Avena sativa (oat)	3152.89	3954.61	> 4375	486	486	4375
Lolium perenne (ryegrass)	191.84	345.07	> 4375	54.0	54.0	4375
Zea mays (maize)	> 4375	> 4375	> 4375	1458	162	4375
Dicots						
Beta vulgaris (sugar beet)	94.63	192.45	> 4375	18.0	18.0	4375
Brassica napus (oilseed rape)	330.66	811.99	> 4375	162	162	4375
Daucus carota (carrot)	242.87	4100.42	> 4375	162	162	4375
Glycine max (soybean)	3768.71	1713.23	> 4375	486	162	4375
Lactuca sativa (lettuce)	484.93	1407.43	> 4375	162	162	4375
Lycopersicon esculentum (tomato)	887.82	2070.52	> 4375	486	162	4375

Validity criteria

The validity criteria for the test were met:

- There was at least 70% emergence in the controls
- The control seedlings did not exhibit any phytotoxic effects
- The mean survival of the emerged control seedlings was at least 90%
- The environmental conditions were identical for all the tested species

Conclusions

A pre-emergent application of A19786A, at rates up to 4375 ml A19786A/ha resulted in ER50 values ranging from 92.99 to > 4375 ml A19786A/ha.

Allium cepa (onion) was the most sensitive species, with ER_{50} values based on dry weight, height and emergence of 92.99, 217.92 and > 4375 ml A19786A/ha, respectively, and a NOER based on dry weight, height and emergence of 6.00, 18.0 and 486 ml A19786A/ha, respectively.

(Bramby-Gunary J, 2012a)

IIIA 10.8.1.4 Terrestrial field testing

MIII 10.8.2 Effects on non-target aquatic plants

IIIA 10.8.2.1 Aquatic plant growth – Lemna

Comments of zRMS:	The study is generally acceptable. However, the RMS points out that the product test is considered a tier 1 test that should be conducted under constant exposure and the analysed substance pinoxaden was not stable (was not found to be in the margin of +/- 20 % of nominal). Thus, in addition to the endpoints expressed based on nominal (more correctly it would be initial) concentrations, the RMS expressed the endpoints based on the measured average recovery of pinoxaden as "mean measured". This translates into the following value considered for the risk assessment: E_rC_{50} = **0.1123 (mm)** E_yC_{50} = 0.0613 (mm) NOE_rC = 0.01276 µg/L (mm) The RMS is aware that by doing so the measured dissipation of pinoxaden is projected to the other active ingredients, which presents a worst-case approach in this given case. The study summary was provided by the applicant.

Reference:	IIIA 10.8.2.1, Pinoxaden/Pyroxsulam/Cloquintocet-mexyl EC (A19786A) - Toxicity to the aquatic higher plant Lemna gibba in a 7-day growth inhibition test
Author(s), year:	Liedtke A, 2013
Report/Doc number:	Report Number D62645, Syngenta file no A19786a_10014
Guidelines:	Yes, OECD Guidelines for Testing of Chemicals, Section 2 - Effects on Biotic Systems, Method 221: Lemna sp. Growth Inhibition Test (2006) Commission Regulation (EC) No 761/2009 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), 2009, C.26: Lemna sp. Growth Inhibition Test US EPA Ecological Effects Test Guidelines, OPPTS 850.4400: Aquatic Plant Toxicity using Lemna spp., Tiers I and II, (1996)
GLP:	Yes

Deviations:	No
Validity:	Yes

Executive Summary

The toxicity of A19786A to the aquatic plant *Lemna gibba* was determined in a 7-day semi-static test with medium renewal every 48 or 72 hours. The *Lemna* were exposed to nominal concentrations of 0.016, 0.050, 0.16, 0.50, 1.6 and 5.0 mg A19786A/L alongside a dilution water control.

For frond number, the 7-day EC_{50} for yield (EyC_{50}) and growth rate (E_rC_{50}) for A19786A to *Lemna gibba*, were 0.24 and 0.44 mg A19786A/L, respectively, based on nominal concentrations. For dry weight, the 7-day EC_{50} for yield (E_yC_{50}) and growth rate (E_rC_{50}) were 0.40 and 3.6 mg A19786A/L, respectively, based on nominal concentrations.

Materials

Test Material	A19786A	
	Pinoxaden/Pyroxsulam EC (033.3/008.33) & S :Cloquintocet-mexyl (008.33)	
Lot/Batch #:	SMU2AL001	
Actual content of active ingredients:	Pinoxaden:	3.20 % w/w corresponding to 33.7 g/L
	Pyroxsulam:	0.77 % w/w corresponding to 8.11 g/L
	Cloquintocet-mexyl:	0.77 % w/w corresponding to 8.11 g/L.
Description:	Brown clear liquid	
Stability of test compound:	Stable under standard conditions	
Reanalysis/expiry date:	31 March 2015	
Density:	1053 kg/m3	
Treatments		
Test concentrations:	Dilution water control; nominal concentration of 0.016, 0.050, 0.16, 0.50, 1.6 and 5.0 mg A19786A/L	
Solvent:	None	
Vehicle and/or positive control:	3,5-dichlorophenol is used as a positive control twice a year. (Latest positive control test performed in October 2012, study #: D64322)	
Analysis of test concentrations:	Yes, analysis of the active ingredient pinoxaden in freshly prepared and aged test media on days 0, 2, 5 and 7 using LC-MS/MS analysis	
Test organisms		
Species:	*Lemna gibba* G3 (family Lemnaceae, Macrophyta)	

Source:	The original culture was supplied by Bayer CropScience AG, 40789 Monheim, Germany in 2007. The plants were axenically cultivated at Harlan Laboratories Ltd., for more than four weeks prior to the test
Test design	
Test vessels:	250 mL glass dishes (diameter of approx. 9.5 cm) filled with 150 mL of test medium with glass dish covers
Test medium:	20X AAP-Growth Medium according to OECD guideline
Replication:	Three vessels for the control and each test concentration
Initial frond number:	4 fronds per plant, total 12 fronds per replicate
Exposure regime:	Semi-static; test medium renewal every 48 or 72 hours
Duration:	7 days
Environmental conditions	
Temperature:	24 - 25°C
pH:	7.5 – 8.1 new solutions; 8.6 – 9.1 aged solutions
Lighting:	Continuous illumination at 6690 - 7490 Lux.

Study Design and Methods

Experimental dates: 11 September 2012 to 19 January 2013

A stock solution with a nominal concentration of 100 mg A19786A/L was prepared by mixing 100.01 (Day 0), 100.00 (Day 2) or 100.80 (Day 5) mg of A19786A completely in 1000 mL of test medium by intense stirring for 15 minutes at room temperature. This intensively mixed stock solution was serially diluted with test water to prepare the lower test concentrations. The control consisted of culture medium only.

150 mL of the test solutions were transferred into 250 mL glass dishes and inoculated with Lemna plants. Cultures were then transferred to a temperature-controlled room where they were maintained under the conditions indicated above.

Assessments of frond number were made on days 0, 2, 5 and 7. Fronds were harvested for measurement of dry weight after 7 days, and the initial dry weight was determined using a sample of 12 fronds at the start of the test.

At test initiation, light intensity was measured at nine locations distributed over the test area, level with the surface of the test media. The pH was measured and recorded in each treatment at the start and end of each test medium renewal period. The water temperature was measured in a vessel filled with water (incubated under the same conditions as the test vessels) on each working day. The appearance of the test media was recorded on the counting days of the plants. The water temperature in the temperature-controlled water bath was also measured continuously.

The test concentrations were verified by chemical analysis of the active ingredient pinoxaden in samples from the freshly prepared and aged test media of all test concentrations, and from the control, on days 0, 2, 5 and 7, using LC-MS/MS analysis. For sampling of the aged test media, the test media of three replicates per test concentration were pooled.

Results and Discussion

The analytically determined concentrations of A19786A (based on the measurement of the active ingredient pinoxaden) were between 88 to 98% of the nominal values in fresh solutions and below the limit of quantification and 23% in aged solutions (see table below).. The limit of quantification in this study was 0.100 µg pinoxaden/L. The results show that the correct dosing levels were achieved and so the nominal concentrations were used for the calculation and reporting of results. The rapid hydrolysis of pinoxaden to the active moiety pinoxaden acid (NOA407854) is as aexpected from previous studies).

Table 10.8.2.1-1: Analytical results

Nominal concentrations mg A19786A/L	**A19786A**					
	% of nominal measured at 0 days, 0 hours	**% of nominal measured at 2 days, 48 hours**	**% of nominal measured at 2 days, 0 hours**	**% of nominal measured at 5 days, 72 hours**	**% of nominal measured at 5 days, 0 hours**	**% of nominal measured at 7 days, 48 hours**
Control	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
0.016	95	n.d.	94	n.d.	94	n.d.
0.050	95	n.d.	95	n.d.	93	n.d.
0.16	98	10	94	n.d.	88	6
0.50	94	12	95	2	95	17
1.6	95	13	97	3	94	20
5.0	94	15	93	3	94	23

The tabulated values represent rounded results obtained by calculation using the exact raw data

n.a. = not applicable

n.d. = not determined as less than the limit of quantification (0.100 µg pinoxaden/L)

Data for frond number and dry weight was used to calculate growth rates and yield for the control and each exposure concentration. Probit analysis using linear maximum likelihood regression was then used to calculate the 7-day ErC50 and EyC50, based on percent inhibition relative to the control. For the No Observed Effect Concentration and Lowest Observed Effect Concentration, a multiple Williams t-test was used to determine values significantly different to the control.

Mean frond numbers are presented below along with the growth rate, yield and respective inhibition values, alongside estimated EC50 values:

Table 10.8.2.1-2: Effect of A19786A on growth rate and yield (frond number) of *Lemna gibba*

Nominal concentration (mg A19786A/L)	**Mean No. fronds/replicate (day 7)**	**Based on Frond Number (0-7 days)**			
		Growth Rate (day-1)	**Inhibition of Growth Rate (%)**	**Yield**	**Inhibition of Yield (%)**
Control	177.0	0.384	0.0	165.0	0.0
0.016	183.3	0.389	-1.3	171.3	-3.8
0.050	188.7	0.393	-2.4	176.7	-7.1
0.16	132.7	0.343*	10.8	120.7*	26.9
0.50	33.7	0.147*	61.7	21.7*	86.9
1.6	18.7	0.062*	83.8	6.7*	96.0
5.0	15.0	0.032*	91.7	3.0*	98.2
EC_{50} mg A19786A/L		0.44		0.24	
95% confidence limits		0.38 – 0.51		0.22 – 0.26	
NOEC (mg A19786A/L)		0.050		0.050	
LOEC (mg A19786A/L)		0.16		0.16	

Inoculum = 12 fronds

(-) = increase in growth relative to that of control

* = Mean value statistically significantly lower than in the control (according to Williams t-test, one-sided smaller, α = 0.05)

Mean dry weights are presented below along with the growth rate, yield and respective inhibition values, alongside estimated EC50 values:

Table 10.8.2.1-3: Effect of A19786A on growth rate and yield (dry weight) of *Lemna gibba*

Nominal concentration (mg A19786A/L)	**Mean Dry Weight (mg per test vessel) (day 7)**	**Based on Dry Weight (0-7 days)**			
		Growth Rate (day-1)	**Inhibition of Growth Rate (%)**	**Yield (mg)**	**Inhibition of Yield (%)**
Control	19.9	0.427	0.00	18.9	0.00
0.016	20.8	0.433	-1.41	19.8	-4.76

0.050	21.1	0.435	-1.87	20.1	-6.35
0.16	14.4	0.381*	10.77	13.4*	29.10
0.50	7.4	0.286*	33.02	6.4*	66.14
1.6	5.3	0.238*	44.28	4.3*	77.25
5.0	4.8	0.223*	47.78	3.8*	79.89
EC_{50} mg A19786A/L		3.6		0.40	
95% confidence limits		2.5 – 5.9		0.30 – 0.54	
NOEC (mg A19786A/L)		0.050		0.050	
LOEC (mg A19786A/L)		0.16		0.16	

Inoculum = 1.0 mg dry weight per vessel; the dry weight at the start of the test was determined from a sample of the inoculum culture representative of what was used to begin the test. This value was used for calculation of growth rate and yield.

- = increase in growth relative to that of control

* = Mean value statistically significantly lower than in the control (according to Williams t-test, one-sided smaller, $\alpha = 0.05$)

No abnormalities in appearance of the test plants were recorded in the control and the test concentrations of 0.016 and 0.050 mg A19786A/L. At the concentrations of 0.16 and 0.50 mg A19786A/L, the fronds were smaller. At the concentrations of 1.6 and 5.0 mg A19786A/L, the fronds were smaller and chlorosis was observed.

No mortality of fronds was observed during the test.

Validity Criteria

The validity criterion for the study was fulfilled:

- the doubling time (Td) of frond number in the control must be < 2.5 days (observed: 1.8 days)

Conclusions

For frond number, the 7-day EC_{50} for yield (E_yC_{50}) and growth rate (E_rC_{50}) for A19786A to *Lemna gibba*, were 0.24 and 0.44 mg A19786A/L, respectively, based on nominal concentrations. For dry weight, the 7-day EC_{50} for yield (E_yC_{50}) and growth rate (E_rC_{50}) were 0.40 and 3.6 mg A19786A/L, respectively, based on nominal concentrations.

Based on all parameters, the 7-day NOEC was determined to be 0.050 mg A19786A/L and the 7-day LOEC was determined to be 0.16 mg A19786A/L.

The lowest 7-day EC50 value of 0.24 mg A19786A/L equates to 0.00768 mg pinoxaden/L and 0.00185 mg pyroxsulam/L.

(Liedtke A, 2013)

IIIA 10.8.2.2 Aquatic field testing

REGISTRATION REPORT
Part B

Section 6: Ecotoxicological studies
Detailed summary of the risk assessment

Product code: AVOXA / A19786A
Active Substance: 33.3 g/L pinoxaden
8.33 g/L pyroxsulam
Safener: 8.33 g/L cloquintocet-mexyl

Central Zone
Zonal Rapporteur Member State: Germany

NATIONAL ADDENDUM - Germany

Applicant: Syngenta
Date: Jan. 2018

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Sec 6 ECOTOXICOLOGICAL STUDIES (MIIIA 10)

A full risk assessment according to Uniform Principles for the plant protection product AVOXA / A19786A is documented in detail in the core assessment of the plant protection product AVOXA / A19786A dated from July 2017 performed by zRMS DE.

This national addendum has been produced to support a national decision on a possible authorisation of the product AVOXA / A19786A in Germany for the uses listed below. It reflects the impact of specific German environmental or agricultural circumstances on the risk assessment for AVOXA / A19786A. It must be evaluated by Member States, whether the approaches and conclusions in this national addendum meet the requirements for a risk assessment with regard to their specific environmental or agricultural circumstances.

General information on the formulation AVOXA / A19786A can be found in Table 5.1-1of Section 5 of the National addendum Germany (July 2017).

6.1 Critical GAP and overall conclusion

6.1.1 Overall conclusion

6.1.1.1 *Fehler! Verweisquelle konnte nicht gefunden werden., Fehler! Verweisquelle konnte nicht gefunden werden., Fehler! Verweisquelle konnte nicht gefunden werden.*

Based on tier 1 risk assessment, the calculated TER values for the acute and long-term risk resulting from an exposure of birds and mammals to the active substances pinoxaden and pyroxsulam according to the intended use of the formulation AVOXA / A19786A in cereals achieve the acceptability criteria of TER ≥10 and TER ≥ 5, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for birds and mammals.

6.1.1.2 *Fehler! Verweisquelle konnte nicht gefunden werden.*

Based on the calculated concentrations of AVOXA / A19786A (drift only), pinoxaden and pyroxsulam in surface water (EVA 2.1, EXPOSIT 3.0.1), the calculated TER values for the acute and long-term risk resulting from an exposure of aquatic organisms to AVOXA / A19786A (drift only), pinoxaden and pyroxsulam according to the GAP of the formulation AVOXA / A19786A achieve the acceptability criteria TER ≥ 100 and TER ≥ 10, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. for long-term effects. The results of the assessment indicate an acceptable risk for aquatic organisms due to the intended use of AVOXA / A19786A in cereals according to the label provided that drift reducing technique or buffer strips are applied.

Required Labelling

NW 262	pinoxaden: *S.costatum*, NOErC = 0.52 mg/L mm pyroxsulam: *P. subcapitata* NOE_rC: 0.055 mg/L mm
NW 264	pinoxaden: *D.magna*, EC_{50} (96 h) = 0.40 mg/L A19786A: *O.mykiss*, LC50 = 8.879 mg/L mm, *D.magna* EC50 = 3.78 mg/L mm
NW 265	pinoxaden: *L.gibba*, NOErC = 0.23 mg/L mm pyroxsulam: *L. gibba*, EC_{50} = 0.00257 mg/L mm A19786A: *L.gibba*, E_rC_{50} = 0.1123 (mm)

Conditions for use

NW 605-1/606 NW 468	con. 5 m , 50 % 5 m , 75 % 5 m , 90 % 1 m

6.1.1.3 Fehler! Verweisquelle konnte nicht gefunden werden.

Please refer to the core assessment and the risk assessment outcome as provided by JKI.

6.1.1.4 Fehler! Verweisquelle konnte nicht gefunden werden.

The results of the assessment indicate an acceptable risk for nontarget arthopods (off-field) due to the intended use of AVOXA / A19786A in cereals according to the label.

6.1.1.5 *Fehler! Verweisquelle konnte nicht gefunden werden., Fehler! Verweisquelle konnte nicht gefunden werden.*

Based on the predicted concentrations of AVOXA / A19786A in soils, the TER values describing the acute and longterm risk for earthworms and other non-target soil organisms following exposure to AVOXA / A19786A according to the GAP of the formulation AVOXA / A19786A achieve the acceptability criteria TER ≥ 10 resp. TER ≥ 5 according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for soil organisms due to the intended use of AVOXA / A19786A in cereals according to the label.

6.1.1.6 *Fehler! Verweisquelle konnte nicht gefunden werden.*

Based on the predicted rates of A19786A (AVOXA) in off-field areas and under consideration of risk mitigating measures such as buffer strip and/or drift reducing technique, the TER values describing the risk for non-target plants following exposure to A19786A (AVOXA) according to the GAP of the formulation A19786A (AVOXA) achieve the acceptability criteria TER ≥ 10 resp. ≥ 5 according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for non-target terrestrial plants due to the intended use of A19786A (AVOXA) in cereals according to the label provided that drift reducing technique or buffer strips are applied.

NT 109 90 % + 5m

6.1.2 Grouping of intended uses for risk assessment

Details of the proposed use pattern of the formulation AVOXA / A19786A that will be assessed are presented and summarized in the table below. The intended uses in Germany are generally covered by the core assessment.

The following table lists the grouping of the intended uses in order to perform a risk envelope approach.

Table 6.1-1: Use pattern of AVOXA / A19786A

Group/ use No*	Crop/growth stage	Application method Drift scenario	Number of applications, Minimum application interval, application time, interception	Application rate, cumulative (g as/ha)	Soil effective application rate (g as/ha)
A/ 00-001	winter wheat, winter triticale, winter rye BBCH 10-32	spraying / field crops	1 x, spring (15.02.) 1. 25 %	Pinoxaden 1 x 59.9 Pyroxsulam 1 x 15	Pinoxaden 1 x 45 Pyroxsulam 1 x 11.25

B/ 00-002 **	winter wheat, winter triticale, winter rye BBCH 10-32	spraying / field crops	1 x, spring (15.02.) 1. 25 %	Pinoxaden 1 x 45 Pyroxsulam 1 x 11.3	Pinoxaden 1 x 33.75 Pyroxsulam 1 x 8.5

* For administrative purposes, each intended use of a plant protection product in Germany is assigned with an individual use number from the German Federal Office of Consumer Protection and Food Safety (BVL). A complete list of the individual GAPs in Germany together with their assigned use numbers is given in Appendix 3 of this Addendum.

** please note that in agreement with BVL only use no. 00-001 was assessed in a risk envelope approach

6.1.3 Consideration of metabolites

Please refer to the core assessment.

6.2 Effects on birds (MIIIA 10.1, KCP 10.1, KCP 10.1.1)

For details, please refer to the core assessment.

Dietary risk assessment

Based on the screening assessment step, the calculated TER values for the acute and long-term risk resulting from an exposure of birds to pinoxaden, pyroxsulam and cloquintocet-mexyl (oral exposure and exposure via drinking water and secondary poisoning) according to the GAP of the formulation A19786A (AVOXA) achieve the acceptability criteria TER ≥ 10 resp. TER ≥ 5, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. for acute effects. The results of the assessment indicate an acceptable acute and long-term risk for birds due to the intended use of A19786A (AVOXA) in cereals according to the label.

Risk assessment for exposure via drinking water

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER were necessary for the intended uses of the product A19786A (AVOXA) in cereals. Hence, it can be concluded that the risk for birds due to the intended use of A19786A (AVOXA) in cereals according to the label is acceptable.

Risk assessment for exposure via secondary poisoning

Based on the calculation of the risk arising from secondary poisoning , the calculated TER values for birds exposed to the safener cloquintocet-mexyl according to the GAP of the formulation A19786A (AVOXA) achieve the acceptability criteria TER ≥ 5, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. for long-term effects.

Consequences for authorization:

none

6.3 Effects on Terrestrial Vertebrates Other Than Birds (MIIIA 10.3, KCP 10.1, KCP 10.1.2)

For details, please refer to the core assessment.

Dietary risk assessment

Based on the screening assessment step, the calculated TER values for the acute and long-term risk resulting from an exposure of mammals to pinoxaden, pyroxsulam and cloquintocet-mexyl (oral exposure and exposure via drinking water and secondary poisoning) according to the GAP of the formulation A19786A (AVOXA) achieve the acceptability criteria TER ≥ 10 resp. TER ≥ 5, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. for acute effects. The

results of the assessment indicate an acceptable acute and long-term risk for mammals due to the intended use of A19786A (AVOXA) in cereals according to the label.

Risk assessment for exposure via drinking water

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER were necessary for the intended uses of the product A19786A (AVOXA) in cereals. Hence, it can be concluded that the risk for mammals due to the intended use of A19786A (AVOXA) in cereals according to the label is acceptable.

Risk assessment for exposure via secondary poisoning

Based on the calculation of the risk arising from secondary poisoning , the calculated TER values for mammals exposed to the safener cloquintocet-mexyl according to the GAP of the formulation A19786A (AVOXA) achieve the acceptability criteria TER ≥ 5, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. for long-term effects.

Consequences for authorization:

none

6.4 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

Please refer to the core assessment.

Consequences for authorization:

none

6.5 Effects on aquatic organisms (MIIIA 10.2, KCP 10.2, KCP 10.2.1)

6.5.1 Overview

Results of aquatic risk assessment for the intended for uses of AVOXA / A19786A based on FOCUS Surface Water PEC values are presented in the Core assessment, Part B, Section 6. There, risk mitigation measures are indicated based on FOCUS step 4.

For authorization in Germany, exposure assessment of surface water considers the two routes of entry (i) spraydrift and volatilisation with subsequent deposition and (ii) run-off, drainage separately in order to allow risk mitigation measures separately for each entry route. Hence, aquatic risk assessment differs from the one in the core assessment.

The risk assessment for aquatic organism for authorization of AVOXA / A19786A is outlined in the following chapters.

6.5.2 Toxicity

Please refer to the core assessment.

6.5.3 Justification for new endpoints

Please refer to the core assessment.

6.5.4 Toxicity to exposure ratios for aquatic species (MIIIA 10.2.1)

The evaluation of the risk for aquatic and sediment-dwelling organisms was performed in accordance with the recommendations of the "Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters" (EFSA Journal 2013;11(7):3290).

Mixture toxicity is considered in the core assessment. In summary, most critical is the risk for aquatic higher plants (*Lemna gibba*) based on the toxicity data for the product formulation and the active ingredient pyroxsulam. Based on the presented mixture assessment in the core assessment the endpoint for *Lemna gibba* for pyroxsulam can account for the mixture and it has been shown in the core assessment that not all FOCUS sceanrios pass without consideration of risk mitigation. Since there are some remaining uncertainties regarding the level of protection for primary producers reached by the assessment approach presented in the Aquatic Guidance Document (EFSA 2013) (for details please refer to the CA), for the derivation of risk mitigation measures on national level both, the single substance assessment with pyroxsulam and the product risk assessment with the measured product endpoint, will be considered and as a precaution the lowest TER values will be considered.

6.5.4.1 TER values for the entry into surface water via spraydrift and deposition following volatilization

The calculation of concentrations in surface water is based on spray drift data by Rautmann and Ganzelmeier. Both active substances have a vapour pressure of $< 10^{-5}$ Pa and are therefore classified as non-volatile. Hence, deposition following volatilization has not been considered. The input parameters for active substances are given in Section 5 of the National Addendum (Germany).

Several ecotoxicological endpoints are available to assess the risk of the active substances and the formulation AVOXA / A19786A (see Core Assessment). Data for the safener cloquintocet-mexyl suggest that it is similarly toxic as the active substances, however, many available endpoints are "larger as" values (due to the limited solubility of cloquintocet-mexyl) and thus bear some uncertainties. Also, cloquintocet-mexyl rapidly breaks down to the metabolite CGA 153433 which is less toxic. The quantitative risk assessment is thus based on active substance pyroxsulam and the measured product toxicity which covers for acute effects of cloquintocet-mexyl.

The choice of the relevant scenario is based on the ratio of endpoint to the highest PEC for each active substance and the formulation, related to the relevant TER trigger value.

As already stated within the Core Assessment, there are some uncertainties regarding the level of protection for primary producers reached by the assessment approach presented in the Aquatic Guidance Document (EFSA 2013) (for details please refer to the Core Assessment). Hence Germany considers an interim approach within the national assessment and derives the RAC as follows:

RAC = ErC50 / (AF 10 x EF 3) → ErC50 / 30

→ Consideration of the ErC50 (as stated in the GD) and an assessment factor (AF) of 10 multiplied with an additional extrapolation factor (EF) of 3 to address the potential shift of the protection level in using the ErC50 instead of the lowest endpoint (i.e. usually EbC50 or EyC50).

The consideration of an extrapolation factor of 3 in addition to the AF of 10 does not reflect the same previous protection level as when using the EbC50 or EyC50 and an AF of 10. But this approach is a compromise to cover for the fact that "the EbC50 is consistently lower than the corresponding ErC50 (by a factor of 2.5 and 6.9 in 50 % and 90% of all cases for algae, respectively and by a factor of 1.7 and 3.5 in 50 % and 90% of all cases of Lemna, respectively) (Swarowsky et al., 20151). Therefore, replacing the lowest EC50 by the ErC50 in the risk assessment will reduce the level of protection. Thus the pragmatic decision was drawn to take an overall trigger of 30 (= regular AF of 10 x extrapolation factor of 3).

References:

Martin, S. and Kühnen, U., 2004: Algae and Lemna growth inhibition tests – response variables in the risk assessment. Poster presentation at the SETAC Europe 14th Annual Meeting, 2004

Klaus Swarowsky, Sabine Duquesne, Linda Hönemann, Steffen Matezki, Ute Kühnen, Alf Aagard, Annette Aldrich, Julitta Berchtold, Veronique Poulsen, Peter van Vliet, Virpi Virtanen, Jörn Wogram, 2015: Aquatic primary producers in pesticide risk assessment: endpoints and level of protection. Poster presentation at the SETAC Europe 25th Annual Meeting, 2015

Table 6.5-1: Decision making of the relevant scenario for risk assessment of aquatic organisms based on the lowest ratio of TER to safety factor

Substance	Max. application rate [g/ha]	Drift factor %	Max. PEC (act) [µg/L]	Endpoint, Species, safety factor [µg/L]	TER	TER/SF
Pyroxsulam	15	2.77	0.139	2.57, *Lemna gibba*, 10*	18.6	1.86
A19786A	1800	2.77	16.62	112.3, *Lemna gibba*, 30	6.8	0.23

PEC: predicted environmenral concentration; TER: Toxicity exposure ratio; SF: Safety factor *seemingly the endpoint as listed in the list of endpoint is an EbC50, thus the SF of 10 is kept

Based on the table above, the scenario for the product is relevant and will be considered for risk assessment for the entry path spray drift. For the entry path run-off and drainage, pyroxsulam is the relevant scenario.

Table 6.5-2: Risk assessment for pyroxsulam for aquatic organisms for the entry route via spray-drift and deposition following volatilization under the implementation of different risk mitigation measures

Compound:	A19786A
Crop/Application rate:	winter wheat, winter triticale, winter rye

Growth stage and season			BBCH 10-32					
Intended use group:			A					
DT_{50} water (SFO):			not relevant for single application					
PEC-selection:			actual					
Drift-Percentile:			90. percentile					
Buffer zone	**Entry via spraydrift**		**Entry via deposition following volatilization**		**PECsw; conventional and drift reducing technique**			
					0% conv.	**50% red.**	**75% red.**	**90% red.**
[m]	**[%]**	**[µg/ha]**	**[%]**	**[µg/L]**	**[µg /L]**			
1	2.77%	16.620			16.620	8.310	4.155	1.662
5	0.57%	3.420			3.420	1.710	0.855	0.342
10	0.29%	1.740			1.740	0.870	0.435	0.174
Relevant toxicity endpoint: ErC_{50} = 112.3 µg a.i./L (*L.gibba*) Relevant TER: 30								
Buffer zone [m]					TER			
1					**6.8**	**13.5**	**27.0**	67.6
5					32.8	65.7	131.3	328.4
10					64.5	129.1	258.2	645.4
Risk mitigation measures			NW 605-1/606 (con. 5 m, 50 % 5 m, 75 % 5 m, 90 % 1 m)					

PEC: predicted environmenral concentration; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger.

6.5.4.2 TER values for the entry into surface water via run-off and drainage

The concentration of the active substances pinoxaden and pyroxsulam in adjacent ditch due to surface run-off and drainage is calculated using the model EXPOSIT 3.01. The input parameters for pinoxaden and pyroxsulam for exposure modelling with EXPOSIT 3.01 are given in the German National Addendum Section 5, chapter 5.6.2.

Table 6.5-3: Risk assessment for azoxystrobin for aquatic organisms for the entry route via run-off and drainage under the implementation of different risk mitigation measures

Compound:	pyroxsulam	
Application rate:	1 x 15 g a.s./ha	
Intended use	A , 25 % interception	
Relevant toxicity endpoint:	EC_{50} = 2.57 µg a.s./L (*L. gibba)*	
Relevant TER:	10	
Run-off		
Buffer zone	**PEC**	**TER**
[m]	**[µg/L]**	
0	0.05	47.13
5	0.05	54.38
10	0.04	63.45
20	0.03	90.64

Drainage		
Time of application	**PEC**	**TER**
	[µg/L]	
Autumn/winter/early spring	0.09	28.47
Spring/summer	0.03	87.59
Risk mitigation measures	-	

PEC: predicted environmenral concentration; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger.

6.5.4.3 Consideration of Metabolites

Please refer to the core assessment.

6.5.5 Overall conclusions

Based on the calculated concentrations of AVOXA / A19786A (drift only), pinoxaden and pyroxsulam in surface water (EVA 2.1, EXPOSIT 3.0.1), the calculated TER values for the acute and long-term risk resulting from an exposure of aquatic organisms to AVOXA / A19786A (drift only), pinoxaden and pyroxsulam according to the GAP of the formulation AVOXA / A19786A achieve the acceptability criteria TER ≥ 100 and TER ≥ 10, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. for long-term effects. The results of the assessment indicate an acceptable risk for aquatic organisms due to the intended use of AVOXA / A19786A in cereals according to the label provided that drift reducing technique or buffer strips are applied.

Consequences for authorization:

For the authorization of the plant protection product AVOXA / A19786A following labeling and conditions of use are mandatory:

Required Labelling

NW 262	pinoxaden: *S.costatum*, NOErC = 0.52 mg/L mm pyroxsulam: *P. subcapitata* NOE_rC: 0.055 mg/L mm
NW 264	pinoxaden: *D.magna*, EC_{50} (96 h) = 0.40 mg/L A19786A: *O.mykiss*, LC50 = 8.879 mg/L mm, *D.magna* EC50 = 3.78 mg/L mm
NW 265	pinoxaden: *L.gibba*, NOErC = 0.23 mg/L mm pyroxsulam: *L. gibba*, EC_{50} = 0.00257 mg/L mm A19786A: *L.gibba*, E_rC_{50} = 0.1123 (mm)

Conditions for use

NW 605-1/606 NW 468	con. 5 m , 50 % 5 m , 75 % 5 m , 90 % 1 m

6.6 Effects on bees (MIIIA 10.4, KCP 10.3.1)

Please refer to the core assessment.

Consequences for authorization:

-

6.7 Effects on arthropods other than bees (MIIIA 10.5, KCP 10.3.2)

For details, please refer to the core assessment.

6.7.1 Toxicity

Please refer to the core assessment.

6.7.2 Justification for new endpoints

Please refer to the core assessment.

6.7.3 Risk assessment

The off-field risk is considered acceptable. For details, please refer to the core assessment.

6.7.4 Overall conclusion

The results of the assessment indicate an acceptable risk for nontarget arthopods due to the intended use of AVOXA / A19786A in cereals according to the label.

Consequences for authorization:

none

6.8 Effects on non-target soil meso- and macrofauna (MIIIA 10.6, KCP 10.4, KCP 10.4.1, KCP 10.4.2)

Please refer to the core assessment.

6.8.1 Justification for new endpoints

Please refer to the core assessment.

6.8.2 Toxicity exposure ratios for earthworms and other soil macro- and mesofauna, TER_A and TER_{LT} (MIIIA 10.6.1)

The evaluation of the risk for earthworms and other soil macro-organisms was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

For the calculations of predicted environmental concentrations in soils (PEC soil), reference is made to the environmental fate section (Part B, Section 5) of this submission. The resulting maximum PECsoil values for the active substances and the major soil degradation products are presented in the table below.

For German exposure assessment the applied soil depth is based on experimental data (Fent, Löffler, Kubiak: Ermittlung der Eindringtiefe und Konzentrationsverteilung gesprühter Pflanzenschutzmittelwirkstoffe in den Boden zur Berechnung des PEC-Boden. Abschlussbericht zum Forschungsvorhaben FKZ 360 03 018, UBA, Berlin 1999). Generally for active substances with a $K_{f,oc} < 500$ a soil depth of 2.5 cm is applied whereas for active substances with a $K_{f,oc} > 500$ a soil depth of 1 cm is applied. As soil bulk density 1.5 g $cm^{-3}$is assumed.

For risk assessment purposes, a risk envelope approach was used. Hence, intended uses are grouped according to Table 6.1-1.

The acute risk for earthworms and other non-target soil macro- and mesofauna resulting from an exposure to AVOXA / A19786A, pinoxaden and pyroxsulam as well as the major soil degradation products was assessed by comparing the maximum PEC_{SOIL} with the 14-day LC_{50} value to generate acute TER values. The TER_A was calculated as follows:

$$TER_A = \frac{LC_{50}\ (mg/kg)}{PEC_{soil}\ (mg/kg)}$$

The chronic risk for earthworms, other non-target soil macro- and mesofauna and organic matter breackdown resulting from an exposure to AVOXA / A19786A, pinoxaden and pyroxsulam as well as the major soil degradation products was assessed by comparing the maximum PEC_{SOIL} with the NOEC value to generate chronic TER values. The metabolites of azoxystrobin, that are relevant for soil risk assessment – R234886, R401553 and R402173 – are less toxic than the parent compound and have thus not been included in the quantitative risk assessment for the national addendum.

The TER_{LT} was calculated as follows:

$$TER_{LT} = \frac{NOEC\ (mg/kg)}{PEC_{soil}\ (mg/kg)}$$

The results of the risk assessment are summarized in the following table.

Table 6.8-1: TER values for earthworms and other soil macro- and mesofauna (Tier-1) for the use in oilseed rape (group A and B, reflecting the worst-case in terms of soil relevant application rate for Germany)

Species	**Test item**	**Time scale**	**Endpoint [mg/kg soil dw]**	**Max. PEC_{SOIL} [mg/kg soil dw]**	**TER**
Eisenia fetida	7-OH metabolite of pyroxsulam	chronic	NOEC =0.068 mg/kg soil dw	0.0221	**3.1***

	5-OH metabolite of pyroxsulam	chronic	NOEC = 0.107 mg/kg soil dw	0.0069	15.5
	6-Cl-7-OH metabolite of pyroxsulam	chronic	NOEC = 0.130 mg/kg soil dw	0.0083	15.7
	Pyridine sulfonamide	chronic	NOEC = 0.038 mg/kg soil dw	0.0025	15.2
	A19786A (AVOXA)	chronic	**EC_{10} = 191 mg/kg soil dw** NOEC = 309 mg/kg soil dw EC_{20} = 311 mg/kg soil dw	3.79	50.4
Folsomia candida	7-OH metabolite of pyroxsulam	chronic	NOEC > 0.068 mg/kg soil dw	0.0221	**3.1***
	6-Cl-7-OH metabolite of pyroxsulam	chronic	NOEC = 0.136 mg/kg soil dw	0.0083	16.4
	Pyridine sulfonamide	chronic	NOEC = 0.038 mg/kg soil dw	0.0025	15.2

TER values shown in bold fall below the relevant trigger.

*The available endpoints reflect the highest tested concentration, thus can be considered as ">" values as well as the resulting TER values. Since at the same time no risk is indicated from exposure to the product formulation, the risk is considered acceptable.

6.8.3 Higher tier risk assessment

not needed

6.8.4 Overall conclusions

Based on the predicted concentrations of AVOXA / A19786A in soils, the TER values describing the acute and longterm risk for earthworms and other non-target soil organisms following exposure to AVOXA / A19786A according to the GAP of the formulation AVOXA / A19786A achieve the acceptability criteria TER ≥ 10 resp. TER ≥ 5 according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for soil organisms due to the intended use of AVOXA / A19786A in cereals according to the label.

Consequences for authorization:

none

6.9 Effects on soil microbial activity (MIIIA 10.7, KCP 10.5)

Please refer to the core assessment. The margin of safety has been ≥ 3.9 for all sceanrios and even when considering 2.5 cm as soil depth for the German assessment, this would result in a margin of safety above 1, thus no quantitative national assessment is needed.

6.9.1 Overall conclusions

Based on the predicted concentrations of AVOXA / A19786A and its active substances and relevant metabolites in soils, the risk to soil microbial processes following exposure to AVOXA / A19786A according to the GAP of the formulation AVOXA / A19786A is considered to be acceptable according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2.

Consequences for authorization:

None

6.10 Effects on non-target plants (MIIIA 10.8, KCP 10.6)

6.10.1 Effects on non-target terrestrial plants (MIIIA 10.8.1)

Please refer to the core assessment.

6.10.2 Overall conclusion

The results of the assessment indicate an acceptable risk for non-target terrestrial plants due to the intended use of AVOXA / A19786A in cereals according to the label provided that risk mitigation is implemented.

Consequences for authorization:

NT 109 90 % + 5 m

6.11 Classification and Labelling

6.11.1 GHS Classification and Labelling

Table 6.11-1 Classification and labelling of AVOXA / A19786A

Relevant toxicity/basis for classification	Acute based on measured toxicity data for the formulation: *Oncorhynchus mykiss* LC50 = 8.879 mg/L *Daphnia magna* EC50 = 3.78 mg/L ***Lemna gibba* ErC50 = 0.1123 mg/L, M-facotor: 1** **classified as acute: 1** Chronic based on toxicity data of the a.s.: pyroxsulam (content 0.833 %) *L.gibba NO*EC = 0.000681 mg a.s./L, pinoxaden (content 3.3 %) *L.gibba* NOEC = 0.23 mg/L M-factor: 10 **classified as chronic 1**
Classification and labelling according to Regulation 1272/2008	
Hazard symbol	GHS09
Signal word	Warning

Hazard statement	H400, H410

6.11.2 National labelling and conditions of use (DE)

Labelling requirements according to § 36 (3) PflSchG

NW 262	pinoxaden: *S.costatum*, NOErC = 0.52 mg/L mm pyroxsulam: *P. subcapitata* NOE_rC: 0.055 mg/L mm
NW 264	pinoxaden: *D.magna*, EC_{50} (96 h) = 0.40 mg/L A19786A: *O.mykiss*, LC50 = 8.879 mg/L mm, *D.magna* EC50 = 3.78 mg/L mm
NW 265	pinoxaden: *L.gibba*, NOErC = 0.23 mg/L mm pyroxsulam: *L. gibba*, EC_{50} = 0.00257 mg/L mm A19786A: *L.gibba*, E_rC_{50} = 0.1123 (mm)

Mandatory conditions of use according to § 36 (1) PflSchG (all use groups)

NW 468	Fluids left over from application and their remains, products and their remains, empty containers and packaging, and cleansing and rinsing fluids must not be dumped in water. This also applies to indirect entry via the urban or agrarian drainage system and to rain-water and sewage canals.
NW 605-1/606	con. 5 m , 50 % 5 m , 75 % 5 m , 90 % 1 m
NT 109	90 % 5 m

Appendix 1 Table of Intended Uses in Germany (according to BVL dd.mm.yyyy)

PPP (product name/code)	AVOXA / A19786A	**Formulation type:**	…
active substance 1	…	**Conc. of as 1:**	…
active substance 2	…	**Conc. of as 2:**	…

Please refer to Table 6.1-1: Use pattern of AVOXA / A19786A

REGISTRATION REPORT

Part B

Section 7: Efficacy Data and Information

Detailed Summary

Product Code: AVOXA (A19786A)

Reg. No.: ZV1 008178-00/00

Active Substance: 33.3 g/L pinoxaden,
8.33 g/L pyroxulam,
8.33 g/L cloquintocet-mexyl (safener)

Central Zone

Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Syngenta

Date: January 2014

Evaluator: Julius Kühn-Institut

Date: 2017-11-23

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IIIA1 6 Efficacy Data and Information on the Plant Protection Product

The following data and information was mainly provided by the applicant and was submitted as dRR.
Additional comments and the final evaluation by the zRMS in this Registration Report are marked by green boxes.
Typographical errors have been corrected. Not all appendices mentioned by the applicant are shown. In these cases, the references to the appendices have been deleted.

General information

This document summarises the information related to the efficacy data of the plant protection product A19786A containing pinoxaden, pyroxsulam and cloquintocet-mexyl. Pinoxaden and cloquintocet-mexyl are included in Annex I of Council Directive 91/414/EEC (2012/191/EC and 2006/39/EC respectively). Pyroxsulam is a comparatively new active substance and is currently awaiting inclusion into Annex 1 (dossier complete – 2007/277/EC).
The SANCO/EFSA report for pinoxaden (2039/2008 rev. 1) and cloquintocet-mexyl (10530/2005 rev. 3) are considered to provide the relevant review information or a reference to where such information can be found.
The Annex I Inclusion Directive for pinoxaden and cloquintocet-mexyl provide specific provisions under Part B which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation.
For the implementation of the uniform principles of Annex VI, the conclusions of the review report of pinoxaden and cloquintocet-mexyl, in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 10/04/2012 and 27/01/2006 respectively should be taken into account. Consideration of active substances for Annex 1 inclusion does not include an evaluation of efficacy. Therefore there are no concerns to address arising from the inclusion directive for pinoxaden, pyroxsulam and cloquintocet-mexyl relating to efficacy.
In summary, the data presented in this dossier fully support the label claims for the safe use of A19786A for the control of a range of grassweeds and broadleaf weeds in winter wheat, winter rye and winter triticale. Proposed uses for this product are supplied in Appendix 2, but can be summarised as follows:

- Spring use in winter wheat/rye/triticale from BBCH 10-32
- Use rate of 1.35L/ha A19786A for Apera control only
- 1.8 L/ha A19786A for control of Apera, Alopecurus, Avena, Bromus, Lolium and dicots^

The following table shows the list of Member States where a registration of A19786A is intended:

zRMS	Germany	DE	maritime EPPO zone
cMS	Belgium	BE	maritime EPPO zone
	Austria	AT	
	Czech Republic	CZ	
	Luxemburg	LU	
	Netherlands	NL	
	Poland	PL	north-eastern EPPO zone
	Slowakei	SK	south-eastern EPPO zone

A master label is missing.

Recent registration situation/history of the PPP

In Germany, there is currently no registration for a herbicide including both pinoxaden and pyroxulam. However, both active substances are included in other herbicides alone or in other combinations. Information on other countries has not been submitted by the applicant.

Description of the plant protection product

A19786A is an emulsifiable concentrate (EC) containing 33.3 g/L pinoxaden, 8.33 g/L pyroxsulam and 8.33 g/L of the herbicide safener cloquintocet-mexyl for use in winter wheat, winter rye and winter triticale for the control of annual grass and broadleaf weeds in spring.

A number:	**A19786A**
A.S. content:	33.3 g/l Pinoxaden; 8.33 g/l Pyroxsulam; 8.33 g/l Cloquintocet-mexyl
Formulation type:	Emulsifiable Concentrate (EC)
Synonyms:	SYD 11740 H
Active Substance Nr.: 1	Pinoxaden
IUPAC name:	2,2dimethyl-propionic acid 8-(2,6-diethyl-4-methyl-phenyl)-9-oxo-1,2,4,5-tetrahydro-9H-pyrazolo[1,2-d][1,4,5]oxodiazepin-7-yl ester
Chemical group:	Phenylpyrazolin
Mode of action:	Inhibition of ACCase (Acetyl-coenzyme A carboxylase) preventing efficient synthesis of fatty acids
Plant translocation:	Systemic, taken up by the leaves, translocated to meristematic tissue
Biological action:	Foliar
Active Substance Nr.: 2	Pyroxsulam (syn.: triflosulam; 'DE-742')
IUPAC name:	N-(5,7-dimethoxy[1,2,4]triazolo[1,5-a]pyrimidin-2-yl)-2-methoxy-4-(trifluoromethyl)pyridine-3-sulfonamide
Chemical group:	Triazolopyrimidine sulfonamide
Mode of action:	Inhibition of ALS (Amino-lactate synthase) preventing efficient synthesis of branch chain amino acids
Plant translocation:	Systemic, taken up by the leaves, translocated to meristematic tissue
Biological action:	Foliar
Active Substance Nr.: 3	Cloquintocet-Mexyl (crop safener)
IUPAC name:	(5-chloro-quinolin-8-yloxy)-acetic acid 1-methyl-hexyl ester
Chemical group:	Quinoline derivate
Mode of action:	Induces crop specific metabolic enzymes accelerating herbicide detoxification
Plant translocation:	Systemic, taken up by the leaves, translocated to meristematic tissue
Biological action:	Foliar

Information on the active ingredients (Uptake and mode of action)

Pinoxaden is a representative of the phenylpyrazolin class of chemistry. Pinoxaden is a post emergent herbicide and is taken up by the leaves, almost exclusively. The active ingredient is rapidly degraded in soil and poorly taken up by the roots, thus providing very little soil activity. After foliar absorption, pinoxaden is translocated to the meristematic tissue, where it exerts its action on the lipid synthesis in dividing cells. The mode of action is the inhibition of the enzyme Acetyl Co-A Carboxylase (ACCase), a key enzyme in fatty acid biosynthesis. ACCase activity in plants can be attributed to two different enzymes. The chloroplastic enzyme is responsible for the "de novo" fatty acid biosynthesis, and the cytosolic ACCase, responsible for the elongation of VLFA (very long chain fatty acids). Its product, the cytosolic malonyl-CoA is involved in anthocyan biosynthesis. One of the properties of the existing herbicides (aryloxyphenoxypropionates and cyclohexanediones - fop's and dim's) is their specific inhibition of the chloroplastic ACCase in monocotyledonous plants only. Pinoxaden inhibits both the chloroplastic and cytosolic ACCase enzyme in monocotyledonous weeds. ACCase activity in dicotyledonous species is stated as not affected. There is also evidence from biochemical studies and metabolite profiling that pinoxaden has a different molecular binding site on the chloroplastic ACCase enzymethan the "fop" herbicides such as clodinafop. It is claimed that this is supported by the resistance profile of pinoxaden on certain target site resistant *Lolium* biotypes, which is different to clodinafop.

Crop tolerance within monocotyledonous species is based on different metabolic kinetics. Tolerant crops like wheat, triticale and rye can metabolize the herbicide faster than susceptible monocotyledonous weeds. This tolerance however, is typically insufficient to provide an agronomically adequate margin of crop safety. Co-application of the safener (cloquintocet-mexyl) induces metabolic enzymes specifically in the crop species resulting in degradation of the herbicide to non-phytotoxic compounds before damage can occur to the crop. The safener does not affect metabolism in monocotyledonous weeds. In plants, pinoxaden is rapidly hydrolysed to the main metabolite NOA 407854 (8– (2,6-diethyl–4-methyl-phenyl) -tetrahydro- pyrazolo [1,2-d][1,4,5] oxadiazepine-7,9-dione)). The metabolite is metabolized to SYN 505164 (8-(2,6-diethyl-4-hydroxymethylphenyl) tetrahydro pyrazolo [1,2-d] [1,4,5] oxadiazepine-7,9-dione). SYN 505164 is the main metabolite of pinoxaden 7 to 14 days after application. The additional degradation takes place over three primary routes: 1. Conjugation with glucose; 2. Oxidation; 3. Hydroxylation to metabolite SYN 505887 (8-(2,6-diethyl-4-hydroxymethylphenyl)-8-hydroxy-tetrahydro pyrazolo-1,2-d). Site of action (HRAC-group): A

Pyroxsulam belongs to the chemical group of triazolopyrimidines. Activity is primarily foliar/systemic, although some residuality is a feature of pyroxsulam and some other ALS inhibitor herbicides. Pyroxsulam is taken up by roots or by foliage and redistributes throughout the plant. Pyroxsulam is a systemic, phloem and xylem mobile herbicide. The compound is translocated in plants to meristematic tissue. Pyroxsulam inhibits amino-lactate synthase (ALS-inhibitor), thereby blocking the formation of branch chain amino acids in plants. Pyroxsulam affects the formation of protein and the plants die. Symptoms include stunting and chlorosis, followed by necrosis and then plant death. Selectivity in wheat, rye and triticale is achieved through detoxification via cytochrome P450 mono-oxygenases, a process which is accelerated by the addition of a herbicide safener acting on the cytochrome complex; for example, cloquintocet mexyl. Site of action (HRAC-group): B

Cloquintocet-mexyl is a safener. Cloquintocet-mexyl is used as a safener in conjunction with the herbicide for post-emergence use. It acts as an agonist of cytochrome P450 and accelerates the detoxification in responsive plants (e.g. cereals, rice, maize) of all compounds that are metabolically vulnerable to cytochrome P450s. Site of action (HRAC-group): no classification

Information on crops and pests

Table 6-1: Importance of intended pest/crop in Germany

Pest/Crop	EPPO	Country	Classification	
Pest				
Alopecurus myosuroides	ALOMY	Germany		major
Apera spica-venti	APESV	Germany		major
Bromus species	BROSS	Germany		major
Lolium species	LOLSS	Germany		major
Annual dicotyledonous weeds	TTTDS	Germany		major
Crop				
Winter soft wheat	TRZAW	Germany		major
winter triticale	TTLWI	Germany		major
winter rye	SECCW	Germany		major

Information on the intended uses for Germany

The data concerning minimum effective dose provided by the applicant clearly demonstrate that the intended dose of 1.8 L/ha is only needed for controlling ALOMY, BROSS and GALAP. Other target species will be effectively controlled by only 1.35 L/ha. Thus, JKI suggested to register a second use with this lower dose which was implemented and accepted by the applicant.

Date: 2017-10-25	Product: AVOXA
Use No.	008178-00/00-001
Field of use	Agriculture (field crops)
Crop(s)/object(s)	winter soft wheat (TRZAW), winter triticale (TTLWI), winter rye (SECCW)
Crop stage(s) (BBCH)	10 to 32
Pest(s)/target(s)	*Alopecurus myosuroides* (ALOMY), *Bromus* sp. (BROSS), *Galium aparine* (GALAP)
Area of application	Outdoors
Timing of application	After emergence, spring
Max. number of treatments for the use	1
Max. number of treatments per crop or season	1
Application method/kind of treatment	spraying
Application rate(s)	1.8 L/ha in 200 to 400 L water/ha
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Use No.	008178-00/00-002
Field of use	Agriculture (field crops)
Crop(s)/object(s)	winter soft wheat (TRZAW), winter triticale (TTLWI), winter rye (SECCW)
Crop stage(s) (BBCH)	10 to 32
Pest(s)/target(s)	*Apera spica-venti* (APESV), *Lolium* species (LOLSS), annual di-

	cotyledonous weeds (TTTDS)
Area of application	Outdoors
Timing of application	After emergence, spring
Max. number of treatments for the use	1
Max. number of treatments per crop or season	1
Application method/kind of treatment	spraying
Application rate(s)	1.35 L/ha in 200 to 400 L water/ha
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Supporting information from earlier formulations of the active substance or similar active substances

The final variant A19786A is submitted for registration under regulation (EC) no. 1107/2009. A previous formulation (A18921A) was evaluated in trials during 2011 but failed subsequent formulation stability tests. A19786A was therefore tested to compare it to the previous formulation A18921A in a field trial programme in 2012. The change in the formulation is considered to be a major change. The comparison data for the efficacy and selectivity of the previous formulation to the final formulation is presented under Point IIIA 6.1.1. Information on the detailed composition of A19876A can be found in the confidential dossier of this submission (Registration Report - Part C).

In table 6-1 the two formulations are shown. As it can clearly be seen, the amount of the active ingredients per hectare against the different targets has not changed. Due to a different ratio of the active substances and a higher amount of the solvent in the final formulation, only the proposed rates of the products are different.

Table 6-1: Presentation of the proposed rates and the active ingredients per hectare of the two formulations

	Final formulation A19786A		**A18921A**	
Targets	L/ha	g a.s./ha	L/ha	g a.s./ha
Grasses and broadleaved weed	1.8	60 g Pinoxaden, 15 g Pyroxsulam, 15 g Cloquintocet-mexyl	1.33	60 g Pinoxaden, 15 g Pyroxsulam, 15 g Cloquintocet-mexyl

After the presentation of the comparison results in Point IIIA 6.1.1, all results of A18921A from 2011 will be classified under the final formulation A19786A. This simplifies the presentation of the 2 year results and eliminates confusion.

IIIA1 6.1 Efficacy data

Trials in this dossier were carried out by Syngenta organisations, contractor companies and official research institutes, all of which follow the EPPO standards and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP).

On the basis of the EPPO standard 1/241 (1) "Guidance on comparable climates", the trials included in this dossier have been grouped and summarized in different ways but the basis for

the grouping was done by the climatic EPPO zones. EPPO zones have been defined by taking into account differences between the agro-climatic sub-areas of the EPPO region.

Country	EPPO zone	Regulatory Zone
DK, SE	MARITIME	NORTHERN
AT, BE, CZ, DE, GB, NL	MARITIME	CENTRAL
PL	NORTH EAST	CENTRAL

The Central Regulatory zone covers different countries in the maritime, south-eastern and north-eastern EPPO climatic zones as described in EPPO PP1 / 241 (1).
This zonal submission is intended for a registration in Austria, Belgium, Czech Republic, Germany, Netherlands, Luxembourg, Poland, Slovakia and Switzerland; hence it includes data from the maritime and north-eastern EPPO zone only.

IIIA1 6.1.1 Preliminary range-finding tests

Components justification
The focus at first lies in the consideration of the components justification against *Alopecurus myosuroides* and *Lolium* spp*.* at the maximum rate of A19786A. Secondly, the reduced application rate (75%) for *Apera spica-venti* and *Avena* spp*.* The reduced rates are used here because the individual active ingredients have a sufficient effect under normal circumstances and additionally these rates reflects more the registrations of the single active substances in the different countries. A justification for A19786A against broadleaf weeds makes no sense at this point because pinoxaden has no activity against dicotyledonous weeds and the entire performance is based on the active ingredient pyroxsulam. Due to the broad activity against grasses of both components it is more important to show this benefit of the ready-mix of pinoxaden and pyroxsulam in A19786A (previously A18921A). However, it should be pointed out that there are two active ingredients in A19786A with different modes of action (MOA) combined in this product. This is also a clear benefit in terms of a prevention of resistance in grass weeds.

Comparison of the formulations
This section shows that the original and final field formulations are identical and can be considered as equivalent in efficacy and crop safety. The means presented in this part cover all countries together where a registration is sought and no further subdivision is made.

Efficacy comparison of the formulations
Due to the change of the formulation, 56 bridging trials were conducted in Austria (3), Estonia (1), France (20), Germany (23), Lithuania (1), Latvia (1), the Netherlands (2) and Poland (5), in order to determine the comparability of the two variants to enable the data from both to be combined.
For this objective there were specific efficacy protocols initiated in spring 2012. Two trial protocols cover the maximum application rate of 1.8 L/ha A19786A, which is required for grasses and annual broadleaf weeds. Two further protocols cover 75% of the maximum application rate (1.35 L/ha). The approach with a reduced application rate was chosen in order to better identify any differences and reflect that the maximum dose is not needed on all species.
The focus for the comparison data set is on major targets (e.g. *Alopecurus myosuroides*, *Lolium* spp*., Apera spica-venti, Avena fatua, Galium aparine, Matricaria* spp*., Viola arvensis* and *Veronica* spp*.* etc.) which are controlled by the product or where the data set is large enough for an adequate evaluation.
The summary table below makes a direct comparison between the two formulations against each species. Data are shown for both the maximum application rate of A18921A vs. A19786A (1.33 L/ha vs. 1.8 L/ha) followed by the reduced application rates of A18921A vs. A19786A (1.0

L/ha vs. 1.35 L/ha) across all EPPO zones. A specific discussion of the results in direct comparison to a commercial standard will take place in the efficacy part of this dossier (IIIA 6.1.3) - this section here is purely to show the two variants are comparable with each other.

Table 6.1.1-1: Summary of the comparison of the previous (A18921A) and the final (A19786A) formulation against the major grasses and broadleaf weeds at the maximum and reduced rates, respectively [% weed control].

Weed (Number of data)	**A18921A**			**A19786A**		
	1.33 L/ha			**1.8 L/ha**		
	MEAN	**MEDI-AN**	**SD**	**MEAN**	**MEDI-AN**	**SD**
Alopecurus myosuroides (28)	**89.0**	94.2	13.1	**88.1**	95.9	14.9
Lolium spp. (17)	**94.2**	97.7	9.8	**94.8**	98.7	11.1
Galium aparine (10)	**89.2**	90.8	9.4	**88.2**	87.4	11.0
Matricaria spp. (8)	**78.9**	97.2	33.7	**82.8**	85.7	17.1
Viola arvensis (18)	**82.5**	92.5	22.4	**81.2**	93.7	28.1
Veronica spp. (16)	**72.9**	80.8	30.7	**69.1**	73.3	29.6

Weed (Number of trials)	**A18921A**			**A19786A**		
	1.0 L/ha			**1.35 L/ha**		
	MEAN	**MEDI-AN**	**SD**	**MEAN**	**MEDI-AN**	**SD**
Apera spica-venti (31)	**99.1**	100.0	3.0	**99.0**	100.0	3.5
Avena spp. (7)	**83.2**	96.0	24.1	**93.8**	98.3	8.0
Capsella bursa-pastoris (11)	**85.9**	92.3	15.8	**81.6**	91.7	28.2
Galium aparine (16)	**79.6**	86.7	23.7	**86.7**	88.3	9.4
Matricaria spp. (23)	**83.6**	88.3	19.7	**82.3**	88.3	17.0
Stellaria media (10)	**83.5**	99.0	24.2	**82.6**	95.7	24.5
Viola arvensis (22)	**80.6**	90.3	24.4	**81.3**	91.7	22.3

The results of the comparison show clearly that the formulations are equal. In the majority of the results there are no significant differences between the formulations. The only exception is *Matricaria spp.* but the individual data shows that sometimes the previous and sometimes the final formulation has achieved better results. Broadly these results can be also referred to as equal.

Selectivity comparison of the formulations

Due to the change of the formulations, 27 bridging trials were conducted in Estonia (1), France (7), Germany (8), Latvia (3), Lithuania (2), the Netherlands (1), Poland (2) and Switzerland (3), in order to determine the comparability of the two variants.

For this objective, selectivity trials were initiated in spring 2012. The trial protocol covers the single (maximum) and the double rate of both formulations. The double rate (“2N”) was applied as two immediate sequential applications of the single ('N') rate to accurately simulate a double overlap situation.

The selectivity was tested under a range of environmental conditions in the different climatic zones to fully challenge the formulations. In the summary table below, a comparison of the formulations is made. A specific discussion of the results in direct comparison to a commercial standard will take place in the adverse effects part of this dossier (Annex Point IIIA 6.2.1).

The following summary table shows:

- First and last (i.e. early and late) 'General Phyto' data from selectivity trials
- Yield data from selectivity trials
- First and last (i.e. early and late) 'General Phyto' data from efficacy trials
- Overview of all trials to show equivalency

Table 6.1.1-2: Summary of the phytotoxicity and yield of the previous (A18921A) and the final (A19786A) formulation [% phytotoxicity].

"General Phytotoxicity" in selectivity trials	**Product**	**Check**	**A18921A**	**A18921A**	**A19786A**	**A19786A**
	Rate	untreated	1.33 L/ha	2.66 L/ha	1.8 L/ha	3.6 L/ha
first assessment (n= 25)	**MEAN**	0.0	4.3	6.6	4.5	6.4
	MEDIAN	0.0	1.0	4.3	2.3	4.0
	SD	0.0	6.0	6.6	5.5	6.1
"General Phytotoxicity" in selectivity trials	**Product**	**Check**	**A18921A**	**A18921A**	**A19786A**	**A19786A**
	Rate	untreated	1.33 L/ha	2.66 L/ha	1.8 L/ha	3.6 L/ha
last assessment (n= 27)	**MEAN**	0.0	0.4	0.7	0.5	0.9
	MEDIAN	0.0	0.0	0.0	0.0	0.0
	SD	0.0	1.0	1.1	1.1	1.9
"Yield" in selectivity trials	**Product**	**Check**	**A18921A**	**A18921A**	**A19786A**	**A19786A**
	Rate	untreated	1.33 L/ha	2.66 L/ha	1.8 L/ha	3.6 L/ha
dt/ha (n= 27)	**MEAN**	75.7	74.6	73.7	75.1	74.2
	MEDIAN	77.9	77.6	74.6	76.6	75.7
	SD	22.8	21.5	21.4	21.3	21.4

"General Phytotoxicity" in efficacy trials	**Product**	**Check**	**A18921A**	**A18921A**	**A19786A**	**A19786A**
	Rate	untreated	1.33 L/ha	1.0 L/ha	1.8 L/ha	1.35 L/ha
first assessment (n= 78)	**MEAN**	0.0	6.1	2.2	6.4	2.1
	MEDIAN	0.0	0.0	0.0	0.0	0.0
	SD	0.0	10.7	4.7	11.4	4.6

"General Phytotoxicity" in efficacy trials	Product	Check	A18921A	A18921A	A19786A	A19786A
	Rate	untreated	1.33 L/ha	1.0 L/ha	1.8 L/ha	1.35 L/ha
last assessment (n= 82)	**MEAN**	0.0	0.6	0.1	0.8	0.1
	MEDIAN	0.0	0.0	0.0	0.0	0.0
	SD	0.0	3.1	0.7	3.8	0.7

All shown parameters indicated very clearly that the formulations performed identically in terms of phytotoxicity and yield. Due to this, all results of A18921A from 2011 will be classified under the final formulation A19786A.

Conclusion – comparison of formulations
The submitted bridging studies show that efficacy and selectivity of both formulations A18921A and A19786A are comparable.

IIIA1 6.1.2 Minimum effective dose tests

Field trials were established in order to determine the minimum effective dose for the control of key grass and broadleaf weeds claimed in this dossier. In order to fulfil this, a large series of trials were established across the maritime and the north-eastern EPPO climatic zones over two seasons (2010/2011 and 2011/2012), conducted at mixed grass and broadleaf weed sites in winter wheat, winter rye and winter triticale. As grasses and broadleaf weeds often occur as complexes, the data will show that A19786A should be used at 1.8 L/ha, although certain weed species occurring in isolation may be controlled with lower rates, particularly *Apera spica-venti* (APESV) and *Avena fatua* (AVEFA).
A19786A was tested at 0.9 L/ha, 1.35 and 1.8 L/ha and these ranges reflect 50%, 75% and 100% of the full recommended rate, in accordance with the EPPO standard PP 1/225 (2) “Minimum effective dose.” For *Apera spica-venti* (APESV) and *Avena fatua* (AVEFA) certain lower doses were also included to have a look at the effect of a reduced dose response because the activity from both active ingredients (pyroxsulam and pinoxaden) can be strong by themselves. All doses are selected on the basis of efficacy, performance, product safety parameters and environmental limitations. Efficacy is tested under a range of environmental conditions to fully challenge the product.
A total of 54 efficacy trials were selected to demonstrate the minimum effective dose of A19786A for the submission in the maritime EPPO zone. The basis for the selected trials was the number of available data points for each weed (> 4 are required for an adequate evaluation) and a general effect (>70% at the full rate) of A19786A. In order to evaluate an adequate number of weeds, trials from the maritime climate zone (n=42) were used. In addition, 12 trials were used from Poland. These trials or locations should support the results and have been consistently involved in the evaluation in this section.

In the following table, the results of *Alopecurus myosuroides* (14), *Lolium* spp. (10), *Bromus spp.* (5), *Apera spica-venti* (19), *Avena* spp. (5), *Galium aparine* (11), *Matricaria* spp. (11), *Veronica* spp. (16) and *Viola arvensis* (15) are presented.

Table 6.1.2-1: Overall summary of the "Minimum effective dose" of A19786A against major grasses and broadleaf weeds [% weed control].

Weed species	EPPO zone	No. of	A19786A	A19786A	A19786A

		trials	0.9 L/ha			1.35 L/ha			1.8 L/ha		
			MEAN	MEDIAN	SD	MEAN	MEDIAN	SD	MEAN	MEDIAN	SD
Alopecurus myosuroides	Maritime	12	77.4	82.5	15.6	86.8	92.5	13.7	88.5	95.2	15.3
	North-East	2	65.8	-	-	75.8	-	-	86.3	-	-
	Overall	**14**	**75.8**	**80.8**	**14.9**	**85.3**	**91.2**	**13.4**	**88.2**	**94.8**	**14.1**
Lolium spp.	Maritime	5	86.4	95.7	23.4	87.7	97.7	24.2	90.5	99.0	19.7
	North-East	5	92.4	91.7	6.1	97.7	98.3	3.2	96.3	99.3	4.7
	Overall	**10**	**89.4**	**93.7**	**16.4**	**92.7**	**98.0**	**17.1**	**93.4**	**99.2**	**13.8**
Bromus spp.*	Maritime	4	67.5	70.0	18.1	82.6	90.5	21.0	84.0	87.5	16.3
	North-East	1	90.0	-	-	95.0	-	-	100.0	-	-
	Overall	**5**	**72.0**	**73.3**	**18.6**	**85.1**	**92.7**	**19.0**	**87.2**	**91.7**	**15.8**
Galium aparine	Maritime	7	77.5	78.3	15.5	83.2	86.7	15.1	85.0	90.0	19.5
	North-East	4	85.3	84.7	4.3	87.6	87.7	2.5	89.9	90.5	1.8
	Overall	**11**	**80.3**	**84.3**	**12.8**	**84.8**	**86.7**	**12.0**	**86.8**	**90.0**	**15.3**
Matricaria spp.	Maritime	8	71.7	70.7	19.7	83.4	84.2	12.8	85.4	90.0	14.9
	North-East	3	84.4	83.3	5.1	92.0	100.0	13.9	91.1	95.0	11.3
	Overall	**11**	**75.2**	**80.0**	**17.7**	**85.8**	**90.0**	**13.0**	**86.9**	**90.0**	**13.7**
Veronica spp.	Maritime	9	71.8	81.0	24.2	71.5	78.3	26.5	77.5	78.3	24.8
	North-East	7	80.0	87.0	11.8	83.0	89.0	11.4	84.9	86.7	6.1
	Overall	**16**	**75.4**	**81.3**	**19.6**	**76.5**	**85.8**	**21.5**	**80.7**	**85.8**	**18.9**
Viola arvensis	Maritime	6	65.1	84.7	40.5	73.6	94.3	38.0	75.8	92.7	37.0
	North-East	9	83.6	85.0	7.0	90.6	88.3	5.6	91.3	90.0	3.8
	Overall	**15**	**76.2**	**85.0**	**26.5**	**83.8**	**90.0**	**24.7**	**85.1**	**90.0**	**23.6**
Apera spica-venti	Maritime	17	95.8	99.0	9.7	97.6	99.7	6.2	98.8	100.0	3.0
	North-East	2	100.0	-	-	100.0	-	-	100.0	-	-
	Overall	**19**	**96.2**	**100.0**	**9.3**	**97.8**	**99.7**	**5.8**	**98.9**	**100.0**	**2.8**
Avena spp.	Maritime	3	87.8	86.3	5.0	98.4	99.3	2.2	99.4	99.7	0.8
	North-East	2	100.0	-	-	100.0	-	-	100.0	-	-
	Overall	**5**	**92.7**	**93.3**	**7.6**	**99.0**	**100.0**	**1.8**	**99.6**	**100.0**	**0.7**

Conclusion – minimum effective dose

Data have been provided mainly from the maritime EPPO zone and additionally from the north-eastern zone. However, no trials have been conducted in the south-eastern EPPO zone.

The results show that most of the relevant weed species will be sufficiently controlled by the reduced dose of 1.35 L/ha. Even the mean efficacy against *Alopecurus myosuroides* is similar for the reduced and the intended dose (86.8% vs. 88.5%). The same is true for the median values (92.5% vs. 95.2%). Furthermore, the standard deviation was not affected by the herbicide dose. Consequently, based on the given data a final decision on the registered dose is not possible.

The applicant comments this as follows: “The concerned Member States should make their own decision if they think it is appropriate to label only the top dose of 1.8 L/ha to cover any grass

and broadleaved weed, or differentiate the label by adding a lower rate of 1.35 L/ha for *Apera* and some dicot control."
It is suggested for all Member States (including Germany) to split the intended use into two uses with different doses and target weeds. The use includes the target species *Alopecurus myosuroides* (ALOMY), *Bromus* spp. (BROSS), *Apera spica-venti* (APESV), *Lolium* sp. (LOLSS), annual dicotyledonous weeds (TTTDS) by using 1.8 L/ha. The minimum effective dose data do not demonstrate that - except for *Alopecurus myosuroides, Bromus* spp. and *Galium aparine* the intended dose of 1.8 L/ha is really necessary for a sufficient weed control.
It is recommended that this fact should be expressed by two different uses.
The first use should includes the target species *Alopecurus myosuroides* (ALOMY), *Bromus* spp. (BROSS) and *Galium aparine* (GALAP) by using 1.8 L/ha.
The second use should include *Apera spica-venti* (APESV), but also *Lolium* sp. (LOLSS) and annual dicotyledonous weeds (TTTDS) by using 1.35 L/ha.
For more details please see IIIA1 6.1.3.

IIIA1 6.1.3 Efficacy tests

Trials in this dossier were carried out by Syngenta organisations, contractor companies and official research institutes, all of which follow the EPPO standards and are officially recognized by the relevant authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP).
For the submission of the dossier in the maritime zone all usable trials from Austria, Belgium, the Czech Republic, Denmark, Germany, the Netherlands, Sweden, Switzerland and the United Kingdom (maritime climatic zone) which were conducted in 2011 and 2012 are used. As in Section 6.1.2 additional trials from Poland are also included in the efficacy part of this dossier. These additional trials are from the Regulatory zone Central and from the north-eastern climatic zone and are therefore permissible. These trials are consistently used in the analysis for the submission.

Table 6.1.3-1: Summary of all efficacy trials conducted in 2011 and 2012 for submission in the Central Registration zone, split by country and crop

Crop	AT	BE	CZ	DK	DE	NL	SE	CH	UK	PL (N-E)
Winter wheat	3	2	2*	3	37*	2	2	1	5	15
Winter rye	1	0	0	0	3	0	0	0	0	1
Winter triticale	0	0	0	0	4	0	0	0	0	2

* one in spring wheat

Efficacy data for the grass and broadleaf weeds claimed on the A19786A label are presented from 83 efficacy trials assessed where the pest severity met the required threshold (i.e. 5 plants per square metre or 2% ground cover). These trials were carried out in the 2010/2011 and 2011/2012 seasons in Austria, Belgium, the Czech Republic, Denmark, Germany, the Netherlands, Sweden, Switzerland and the United Kingdom on mixed (in most of the cases because of the natural infestation) grass and broadleaf weed sites.
Table 6.1.3-2 shows the mean % visual control data for 1.8 L/ha against each weed species where control from A19786A is claimed in winter wheat, winter rye and winter triticale. Atlantis at 0.4 kg/ha is the principal registered standard used throughout these trial series.

Table 6.1.3-2: Overall summary of A19786A at 1.8 L/ha against grasses and broadleaf weeds [% weed control].

Weed species	EPPO zone	No. of trials	A19786A	Atlantis + Adjuvant

			1.8 L/ha			0.4 kg/ha + 0.5% v/v		
			MEAN	**MEDIAN**	**SD**	**MEAN**	**MEDIAN**	**SD**
Alopecurus myosuroides	Maritime	26	91.1	95.7	11.7	90.0	93.8	9.7
	North-East	5	83.4	85.0	5.2	86.0	86.7	2.8
	Overall	**31**	**89.8**	**94.7**	**11.3**	**89.3**	**88.3**	**9.0**
Bromus spp. *	Maritime	7	82.8	83.3	15.8	56.5	46.7	26.8
	North-East	1	100.0	-	-	90.0	-	-
	Overall	**8**	**85.0**	**87.5**	**15.8**	**60.7**	**55.0**	**27.5**
Lolium spp.	Maritime	7	92.0	99.0	16.5	93.7	99.3	14.7
	North-East	6	96.9	99.7	4.5	88.5	87.1	6.3
	Overall	**13**	**94.3**	**99.3**	**12.3**	**91.3**	**97.3**	**11.5**
Capsella bursa-pastoris	Maritime	2	95.0	-	-	96.3	-	-
	North-East	4	91.0	90.8	1.9	83.2	90.7	13.8
	Overall	**6**	**92.3**	**90.8**	**4.1**	**88.5**	**91.7**	**12.4**
Galium aparine	Maritime	12	89.1	88.8	10.0	66.1	60.0	29.2
	North-East	7	89.0	90.0	2.0	84.7	87.8	8.7
	Overall	**19**	**89.1**	**90.0**	**7.9**	**72.7**	**85.3**	**25.3**
Lamium purpureum	Maritime	2	93.3	-	-	90.0	-	-
	North-East	3	90.2	91.7	4.0	92.8	92.3	3.7
	Overall	**5**	**91.5**	**91.7**	**5.0**	**91.7**	**92.3**	**7.7**
Matricaria spp.	Maritime	11	87.1	90.0	13.3	95.9	98.0	6.1
	North-East	5	91.7	95.0	9.3	88.5	88.3	12.3
	Overall	**16**	**88.5**	**91.5**	**12.1**	**93.5**	**98.0**	**8.9**
Papaver rhoeas	Maritime	5	64.0	76.7	19.7	90.7	92.7	9.8
	North-East	2	77.2	-	-	99.3	-	-
	Overall	**7**	**70.2**	**76.7**	**19.4**	**91.6**	**92.7**	**7.1**
Polygonum spp.	Maritime	4	90.8	95.0	12.6	40.0	10.0	52.0
	North-East	4	88.2	88.0	2.9	83.5	88.3	12.6
	Overall	**8**	**89.5**	**89.7**	**8.6**	**64.9**	**86.7**	**39.0**
Stellaria media	Maritime	5	95.0	96.7	7.6	96.3	100.0	7.3
	North-East	5	89.8	90.0	2.5	82.9	88.8	13.9
	Overall	**10**	**92.4**	**91.7**	**6.0**	**90.3**	**91.7**	**12.2**
Veronica spp.	Maritime	14	79.8	81.7	21.2	49.9	55.5	25.6
	North-East	10	84.2	87.5	6.8	70.5	81.3	24.1
	Overall	**24**	**81.7**	**85.8**	**16.6**	**58.9**	**61.7**	**26.5**
Viola arvensis	Maritime	8	90.8	98.2	13.3	61.6	62.5	30.5
	North-East	13	91.6	90.0	3.5	82.7	85.0	11.4
	Overall	**21**	**91.3**	**91.7**	**8.3**	**74.7**	**84.3**	**22.7**
Anthemis arvensis	Maritime	1	100.0	-	-	100.0	-	-
	North-East	2	90.2	-	-	78.0	-	-

Weed species	EPPO zone	No. of trials	A19786A			Atlantis + Adjuvant		
			1.8 L/ha			0.4 kg/ha + 0.5% v/v		
			MEAN	MEDIAN	SD	MEAN	MEDIAN	SD
	Overall	**3**	**93.4**	**-**	**-**	**85.3**	**-**	**-**
Centaurea cyanus	Maritime	2	70.0	-	-	65.3	-	-
	North-East	-	-	-	-	-	-	-
	Overall	**2**	**70.0**	**-**	**-**	**65.3**	**-**	**-**
Geranium pusillum	Maritime	1	81.0	-	-	67.3	-	-
	North-East	1	93.3	-	-	96.7	-	-
	Overall	**2**	**87.2**	**-**	**-**	**82.0**	**-**	**-**
Myosotis arvensis	Maritime	2	71.4	-	-	72.5	-	-
	North-East	1	100.0	-	-	63.3	-	-
	Overall	**3**	**80.1**	**-**	**-**	**69.4**	**-**	**-**
Raphanus raphanistrum	Maritime	1	98.0	-	-	100.0	-	-
	North-East	-	-	-	-	-	-	-
	Overall	**1**	**98.0**	**-**	**-**	**100.0**	**-**	**-**
Sinapis arvensis	Maritime	1	100.0	-	-	100.0	-	-
	North-East	1	98.3	-	-	100.0	-	-
	Overall	**2**	**99.2**	**-**	**-**	**100.0**	**-**	**-**
Sisymbrium sophia	Maritime	1	63.3	-	-	43.3	-	-
	North-East	-	-	-	-	-	-	-
	Overall	**1**	**63.3**	**-**	**-**	**43.3**	**-**	**-**

Weed species	EPPO zone	No. of trials	A19786A			Atlantis + Adjuvant		
			1.35 L/ha			0.4 kg/ha + 0.5 % v/v		
			MEAN	MEDIAN	SD	MEAN	MEDIAN	SD
Apera spica-venti	Maritime	33	99.1	100.0	2.2	97.3	99.3	4.9
	North-East	5	100.0	100.0	0.0	100.0	100.0	0.0
	Overall	**38**	**99.2**	**100.0**	**2.1**	**97.7**	**99.8**	**4.6**
Avena spp.	Maritime	7	89.5	98.4	16.2	66.5	65.0	25.6
	North-East	2	100.0	-	-	100.0	-	-
	Overall	**9**	**91.8**	**99.7**	**14.8**	**76.1**	**89.0**	**26.5**

* Standard in this trial series was Monitor + Adjuvant (0.025 kg/ha + 0.5% v/v)

Efficacy Data: Summary/discussion for each target

Alopecurus myosuroides (ALOMY)

The data clearly demonstrate that A19786A at the proposed rate of 1.8 L/ha was generally equivalent to the efficacy of the standard 0.4 kg/ha Atlantis + 0.5%v/v adjuvant (Biopower) against *Alopecurus myosuroides*. This rate should thus be considered to be effective against *Alopecurus myosuroides* in all varieties of winter wheat, rye and triticale. Exceptions are two trials that were placed in the same field (different crops) where a resistance to FOP was present. Also the local standard Axial 50 (1.2 L/ha) had a very poor efficacy in this field (0-67%). It

must therefore be assumed that the product should not be used as a standalone solution in such areas. Here, the product should be included in an anti-resistance management strategy, e.g. in sequences with other herbicides (e.g. autumn followed by a spring application) with other mode of actions (MOA - see HRAC). The same is valid for the standard product Atlantis which also had not a satisfactory efficacy in this particular field.

Lolium spp. (LOLSS)

The data clearly demonstrate that A19786A at the proposed rate of 1.8 L/ha was generally equivalent and sometimes superior to the efficacy of the standard 0.4 kg/ha Atlantis + 0.5%v/v adjuvant (Biopower or Actirob B) against all occurring *Lolium* species. This rate should thus be considered to be very effective against *Lolium* spp. in all varieties of winter wheat, rye and triticale.

Bromus spp. (BROSS)

The data clearly demonstrate that A19786A at the proposed rate of 1.8 L/ha was generally superior to the efficacy of the standard 0.025 kg/ha Monitor + 0.5%v/v adjuvant (Genamin T200 BM) against all occurring *Bromus* species. This rate should thus be considered to be very effective against *Bromus* spp. in all varieties of winter wheat, rye and triticale.

Apera spica-venti (APESV) & *Avena* spp. (AVESS)

The data clearly demonstrate that A19786A at the tested rate of 1.35 L/ha was generally equivalent to the efficacy of the standard 0.4 kg/ha Atlantis + 0.5%v/v adjuvant (Biopower) against *Apera spica-venti* and *Avena* spp. Whilst this rate is effective against APESV and AVESS in all varieties of winter wheat, rye and triticale, a rate of 1.8 L/ha could clearly provide a higher level of control of an impressive spectrum of grass and broadleaf weed species [*Galium aparine, Matricaria* spp., *Stellaria media, Veronica* spp., *Viola arvensis, Lamium purpureum, Polygonum* spp., *Capsella bursa-pastoris* and *Anthemis arvensis*] and resistance management benefits.

Broadleaf weed targets

The data clearly demonstrate that A19786A at the proposed rate of 1.8 L/ha was generally equivalent to or superior than the efficacy of the standard 0.4 kg/ha Atlantis + 0.5%v/v adjuvant (Biopower) against *Galium aparine, Matricaria* spp., *Stellaria media, Veronica* spp., *Viola arvensis, Lamium purpureum, Polygonum* spp., *Capsella bursa-pastoris* and *Anthemis arvensis*. This rate should thus be considered to be effective against each of these broadleaf weed species in all varieties of winter wheat, rye and triticale. It should be noted that VIOAR should be treated before BBCH 61 in order to achieve good efficiency.
Limited data also demonstrate strong efficacy against *Geranium pusillum*, *Raphanus raphanistrum* and *Sinapis arvensis.*
The data also demonstrate that control of *Papaver rhoeas, Centaurea cyanus, Myosotis arvensis* and *Sisymbrium sophia* by A19786A means it is not a strong solution for these weeds.

Additional broadleaf weed claims for Poland only

For a registration of the product in Poland, data from the Baltic countries (also in the north-eastern EPPO climatic zone) can be considered as well. Therefore the following weeds will be claimed in addition.

Table 6.1.3-3: Additional broadleaf weed claims for the registration of A19786A in Poland, based on data from the Baltics [% weed control].

Weed	EPPO zone	No. of trials	A19786A	Atlantis + Adjuvant
			1.8 L/ha	0.4 kg/ha + 0.5 % v/v

			MEAN	MEDIAN	SD	MEAN	MEDIAN	SD
Chenopodium album	North-East	8	**88.0**	91.7	16.6	**88.0**	93.3	13.7
Polygonum convolvulus	North-East	5	**90.1**	89.3	5.1	**84.5**	88.3	11.1

Conclusion – efficacy data
Data have been provided mainly from the maritime EPPO zone and additionally from the north-eastern zone for the dose of 1.8 L/ha A19786A. However, no trials have been conducted in the south-eastern EPPO zone.
For both EPPO zones covered by these efficacy trials the dose of 1.8 L/ha of A19786A is sufficiently effective against several relevant weed species, especially grasses. However, as discussed under IIIA1 6.1.2 (minimum effective dose) the requested dose depends on the weed species and most of them will be controlled with lower doses.
The applicant did not provide efficacy data for the lower dose (1.35 L/ha) separately for the EPPO zones. However, following the data of the minimum efficacy trials (see above) it can be assumed that there are similar ranges of susceptibility of most relevant weeds at doses of 1.35 and 1.8 L/ha in the maritime and the north-eastern EPPO zone. Specific conditions like other weed species or high weed densities should be organized on Member State level.
According to the GAP table the intended uses for Germany are different to the other Member States which is not supported by the submitted data. It can be assumed that the intended uses are similar to those of the other Member States in the Central registration zone.
However, for Germany the intended use of 1.8 L/ha can only be positively evaluated if also 1.35 L/ha will be registered for smaller spectrum of target weed species (excluding *Alopecurus myosuroides, Bromus* spp. and *Galium aparine*). The label should consist a list of target weed species and the species-depending required dose. By doing so, these registration will be equal within the Central registration zone.
At least for Germany the application rate of water should be adapted to the standard of 200-400 L/ha.

IIIA1 6.1.4 Effects on yield and quality

IIIA1 6.1.4.1 Impact on the quality of plants and plant products

No specific data are presented in this section; pinoxaden and pyroxsulam are widely registered in winter wheat, rye and triticale and possess no label restrictions of specific requirements with regards to grain quality. As such, no adverse effects on end use quality is anticipated.

IIIA1 6.1.4.2 Effects on the processing procedure

Specific data are included in this section from two trials carried out in France to look at the effect on grain quality and bread making of winter wheat treated with A19786A in comparison with Atlantis. The effect on yield is covered in a subsequent section of this dossier.
All of the active ingredients in A19786A are widely registered in winter wheat, rye and triticale and possess no label restrictions or specific requirements with regard to grain processing (milling, baking). Brewing and malting studies have not been conducted for A19786A as these apply principally to barley, where use of the formulation is not claimed.
The data show that there were no significant differences between A19786A and Atlantis for the following parameters tested and that neither formulation gave an unacceptable conclusion for any parameter:
Grain quality

- Specific weight

- Protein content
- Thousand grain weight
- Impurity weight

Flour quality

- Hagberg falling number
- Sedimentation value (Zeleny test)
- Chopin alveogram (tenacity, swelling, deformation)
- Baking test (dough note, bread note, crumb note)

IIIA1 6.1.4.3 Effects on the yield of treated plants and plant products

A total of 22 trials were applied in spring 2011 and spring 2012 in the maritime zone (except France) in Belgium, the Czech Republic, Germany, the Netherlands, Switzerland and UK. The objective for each was to confirm the absence of adverse effects on the yield of winter wheat, winter triticale and winter rye (table 6.1.4.3-1). In each series, A19786A was applied at the 'n' and '2n' rates [1.8 and 3.6 L/ha respectively]. The 3.6 L/ha ['2n'] rates were applied as two immediate sequential applications of 1.8 L/ha to accurately simulate a double overlap situation. In the series, the yield was compared to 'n' and '2n' rates of the standard Atlantis + 0.5% Biopower (=0.5 and 1.0 kg/ha); in a few cases a local standard was also included.
Yield data are provided in up to three forms – dt/ha, hectolitre weight and/or thousand grain weight.
The weed free yield trial data from France (maritime part) could theoretically be used to support this section as well, however there is already a good data set from the other maritime countries presented here. The data from France did support the safe use of A19786A in all the cereals claimed if reference to this data is required.

Table 6.1.4.3-1: Summary of all weed free yield trials, split by country and crop

Country	Number of weed free yield trials		
	Winter wheat	Winter rye	Winter triticale
Belgium	1	-	-
Czech Republic	1	1	1
Germany	3	5	5
Netherlands	1	-	-
Switzerland	1	1	1
UK	1	-	-

Table 6.1.4.3-2.: Summary of the Yield data [Yield, thousand grain weight, hectolitre weight] for A19786A in winter cereals, with Atlantis as standard

crop	**target**	**# trials**	**Product**	**CHECK**	**A19786A**	**A19786A**	**Atlantis***	**Atlantis***	****Local stand-ard**	****Local stand-ard**
			Rate	**-**	**1.8 L/ha**	**3.6 L/ha**	**0.5 kg/ha**	**1.0 kg/ha**	**1 N**	**2 N**
Winter Wheat	Yield (dt/ha)	8	MEAN	98,9	97,6	97,0	98,9	97,7	98,6	97,1
			SD	13,6	11,1	11,1	11,4	11,4	14,0	14,7
	hectolitre weight (kg/Hl)	7	MEAN	76,5	75,5	75,6	75,8	75,6	75,1	75,0
			SD	4,8	4,3	4,1	5,0	5,0	3,2	3,4
	thousand	7	MEAN	44,7	43,6	43,9	44,1	43,3	42,0	41,7

	grain weight (g)		SD	6,7	6,3	5,3	6,5	6,0	5,4	5,5
Winter Triticale	Yield (dt/ha)	7	MEAN	78,9	77,3	76,6	76,2	76,0	75,1	71,9
			SD	20,7	20,1	20,0	18,3	21,3	21,7	22,1
	hectolitre weight (kg/Hl)	6	MEAN	66,3	66,5	64,5	66,4	66,1	64,7	64,2
			SD	4,1	4,2	7,3	4,1	4,4	1,9	1,5
	thousand grain weight (g)	5	MEAN	40,5	39,9	39,4	39,6	38,6	38,9	36,6
			SD	3,2	3,0	3,5	3,1	3,7	1,0	4,1
Winter Rye	Yield (dt/ha)	7	MEAN	86,0	84,9	84,4	81,3	77,5	85,9	84,4
			SD	12,0	10,9	8,0	7,5	9,2	10,6	8,2
	hectolitre weight (kg/Hl)	6	MEAN	73,1	73,1	73,2	72,2	71,9	74,4	74,4
			SD	2,5	2,6	2,9	3,1	3,5	2,7	2,7
	thousand grain weight (g)	7	MEAN	35,6	36,0	35,1	33,5	32,3	34,8	34,3
			SD	4,3	3,6	4,1	4,9	4,8	4,1	4,5

Conclusion for effects on the yield of treated plants and plant products
Winter wheat
A19786A at the proposed label rate of 1.8 L/ha had in comparison to the standard Atlantis [+adjuvant] no negative effect on the yield of winter wheat in the absence of weeds in the maritime zone. A19786A showed also in 6 of 8 cases that there is no negative impact in comparison to the untreated control and can be used in all varieties of winter wheat up to BBCH 32 of the crop.

Winter triticale
The single rate of A19786A gave no statistically significant differences for any yield parameter in comparison with the untreated control or the standard Atlantis [+adjuvant], indicating that no adverse effects on yield were recorded. Therefore, A19786A at the proposed label rate of 1.8 L/ha shows no negative effects on the yield of winter triticale in the maritime zone in the absence of weeds.

Winter rye
The application of A19786A gave in only one of seven trials a statistically significant difference for the yield parameter in comparison with the untreated control. However in this trial, all treated variants had a negative impact on the yield, including the standard Atlantis and the local standard. It seems that the drought in April had an negative impact on the herbicide application in this particular trial. Overall, A19786A at the proposed label rate of 1.8 L/ha shows no negative effects on the yield of winter rye in the maritime zone in the absence of weeds.

Conclusion – effects on yield and quality
Under weed-free conditions the herbicide A19786A reduced the yield of winter wheat by 1% and 2% (single and double dose), respectively 2% and 3% for winter triticale and 1% and 2% for winter rye. Concerning hectolitre and thousand grain weight effects of the herbicide ranged from +1% to -3%. By trend the effects at the double dose were slightly stronger compared to the single dose. No differences between the test and standard herbicide have been observed.
Consequently, the herbicide A19786A has no negative effect on yield and yield parameters. The trials have been conducted only in the maritime EPPO zone.

IIIA1 6.2 Adverse effects

IIIA1 6.2.1 Phytotoxicity to host crop

Trials in this dossier were carried out by Syngenta organisations, contractor companies and official research institutes, all of which follow the EPPO standards and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP).
For the submission of the dossier in the maritime zone all trials from Austria, Belgium, the Czech Republic, Denmark, Germany, the Netherlands, Sweden, Switzerland and the United Kingdom (maritime climatic zone) which were conducted in 2011 and 2012 are used. As in previous sections, additional trials from Poland are also included in the *phytotoxicity to host crop* part of this dossier (table 6.2.1-1). These additional trials are from the Regulatory zone Central and from the north-eastern climatic zone and are therefore permissible. These trials are consistently used in the analysis for the submission. The data from the maritime zone of France were omitted.

Table 6.2.1-1: Summary of all trials conducted in 2011 and 2012 for submission in the Central Registration zone, split by country and crop

Crop	Trial type	AT	BE	CZ	DK	DE	NL	SE	CH	UK	PL (N-E)
Winter wheat	Efficacy	3	2	2*	3	37*	2	2	1	5	15
	Yield	0	1	1	0	3	1	0	1	1	0
Winter rye	Efficacy	1	0	0	0	3	0	0	0	0	1
	Yield	0	0	1	0	5	0	0	1	0	0
Winter triticale	Efficacy	0	0	0	0	4	0	0	0	0	2
	Yield	0	0	1	0	5	0	0	1	0	0

* one in spring wheat

Winter wheat
58 trials out of a total of 80 trials, conducted on a wide range of wheat varieties, showed zero or negligible phytotoxicity (≤5% recorded at a single interval only) for the highest tested rate of A19786A.

Table 6.2.1-2 shows the details for all efficacy and weed-free yield trials respectively, where crop phytotoxicity >5% was recorded at least once in the dataset. Injury occurred typically around 2 weeks after application and was highly transitory. In no cases did injury persist for more than a few weeks and as shown under Annex Point IIIA 6.1.4.3 had no negative effects on the yield. Symptoms were generally discolouration and/or minor stunting in line with well-known ALS and ACCase commercial products. In all trials, there was no direct link between the injury recorded and the crop variety, the growth stage at application or the country/region in which the trial was located.

Table 6.2.1-2: Efficacy and weed-free yield trials in winter wheat where phytotoxicity >5% on the crop was observed conducted in the maritime EPPO zone [WW = winter wheat]

Trial reference	Country EPPO zone	Trial type	Crop	Maximum phytotoxicity (%) recorded for A19786A
DENOZH1242012	DE (Mar.)	Efficacy	WW, Kredo	6,7

Trial reference	Country EPPO zone	Trial type	Crop	Maximum phytotoxicity (%) recorded for A19786A
DEOSZH3432011	DE (Mar.)	Efficacy	WW, Hystar	8,0
DEWEZH2142011	DE (Mar.)	Efficacy	WW, Manager	8,0
DESWZH5762012	DE (Mar.)	Efficacy	WW, Arsano	8,7
DKFBZH10322011	DK (Mar.)	Efficacy	WW, Hereford	10,0
DENOZH1222012	DE (Mar.)	Efficacy	WW, Julius	10,0
DESWZH5572012	DE (Mar.)	Efficacy	WW, Arsano	10,0
DESWZH5552012	DE (Mar.)	Efficacy	WW, Meister	10.0
DENOZH1252011	DE (Mar.)	Efficacy	WW, Kredo	10.0
DENOZH1232012	DE (Mar.)	Efficacy	WW, Inspiration	10.7
DEWEZH2162011	DE (Mar.)	Efficacy	WW, Biskay	11.0
GB32ZH2012011	GB (Mar.)	Efficacy	WW, Robigus	12.0
DESEZH4222011	DE (Mar.)	Yield	WW, Akteur	7.3 (N rate) and 16.3 (2N rate)
DENOZH1282011	DE (Mar.)	Efficacy	WW, JB Arsano	18.3
DEESZH3212011	DE (Mar.)	Efficacy	WW, unknown	20.0
DKAVZH1022011	DK (Mar.)	Efficacy	WW, Taureg	26.7
DESSZH5572011	DE (Mar.)	Efficacy	WW, Potential	33.3
BERDZH9032011	BE (Mar.)	Efficacy	WW, Contender	35.0
CZKRZH1022011	CZ (Mar.)	Yield	WW, Sultan	12.5 (N rate) and 35.0 (2N rate)
DEWEZH2102011	DE (Mar.)	Efficacy	WW, Tabasco	46.7
BERDZH9012011	BE (Mar.)	Yield	WW, Expert	50.0 (N rate) and 63.8 (2N rate)
NLWHZH2502012	NL (Mar.)	Yield	WW, Claire	12.8 (N rate) and 76.3 (2N rate)

Winter triticale

11 trials out of a total of 13 trials, conducted on a wide range of winter triticale varieties, showed zero or negligible phytotoxicity (≤5% recorded at a single interval only) for the highest tested rate of A19786A.

Table 6.2.1-3 shows the data for the two weed-free yield trials where crop phytotoxicity >5% was recorded at least once in the dataset. Injury occurred typically around 2 weeks after application and was highly transitory. In no cases did injury persist for more than a few weeks and as shown under Annex Point IIIA 6.1.4.3 had no negative effects on the yield. Symptoms were generally discolouration and/or minor stunting in line with well-known ALS and ACCase commercial products. In all trials, there was no direct link between the injury recorded and the crop variety, the growth stage at application or the country/region in which the trial was located.

Table 6.2.1-3: Weed-free yield trials in winter triticale where phytotoxicity >5% on the crop was observed conducted in the maritime EPPO zone [WT = winter triticale]

Trial reference	Country EPPO zone	Trial type	Crop	Maximum phytotoxicity (%) recorded for A19786A
DENOZH1252012	DE (Mar.)	Yield	WT, Dinaro	9.0 (N rate) and 13.5 (2N rate)
CHCOZH1052012	CH (Mar.)	Yield	WT, Triament	16.3 (N rate) and 15.0 (2N rate)

Winter rye

8 trials out of a total of 12 trials, conducted on a wide range of winter rye varieties, showed zero or negligible phytotoxicity (≤5% recorded at a single interval only) for the highest tested rate of A19786A.

Table 6.2.1-4 shows the data for the weed-free yield trials where crop phytotoxicity >5% was recorded at least once in the dataset. Injury occurred typically around 2 weeks after application and was highly transitory. In no cases did injury persist for more than a few weeks and as shown under Annex Point IIIA 6.1.4.3 had no negative effects on the yield. Symptoms were generally discolouration and/or minor stunting in line with well-known ALS and ACCase commercial products. In all trials, there was no direct link between the injury recorded and the crop variety, the growth stage at application or the country/region in which the trial was located. Each trial is discussed individually in the Biological Assessment Dossier.

Table 6.2.1-4: Efficacy and weed-free yield trials in winter rye where phytotoxicity >5% on the crop was observed conducted in the maritime EPPO zone [WR = winter rye]

Trial reference	Country EPPO zone	Trial type	Crop	Maximum phytotoxicity (%) recorded for A19786A
DEMVZH9052012	DE (Mar.)	Efficacy	WR, Minello	7,0
DEMVZH9072012	DE (Mar.)	Yield	WR, Conduct	9,5 (N rate) and 15,5 (2N rate)
DEWEZH2172011	DE (Mar.)	Yield	WR, Amato	9,5 (N rate) and 16,3 (2N rate)
CHCOZH1062012	CH (Mar.)	Yield	WR, Palazzo	20,0 (N rate) and 23,8 (2N rate)

Conclusions by the applicant
A19786A can be used on all varieties of winter wheat, rye and triticale from BBCH 10-32 in spring. This is additionally supported by the fact that both active ingredients in A19786A, pinoxaden and pyroxsulam, are fully approved and widely registered for use on winter wheat, rye and triticale solo or in mixture with other products.
In common with other herbicides containing ALS and/or ACCase inhibitors, transitory crop safety effects in form of stunting or chlorosis may be observed when weather conditions are less than optimal or the crop is under stress. However no long-lasting crop injury or negative impact on the yield is expected (see also Section 6.1.4.3 of this dossier).
It is therefore suggested that 1.8 L/ha of A19786A can be safely used in all winter cereals claimed. A spray overlap during application and unfavourable weather conditions should be avoided though.

Conclusion – phytotoxicity to host crop
In most of the selectivity trials the use of the herbicide A19786A did not result in any crop damage. However, in some cases phytotoxic effects of more than 20% occurred. Although there were no negative yield effects it is suggested to put a warning on the label e.g. “crop damage is possible”.

IIIA1 6.2.2 Adverse effects on health of host animals

This is not an EC data requirement.

IIIA1 6.2.3 Adverse effects on site of application

This is not an EC data requirement.

IIIA1 6.2.4 Adverse effects on beneficial organisms (other than bees)

The herbicide A19786A (33.3 g/L pinoxaden + 8.33 g/L pyroxsulam + 8.33 g/L cloquintocet-mexyl as safener, EC) has been proposed in winter cereals for one post-emergence treatment per crop and season in spring with a maximum application rate of 1.8 L/ha.

No specific assessments of beneficial and other non-target organisms were taken in the efficacy and crop safety trials. However, no adverse effects were noted when visual observations were made within these field trial sites.

Appropriate studies on the potential adverse effects of the test product on beneficial arthropods were available from Registration Report Part B, Section 6, Annex Point IIIA 10.5 (Effects on Arthropods Other Than Bees), Core Assessment.

The toxicity of A19786A has been investigated by carrying out extended laboratory tests with the two indicator species *Typhlodromus pyri* and *Aphidius rhopalosiphi* (table 6.2.4-1).

Table 6.2.4-1: Effects of A19786A (33.7 g/L pinoxaden + 8.11 g/L pyroxsulam + 8.11 g/L cloquintocet-mexyl) on beneficial organisms in extended laboratory tests

Species (Exposed Stage)	Substrate	Rate Product [L/ha]	Corrected Mortality [%]	Sublethal Effect (Re) [%]	Reference
T. pyri (PN)	Bean leaf discs	1.8	57	29.4	SYN-12-43 (Fallowfield, 2013)
		0.9	19	7.4	
		0.45	11	11.8	
		0.225	8	-10.3	
		0.1125	0	-2.9	
A. rhopalosiphi (A)	Barley	1	0	-7.9	SYN-12-44 (Stevens, 2012)
		0.5	3.3	4.1	
		0.25	0	-10.4	
		0.125	0		
		0.0625	0		

PN = protonymphs, A = adults, Re = reproduction

On the basis of these results, effects ≥ 50% are expected for populations of the predatory mite *Typhlodromus pyri*, at the proposed maximum application rate of 1.8 L/ha. The LR_{50} was calculated to be 1.652 L product/ha.
The indicator species *Typhlodromus pyri* is not a relevant antagonist for the proposed crops. However, the results for this species indicate that effects ≥ 50% on relevant predatory mites and spiders cannot be excluded.

No effects ≥ 25% are expected for populations of the parasitoid wasp *Aphidius rhopalosiphi* at the proposed maximum application rate of 1.8 L/ha.

Further information from 8 studies on beneficial organisms using formulations of either pinoxaden or pyroxsulam on beneficial organisms could not contribute to a further assessment of the test product.

Conclusion

On the basis of the results of extended laboratory studies, A19786A is classified as not harmful for the parasitoid wasp *Aphidius rhopalosiphi*, but as harmful for relevant predatory mites and spiders at the proposed maximum application rate of 1.8 L/ha.

Classification:
Extended laboratory tests on natural substrates
< 25% = not harmful
25 - 50% = slightly harmful
> 50% = harmful

Adverse effects on soil quality indicators (e. g. microorganisms, earthworms) are considered in Section 6 Ecotoxicological Studies in the Registration Report.

IIIA1 6.2.5 Adverse effects on parts of plant used for propagating purposes

Potential adverse effects on parts of plants used for propagating purposes [cereal germination tests] are referenced in Part B Section 4 Annex Point IIIA 8.5 in order to demonstrate the safety of A19786A to propagation materials (cereal seed):
For both pinoxaden and pyroxsulam, residue levels are extremely low and the level of each found in raw agricultural commodities (e.g. cereal seed for establishing new crops) is negligible.
In Part B Section 6 Annex Point IIIA 10.8.1 [Effects on non-target plants] also shows that exposure to simulated residues of A19786A does not pose an unacceptable risk to germination or vegetative vigour of potential seed crops.

IIIA1 6.2.6 Impact on succeeding crops

A19786A is intended for spring application to winter varieties of wheat, rye and triticale up to BBCH 32 and therefore crops that would be primarily at risk of carryover effects are those planted in the autumn following a spring application. A full risk analysis is provided in the Biological Assessment Dossier with a summary provided below.

EC_{10}-values
In 2014 a pre-plant incorporation test (PPI) for the test product A19786A was conducted for nine different crops to determine the EC_{10}-estimates. Applied rates and EC_{10} values are expressed as g a.s./ha or mg a.s./kg soil, with “a.s.” expressing the sum of the pinoxaden and pyroxsulam components of A19786A. With regards to the results sugarbeet is the most sensitive crop. Maize, soya, pea, sunflower, sorghum and oilseed rape show intermediate sensitivity. Wheat and barley are the most tolerant. The resulting EC_{10}-estimates are available in table 6.2.6-1. For the most sensitive crop sugarbeet the EC_{10}-estimate is 0.00215 mg a.s./kg soil at a ratio of 4 to 1 for pinoxaden (0.00172 mg/kg soil) to pyroxsulam (0.00043 mg/kg soil).

Table **Fehler! Kein Text mit angegebener Formatvorlage im Dokument.**-1: EC_{10}-estimates (g a.s./kg soil) for A19786A

Crop	EC_{10} for A19786A (mg a.s./kg soil)	EC_{10} for A19786A contains	
		(mg Pinoxaden/kg soil)	(mg Pyroxsulam/kg soil)
Sugar beet	**0.00215**	**0.00172**	**0.00043**
Oilseed rape	0.01169	0.009352	0.002338
Wheat	0.01495	0.01196	0.00299
Barley	0.01592	0.012736	0.003184
Maize	0.01015	0.00812	0.00203
Sunflower	0.00766	0.006128	0.001532
Soya	0.00497	0.003976	0.000994
Sorghum	0.01400	0.0112	0.0028
Pea	0.00529	0.004232	0.001058

PEC-values and TER-calculation

For the calculation of the relevant TER-values of A19786A and its active substances the PEC_S-values after 60, 90 and 120 days were chosen according to EPPO standard PP1/207 (2), within two different scenarios. One scenario is calculated for the situation without ploughing (5 cm) and the other one with ploughing (20 cm). Results are shown in Table Fehler! Kein Text mit angegebener Formatvorlage im Dokument.-2 and Table Fehler! Kein Text mit angegebener Formatvorlage im Dokument.-3.

The quotient of the EC_{10}-estimates and the PECs-values indicates for pinoxaden (Table Fehler! Kein Text mit angegebener Formatvorlage im Dokument.-2) that for all considered scenarios for the most sensitive crop sugar beet the TER-values are above the trigger of 1 (TER-value is > 17.2).

For pyroxsulam the calculated TER-values show a differentiated perspective (Table Fehler! Kein Text mit angegebener Formatvorlage im Dokument.-3). With ploughing the TER-value demonstrates that there is no concern regarding succeeding sugar beets for the relevant period (60 to 120 days). For the scenario with reduced soil tillage the recommended waiting time for the grower needs to be a minimum of 90 days because for the critical period of 60 days the calculated TER-value of pyroxsulam is below the trigger of 1 when no soil tillage is carried out (TER-value is 0.33).

Table **Fehler! Kein Text mit angegebener Formatvorlage im Dokument.**-2: Calculated TER-values for pinoxaden 60, 90 and 120 days after application in 5 and 20 cm incorporation depth

Active substance	incorporation depth (cm)	EC_{10} (mg a.s./kg) for the most sensitive crop (sugar beet)	PEC_S mg a.s./kg after 60 days	TER-value after 60 days	PEC_S mg a.s./kg after 90 days	TER-value after 90 days	PEC_S mg a.s./kg after 120 days	TER-value after 120 days
pinoxaden	5	0.00172	<0.0001	**>17.2**	<0.0001	**>17.2**	<0.0001	**>17.2**
	20	0.00172	<0.0001	**>17.2**	<0.0001	**>17.2**	<0.0001	**>17.2**

Table **Fehler! Kein Text mit angegebener Formatvorlage im Dokument.**-3: Calculated TER-values for pyroxsulam 60, 90 and 120 days after application in 5 and 20 cm incorporation depth

Active	incor-	EC_{10}	PEC_S	TER-	PEC_S	TER-	PEC_S	TER-

sub-stance	poration depth (cm)	(mg a.s./kg) for the most sensi-tive crop (sugar beet)	mg a.s./kg after 60 days	value after 60 days	mg a.s./kg after 90 days	value after 90 days	mg a.s./kg after 120 days	value after 120 days
pyroxsulam	5	0.00043	0.00130	**0.33**	0.00038	**1.1**	0.00011	**3.9**
	20	0.00043	0.00033	**1.3**	<0.0001	**>4.3**	<0.0001	**>4.3**

In order to interpret the presented glasshouse results within the context of the situation in the field (rotational/replacement crops), 4 field trials are described in the following paragraph.

Field studies

The effect of A18291A (an earlier variant of A19786A, delivering identical active ingredient rates per hectare at the full rate) at 1.34 L/ha and 2.68 L/ha ('n' and '2n' rates) on succeeding crops was investigated in 4 field trials in situations to recreate normal crop rotation. The effects were compared to those observed for the standard Atlantis at 0.5 kg/ha and 1.0 kg/ha.

All trials were conducted in areas were cereal crops are commercially grown. Target and rotational crops were managed by normal crop husbandry, applied to the whole trial area by the grower according to crop requirements and in accordance with good agricultural practice.

In the trials, the treated crop was followed by a rotational crop of regional importance and one which potentially could show a sensitivity to A19786A. The data is summarised in table 6.2.6-4.

Table **Fehler! Kein Text mit angegebener Formatvorlage im Dokument.**-4: Effects of A19786A on succeeding crops based on field trials

Treated crop (growth stage)	Cultivation / Tillage	Succeeding crop	Succeeding crop sown DAT	Phytotoxicity and/or other side effects			
				A18291A 1.34 & 2.68 L/ha		Atlantis 0.5 & 1.0 kg/ha	
				Number of trials with phy-to/total	Min-max	Number of trials with phy-to/total	Min-max
Wheat (BBCH 30-31)	Ploughing	Sugar beet	239-382	1/3	0-10%	2/3	0-10%
		Alfalfa	133-181	1/2	0-5%	1/2	0-10%
		Winter rape	137-239	1/4	0-1.5%	1/4	0-6.5%
		Phacelia	133-181	1/3	0-1.5%	2/3	0-5%
		Soybeans	340	0/1	0%	0/1	0%
		Durum wheat	239	0/1	0%	0/1	0%
		Spring barley	295-340	0/2	0%	0/2	0%
		Winter barley	167-239	0/4	0%	1/4	0-1%
		Winter wheat	181-203	0/3	0%	0/3	0%
	No plough-ing	Sugar beet	239-382	1/2	0-3%	2/3	0-10%
		Alfalfa	133-181	1/2	0-2.5%	1/2	0-7.5%
		Winter rape	137-239	2/4	0-10%	3/4	0-17.5%
		Phacelia	133-181	2/3	0-2.5%	2/3	0-7.5%

		Soybeans	340-382	0/2	0%	0/2	0%
		Durum wheat	239	0/1	0%	0/1	0%
		Spring barley	295-340	0/2	0%	0/2	0%
		Winter barley	167-239	0/4	0%	0/4	0%
		Winter wheat	181-203	0/3	0%	0/3	0%
		Winter wheat	181-203	0/3	0%	0/3	0%

Conclusion by the applicant
Glasshouse trials in combination with field trials for the herbicide A19786A with the proposed cGAP of one time 1.8 L/ha in winter cereals, indicate that the risk of negatively impacted succeeding crops can be regarded as low. As shown by the TER-values > 1 for pinoxaden and pyroxsulam, the risk of damaging even the most sensitive crop (sugar beet) is negligible after 90 days without ploughing, and after 60 days with ploughing. The additional field trials support the approach that ploughing should be recommended as standard procedure before recropping. To avoid any negative influence of A19786A against sugar beet this crop should be excluded as replacement crop within the same season.

Conclusion – impact on succeeding crops
Based on the PEC- and TER calculation there is a theoretical risk for succeeding crops by pyroxualm whereas the risk of pinoxaden can be considered as low. An evaluation based on the herbicide A19786A instead of both active substances have not been submitted by the applicant. The most sensitive crops are spring crops like sugar beet, soya, sunflower and peas. Since these crops are sown much later than 120 DAT (TER > 3.9) the risk can be considered as low. These findings have been supported by field experiments where no unacceptable crop damage occurred in normal crop rotation. Crop damage of the herbicide A19786A was on a lower level than at the reference product Atlantis.

IIIA1 6.2.7 Impact on other plants including adjacent crops

Vegetative Vigour
The potential effects of A19786A on seedling emergence and vegetative vigour in non-target plants were evaluated in glasshouse studies. Further details of the studies are given under Annex Points IIIA 10.8.1.2 and 10.8.1.3 of Section 6 which are not cited in the Biological Assessment Dossier. A summary of the endpoints for use in risk assessment is given in the tables below (table 6.2.7-2 and table 6.2.7-3).

Table **Fehler! Kein Text mit angegebener Formatvorlage im Dokument.**-1: ER_{50} values estimated from vegetative vigour studies

Species	**Biomass (mL A19786A/ha)**	**Height (mL A19786A/ha)**
	ER_{50}	**ER_{50}**
Monocots		
Allium cepa (onion)	417.52	> 4375
Avena sativa (oat)*	3.62*	150.64*
Avena sativa (oat)*	61.41*	210.26*
Lolium perenne (ryegrass)	71.12	182.91
Zea mays (maize)	82.15	167.77
Dicots		
Beta vulgaris (Sugar beet)	50.82	303.36
Brassica napus (oilseed rape)	125.21	273.80
Daucus carota (carrot)	126.45	301.47

Species	Biomass (mL A19786A/ha)	Height (mL A19786A/ha)
	ER_{50}	ER_{50}
Glycine max (soya bean)	124.52	85.28
Lactuca sativa (lettuce)	155.11	429.26
Lycopersicon esculentum (tomato)	26.99	130.79

* Study repeated for *Avena sativa* see notes below

In the first study conducted for vegetative vigour, an initial ER_{50} of 3.62 mL/ha for biomass was derived for *Avena sativa*. This sensitivity was far lower than seen for the other species and did not correspond to the sensitivity of this species seen in the same test for height and survival. Therefore due to the discrepancy seen for *Avena sativa* the study was repeated and an ER_{50} of 61.41 mL/ha was reported for biomass which shows more consistency with the other species, the results for the other endpoints, and the expected result based upon the toxicity of the active substances. Further explanation to this discrepancy is also given by the document Sutton & Spatz (2015) which explains the relevant reasons why the first test of *Avena sativa* should be discarded.
The lowest reported ER_{50} 26.99 mL/ha for *Lycopersicon esculentum* (tomato) was therefore used for the risk assessment on vegetative vigour.

Seedling emergence

Table **Fehler! Kein Text mit angegebener Formatvorlage im Dokument.**-2: ER_{50} values estimated from seedling emergence

Species	ER_{50} (mL A19786A/ha)		
	Dry weight	Height	Emergence
Monocots			
Allium cepa (onion)	92.99	217.92	> 4375
Avena sativa (oat)	3152.89	3954.61	> 4375
Lolium perenne (ryegrass)	191.84	345.07	> 4375
Zea mays (maize)	> 4375	> 4375	> 4375
Dicots			
Beta vulgaris (sugar beet)	94.63	192.45	> 4375
Brassica napus (oilseed rape)	330.66	811.99	> 4375
Daucus carota (carrot)	242.87	4100.42	> 4375
Glycine max (soybean)	3768.71	1713.23	> 4375
Lactuca sativa (lettuce)	484.93	1407.43	> 4375
Lycopersicon esculentum (tomato)	887.82	2070.52	> 4375

The lowest reported ER_{50} of 92.99 mL/ha for dry weight was used in the risk assessment for seedling emergence.

Exposure
Effects on non-target plants are of concern in the off-field environment, where they may be exposed to spray drift. The amount of spray drift reaching off-crop habitats is calculated using the 90th percentile estimates derived by the *BBA* (2000) from the spray-drift predictions of *Ganzelmeier & Rautmann* (2000). Only a single application is relevant for the intended use of A19786A and for wheat 2.77% of the application rate was assumed to reach areas at 1 m from the edge of the crop (worst-case scenario). The highest single application rate of A19786A is 1800 mL product/ha and was used with the relevant drift rates to calculate the off field exposure.
For effects on seedling emergence, 50% of drift was assumed to be deposited on soil, and for effects on emerged vegetation, 100% of drift was assumed to be intercepted by the vegetation. PER-values were also estimated assuming the use of 50, 75 and 90 % drift reduction.

Table **Fehler! Kein Text mit angegebener Formatvorlage im Dokument.**-3: Exposure to non-target plants in off-field areas from application of A19786A

Interception	Spray buffer (m)	Drift (%)	Exposure (mLA1976A/ha) when using specific nozzle (PER)			
			Conventional	50% drift reduction	75% drift reduction	90% drift reduction
None (effects on vegetative vigour and seedling emergence assuming no interception)	1	2.77	49.86	24.93	12.47	4.99
	5	0.57	10.26	5.13	2.57	1.03
50% (effects on seedling emergence assuming interception by surround vegetation)	1	1.39	25.02	12.51	6.26	2.50
	5	0.29	5.22	2.61	1.31	0.522

Risk assessment

Table **Fehler! Kein Text mit angegebener Formatvorlage im Dokument.**-4: Risk assessment for effects on non-target terrestrial plants

Test Substance	Most sensitive species	ER_{50} (mL A19786A /ha)	Conventional nozzle (1 m buffer)		Conventional nozzle (5 m buffer)		50% drift reduction nozzle (1 m buffer)	
			PER (mL/ha)	TER	PER (mL/ha)	TER	PER (mL/ha)	TER
A19786A (vegetative vigour)	Tomato	26.99	49.86	0.54	10.26	**2.6**	24.93	**1.1**
A19786A (seedling emergence)	Onion	92.99	25.02	**3.7**	5.22	**17.8**	12.51	**7.4**

With regards to EPPO standard PP 1/256 (1) *Effects on adjacent crops* a TER-value for non-target plants (emergence and vegetative vigour) higher than 1 is required to stop testing and to achieve a registration without restrictions. As shown in
Table Fehler! Kein Text mit angegebener Formatvorlage im Dokument.-**4** the TER-values for seedling emergence show acceptable risk for 1 m buffer with conventional nozzles. For vegetative vigour acceptable risk is shown when 5 m with conventional nozzles or 1 m buffer with 50% drift reduction is applied. Therefore, with the use of the appropriate mitigation, A19786A poses a relatively low risk to most species of non-target plants found in field margins.

Conclusion by the applicant
If A19786A is used as a foliar spray in cereals much less than 1.8 L/ha will reach adjacent crops by spray drift, when application is done according to good agricultural practice. With the use of a 5 m buffer in combination with conventional nozzles or 1 m buffer with 50% drift reduction the risk that A19786A will negatively impact adjacent crops is regarded as very low (TER>1). Therefore, with the use of the appropriate mitigation, A19786A can be proposed for registration.
A19786A has no negative impact on adjacent crops or non-target plants if spray drift is avoided through the use of a 5 m buffer in combination with conventional nozzles or 1 m buffer with 50% drift reduction.
Extreme care must be taken to avoid spray drift onto non-crop plants outside the target area.

Conclusion – impact on other plants including adjacent crops

Based on the data submitted by the applicant there is a risk for adjacent crop by the herbicide A19786A. By using conventional nozzles a buffer zone of 5 m is recommended respectively 1 m for 50% drift reduction. A warning information should be given in the label.

IIIA1 6.2.8 Possible development of resistance or cross-resistance

The resistance risk analysis presented in the dRR was generally prepared according to EPPO standard PP 1/213(3) 'Efficacy evaluation of plant protection products – Resistance risk analysis".

Mechanism of resistance
A19786A is a herbicide containing the two active ingredients pinoxaden and pyroxsulam and the safener cloquintocet. As the applicant claims that the safener holds no herbicidal activity against weeds, it will not be considered regarding its resistance risk in the following assessment.
Pinoxaden is a phenylpyrazoline ('DEN') compound that belongs to the ACCase inhibiting herbicide group (HRAC group A). Regarding the HRAC group A, resistance can be caused by an altered target site, enhanced metabolism, overproduction of the target enzyme and membrane repair.
The mode of action of pyroxsulam is to inhibit the acetolactate synthase (ALS) and these active substances have therefore been classified as herbicides inhibiting the ALS (HRAC group B). The HRAC group B active substances are divided into five sub-groups, which differentiate in direction of resistance development and cross-resistance patterns.
Resistance to ALS inhibitors can be caused by an insensitive target enzyme or by metabolic processes. Regarding dicotyledonous weed species, mainly target site resistance mechanisms have been detected whereas both target site resistance and enhanced metabolism are assumed to be responsible for resistance in grass species such as *Lolium* spp. and *Apera spica-venti.* Different mutations have been detected on the ALS gene of resistant weed species and several amino acids have been identified whose exchange may result in resistance towards ALS inhibitors. The inherence mode of the target site mutation is dominant/semi-dominant. Resistance to ALS-inhibitors can also occur as non-target site resistance based on an acceleration of the metabolism and on an increased rate of decontamination.

Evidence of resistance and cross resistance
According to the website of Ian Heap (www.weedscience.org; November 2017), resistance to HRAC group A has been detected in 48 weed species worldwide. Resistance to pinoxaden has been reported for 50 biotypes with 26 of these cases reported in Europe. Target weed species of A19786A for which resistance against pinoxaden has been reported in Europe are: *Alopecurus myosuroides* (Poland, Italy and Germany), *Lolium* spp. (Italy and Germany) and *Apera spica-venti* (Germany and Poland). Multiple resistance has been found in most of these reported biotypes. Cross resistance within the group of phenylpyrazoline herbicides is common. Studies have indicated that cross resistance within the group is not 100% but there is a high degree of correlation between resistance to a single member of the group and resistance to one or other members of the group. Cross resistance between the groups of ACCase inhibitors has been demonstrated in at least 10 species of grass weeds.

Because of the frequent application of ALS inhibitors (mainly sulfonylureas, imidazolinones and triazolopyrimidines) in Europe and worldwide, numerous weed species have evolved resistance to HRAC group B substances. In the global database of Ian Heap, 159 weed species with resistance to at least one active substance of the ALS inhibitors are listed (www.weedscience.org, accessed November 2017). In the EU, herbicide resistance to ALS inhibitors in *Alopecurus myosuroides, Apera spica-venti*, *Lolium* spp. and *Avena* spp. shows the highest significance. However, resistance is also present in important dicotyledonous weed species. For example, resistance to ALS herbicides is reported in wheat for *Matricaria* spp. for Germany and Denmark.

Cases of resistance for *Papaver rhoeas* and *Stellaria media* are reported for different countries and a range of ALS herbicides.
Cases of resistance to pyroxsulam have been reported for 43 biotypes of which 21 are reported for Europe. Target weed species of A19786A for which resistance against pyroxsulam has been reported in Europe are: *Alopecurus myosuroides* (UK, Turkey and Sweden), *Lolium* spp. (Denmark and Germany), *Bromus* spp. (France), *Stellaria media* (Germany) and *Apera spica-venti* (Germany, Czech Republic and France).

Cross resistance to other HRAC group B substances is very common especially among the resistant grass weeds. However, different mutations on the binding site for the ALS enzyme result in different cross-resistance patterns. For example a modification of the target site, as is the case in certain sulfonylurea resistant biotypes, will result in cross-resistance to other sulfonylureas and other groups of ALS inhibitors, *e.g.* imidazolinones. In the case of ALS resistant biotypes with metabolic resistance mechanisms, resistance may also occur towards substances from other HRAC groups. There are also many weed species with multiple resistance mechanisms against various modes of action.

Analysis of the inherent risk
Because of the high number of reported resistance cases in Europe, the active compounds pinoxaden and pyroxsulam have to be classified with a high inherent risk of resistance. In addition, the grass target weeds of A19786A are also classified with high inherent risk. Among the dicotyledonous target weed species of A19786A are several species with a high resistance risk. Especially the following species exhibit an enhanced resistance risk: *Papaver rhoeas, Stellaria media* and *Matricaria* spp.

The applicant has submitted resistance monitoring data for the target species *Alopecurus myosuroides, Apera spica-venti, Lolium* spp., and *Stellaria media* mainly for Germany.

For *Alopecurus myosuroides* 356 samples from the years 2012, 2013 and 2014 were analyzed concerning their resistance status towards pinoxaden (Axial), pyroxsulam (Broadway or Abak) and A19786A. As shown in table 6.2.8-1, 75-85% of the biotypes showed a decreased sensitivity against pinoxaden (Axial), whereas pyroxsulam and A19786A were able to control many biotypes. A19786A was able to control about 77% of the tested biotypes (Resistance class 0). But there are also biotypes present that could not be controlled by pinoxaden, pyroxsulam or the combination A19786A. This data underlines the high level of ACCase herbicide resistance and ongoing development of ALS herbicide resistance in *Alopecurus myosuroides*.

Table 6.2.8-1: Summary of variation in sensitivity for *Alopecurus myosuroides*

Resistance class	**Axial 1.2 L/ha**	**Broadway/Abak 240 g/ha**	**A19786A 1.8 L/ha**
0 (85 – 100%)	63	227	273
1 (< 85 – 70%)	19	38	30
2 (<70 – 55%)	34	20	13
3 (< 55 – 40%)	52	28	9
4 (< 40 – 25%)	56	21	11

5 (< 25 – 0%)	125	15	13
n.a.	7	7	7
	356	**356**	**356**

n.a.: no emergence / resistance class: according to herbicide efficacy %

For *Apera spica-venti* a total of 415 biotypes from the growing seasons 2012, 2013 and 2014 included into the monitoring. The samples came from all over Germany and Austria. In 2014 there were also seed samples included from the Czech Republic and Poland.
In the past years, resistance to ALS-inhibitors such as iodosulfuron or pyroxsulam is established and has been increasing. In table 6.2.8-2, the results from 2012, 2013 and 2014 are summarized according to resistance classes. It becomes obvious that *Apera spica-venti* biotypes tested here are mainly exhibiting pyroxsulam resistance. Pinoxaden and A19786A were able to control the majority of biotypes. Nevertheless, cross resistance to pinoxaden respectively pyroxsulam (or to both herbicides) does occur.

Table 6.2.8-2: Summary of variation in sensitivity for *Apera spica-venti*

Resistance class	**Axial 0.9 L/ha**	**Broadway/Abak 130 g/ha**	**A19786A 1.3 L/ha**
0 (85 – 100%)	362	304	355
1 (< 85 – 70%)	11	30	20
2 (<70 – 55%)	10	26	10
3 (< 55 – 40%)	6	7	3
4 (< 40 – 25%)	3	11	5
5 (< 25 – 0%)	1	16	0
n.a.	22	21	22
	415	**415**	**415**

n.a.: no emergence / resistance class: according to herbicide efficacy %

For *Lolium* spp. a total of 14 biotypes from 2012, 2013 and 2014 were monitored. The samples came from all over Germany. Some *Lolium* samples showed strong resistance to ACCase inhibitors indicating target site resistance. In 2014 resistance to pinoxaden (Axial) in ryegrass could be found in 5 out of 7 samples. In all years, A19786A, the combination of pyroxsulam and pinoxaden, showed overall better efficacy compared to the solo application of pinoxaden (Axial) or pyroxsulam (Abak or Broadway). However, some biotypes showed resistance to all or nearly all herbicides tested.

ALS-resistance in *Stellaria media* and specifically to pyroxsulam has been first reported in Germany in 2011.
The applicant participated in the ALS-resistance monitoring program for different weed species including *Stellaria media* in Germany since 2014. All 15 samples of *Stellaria media* collected in

2014 did not show any reduced sensitivity to all tested ALS-inhibitors such as Primus, Pointer SX, Hoestar Super. Recently, *Stellaria media* was reported to show reduced sensitivity to herbicides containing ALS-inhibitors. But resistance is not widespread yet.

In summary, the data on variation in sensitivity presented here, show that resistance to pinoxaden and pyrosulam is very prominent in *Alopecurus myosuroides*. To a lesser extent resistance to both active ingredients of A19786A was also already found in *Apera spica-venti* and *Lolium* spp.. Therefore the inherent risk of resistance development has to be classified high for the mentioned grass weed species.

Analysis of the agronomic risk
The herbicide A19786A is aimed at being applied for control of *Alopecurus myosuroides, Apera spica-venti, Lolium* spp*., Bromus* spp*.* and annual dicotyledonous species in winter cereals. Under many situations, the herbicide will be applied in tank mixtures or sequences with other active substances or MoA. Some of the target species of A19786A may therefore also be controlled by other substances so that the selection pressure and resistance risk is slightly reduced. In a typical crop rotation scheme in Central Europe, the crops in which A19786A is applied can be rotated with dicotyledonous crops. Weeds which are not or insufficiently controlled by A19786A can then be controlled in oilseed rape, or other crops with alternative herbicides (other modes of action groups). However, cereals are often grown in continuous rotation (monocropping) so that there is an additional risk of repeated applications of ALS and ACCase inhibitor herbicides over many years. In addition, other active substances from the group of ALS inhibitors might additionally be used for weed control in oilseed rape as part of the Clearfield system and ACCase herbicides are already used in oilseed rape for grass and volunteer cereal control. In general, it can be stated that ACCase and ALS inhibitors are commonly used in various crops and therefore have to be classified with a high agronomic risk under current normal European agricultural practice.
The design of the respective crop rotations and the associated frequency of application of A19786A may differ in the various Member States in the EU and a national-specific assessment of the agronomic risk is therefore recommended.

Summary and conclusion
The applicant claims that the resistance risk inherent in A19786A can be assumed to be comparable to that of other herbicides in HRAC group A and B, i. e. medium-high. This conclusion can generally be followed. The increasing occurrence of dicotyledonous biotypes with ALS resistance in Europe emphasizes an increasing risk of resistance evolution for ALS active substances. In addition, most of the grass target species can be regarded as high risk species and ACCase and ALS inhibitors are frequently used in other main crop species in central Europe. The general resistance risk of A19786A is therefore assessed as high. The applicant has not provided any information on the individual resistance risk within the different Member States of the EU.

The label warning WH951 (The risk of resistance has to be indicated on the package and in the instructions of use. Particularly measures for an appropriate risk management have to be declared.) is proposed.

Management strategy
The applicant has the management strategies:

- Avoid continued use of the same herbicide or herbicides having the same mode of action in the same field unless it is integrated with other weed control practices
- Include active ingredients which both give high levels of control of the target weed(s) resistant or prone to develop resistance
- Limit the number of applications of a single herbicide or herbicides having the same mode of action in a single growing season

- Where possible, use mixtures or sequential treatments of herbicides having a different mode of action but which are active on the same target weeds
- Use non-selective herbicides to control early flushes of weeds (prior to crop emergence) and/or weed escapes

IIIA1 6.3 Economics

This is not an EC data requirement.

IIIA1 6.4 Benefits

IIIA1 6.4.1 Survey of alternative pest control measures

This is not an EC data requirement.

IIIA1 6.4.2 Compatibility with current management practices including IPM

This is not an EC data requirement.

IIIA1 6.4.3 Contribution to risk reduction

This is not an EC data requirement.

IIIA1 6.5 Other/special studies

IIIA1 6.6 Summary and assessment of data according to points 6.1 to 6.5

Minimum effective dose tests

Data have been provided mainly from the maritime EPPO zone and additionally from the north-eastern zone. However, no trials have been conducted in the south-eastern EPPO zone.

The results show that most of the relevant weed species will be sufficiently controlled by the reduced dose of 1.35 L/ha. Even the mean efficacy against *Alopecurus myosuroides* is similar for the reduced and the intended dose (86.8% vs. 88.5%). The same is true for the median values (92.5% vs. 95.2%). Furthermore, the standard deviation was not affected by the herbicide dose. Consequently, based on the given data a final decision on the registered dose is not possible.

The applicant comments this as follows: “The concerned Member States should make their own decision if they think it is appropriate to label only the top dose of 1.8 L/ha to cover any grass and broadleaved weed, or differentiate the label by adding a lower rate of 1.35 L/ha for Apera and some dicot control.”

It is suggested for all Member States (including Germany) to split the intended use into two uses with different doses and target weeds. The use includes the target species *Alopecurus myosuroides* (ALOMY), *Bromus* spp. (BROSS), *Apera spica-venti* (APESV), *Lolium* sp. (LOLSS), annual dicotyledonous weeds (TTTDS) by using 1.8 L/ha. The minimum effective dose data do not demonstrate that - except for *Alopecurus myosuroides, Bromus* spp. and *Galium aparine* the intended dose of 1.8 L/ha is really necessary for a sufficient weed control.

It is recommended that this fact should be expressed by two different uses.

The first use should includes the target species *Alopecurus myosuroides* (ALOMY), *Bromus* spp. (BROSS) and *Galium aparine* (GALAP) by using 1.8 L/ha.

The second use should include *Apera spica-venti* (APESV), but also *Lolium* sp. (LOLSS) and annual dicotyledonous weeds (TTTDS) by using 1.35 L/ha. For more details please see IIIA1 6.1.3.

Efficacy tests

Data have been provided mainly from the maritime EPPO zone and additionally from the north-eastern zone for the dose of 1.8 L/ha A19786A. However, no trials have been conducted in the south-eastern EPPO zone.

For both EPPO zones covered by these efficacy trials the dose of 1.8 L/ha of A19786A is sufficiently effective against several relevant weed species, especially grasses. However, as discussed under IIIA1 6.1.2 (minimum effective dose) the requested dose depends on the weed species and most of them will be controlled with lower doses.

The applicant did not provide efficacy data for the lower dose (1.35 L/ha) separately for the EPPO zones. However, following the data of the minimum efficacy trials (see above) it can be assumed that there are similar ranges of susceptibility of most relevant weeds at doses of 1.35 and1.8 L/ha in the maritime and the north-eastern EPPO zone. Specific conditions like other weed species or high weed densities should be organized on Member State level.

According to the GAP table the intended uses for Germany are different to the other Member States which is not supported by the submitted data. It can be assumed that the intended uses are similar to those of the other Member States in the Central registration zone.

However, for Germany the intended use of 1.8 L/ha can only be positively evaluated if also 1.35 L/ha will be registered for smaller spectrum of target weed species (excluding *Alopecurus myosuroides, Bromus* spp. and *Galium aparine*). The label should consist a list of target weed species and the species-depending required dose. By doing so, these registration will be equal within the Central registration zone.

At least for Germany the application rate of water should be adapted to the standard of 200-400 L/ha.

Effects on yield and quality

Under weed-free conditions the herbicide A19786A reduced the yield of winter wheat by 1% and 2% (single and double dose), respectively 2% and 3% for winter triticale and 1% and 2% for winter rye. Concerning hectolitre and thousand grain weight effects of the herbicide ranged from +1% to -3%. By trend the effects at the double dose were slightly stronger compared to the single dose. No differences between the test and standard herbicide have been observed.

Consequently, the herbicide A19786A has no negative effect on yield and yield parameters. The trials have been conducted only in the maritime EPPO zone.

Phytotoxicity to host crop

In most of the selectivity trials the use of the herbicide A19786A did not result in any crop damage. However, in some cases phytotoxic effects of more than 20% occurred. Although there were no negative yield effects it is suggested to put a warning on the label e.g. “crop damage is possible”.

Adverse effects on beneficial organisms (other than bees)

A19786A is classified as not harmful for the parasitoid wasp *Aphidius rhopalosiphi*, but as harmful for relevant predatory mites and spiders at the proposed maximum application rate of 1.8 L/ha.

Impact on succeeding crops

Based on the PEC- and TER calculation there is a theoretical risk for succeeding crops by pyroxualm whereas the risk of pinoxaden can be considered as low. An evaluation based on the herbicide A19786A instead of both active substances have not been submitted by the applicant.

The most sensitive crops are spring crops like sugar beet, soya, sunflower and peas. Since these crops are sown much later than 120 DAT (TER > 3.9) the risk can be considered as low.

These findings have been supported by field experiments where no unacceptable crop damage occurred in normal crop rotation. Crop damage of the herbicide A19786A was on a lower level than at the reference product Atlantis.

Impact on other plants including adjacent crops
Based on the data submitted by the applicant there is a risk for adjacent crop by the herbicide A19786A. By using conventional nozzles a buffer zone of 5 m is recommended respectively 1 m for 50% drift reduction. A warning information should be given in the label.

Possible development of resistance or cross-resistance
The applicant claims that the resistance risk inherent in A19786A can be assumed to be comparable to that of other herbicides in HRAC group A and B, i. e. medium-high. This conclusion can generally be followed. The increasing occurrence of dicotyledonous biotypes with ALS resistance in Europe emphasizes an increasing risk of resistance evolution for ALS active substances. In addition, most of the grass target species can be regarded as high risk species and ACCase and ALS inhibitors are frequently used in other main crop species in central Europe. The general resistance risk of A19786A is therefore assessed as high. The applicant has not provided any information on the individual resistance risk within the different Member States of the EU.

The label warning WH951 (The risk of resistance has to be indicated on the package and in the instructions of use. Particularly measures for an appropriate risk management have to be declared.) is proposed.

IIIA1 6.7 List of test facilities including the corresponding certificates

Test facility	Country	Address	Number of trials		
			2011	2012	Total
ATC - Agro Trial Center GmbH	AT	Am Futterplatz 2471 Rohrau	-	3	**3**
Syngenta CP Austria	AT	Anton-Baumgartner-Strasse 125/2/3/1 1230 Wien	1	-	**1**
Redebel S.A.	BE	Rue de Chassart 4 6221 Saint-Amand	3	-	**3**
Syngenta Crop Protection AG	CH	Schwarzwaldallee 215 4058 Basel	3	3	**6**
Agricultural Research Institute	CZ	Havlíčkova 2787 767 01 Kroměříž	1	-	**1**
Crop Research Institute Prague (VURV Praha)	CZ	Drnovská 507 161 06 Praha 6	1	-	**1**
Experimental station Kluky	CZ	Kluky 200 398 19 Kluky	1	-	**1**
Zemedelska ZC Kujavy	CZ	Kujavy 48 724 44 Kujavy	1	-	**1**
ZS Rýmarov, s.r.o., Rymarov	CZ	Května 61 795 01 Rýmařov	1	-	**1**
BioChem Agrar GmbH	DE	Kupferstraße 6 04827 Gerichshain	-	3	**3**

Syngenta Agro GmbH	DE	Am Technologiepark 1-5 63477 Maintal	22	32	**54**
Aarhus University	DK	Forsøgsvej 1 4200 Slagelse	1	-	**1**
Agronova - Gefion Field Trials	DK	Møllevej 15 4140 Borup	2	-	**2**
Estonia Research Institute of Agriculture	EE	Teaduse 13 Saku 75501 Harju-maa	-	2	**2**
MTT Agifood Research Finnland	FI	Rillitie 1 31600 Jokioinen	3	-	**3**
BIOTEK Agriculture	FR	Route de Viélaines 10120 Saint Pouange	-	8	**8**
ESSAIS PLUS	FR	1, rue du 8 mai 62128 Boyelles	-	3	**3**
SGS Agri Min	FR	227 route de Fronton 31140 Aucamville	-	6	**6**
Syngenta Agro SAS	FR	20, rue Marat 78212 Saint-Cyr-L'Ecole	12	5	**17**
SynTech Research France SAS	FR	613 route du bois de Loyse 71570 La Chapelle de Guinchay	7	6	**13**
Syngenta Crop Protection S.p.A.	IT	Via Gallarate 139 20151 Milano	1	-	**1**
Latvian Plant Protection Research Centre	LV	Lielvardes 36/38 1006 Riga	4	4	**8**
Lithuanian Institute of Agriculture	LT	Instituto al. 1 58 344 Akademija Kedainiai	8	3	**11**
Syngenta Crop Protection B.V.	NL	Jacob Obrechtlaan 3 4611 AP Bergen Op Zoom	-	3	**3**
Agrostat Sp. z o. o.	PL	ul. Ziębicka 2 60-164 Poznań	2	-	**2**
Field Research Support	PL	ul. Dworcowa 2 64-000 Koscian	-	1	**1**
Institute Ochrony Roslin Oddzial Sosnicowice	PL	ul. Gliwicka 29 44-153 Sosnicowice	2	-	**2**
Lublin University (Uniwersytet Przyrodniczy w Lublinie)	PL	ul. Skromna 8 20-704 Lublin	4	1	**5**
Plant Protection Institute Poznan (Uniwersytet Przyrodniczy ZDD Gorzyn)	PL	ul. Mazowiecka 45/46 60-623 Poznan	6	2	**8**
Staphyt Sp. z o. o.	PL	ul. Ziębicka 2 60-164 Poznań	-	2	**2**
Syngenta Poland	PL	ul. Powazkowska 44c 01-797 Warszawa	6	2	**8**

Oxford Agricultural Trials Ltd.	UK	West Farm Barns Launton Road Stratton Audley, Bicester Oxfordshire OX27 9AS	1	-	**1**
Syngenta Crop Protection UK LTD	UK	CPC4 Capital Park, Fulbourn Cambridge CB21 5XE	5	-	**5**
Agronova - Gefion Field Trials (Husec AB)	SE	Kongstedvej 4B 4100 Ringsted	2	-	**2**
		Grand Total	**100**	**89**	**189**

Appendix 1: Lists of data considered in support of the evaluation 08.11.2017

List of data submitted by the applicant and relied on

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIIA1 1.7	del la Fuente, K.	2003	Cloquintocet-mexyl - Document I, Part 1 - Identity, physical and chemical properties NOA407855/0468 N/N N 2603121/368323	N	N		Syngenta Agro
KIIIA1 10.5.2	Stevens, J.	2012	Pinoxaden/Pyroxsulam/Cloquintocet-mexyl EC (A19786A) - A rate-response extended laboratory bioassay of the effects of fresh residues the parasitic wasp Aphidius rhopalosiphi (Hymenoptera, Braconidae) A19786A_10003 ! SYN-12-44 Syngenta J/O N 2603187/368328	N	J		Syngenta Agro
KIIIA1 10.5.2	Fallowfield, L.	2013	Pinoxaden/Pyroxsulam/Cloquintocet-mexyl EC (A19786A) - A rate-response extended laboratory bioassay of the effects of fresh residues on the predatory mite Typhlodromus pyri (Acari: Phytoseiidae) A19786A_10004 ! SYN-12-43 Syngenta J/O N 2603188/368329	N	J		Syngenta Agro

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIIA1 10.8.1.2	Bramby-Gunary, J.	2012	Draft Report - Pinoxaden/Pyroxsulam/cloquintocet-mexyl EC (A19786A) - Evaluation of the Phytotoxicity to Non Target Terrestrial Plant Vegetative Vigour Test A19786A_10002 ! ACE-12-050 Syngenta J/O N 2603191/368330	N	J		Syngenta Agro
KIIIA1 10.8.1.2	Stefanut, M.	2013	Pinoxaden/Pyroxsulam/cloquintocet-mexyl EC (A19786A) - Evaluation of the Phytotoxicity to Avena sativa Plant Vegetative Vigour Test A19786A_10056 ! ACE-13-080 Syngenta J/O N 2603192/368331	N	J		Syngenta Agro
KIIIA1 10.8.1.3	Bramby-Gunary, J.	2012	Pinoxaden/Pyroxsulam/cloquintocet-mexyl EC (A19786A) - Evaluation of the Phytotoxicity to Non Target Terrestrial Plant Seedling Emergence and Seedling Growth Test A19786A_10001 ! ACE-12-049 Syngenta J/O N 2603193/368332	N	J		Syngenta Agro
KIIIA1 6	Pflughoeft, O., Weber, C.	2014	BAD A19786A Pyroxsulam Pinoxaden EC041.66 A19786A_10465 Syngenta N/N N 2603196/368333	N	J		Syngenta Agro
KIIIA1 6.1.1	Schmitt, B.	2012	A19786A (PXD/PYR) dose response trial against Alopecurus and Lolium A19786A_10378 Syngenta N/J N 2603197/368334	N	J		Syngenta Agro

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protec-tion claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIIA1 6.1.1	Kaiser, B.	2012	A19786A (PXD/PYR) dose response trial against Alopecurus and dicots A19786A_10292 Syngenta N/J N 2603198/368335	N	J		Syngenta Agro
KIIIA1 6.1.1	Griehl, T.	2012	A19786A (PXD/PYR) dose response trial against Alopecurus and dicots A19786A_10438 Syngenta N/J N 2603199/368336	N	J		Syngenta Agro
KIIIA1 6.1.1	Griehl, T.	2012	A19786A (PXD/PYR) dose response trial against Alopecurus and dicots A19786A_10426 Syngenta N/J N 2603200/368337	N	J		Syngenta Agro
KIIIA1 6.1.1	Terhalle, S.	2012	A19786A (PXD/PYR) dose response trial against Alopecurus and dicots A19786A_10455 Syngenta N/J N 2603201/368338	N	J		Syngenta Agro
KIIIA1 6.1.1	Weigl, A.	2012	A19786A (PXD/PYR) dose response trial against Alopecurus and dicots A19786A_10406 Syngenta N/J N 2603202/368339	N	J		Syngenta Agro

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protec-tion claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIIA1 6.1.1	Bourgeois, B.	2012	A19786A (PXD/PYR) dose response trial against Alopecurus and dicots A19786A_10308 Syngenta N/J N 2603203/368340	N	J		Syngenta Agro
KIIIA1 6.1.1	Rivet, J.	2012	A19786A (PXD/PYR) dose response trial against Alopecurus and dicots A19786A_10422 Syngenta N/J N 2603204/368341	N	J		Syngenta Agro
KIIIA1 6.1.1	Rivet, J.	2012	A19786A (PXD/PYR) dose response trial against Alopecurus and dicots A19786A_10314 Syngenta N/J N 2603205/368342	N	J		Syngenta Agro
KIIIA1 6.1.1	Rigail, J.	2012	A19786A (PXD/PYR) dose response trial against Alopecurus A19786A_10350 Syngenta N/J N 2603206/368343	N	J		Syngenta Agro
KIIIA1 6.1.1	Kuhle, B.	2012	A19786A (PXD/PYR) timing trial against Alopecurus and dicots A19786A_10457 Syngenta N/J N 2603207/368344	N	J		Syngenta Agro

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protec-tion claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIIA1 6.1.1	Griehl, T.	2012	A19786A (PXD/PYR) timing trial against Alopecurus and dicots A19786A_10432 Syngenta N/J N 2603208/368345	N	J		Syngenta Agro
KIIIA1 6.1.1	Delebarre, O.	2012	A19786A (PXD/PYR) timing trial against Alopecurus and dicots A19786A_10298 Syngenta N/J N 2603209/368346	N	J		Syngenta Agro
KIIIA1 6.1.1	Ponsard, P.	2012	A19786A (PXD/PYR) timing trial against Alopecurus and dicots A19786A_10322 Syngenta N/J N 2603210/368347	N	J		Syngenta Agro
KIIIA1 6.1.1	Rigail, J.	2012	A19786A (PXD/PYR) timing trial against Alopecurus A19786A_10328 Syngenta N/J N 2603211/368348	N	J		Syngenta Agro
KIIIA1 6.1.1	Hooghiemstra, J.	2012	A19786A (PXD/PYR) timing trial against Alopecurus and dicots A19786A_10462 Syngenta N/J N 2603212/368349	N	J		Syngenta Agro

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protec-tion claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIIA1 6.1.1	Thiel, M.	2012	A19786A (PXD/PYR) dose response trial against Lolium A19786A_10356 Syngenta N/J N 2603213/368350	N	J		Syngenta Agro
KIIIA1 6.1.1	Stuebner, B.	2012	A19786A (PXD/PYR) dose response trial against Lolium and dicots A19786A_10458 Syngenta N/J N 2603214/368351	N	J		Syngenta Agro
KIIIA1 6.1.1	Bertin, B.	2012	A19786A (PXD/PYR) dose response trial against Lolium A19786A_10410 Syngenta N/J N 2603215/368352	N	J		Syngenta Agro
KIIIA1 6.1.1	Largilliere, J.	2012	A19786A (PXD/PYR) dose response trial against Lolium and dicots A19786A_10320 Syngenta N/J N 2603216/368353	N	J		Syngenta Agro
KIIIA1 6.1.1	Beaufort, M.	2012	A19786A (PXD/PYR) dose response trial against Lolium and dicots A19786A_10346 Syngenta N/J N 2603217/368354	N	J		Syngenta Agro

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protec-tion claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIIA1 6.1.1	Piatte, P.	2012	A19786A (PXD/PYR) dose response trial against Lolium and dicots A19786A_10348 Syngenta N/J N 2603218/368355	N	J		Syngenta Agro
KIIIA1 6.1.1	Rigail, J.	2012	A19786A (PXD/PYR) dose response trial against Lolium and dicots A19786A_10326 Syngenta N/J N 2603219/368356	N	J		Syngenta Agro
KIIIA1 6.1.1	Pawlak, A.	2012	A19786A (PXD/PYR) dose response trial against Lolium and dicots A19786A_10304 Syngenta N/J N 2603220/368357	N	J		Syngenta Agro
KIIIA1 6.1.1	Poivey, B.	2012	A19786A (PXD/PYR) dose response trial against Lolium and dicots A19786A_10240 Syngenta N/J N 2603221/368358	N	J		Syngenta Agro
KIIIA1 6.1.1	Idziak, R.	2012	A19786A (PXD/PYR) dose response trial against Lolium and dicots A19786A_10280 Syngenta N/J N 2603222/368359	N	J		Syngenta Agro

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protec-tion claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIIA1 6.1.1	Carriou, S.	2012	A19786A (PXD/PYR) timing trial against Lolium and dicots A19786A_10414 Syngenta N/J N 2603223/368360	N	J		Syngenta Agro
KIIIA1 6.1.1	Cailliau, B.	2011	A19786A (PXD/PYR) timing trial against Lolium A19786A_10418 Syngenta N/J N 2603224/368361	N	J		Syngenta Agro
KIIIA1 6.1.1	Reisenhofer, A.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10370 Syngenta N/J N 2603225/368362	N	J		Syngenta Agro
KIIIA1 6.1.1	Reisenhofer, A.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10372 Syngenta N/J N 2603226/368363	N	J		Syngenta Agro
KIIIA1 6.1.1	Anzengruber, J.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10338 Syngenta N/J N 2603227/368364	N	J		Syngenta Agro

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protec-tion claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIIA1 6.1.1	Stuebner, B.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10459 Syngenta N/J N 2603228/368365	N	J		Syngenta Agro
KIIIA1 6.1.1	Stuebner, B.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10453 Syngenta N/J N 2603229/368366	N	J		Syngenta Agro
KIIIA1 6.1.1	Stuebner, B.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10452 Syngenta N/J N 2603230/368367	N	J		Syngenta Agro
KIIIA1 6.1.1	Krueger, D.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10424 Syngenta N/J N 2603231/368368	N	J		Syngenta Agro

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protec-tion claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIIA1 6.1.1	Krueger, D.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10436 Syngenta N/J N 2603232/368369	N	J		Syngenta Agro
KIIIA1 6.1.1	Carstens, H.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10456 Syngenta N/J N 2603233/368370	N	J		Syngenta Agro
KIIIA1 6.1.1	Ehrenschwender, G.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10440 Syngenta N/J N 2603234/368371	N	J		Syngenta Agro
KIIIA1 6.1.1	Terhalle, S.	2012	A19786A (PXD/PYR) dose response trial against Alomy, Apera and dicots A19786A_10460 Syngenta N/J N 2603235/368372	N	J		Syngenta Agro

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protec-tion claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIIA1 6.1.1	Ilumae, E.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10218 Syngenta N/J N 2603236/368373	N	J		Syngenta Agro
KIIIA1 6.1.1	Delebarre, O.	2012	A19786A (PXD/PYR) dose response trial against Alomy, Apera and dicots A19786A_10300 Syngenta N/J N 2603237/368374	N	J		Syngenta Agro
KIIIA1 6.1.1	Rivet, J.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10312 Syngenta N/J N 2603238/368375	N	J		Syngenta Agro
KIIIA1 6.1.1	Psibisauskiene, G.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10232 Syngenta N/J N 2603239/368376	N	J		Syngenta Agro

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protec-tion claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIIA1 6.1.1	Vanaga, I.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10266 Syngenta N/J N 2603240/368377	N	J		Syngenta Agro
KIIIA1 6.1.1	Hooghiemstra, J.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10464 Syngenta N/J N 2603241/368378	N	J		Syngenta Agro
KIIIA1 6.1.1	Kroehnke, J.	2012	A19786A (PXD/PYR) dose response trial against Apera, Avena and dicots A19786A_10242 Syngenta N/J N 2603242/368379	N	J		Syngenta Agro
KIIIA1 6.1.1	Kroehnke, J.	2012	A19786A (PXD/PYR) dose response trial against Apera, Avena and dicots A19786A_10270 Syngenta N/J N 2603243/368381	N	J		Syngenta Agro

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KIIIA1 6.1.1	Krueger, D.	2012	A19786A (PXD/PYR) timing trial against Apera and dicots A19786A_10428 Syngenta N/J N 2603244/368382	N	J		Syngenta Agro
KIIIA1 6.1.1	Carstens, H.	2012	A19786A (PXD/PYR) timing trial against Apera and dicots A19786A_10451 Syngenta N/J N 2603245/368383	N	J		Syngenta Agro
KIIIA1 6.1.1	Ehrenschwender, G.	2012	A19786A (PXD/PYR) timing trial against Apera and dicots A19786A_10448 Syngenta N/J N 2603246/368384	N	J		Syngenta Agro
KIIIA1 6.1.1	Terhalle, S.	2012	A19786A (PXD/PYR) timing trial against Alopecurus, Apera and dicots A19786A_10454 Syngenta N/J N 2603247/368385	N	J		Syngenta Agro

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KIIIA1 6.1.1	Thibault, A.	2012	A19786A (PXD/PYR) dose response trial against Avena and dicots A19786A_10366 Syngenta N/J N 2603248/368386	N	J		Syngenta Agro
KIIIA1 6.1.1	Leger, D.	2012	A19786A (PXD/PYR) dose response trial against Avena A19786A_10318 Syngenta N/J N 2603249/368387	N	J		Syngenta Agro
KIIIA1 6.1.1	Rabot, L.	2012	A19786A (PXD/PYR) dose response trial against Avena A19786A_10352 Syngenta N/J N 2603250/368388	N	J		Syngenta Agro
KIIIA1 6.1.1	Ruppert, R.	2012	A19786A (PXD/PYR) timing trial against Avena and dicots A19786A_10442 Syngenta N/J N 2603251/368389	N	J		Syngenta Agro

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KIIIA1 6.1.1	Guichard, J.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter triticale A19786A_10178 Syngenta N/J N 2603252/368390	N	J		Syngenta Agro
KIIIA1 6.1.1	Stuebner, B.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter triticale A19786A_10188 Syngenta N/J N 2603253/368391	N	J		Syngenta Agro
KIIIA1 6.1.1	Krueger, D.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter triticale A19786A_10172 Syngenta N/J N 2603254/368392	N	J		Syngenta Agro
KIIIA1 6.1.1	Kuhle, B.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter triticale A19786A_10174 Syngenta N/J N 2603255/368393	N	J		Syngenta Agro

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KIIIA1 6.1.1	Delebarre, O.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter triticale A19786A_10182 Syngenta N/J N 2603256/368394	N	J		Syngenta Agro
KIIIA1 6.1.1	Malbete, A.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter triticale A19786A_10216 Syngenta N/J N 2603257/368395	N	J		Syngenta Agro
KIIIA1 6.1.1	Potocka, E.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter triticale A19786A_10126 Syngenta N/J N 2603258/368396	N	J		Syngenta Agro
KIIIA1 6.1.1	Guichard, J.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter rye A19786A_10198 Syngenta N/J N 2603259/368397	N	J		Syngenta Agro

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KIIIA1 6.1.1	Krueger, D.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter rye A19786A_10154 Syngenta N/J N 2603260/368398	N	J		Syngenta Agro
KIIIA1 6.1.1	Carstens, H.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter rye A19786A_10186 Syngenta N/J N 2603261/368399	N	J		Syngenta Agro
KIIIA1 6.1.1	Kaiser, B.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter rye A19786A_10210 Syngenta N/J N 2603262/368400	N	J		Syngenta Agro
KIIIA1 6.1.1	Ilumae, E.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter rye A19786A_10140 Syngenta N/J N 2603263/368401	N	J		Syngenta Agro

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KIIIA1 6.1.1	Fluchon, V.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter rye A19786A_10146 Syngenta N/J N 2603264/368402	N	J		Syngenta Agro
KIIIA1 6.1.1	Vanaga, I.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter rye A19786A_10118 Syngenta N/J N 2603265/368403	N	J		Syngenta Agro
KIIIA1 6.1.1	Guichard, J.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10196 Syngenta N/J N 2603266/368404	N	J		Syngenta Agro
KIIIA1 6.1.1	Carstens, H.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10206 Syngenta N/J N 2603267/368405	N	J		Syngenta Agro

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KIIIA1 6.1.1	Kaiser, B.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10168 Syngenta N/J N 2603268/368406	N	J		Syngenta Agro
KIIIA1 6.1.1	Boudinet, P.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10192 Syngenta N/J N 2603269/368407	N	J		Syngenta Agro
KIIIA1 6.1.1	Touron, B.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10148 Syngenta N/J N 2603270/368408	N	J		Syngenta Agro
KIIIA1 6.1.1	Montier, L.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10158 Syngenta N/J N 2603271/368409	N	J		Syngenta Agro

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KIIIA1 6.1.1	Psibisauskiene, G.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10142 Syngenta N/J N 2603272/368410	N	J		Syngenta Agro
KIIIA1 6.1.1	Psibisauskiene, G.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10144 Syngenta N/J N 2603273/368411	N	J		Syngenta Agro
KIIIA1 6.1.1	Vanaga, I.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10116 Syngenta N/J N 2603274/368412	N	J		Syngenta Agro
KIIIA1 6.1.1	Hooghiemstra, J.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10160 Syngenta N/J N 2603275/368413	N	J		Syngenta Agro

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KIIIA1 6.1.1	Uminski, P.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10120 Syngenta N/J N 2603276/368414	N	J		Syngenta Agro
KIIIA1 6.1.1	Vanaga, I.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter triticale A19786A_10108 Syngenta N/J N 2603277/368415	N	J		Syngenta Agro
KIIIA1 6.1.1	Cloix, J.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter rye A19786A_10162 Syngenta N/J N 2603278/368416	N	J		Syngenta Agro
KIIIA1 6.1.1	Camus, O.	2012	A19786A (PXD/PYR) timing trial against Avena A19786A_10463 Syngenta N/J N 2603279/368417	N	J		Syngenta Agro

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KIIIA1 6.1.1	Pietryga, J.	2011	A19786A (PXD/PYR) formulation justification study A19786A_10246 Syngenta N/J N 2603280/368418	N	J		Syngenta Agro
KIIIA1 6.1.1	Potocka, E.	2011	A19786A (PXD/PYR) formulation justification study A19786A_10274 Syngenta N/J N 2603281/368419	N	J		Syngenta Agro
KIIIA1 6.1.1	Sobiech, L.	2011	A19786A (PXD/PYR) formulation justification study A19786A_10278 Syngenta N/J N 2603282/368420	N	J		Syngenta Agro
KIIIA1 6.1.1	Terhalle, S.	2011	A19786A (PXD/PYR) efficacy trial against Alopecurus and dicots A19786A_10382 Syngenta N/J N 2603283/368421	N	J		Syngenta Agro

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KIIIA1 6.1.1	Hvid, P.	2011	A19786A (PXD/PYR) efficacy trial against Alopecurus and dicots A19786A_10408 Syngenta N/J N 2603284/368422	N	J		Syngenta Agro
KIIIA1 6.1.1	Speyer, M.	2011	A19786A (PXD/PYR) efficacy trial against Alopecurus and Avena A19786A_10332 Syngenta N/J N 2603285/368423	N	J		Syngenta Agro
KIIIA1 6.1.1	Hvid, P.	2011	A19786A (PXD/PYR) efficacy trial against Alopecurus and dicots A19786A_10222 Syngenta N/J N 2603286/368424	N	J		Syngenta Agro
KIIIA1 6.1.1	Auskalniene, O.	2011	A19786A (PXD/PYR) formulation justification study A19786A_10262 Syngenta N/J N 2603287/368425	N	J		Syngenta Agro

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KIIIA1 6.1.1	Wielgat, D.	2011	A19786A (PXD/PYR) formulation justification study A19786A_10238 Syngenta N/J N 2603288/368426	N	J		Syngenta Agro
KIIIA1 6.1.1	Bertin, B.	2011	A19786A (PXD/PYR) efficacy trial against Lolium A19786A_10296 Syngenta N/J N 2603289/368427	N	J		Syngenta Agro
KIIIA1 6.1.1	Piatte, P.	2011	A19786A (PXD/PYR) efficacy trial against Lolium and dicots A19786A_10362 Syngenta N/J N 2603290/368428	N	J		Syngenta Agro
KIIIA1 6.1.1	Fairweather, A.	2011	A19786A (PXD/PYR) efficacy trial against Lolium A19786A_10358 Syngenta N/J N 2603291/368429	N	J		Syngenta Agro

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KIIIA1 6.1.1	Svobodnik, A.	2011	A19786A (PXD/PYR) efficacy trial against Apera and dicots A19786A_10380 Syngenta N/J N 2603292/368430	N	J		Syngenta Agro
KIIIA1 6.1.1	Carstens, H.	2011	A19786A (PXD/PYR) efficacy trial against Apera and dicots A19786A_10390 Syngenta N/J N 2603293/368431	N	J		Syngenta Agro
KIIIA1 6.1.1	Rosenhauer, M., Petersen, J.	2012	A19786A resistance monitoring of ALOMY - University Bingen 2012 A19786A_10093 Syngenta N/J N 2603294/368432	N	J		Syngenta Agro
KIIIA1 6.1.2	Rigail, J.	2012	A19786A (PXD/PYR) dose response trial against Alopecurus A19786A_10350 Syngenta N/J N 2603295/368433	N	J		Syngenta Agro

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KIIIA1 6.1.2	Bourgeois, B.	2012	A19786A (PXD/PYR) dose response trial against Alopecurus and dicots A19786A_10308 Syngenta N/J N 2603296/368434	N	J		Syngenta Agro
KIIIA1 6.1.2	Rivet, J.	2012	A19786A (PXD/PYR) dose response trial against Alopecurus and dicots A19786A_10422 Syngenta N/J N 2603297/368435	N	J		Syngenta Agro
KIIIA1 6.1.2	Rivet, J.	2012	A19786A (PXD/PYR) dose response trial against Alopecurus and dicots A19786A_10314 Syngenta N/J N 2603298/368437	N	J		Syngenta Agro
KIIIA1 6.1.2	Bourgeois, B.	2011	A19786A (PXD/PYR) dose response trial against Alopecurus and dicots A19786A_10416 Syngenta N/J N 2603299/368438	N	J		Syngenta Agro

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KIIIA1 6.1.2	Clement, O.	2011	A19786A (PXD/PYR) dose response trial against Alopecurus A19786A_10420 Syngenta N/J N 2603300/368439	N	J		Syngenta Agro
KIIIA1 6.1.2	Doerig, B.	2011	A19786A (PXD/PYR) dose response trial against Alopecurus and dicots A19786A_10374 Syngenta N/J N 2603301/368440	N	J		Syngenta Agro
KIIIA1 6.1.2	Ruppert, R.	2012	A19786A (PXD/PYR) efficacy trial against Bromus and dicots A19786A_10444 Syngenta N/J N 2603302/368441	N	J		Syngenta Agro
KIIIA1 6.1.2	Ruppert, R.	2012	A19786A (PXD/PYR) efficacy trial against Bromus and dicots A19786A_10434 Syngenta N/J N 2603303/368442	N	J		Syngenta Agro

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KIIIA1 6.1.2	Schmitt, B.	2012	A19786A (PXD/PYR) dose response trial against Alopecurus and Lolium A19786A_10378 Syngenta N/J N 2603304/368443	N	J		Syngenta Agro
KIIIA1 6.1.2	Schmitt, B.	2012	A19786A (PXD/PYR) dose response trial against Alopecurus and Bromus A19786A_10396 Syngenta N/J N 2603305/368444	N	J		Syngenta Agro
KIIIA1 6.1.2	Piatte, P.	2012	A19786A (PXD/PYR) dose response trial against Lolium and dicots A19786A_10348 Syngenta N/J N 2603306/368445	N	J		Syngenta Agro
KIIIA1 6.1.2	Rigail, J.	2012	A19786A (PXD/PYR) dose response trial against Lolium and dicots A19786A_10326 Syngenta N/J N 2603307/368446	N	J		Syngenta Agro

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KIIIA1 6.1.2	Bertin, B.	2012	A19786A (PXD/PYR) dose response trial against Lolium A19786A_10410 Syngenta N/J N 2603308/368447	N	J		Syngenta Agro
KIIIA1 6.1.2	Largilliere, J.	2012	A19786A (PXD/PYR) dose response trial against Lolium and dicots A19786A_10320 Syngenta N/J N 2603309/368448	N	J		Syngenta Agro
KIIIA1 6.1.2	Beaufort, M.	2012	A19786A (PXD/PYR) dose response trial against Lolium and dicots A19786A_10346 Syngenta N/J N 2603310/368449	N	J		Syngenta Agro
KIIIA1 6.1.2	Rigail, J.	2012	A19786A (PXD/PYR) efficacy trial against Bromus and dicots A19786A_10324 Syngenta N/J N 2603311/368450	N	J		Syngenta Agro

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KIIIA1 6.1.2	Fluchon, V.	2012	A19786A (PXD/PYR) efficacy trial against Bromus A19786A_10412 Syngenta N/J N 2603312/368451	N	J		Syngenta Agro
KIIIA1 6.1.2	Ruppert, R.	2012	A19786A (PXD/PYR) efficacy trial against Bromus A19786A_10450 Syngenta N/J N 2603313/368452	N	J		Syngenta Agro
KIIIA1 6.1.2	Delebarre, O.	2012	A19786A (PXD/PYR) dose response trial against Alomy, Apera and dicots A19786A_10300 Syngenta N/J N 2603314/368453	N	J		Syngenta Agro
KIIIA1 6.1.2	Rivet, J.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10312 Syngenta N/J N 2603315/368454	N	J		Syngenta Agro

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KIIIA1 6.1.2	Reynens, P.	2011	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10376 Syngenta N/J N 2603316/368455	N	J		Syngenta Agro
KIIIA1 6.1.2	Reisenhofer, A.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10370 Syngenta N/J N 2603317/368456	N	J		Syngenta Agro
KIIIA1 6.1.2	Reisenhofer, A.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10372 Syngenta N/J N 2603318/368458	N	J		Syngenta Agro
KIIIA1 6.1.2	Anzengruber, J.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10338 Syngenta N/J N 2603319/368459	N	J		Syngenta Agro

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KIIIA1 6.1.2	Ehrenschwender, G.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10440 Syngenta N/J N 2603320/368460	N	J		Syngenta Agro
KIIIA1 6.1.2	Hooghiemstra, J.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10464 Syngenta N/J N 2603321/368461	N	J		Syngenta Agro
KIIIA1 6.1.2	Marcato, G.	2011	A19786A (PXD/PYR) dose response trial against Avena and dicots A19786A_10316 Syngenta N/J N 2603322/368462	N	J		Syngenta Agro
KIIIA1 6.1.2	Thibault, A.	2012	A19786A (PXD/PYR) dose response trial against Avena and dicots A19786A_10366 Syngenta N/J N 2603323/368463	N	J		Syngenta Agro

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KIIIA1 6.1.2	Gainville, C.	2011	A19786A (PXD/PYR) dose response trial against Avena and dicots A19786A_10330 Syngenta N/J N 2603324/368464	N	J		Syngenta Agro
KIIIA1 6.1.2	Leger, D.	2012	A19786A (PXD/PYR) dose response trial against Avena A19786A_10318 Syngenta N/J N 2603325/368465	N	J		Syngenta Agro
KIIIA1 6.1.2	Rabot, L.	2012	A19786A (PXD/PYR) dose response trial against Avena A19786A_10352 Syngenta N/J N 2603326/368466	N	J		Syngenta Agro
KIIIA1 6.1.2	Ruppert, R.	2011	A19786A (PXD/PYR) dose response trial against Avena and dicots A19786A_10430 Syngenta N/J N 2603327/368467	N	J		Syngenta Agro
KIIIA1 6.1.2	Bourgeois, B.	2011	A19786A (PXD/PYR) efficacy trial against dicots A19786A_10306 Syngenta N/J N 2603328/368468	N	J		Syngenta Agro

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KIIIA1 6.1.2	Reynens, P.	2011	A19786A (PXD/PYR) dose response trial against dicots A19786A_10340 Syngenta N/J N 2603329/368470	N	J		Syngenta Agro
KIIIA1 6.1.2	Kaiser, B.	2011	A19786A (PXD/PYR) dose response trial against Alopecurus and dicots A19786A_10402 Syngenta N/J N 2603330/368471	N	J		Syngenta Agro
KIIIA1 6.1.2	Terhalle, S.	2011	A19786A (PXD/PYR) dose response trial against Alopecurus and dicots A19786A_10394 Syngenta N/J N 2603331/368472	N	J		Syngenta Agro
KIIIA1 6.1.2	Kaiser, B.	2012	A19786A (PXD/PYR) dose response trial against Alopecurus and dicots A19786A_10292 Syngenta N/J N 2603332/368473	N	J		Syngenta Agro
KIIIA1 6.1.2	Griehl, T.	2012	A19786A (PXD/PYR) dose response trial against Alopecurus and dicots A19786A_10438 Syngenta N/J N 2603333/368474	N	J		Syngenta Agro

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KIIIA1 6.1.2	Griehl, T.	2012	A19786A (PXD/PYR) dose response trial against Alopecurus and dicots A19786A_10426 Syngenta N/J N 2603334/368475	N	J		Syngenta Agro
KIIIA1 6.1.2	Terhalle, S.	2012	A19786A (PXD/PYR) dose response trial against Alopecurus and dicots A19786A_10455 Syngenta N/J N 2603335/368476	N	J		Syngenta Agro
KIIIA1 6.1.2	Weigl, A.	2012	A19786A (PXD/PYR) dose response trial against Alopecurus and dicots A19786A_10406 Syngenta N/J N 2603336/368477	N	J		Syngenta Agro
KIIIA1 6.1.2	Pietryga, J.	2011	A19786A (PXD/PYR) dose response trial against Alopecurus and dicots A19786A_10244 Syngenta N/J N 2603337/368478	N	J		Syngenta Agro
KIIIA1 6.1.2	Sobiech, L.	2011	A19786A (PXD/PYR) dose response trial against Alopecurus and dicots A19786A_10220 Syngenta N/J N 2603338/368479	N	J		Syngenta Agro

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KIIIA1 6.1.2	Thiel, M.	2012	A19786A (PXD/PYR) dose response trial against Lolium A19786A_10356 Syngenta N/J N 2603339/368480	N	J		Syngenta Agro
KIIIA1 6.1.2	Stuebner, B.	2012	A19786A (PXD/PYR) dose response trial against Lolium and dicots A19786A_10458 Syngenta N/J N 2603340/368481	N	J		Syngenta Agro
KIIIA1 6.1.2	Scott, T.	2011	A19786A (PXD/PYR) dose response trial against Lolium A19786A_10334 Syngenta N/J N 2603341/368482	N	J		Syngenta Agro
KIIIA1 6.1.2	Dyas, D.	2011	A19786A (PXD/PYR) dose response trial against Lolium A19786A_10336 Syngenta N/J N 2603342/368483	N	J		Syngenta Agro
KIIIA1 6.1.2	Poivey, B.	2011	A19786A (PXD/PYR) dose response trial against Lolium and dicots A19786A_10268 Syngenta N/J N 2603343/368484	N	J		Syngenta Agro

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KIIIA1 6.1.2	Sobiech, L.	2011	A19786A (PXD/PYR) dose response trial against Apera Lolium and dicots A19786A_10252 Syngenta N/J N 2603344/368485	N	J		Syngenta Agro
KIIIA1 6.1.2	Pawlak, A.	2012	A19786A (PXD/PYR) dose response trial against Lolium and dicots A19786A_10304 Syngenta N/J N 2603345/368486	N	J		Syngenta Agro
KIIIA1 6.1.2	Poivey, B.	2012	A19786A (PXD/PYR) dose response trial against Lolium and dicots A19786A_10240 Syngenta N/J N 2603346/368487	N	J		Syngenta Agro
KIIIA1 6.1.2	Idziak, R.	2012	A19786A (PXD/PYR) dose response trial against Lolium and dicots A19786A_10280 Syngenta N/J N 2603347/368488	N	J		Syngenta Agro
KIIIA1 6.1.2	Majchrzak, L.	2012	A19786A (PXD/PYR) efficacy trial against Bromus and dicots A19786A_10282 Syngenta N/J N 2603348/368489	N	J		Syngenta Agro

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KIIIA1 6.1.2	Krueger, D.	2011	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10398 Syngenta N/J N 2603349/368490	N	J		Syngenta Agro
KIIIA1 6.1.2	Carstens, H.	2011	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10400 Syngenta N/J N 2603350/368491	N	J		Syngenta Agro
KIIIA1 6.1.2	Terhalle, S.	2011	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10404 Syngenta N/J N 2603351/368492	N	J		Syngenta Agro
KIIIA1 6.1.2	Terhalle, S.	2012	A19786A (PXD/PYR) dose response trial against Alomy, Apera and dicots A19786A_10460 Syngenta N/J N 2603352/368493	N	J		Syngenta Agro
KIIIA1 6.1.2	Stuebner, B.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10459 Syngenta N/J N 2603353/368494	N	J		Syngenta Agro

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KIIIA1 6.1.2	Stuebner, B.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10453 Syngenta N/J N 2603354/368495	N	J		Syngenta Agro
KIIIA1 6.1.2	Stuebner, B.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10452 Syngenta N/J N 2603355/368496	N	J		Syngenta Agro
KIIIA1 6.1.2	Krueger, D.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10424 Syngenta N/J N 2603356/368497	N	J		Syngenta Agro
KIIIA1 6.1.2	Krueger, D.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10436 Syngenta N/J N 2603357/368498	N	J		Syngenta Agro
KIIIA1 6.1.2	Carstens, H.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10456 Syngenta N/J N 2603358/368499	N	J		Syngenta Agro

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KIIIA1 6.1.2	Hvid, P.	2011	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10364 Syngenta N/J N 2603359/368500	N	J		Syngenta Agro
KIIIA1 6.1.2	Kroehnke, J.	2012	A19786A (PXD/PYR) dose response trial against Apera, Avena and dicots A19786A_10242 Syngenta N/J N 2603360/368501	N	J		Syngenta Agro
KIIIA1 6.1.2	Kroehnke, J.	2012	A19786A (PXD/PYR) dose response trial against Apera, Avena and dicots A19786A_10270 Syngenta N/J N 2603361/368502	N	J		Syngenta Agro
KIIIA1 6.1.2	Janecek, M.	2011	A19786A (PXD/PYR) dose response trial against Avena and dicots A19786A_10342 Syngenta N/J N 2603362/368503	N	J		Syngenta Agro
KIIIA1 6.1.2	Dyas, D.	2011	A19786A (PXD/PYR) dose response trial against Avena A19786A_10354 Syngenta N/J N 2603363/368504	N	J		Syngenta Agro

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KIIIA1 6.1.2	Kuhle, B.	2011	A19786A (PXD/PYR) dose response trial against dicots A19786A_10388 Syngenta N/J N 2603364/368505	N	J		Syngenta Agro
KIIIA1 6.1.2	Idziak, R.	2011	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10250 Syngenta N/J N 2603365/368506	N	J		Syngenta Agro
KIIIA1 6.1.2	Idziak, R.	2011	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10254 Syngenta N/J N 2603366/368507	N	J		Syngenta Agro
KIIIA1 6.1.2	Krueger, D.	2011	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10386 Syngenta N/J N 2603367/368508	N	J		Syngenta Agro
KIIIA1 6.1.2	Hvid, P.	2011	A19786A (PXD/PYR) efficacy trial against dicots A19786A_10360 Syngenta N/J N 2603368/368509	N	J		Syngenta Agro

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KIIIA1 6.1.2	Stuebner, B.	2011	A19786A (PXD/PYR) efficacy trial against dicots A19786A_10384 Syngenta N/J N 2603369/368510	N	J		Syngenta Agro
KIIIA1 6.1.2	Auskalniene, O.	2011	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10260 Syngenta N/J N 2603370/368511	N	J		Syngenta Agro
KIIIA1 6.1.2	Auskalniene, O.	2011	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10258 Syngenta N/J N 2603371/368512	N	J		Syngenta Agro
KIIIA1 6.1.2	Auskalniene, O.	2011	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10230 Syngenta N/J N 2603372/368513	N	J		Syngenta Agro
KIIIA1 6.1.2	Vanaga, I.	2011	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10234 Syngenta N/J N 2603373/368514	N	J		Syngenta Agro

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KIIIA1 6.1.2	Ilumae, E.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10218 Syngenta N/J N 2603374/368515	N	J		Syngenta Agro
KIIIA1 6.1.2	Psibisauskiene, G.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10232 Syngenta N/J N 2603375/368516	N	J		Syngenta Agro
KIIIA1 6.1.2	Vanaga, I.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10266 Syngenta N/J N 2603376/368517	N	J		Syngenta Agro
KIIIA1 6.1.2	Vanaga, I.	2011	A19786A (PXD/PYR) dose response trial against dicots A19786A_10236 Syngenta N/J N 2603377/368518	N	J		Syngenta Agro
KIIIA1 6.1.3	Reisenhofer, A.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10370 Syngenta N/J N 2603378/368519	N	J		Syngenta Agro

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KIIIA1 6.1.3	Reisenhofer, A.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10372 Syngenta N/J N 2603379/368520	N	J		Syngenta Agro
KIIIA1 6.1.3	Anzengruber, J.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10338 Syngenta N/J N 2603380/368521	N	J		Syngenta Agro
KIIIA1 6.1.3	Rohringer, G.	2011	A19786A (PXD/PYR) efficacy trial against Avena and dicots A19786A_10288 Syngenta N/J N 2603381/368522	N	J		Syngenta Agro
KIIIA1 6.1.3	Reynens, P.	2011	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10376 Syngenta N/J N 2603382/368523	N	J		Syngenta Agro
KIIIA1 6.1.3	Reynens, P.	2011	A19786A (PXD/PYR) dose response trial against dicots A19786A_10340 Syngenta N/J N 2603383/368524	N	J		Syngenta Agro

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KIIIA1 6.1.3	Doerig, B.	2011	A19786A (PXD/PYR) dose response trial against Alopecurus and dicots A19786A_10374 Syngenta N/J N 2603384/368525	N	J		Syngenta Agro
KIIIA1 6.1.3	Schmitt, B.	2012	A19786A (PXD/PYR) dose response trial against Alopecurus and Lolium A19786A_10378 Syngenta N/J N 2603385/368526	N	J		Syngenta Agro
KIIIA1 6.1.3	Schmitt, B.	2012	A19786A (PXD/PYR) dose response trial against Alopecurus and Bromus A19786A_10396 Syngenta N/J N 2603386/368527	N	J		Syngenta Agro
KIIIA1 6.1.3	Ehrenschwender, G.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10440 Syngenta N/J N 2603387/368528	N	J		Syngenta Agro
KIIIA1 6.1.3	Ehrenschwender, G.	2012	A19786A (PXD/PYR) timing trial against Apera and dicots A19786A_10448 Syngenta N/J N 2603388/368529	N	J		Syngenta Agro

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KIIIA1 6.1.3	Ruppert, R.	2011	A19786A (PXD/PYR) efficacy trial against Alopecurus and Bromus A19786A_10446 Syngenta N/J N 2603389/368530	N	J		Syngenta Agro
KIIIA1 6.1.3	Ruppert, R.	2012	A19786A (PXD/PYR) timing trial against Avena and dicots A19786A_10442 Syngenta N/J N 2603390/368531	N	J		Syngenta Agro
KIIIA1 6.1.3	Ruppert, R.	2011	A19786A (PXD/PYR) dose response trial against Avena and dicots A19786A_10430 Syngenta N/J N 2603391/368532	N	J		Syngenta Agro
KIIIA1 6.1.3	Ruppert, R.	2012	A19786A (PXD/PYR) efficacy trial against Bromus and dicots A19786A_10444 Syngenta N/J N 2603392/368533	N	J		Syngenta Agro
KIIIA1 6.1.3	Ruppert, R.	2012	A19786A (PXD/PYR) efficacy trial against Bromus and dicots A19786A_10434 Syngenta N/J N 2603393/368534	N	J		Syngenta Agro

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KIIIA1 6.1.3	Thibault, A.	2012	A19786A (PXD/PYR) dose response trial against Avena and dicots A19786A_10366 Syngenta N/J N 2603394/368535	N	J		Syngenta Agro
KIIIA1 6.1.3	Bertin, B.	2012	A19786A (PXD/PYR) dose response trial against Lolium A19786A_10410 Syngenta N/J N 2603395/368536	N	J		Syngenta Agro
KIIIA1 6.1.3	Bertin, B.	2011	A19786A (PXD/PYR) efficacy trial against Lolium A19786A_10296 Syngenta N/J N 2603396/368537	N	J		Syngenta Agro
KIIIA1 6.1.3	Fluchon, V.	2012	A19786A (PXD/PYR) efficacy trial against Bromus A19786A_10412 Syngenta N/J N 2603397/368538	N	J		Syngenta Agro
KIIIA1 6.1.3	Delebarre, O.	2012	A19786A (PXD/PYR) timing trial against Alopecurus and dicots A19786A_10298 Syngenta N/J N 2603398/368539	N	J		Syngenta Agro

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KIIIA1 6.1.3	Carriou, S.	2012	A19786A (PXD/PYR) timing trial against Lolium and dicots A19786A_10414 Syngenta N/J N 2603399/368540	N	J		Syngenta Agro
KIIIA1 6.1.3	Delebarre, O.	2012	A19786A (PXD/PYR) dose response trial against Alomy, Apera and dicots A19786A_10300 Syngenta N/J N 2603400/368541	N	J		Syngenta Agro
KIIIA1 6.1.3	Bourgeois, B.	2012	A19786A (PXD/PYR) dose response trial against Alopecurus and dicots A19786A_10308 Syngenta N/J N 2603401/368542	N	J		Syngenta Agro
KIIIA1 6.1.3	Bourgeois, B.	2011	A19786A (PXD/PYR) dose response trial against Alopecurus and dicots A19786A_10416 Syngenta N/J N 2603402/368543	N	J		Syngenta Agro
KIIIA1 6.1.3	Bourgeois, B.	2011	A19786A (PXD/PYR) efficacy trial against dicots A19786A_10306 Syngenta N/J N 2603403/368544	N	J		Syngenta Agro

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KIIIA1 6.1.3	Cailliau, B.	2011	A19786A (PXD/PYR) timing trial against Lolium A19786A_10418 Syngenta N/J N 2603404/368545	N	J		Syngenta Agro
KIIIA1 6.1.3	Clement, O.	2011	A19786A (PXD/PYR) efficacy trial against Bromus A19786A_10310 Syngenta N/J N 2603405/368546	N	J		Syngenta Agro
KIIIA1 6.1.3	Clement, O.	2011	A19786A (PXD/PYR) dose response trial against Alopecurus A19786A_10420 Syngenta N/J N 2603406/368547	N	J		Syngenta Agro
KIIIA1 6.1.3	Rivet, J.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10312 Syngenta N/J N 2603407/368548	N	J		Syngenta Agro
KIIIA1 6.1.3	Rivet, J.	2012	A19786A (PXD/PYR) dose response trial against Alopecurus and dicots A19786A_10422 Syngenta N/J N 2603408/368549	N	J		Syngenta Agro

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KIIIA1 6.1.3	Rivet, J.	2012	A19786A (PXD/PYR) dose response trial against Alopecurus and dicots A19786A_10314 Syngenta N/J N 2603409/368550	N	J		Syngenta Agro
KIIIA1 6.1.3	Marcato, G.	2011	A19786A (PXD/PYR) dose response trial against Avena and dicots A19786A_10316 Syngenta N/J N 2603410/368551	N	J		Syngenta Agro
KIIIA1 6.1.3	Jollivet, B.	2011	A19786A (PXD/PYR) efficacy trial against Bromus A19786A_10344 Syngenta N/J N 2603411/368552	N	J		Syngenta Agro
KIIIA1 6.1.3	Leger, D.	2012	A19786A (PXD/PYR) dose response trial against Avena A19786A_10318 Syngenta N/J N 2603412/368553	N	J		Syngenta Agro
KIIIA1 6.1.3	Largilliere, J.	2012	A19786A (PXD/PYR) dose response trial against Lolium and dicots A19786A_10320 Syngenta N/J N 2603413/368554	N	J		Syngenta Agro

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KIIIA1 6.1.3	Beaufort, M.	2012	A19786A (PXD/PYR) dose response trial against Lolium and dicots A19786A_10346 Syngenta N/J N 2603414/368555	N	J		Syngenta Agro
KIIIA1 6.1.3	Ponsard, P.	2012	A19786A (PXD/PYR) timing trial against Alopecurus and dicots A19786A_10322 Syngenta N/J N 2603415/368556	N	J		Syngenta Agro
KIIIA1 6.1.3	Piatte, P.	2012	A19786A (PXD/PYR) dose response trial against Lolium and dicots A19786A_10348 Syngenta N/J N 2603416/368557	N	J		Syngenta Agro
KIIIA1 6.1.3	Piatte, P.	2011	A19786A (PXD/PYR) efficacy trial against Lolium and dicots A19786A_10362 Syngenta N/J N 2603417/368558	N	J		Syngenta Agro
KIIIA1 6.1.3	Rigail, J.	2012	A19786A (PXD/PYR) efficacy trial against Bromus and dicots A19786A_10324 Syngenta N/J N 2603418/368559	N	J		Syngenta Agro

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KIIIA1 6.1.3	Rigail, J.	2012	A19786A (PXD/PYR) dose response trial against Lolium and dicots A19786A_10326 Syngenta N/J N 2603419/368560	N	J		Syngenta Agro
KIIIA1 6.1.3	Rigail, J.	2012	A19786A (PXD/PYR) dose response trial against Alopecurus A19786A_10350 Syngenta N/J N 2603420/368561	N	J		Syngenta Agro
KIIIA1 6.1.3	Rigail, J.	2012	A19786A (PXD/PYR) timing trial against Alopecurus A19786A_10328 Syngenta N/J N 2603421/368562	N	J		Syngenta Agro
KIIIA1 6.1.3	Rabot, L.	2012	A19786A (PXD/PYR) dose response trial against Avena A19786A_10352 Syngenta N/J N 2603422/368563	N	J		Syngenta Agro
KIIIA1 6.1.3	Speyer, M.	2011	A19786A (PXD/PYR) efficacy trial against Alopecurus and Avena A19786A_10332 Syngenta N/J N 2603423/368564	N	J		Syngenta Agro

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KIIIA1 6.1.3	Gainville, C.	2011	A19786A (PXD/PYR) dose response trial against Avena and dicots A19786A_10330 Syngenta N/J N 2603424/368565	N	J		Syngenta Agro
KIIIA1 6.1.3	Hooghiemstra, J.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10464 Syngenta N/J N 2603425/368566	N	J		Syngenta Agro
KIIIA1 6.1.3	Hooghiemstra, J.	2012	A19786A (PXD/PYR) timing trial against Alopecurus and dicots A19786A_10462 Syngenta N/J N 2603426/368567	N	J		Syngenta Agro
KIIIA1 6.1.3	Svobodnik, A.	2011	A19786A (PXD/PYR) efficacy trial against Apera and dicots A19786A_10380 Syngenta N/J N 2603427/368568	N	J		Syngenta Agro
KIIIA1 6.1.3	Janecek, M.	2011	A19786A (PXD/PYR) dose response trial against Avena and dicots A19786A_10342 Syngenta N/J N 2603428/368569	N	J		Syngenta Agro

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KIIIA1 6.1.3	Thiel, M.	2012	A19786A (PXD/PYR) dose response trial against Lolium A19786A_10356 Syngenta N/J N 2603429/368570	N	J		Syngenta Agro
KIIIA1 6.1.3	Siegert, E.	2011	A19786A (PXD/PYR) efficacy trial against Apera and dicots A19786A_10286 Syngenta N/J N 2603430/368571	N	J		Syngenta Agro
KIIIA1 6.1.3	Siegert, E.	2011	A19786A (PXD/PYR) efficacy trial against Lolium A19786A_10290 Syngenta N/J N 2603431/368572	N	J		Syngenta Agro
KIIIA1 6.1.3	Stuebner, B.	2012	A19786A (PXD/PYR) dose response trial against Lolium and dicots A19786A_10458 Syngenta N/J N 2603432/368573	N	J		Syngenta Agro
KIIIA1 6.1.3	Stuebner, B.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10459 Syngenta N/J N 2603433/368574	N	J		Syngenta Agro

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KIIIA1 6.1.3	Stuebner, B.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10453 Syngenta N/J N 2603434/368575	N	J		Syngenta Agro
KIIIA1 6.1.3	Stuebner, B.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10452 Syngenta N/J N 2603435/368576	N	J		Syngenta Agro
KIIIA1 6.1.3	Stuebner, B.	2011	A19786A (PXD/PYR) efficacy trial against dicots A19786A_10384 Syngenta N/J N 2603436/368577	N	J		Syngenta Agro
KIIIA1 6.1.3	Krueger, D.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10424 Syngenta N/J N 2603437/368578	N	J		Syngenta Agro
KIIIA1 6.1.3	Krueger, D.	2011	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10398 Syngenta N/J N 2603438/368579	N	J		Syngenta Agro

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KIIIA1 6.1.3	Krueger, D.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10436 Syngenta N/J N 2603439/368580	N	J		Syngenta Agro
KIIIA1 6.1.3	Krueger, D.	2011	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10386 Syngenta N/J N 2603440/368581	N	J		Syngenta Agro
KIIIA1 6.1.3	Krueger, D.	2012	A19786A (PXD/PYR) timing trial against Apera and dicots A19786A_10428 Syngenta N/J N 2603441/368582	N	J		Syngenta Agro
KIIIA1 6.1.3	Carstens, H.	2012	A19786A (PXD/PYR) timing trial against Apera and dicots A19786A_10451 Syngenta N/J N 2603442/368583	N	J		Syngenta Agro
KIIIA1 6.1.3	Kuhle, B.	2011	A19786A (PXD/PYR) dose response trial against dicots A19786A_10388 Syngenta N/J N 2603443/368584	N	J		Syngenta Agro

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KIIIA1 6.1.3	Kuhle, B.	2012	A19786A (PXD/PYR) timing trial against Alopecurus and dicots A19786A_10457 Syngenta N/J N 2603444/368586	N	J		Syngenta Agro
KIIIA1 6.1.3	Carstens, H.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10456 Syngenta N/J N 2603445/368588	N	J		Syngenta Agro
KIIIA1 6.1.3	Kuhle, B.	2011	A19786A (PXD/PYR) efficacy trial against Alopecurus and dicots A19786A_10284 Syngenta N/J N 2603446/368589	N	J		Syngenta Agro
KIIIA1 6.1.3	Carstens, H.	2011	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10400 Syngenta N/J N 2603447/368590	N	J		Syngenta Agro
KIIIA1 6.1.3	Carstens, H.	2011	A19786A (PXD/PYR) efficacy trial against Apera and dicots A19786A_10390 Syngenta N/J N 2603448/368591	N	J		Syngenta Agro

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KIIIA1 6.1.3	Kaiser, B.	2011	A19786A (PXD/PYR) dose response trial against Alopecurus and dicots A19786A_10402 Syngenta N/J N 2603449/368592	N	J		Syngenta Agro
KIIIA1 6.1.3	Kaiser, B.	2012	A19786A (PXD/PYR) dose response trial against Alopecurus and dicots A19786A_10292 Syngenta N/J N 2603450/368593	N	J		Syngenta Agro
KIIIA1 6.1.3	Griehl, T.	2011	A19786A (PXD/PYR) efficacy trial against Alopecurus and dicots A19786A_10392 Syngenta N/J N 2603451/368594	N	J		Syngenta Agro
KIIIA1 6.1.3	Griehl, T.	2012	A19786A (PXD/PYR) dose response trial against Alopecurus and dicots A19786A_10438 Syngenta N/J N 2603452/368595	N	J		Syngenta Agro
KIIIA1 6.1.3	Griehl, T.	2012	A19786A (PXD/PYR) dose response trial against Alopecurus and dicots A19786A_10426 Syngenta N/J N 2603453/368596	N	J		Syngenta Agro

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KIIIA1 6.1.3	Griehl, T.	2012	A19786A (PXD/PYR) timing trial against Alopecurus and dicots A19786A_10432 Syngenta N/J N 2603454/368597	N	J		Syngenta Agro
KIIIA1 6.1.3	Ruppert, R.	2012	A19786A (PXD/PYR) efficacy trial against Bromus A19786A_10450 Syngenta N/J N 2603455/368598	N	J		Syngenta Agro
KIIIA1 6.1.3	Terhalle, S.	2011	A19786A (PXD/PYR) efficacy trial against Alopecurus and dicots A19786A_10294 Syngenta N/J N 2603456/368599	N	J		Syngenta Agro
KIIIA1 6.1.3	Terhalle, S.	2011	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10404 Syngenta N/J N 2603457/368600	N	J		Syngenta Agro
KIIIA1 6.1.3	Terhalle, S.	2011	A19786A (PXD/PYR) dose response trial against Alopecurus and dicots A19786A_10394 Syngenta N/J N 2603458/368601	N	J		Syngenta Agro

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KIIIA1 6.1.3	Terhalle, S.	2011	A19786A (PXD/PYR) efficacy trial against Alopecurus and dicots A19786A_10382 Syngenta N/J N 2603459/368602	N	J		Syngenta Agro
KIIIA1 6.1.3	Terhalle, S.	2012	A19786A (PXD/PYR) dose response trial against Alopecurus and dicots A19786A_10455 Syngenta N/J N 2603460/368603	N	J		Syngenta Agro
KIIIA1 6.1.3	Weigl, A.	2012	A19786A (PXD/PYR) dose response trial against Alopecurus and dicots A19786A_10406 Syngenta N/J N 2603461/368604	N	J		Syngenta Agro
KIIIA1 6.1.3	Terhalle, S.	2012	A19786A (PXD/PYR) timing trial against Alopecurus, Apera and dicots A19786A_10454 Syngenta N/J N 2603462/368605	N	J		Syngenta Agro
KIIIA1 6.1.3	Terhalle, S.	2012	A19786A (PXD/PYR) dose response trial against Alomy, Apera and dicots A19786A_10460 Syngenta N/J N 2603463/368606	N	J		Syngenta Agro

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KIIIA1 6.1.3	Hvid, P.	2011	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10364 Syngenta N/J N 2603464/368607	N	J		Syngenta Agro
KIIIA1 6.1.3	Hvid, P.	2011	A19786A (PXD/PYR) efficacy trial against Alopecurus and dicots A19786A_10408 Syngenta N/J N 2603465/368608	N	J		Syngenta Agro
KIIIA1 6.1.3	Henriksen, K.	2011	A19786A (PXD/PYR) efficacy trial against Bromus A19786A_10368 Syngenta N/J N 2603466/368609	N	J		Syngenta Agro
KIIIA1 6.1.3	Dyas, D.	2011	A19786A (PXD/PYR) dose response trial against Avena A19786A_10354 Syngenta N/J N 2603467/368610	N	J		Syngenta Agro
KIIIA1 6.1.3	Scott, T.	2011	A19786A (PXD/PYR) dose response trial against Lolium A19786A_10334 Syngenta N/J N 2603468/368611	N	J		Syngenta Agro

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KIIIA1 6.1.3	Dyas, D.	2011	A19786A (PXD/PYR) dose response trial against Lolium A19786A_10336 Syngenta N/J N 2603469/368612	N	J		Syngenta Agro
KIIIA1 6.1.3	Fairweather, A.	2011	A19786A (PXD/PYR) efficacy trial against Lolium A19786A_10358 Syngenta N/J N 2603470/368615	N	J		Syngenta Agro
KIIIA1 6.1.3	Scott, T.	2011	A19786A (PXD/PYR) efficacy trial against Bromus A19786A_10302 Syngenta N/J N 2603471/368618	N	J		Syngenta Agro
KIIIA1 6.1.3	Wielgat, D.	2011	A19786A (PXD/PYR) formulation justification study A19786A_10238 Syngenta N/J N 2603472/368620	N	J		Syngenta Agro
KIIIA1 6.1.3	Pawlak, A.	2012	A19786A (PXD/PYR) dose response trial against Lolium and dicots A19786A_10304 Syngenta N/J N 2603473/368623	N	J		Syngenta Agro

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KIIIA1 6.1.3	Poivey, B.	2012	A19786A (PXD/PYR) dose response trial against Lolium and dicots A19786A_10240 Syngenta N/J N 2603474/368626	N	J		Syngenta Agro
KIIIA1 6.1.3	Poivey, B.	2011	A19786A (PXD/PYR) dose response trial against Lolium and dicots A19786A_10268 Syngenta N/J N 2603475/368628	N	J		Syngenta Agro
KIIIA1 6.1.3	Kroehnke, J.	2012	A19786A (PXD/PYR) dose response trial against Apera, Avena and dicots A19786A_10242 Syngenta N/J N 2603476/368631	N	J		Syngenta Agro
KIIIA1 6.1.3	Kroehnke, J.	2012	A19786A (PXD/PYR) dose response trial against Apera, Avena and dicots A19786A_10270 Syngenta N/J N 2603477/368633	N	J		Syngenta Agro
KIIIA1 6.1.3	Pietryga, J.	2011	A19786A (PXD/PYR) dose response trial against Alopecurus and dicots A19786A_10244 Syngenta N/J N 2603478/368636	N	J		Syngenta Agro

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KIIIA1 6.1.3	Pietryga, J.	2011	A19786A (PXD/PYR) formulation justification study A19786A_10246 Syngenta N/J N 2603479/368637	N	J		Syngenta Agro
KIIIA1 6.1.3	Potocka, E.	2011	A19786A (PXD/PYR) formulation justification study A19786A_10272 Syngenta N/J N 2603480/368639	N	J		Syngenta Agro
KIIIA1 6.1.3	Potocka, E.	2011	A19786A (PXD/PYR) formulation justification study A19786A_10248 Syngenta N/J N 2603481/368641	N	J		Syngenta Agro
KIIIA1 6.1.3	Potocka, E.	2011	A19786A (PXD/PYR) formulation justification study A19786A_10274 Syngenta N/J N 2603482/368643	N	J		Syngenta Agro
KIIIA1 6.1.3	Idziak, R.	2011	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10250 Syngenta N/J N 2603483/368646	N	J		Syngenta Agro

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KIIIA1 6.1.3	Sobiech, L.	2011	A19786A (PXD/PYR) dose response trial against Apera Lolium and dicots A19786A_10252 Syngenta N/J N 2603484/368649	N	J		Syngenta Agro
KIIIA1 6.1.3	Sobiech, L.	2011	A19786A (PXD/PYR) formulation justification study A19786A_10278 Syngenta N/J N 2603485/368651	N	J		Syngenta Agro
KIIIA1 6.1.3	Idziak, R.	2011	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10254 Syngenta N/J N 2603486/368652	N	J		Syngenta Agro
KIIIA1 6.1.3	Idziak, R.	2012	A19786A (PXD/PYR) dose response trial against Lolium and dicots A19786A_10280 Syngenta N/J N 2603487/368654	N	J		Syngenta Agro
KIIIA1 6.1.3	Majchrzak, L.	2012	A19786A (PXD/PYR) efficacy trial against Bromus and dicots A19786A_10282 Syngenta N/J N 2603488/368656	N	J		Syngenta Agro

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KIIIA1 6.1.3	Sobiech, L.	2011	A19786A (PXD/PYR) dose response trial against Alopecurus and dicots A19786A_10220 Syngenta N/J N 2603489/368658	N	J		Syngenta Agro
KIIIA1 6.1.3	Hvid, P.	2011	A19786A (PXD/PYR) efficacy trial against Alopecurus and dicots A19786A_10222 Syngenta N/J N 2603490/368662	N	J		Syngenta Agro
KIIIA1 6.1.3	Hvid, P.	2011	A19786A (PXD/PYR) efficacy trial against dicots A19786A_10360 Syngenta N/J N 2603491/368664	N	J		Syngenta Agro
KIIIA1 6.1.3	Ilumae, E.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10218 Syngenta N/J N 2603492/368666	N	J		Syngenta Agro
KIIIA1 6.1.3	Junnila, S.	2011	A19786A (PXD/PYR) dose response trial against Avena and dicots A19786A_10224 Syngenta N/J N 2603493/368668	N	J		Syngenta Agro

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KIIIA1 6.1.3	Junnila, S.	2011	A19786A (PXD/PYR) dose response trial against Poa and dicots A19786A_10256 Syngenta N/J N 2603494/368670	N	J		Syngenta Agro
KIIIA1 6.1.3	Junnila, S.	2011	A19786A (PXD/PYR) formulation justification study A19786A_10226 Syngenta N/J N 2603495/368673	N	J		Syngenta Agro
KIIIA1 6.1.3	Auskalniene, O.	2011	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10258 Syngenta N/J N 2603496/368675	N	J		Syngenta Agro
KIIIA1 6.1.3	Auskalniene, O.	2011	A19786A (PXD/PYR) formulation justification study A19786A_10228 Syngenta N/J N 2603497/368677	N	J		Syngenta Agro
KIIIA1 6.1.3	Auskalniene, O.	2011	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10260 Syngenta N/J N 2603498/368679	N	J		Syngenta Agro

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KIIIA1 6.1.3	Auskalniene, O.	2011	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10230 Syngenta N/J N 2603499/368680	N	J		Syngenta Agro
KIIIA1 6.1.3	Psibisauskiene, G.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10232 Syngenta N/J N 2603500/368682	N	J		Syngenta Agro
KIIIA1 6.1.3	Auskalniene, O.	2011	A19786A (PXD/PYR) formulation justification study A19786A_10262 Syngenta N/J N 2603501/368685	N	J		Syngenta Agro
KIIIA1 6.1.3	Vanaga, I.	2011	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10234 Syngenta N/J N 2603502/368688	N	J		Syngenta Agro
KIIIA1 6.1.3	Vanaga, I.	2011	A19786A (PXD/PYR) formulation justification study A19786A_10264 Syngenta N/J N 2603503/368690	N	J		Syngenta Agro

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KIIIA1 6.1.3	Vanaga, I.	2011	A19786A (PXD/PYR) dose response trial against dicots A19786A_10236 Syngenta N/J N 2603504/368693	N	J		Syngenta Agro
KIIIA1 6.1.3	Vanaga, I.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10266 Syngenta N/J N 2603505/368696	N	J		Syngenta Agro
KIIIA1 6.1.3	Majchrzak, L.	2011	A19786A (PXD/PYR) dose response trial against Avena A19786A_10276 Syngenta N/J N 2603506/368698	N	J		Syngenta Agro
KIIIA1 6.1.4.2	Aubin, C.	2013	BPE12/089/HGC01 impact of A19786A on yield quality A19786A_10094 Syngenta N/J N 2603507/368700	N	J		Syngenta Agro
KIIIA1 6.1.4.2	Aubin, C.	2013	BPE12/089/HGC02 impact of A19786A on yield quality A19786A_10095 Syngenta N/J N 2603508/368703	N	J		Syngenta Agro

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KIIIA1 6.1.4.3	Reynens, P.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10176 Syngenta N/J N 2603509/368705	N	J		Syngenta Agro
KIIIA1 6.1.4.3	Guichard, J.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10196 Syngenta N/J N 2603510/368707	N	J		Syngenta Agro
KIIIA1 6.1.4.3	Guichard, J.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter triticale A19786A_10178 Syngenta N/J N 2603511/368709	N	J		Syngenta Agro
KIIIA1 6.1.4.3	Guichard, J.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter rye A19786A_10198 Syngenta N/J N 2603512/368713	N	J		Syngenta Agro
KIIIA1 6.1.4.3	Thibault, A.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10212 Syngenta N/J N 2603513/368715	N	J		Syngenta Agro

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KIIIA1 6.1.4.3	Delebarre, O.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter triticale A19786A_10182 Syngenta N/J N 2603514/368717	N	J		Syngenta Agro
KIIIA1 6.1.4.3	Fluchon, V.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter rye A19786A_10146 Syngenta N/J N 2603515/368719	N	J		Syngenta Agro
KIIIA1 6.1.4.3	Boudinet, P.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10192 Syngenta N/J N 2603516/368722	N	J		Syngenta Agro
KIIIA1 6.1.4.3	Touron, B.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10148 Syngenta N/J N 2603517/368724	N	J		Syngenta Agro
KIIIA1 6.1.4.3	Cloix, J.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter rye A19786A_10194 Syngenta N/J N 2603518/368726	N	J		Syngenta Agro

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KIIIA1 6.1.4.3	Cloix, J.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter rye A19786A_10162 Syngenta N/J N 2603519/368728	N	J		Syngenta Agro
KIIIA1 6.1.4.3	Leger, D.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter rye A19786A_10150 Syngenta N/J N 2603520/368730	N	J		Syngenta Agro
KIIIA1 6.1.4.3	Leger, D.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10166 Syngenta N/J N 2603521/368732	N	J		Syngenta Agro
KIIIA1 6.1.4.3	Largilliere, J.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter triticale A19786A_10152 Syngenta N/J N 2603522/368734	N	J		Syngenta Agro
KIIIA1 6.1.4.3	Largilliere, J.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10156 Syngenta N/J N 2603523/368736	N	J		Syngenta Agro

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KIIIA1 6.1.4.3	Masson, O.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter triticale A19786A_10164 Syngenta N/J N 2603524/368738	N	J		Syngenta Agro
KIIIA1 6.1.4.3	Malbete, A.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter triticale A19786A_10216 Syngenta N/J N 2603525/368740	N	J		Syngenta Agro
KIIIA1 6.1.4.3	Montier, L.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10158 Syngenta N/J N 2603526/368742	N	J		Syngenta Agro
KIIIA1 6.1.4.3	Hooghiemstra, J.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10160 Syngenta N/J N 2603527/368744	N	J		Syngenta Agro
KIIIA1 6.1.4.3	Bernardova, M.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter triticale A19786A_10184 Syngenta N/J N 2603528/368746	N	J		Syngenta Agro

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KIIIA1 6.1.4.3	Spacilova, V.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10190 Syngenta N/J N 2603529/368748	N	J		Syngenta Agro
KIIIA1 6.1.4.3	Konvalinkova, J.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter rye A19786A_10200 Syngenta N/J N 2603530/368751	N	J		Syngenta Agro
KIIIA1 6.1.4.3	Stuebner, B.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter triticale A19786A_10188 Syngenta N/J N 2603531/368753	N	J		Syngenta Agro
KIIIA1 6.1.4.3	Stuebner, B.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter triticale A19786A_10202 Syngenta N/J N 2603532/368755	N	J		Syngenta Agro
KIIIA1 6.1.4.3	Krueger, D.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter rye A19786A_10154 Syngenta N/J N 2603533/368757	N	J		Syngenta Agro

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KIIIA1 6.1.4.3	Krueger, D.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter rye A19786A_10204 Syngenta N/J N 2603534/368759	N	J		Syngenta Agro
KIIIA1 6.1.4.3	Krueger, D.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter triticale A19786A_10172 Syngenta N/J N 2603535/368761	N	J		Syngenta Agro
KIIIA1 6.1.4.3	Kuhle, B.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter triticale A19786A_10174 Syngenta N/J N 2603536/368763	N	J		Syngenta Agro
KIIIA1 6.1.4.3	Carstens, H.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10206 Syngenta N/J N 2603537/368766	N	J		Syngenta Agro
KIIIA1 6.1.4.3	Carstens, H.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter rye A19786A_10186 Syngenta N/J N 2603538/368768	N	J		Syngenta Agro

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KIIIA1 6.1.4.3	Carstens, H.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter triticale A19786A_10208 Syngenta N/J N 2603539/368771	N	J		Syngenta Agro
KIIIA1 6.1.4.3	Kaiser, B.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10168 Syngenta N/J N 2603540/368773	N	J		Syngenta Agro
KIIIA1 6.1.4.3	Kaiser, B.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter rye A19786A_10210 Syngenta N/J N 2603541/368774	N	J		Syngenta Agro
KIIIA1 6.1.4.3	Ehrenschwend, G.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10170 Syngenta N/J N 2603542/368776	N	J		Syngenta Agro
KIIIA1 6.1.4.3	Terhalle, S.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter rye A19786A_10180 Syngenta N/J N 2603543/368778	N	J		Syngenta Agro

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KIIIA1 6.1.4.3	Thorpe, A.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10214 Syngenta N/J N 2603544/368781	N	J		Syngenta Agro
KIIIA1 6.1.4.3	Ilumae, E.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter rye A19786A_10140 Syngenta N/J N 2603545/368783	N	J		Syngenta Agro
KIIIA1 6.1.4.3	Auskalniene, O.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter rye A19786A_10112 Syngenta N/J N 2603546/368784	N	J		Syngenta Agro
KIIIA1 6.1.4.3	Auskalniene, O.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter triticale A19786A_10138 Syngenta N/J N 2603547/368786	N	J		Syngenta Agro
KIIIA1 6.1.4.3	Auskalniene, O.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10114 Syngenta N/J N 2603548/368788	N	J		Syngenta Agro

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KIIIA1 6.1.4.3	Psibisauskiene, G.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10142 Syngenta N/J N 2603549/368790	N	J		Syngenta Agro
KIIIA1 6.1.4.3	Psibisauskiene, G.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10144 Syngenta N/J N 2603550/368792	N	J		Syngenta Agro
KIIIA1 6.1.4.3	Vanaga, I.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter triticale A19786A_10108 Syngenta N/J N 2603551/368795	N	J		Syngenta Agro
KIIIA1 6.1.4.3	Vanaga, I.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10116 Syngenta N/J N 2603552/368798	N	J		Syngenta Agro
KIIIA1 6.1.4.3	Vanaga, I.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter rye A19786A_10118 Syngenta N/J N 2603553/368800	N	J		Syngenta Agro

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KIIIA1 6.1.4.3	Vanaga, I.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10110 Syngenta N/J N 2603554/368802	N	J		Syngenta Agro
KIIIA1 6.1.4.3	Uminski, P.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10120 Syngenta N/J N 2603555/368804	N	J		Syngenta Agro
KIIIA1 6.1.4.3	Kroehnke, J.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter rye A19786A_10128 Syngenta N/J N 2603556/368805	N	J		Syngenta Agro
KIIIA1 6.1.4.3	Kroehnke, J.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter triticale A19786A_10122 Syngenta N/J N 2603557/368806	N	J		Syngenta Agro
KIIIA1 6.1.4.3	Kroehnke, J.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10130 Syngenta N/J N 2603558/368808	N	J		Syngenta Agro

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KIIIA1 6.1.4.3	Potocka, E.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10124 Syngenta N/J N 2603559/368809	N	J		Syngenta Agro
KIIIA1 6.1.4.3	Potocka, E.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter triticale A19786A_10126 Syngenta N/J N 2603560/368810	N	J		Syngenta Agro
KIIIA1 6.1.4.3	Slowiak, M.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter rye A19786A_10132 Syngenta N/J N 2603561/368812	N	J		Syngenta Agro
KIIIA1 6.1.4.3	Slowiak, M.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter triticale A19786A_10134 Syngenta N/J N 2603562/368814	N	J		Syngenta Agro
KIIIA1 6.1.4.3	Slowiak, M.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10136 Syngenta N/J N 2603563/368816	N	J		Syngenta Agro

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KIIIA1 6.2.1	Reisenhofer, A.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10372 Syngenta N/J N 2603564/368817	N	J		Syngenta Agro
KIIIA1 6.2.1	Anzengruber, J.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10338 Syngenta N/J N 2603565/368818	N	J		Syngenta Agro
KIIIA1 6.2.1	Rohringer, G.	2011	A19786A (PXD/PYR) efficacy trial against Avena and dicots A19786A_10288 Syngenta N/J N 2603566/368819	N	J		Syngenta Agro
KIIIA1 6.2.1	Reynens, P.	2011	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10376 Syngenta N/J N 2603567/368820	N	J		Syngenta Agro
KIIIA1 6.2.1	Doerig, B.	2011	A19786A (PXD/PYR) dose response trial against Alopecurus and dicots A19786A_10374 Syngenta N/J N 2603568/368821	N	J		Syngenta Agro

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KIIIA1 6.2.1	Ehrenschwender, G.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10440 Syngenta N/J N 2603569/368822	N	J		Syngenta Agro
KIIIA1 6.2.1	Ruppert, R.	2011	A19786A (PXD/PYR) dose response trial against Avena and dicots A19786A_10430 Syngenta N/J N 2603570/368823	N	J		Syngenta Agro
KIIIA1 6.2.1	Bertin, B.	2012	A19786A (PXD/PYR) dose response trial against Lolium A19786A_10410 Syngenta N/J N 2603571/368824	N	J		Syngenta Agro
KIIIA1 6.2.1	Bertin, B.	2011	A19786A (PXD/PYR) efficacy trial against Lolium A19786A_10296 Syngenta N/J N 2603572/368825	N	J		Syngenta Agro
KIIIA1 6.2.1	Bourgeois, B.	2011	A19786A (PXD/PYR) efficacy trial against dicots A19786A_10306 Syngenta N/J N 2603573/368826	N	J		Syngenta Agro

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KIIIA1 6.2.1	Clement, O.	2011	A19786A (PXD/PYR) dose response trial against Alopecurus A19786A_10420 Syngenta N/J N 2603574/368827	N	J		Syngenta Agro
KIIIA1 6.2.1	Rivet, J.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10312 Syngenta N/J N 2603575/368828	N	J		Syngenta Agro
KIIIA1 6.2.1	Rivet, J.	2012	A19786A (PXD/PYR) dose response trial against Alopecurus and dicots A19786A_10422 Syngenta N/J N 2603576/368829	N	J		Syngenta Agro
KIIIA1 6.2.1	Rivet, J.	2012	A19786A (PXD/PYR) dose response trial against Alopecurus and dicots A19786A_10314 Syngenta N/J N 2603577/368830	N	J		Syngenta Agro
KIIIA1 6.2.1	Marcato, G.	2011	A19786A (PXD/PYR) dose response trial against Avena and dicots A19786A_10316 Syngenta N/J N 2603578/368831	N	J		Syngenta Agro

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KIIIA1 6.2.1	Jollivet, B.	2011	A19786A (PXD/PYR) efficacy trial against Bromus A19786A_10344 Syngenta N/J N 2603579/368832	N	J		Syngenta Agro
KIIIA1 6.2.1	Leger, D.	2012	A19786A (PXD/PYR) dose response trial against Avena A19786A_10318 Syngenta N/J N 2603580/368833	N	J		Syngenta Agro
KIIIA1 6.2.1	Beaufort, M.	2012	A19786A (PXD/PYR) dose response trial against Lolium and dicots A19786A_10346 Syngenta N/J N 2603581/368834	N	J		Syngenta Agro
KIIIA1 6.2.1	Rigail, J.	2012	A19786A (PXD/PYR) efficacy trial against Bromus and dicots A19786A_10324 Syngenta N/J N 2603582/368835	N	J		Syngenta Agro
KIIIA1 6.2.1	Rigail, J.	2012	A19786A (PXD/PYR) dose response trial against Lolium and dicots A19786A_10326 Syngenta N/J N 2603583/368836	N	J		Syngenta Agro

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KIIIA1 6.2.1	Camus, O.	2012	A19786A (PXD/PYR) timing trial against Avena A19786A_10463 Syngenta N/J N 2603584/368837	N	J		Syngenta Agro
KIIIA1 6.2.1	Rabot, L.	2012	A19786A (PXD/PYR) dose response trial against Avena A19786A_10352 Syngenta N/J N 2603585/368838	N	J		Syngenta Agro
KIIIA1 6.2.1	Hooghiemstra, J.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10464 Syngenta N/J N 2603586/368839	N	J		Syngenta Agro
KIIIA1 6.2.1	Hooghiemstra, J.	2012	A19786A (PXD/PYR) timing trial against Alopecurus and dicots A19786A_10462 Syngenta N/J N 2603587/368841	N	J		Syngenta Agro
KIIIA1 6.2.1	Clement, O.	2011	A19786A (PXD/PYR) efficacy trial against Bromus A19786A_10310 Syngenta N/J N 2603588/368842	N	J		Syngenta Agro

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KIIIA1 6.2.1	Ruppert, R.	2012	A19786A (PXD/PYR) efficacy trial against Bromus and dicots A19786A_10444 Syngenta N/J N 2603589/368843	N	J		Syngenta Agro
KIIIA1 6.2.1	Thibault, A.	2012	A19786A (PXD/PYR) dose response trial against Avena and dicots A19786A_10366 Syngenta N/J N 2603590/368845	N	J		Syngenta Agro
KIIIA1 6.2.1	Largilliere, J.	2012	A19786A (PXD/PYR) dose response trial against Lolium and dicots A19786A_10320 Syngenta N/J N 2603591/368846	N	J		Syngenta Agro
KIIIA1 6.2.1	Fluchon, V.	2012	A19786A (PXD/PYR) efficacy trial against Bromus A19786A_10412 Syngenta N/J N 2603592/368847	N	J		Syngenta Agro
KIIIA1 6.2.1	Ehrenschwender, G.	2012	A19786A (PXD/PYR) timing trial against Apera and dicots A19786A_10448 Syngenta N/J N 2603593/368848	N	J		Syngenta Agro

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KIIIA1 6.2.1	Touron, B.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10148 Syngenta N/J N 2603594/368849	N	J		Syngenta Agro
KIIIA1 6.2.1	Guichard, J.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10196 Syngenta N/J N 2603595/368850	N	J		Syngenta Agro
KIIIA1 6.2.1	Piatte, P.	2012	A19786A (PXD/PYR) dose response trial against Lolium and dicots A19786A_10348 Syngenta N/J N 2603596/368851	N	J		Syngenta Agro
KIIIA1 6.2.1	Delebarre, O.	2012	A19786A (PXD/PYR) dose response trial against Alomy, Apera and dicots A19786A_10300 Syngenta N/J N 2603597/368852	N	J		Syngenta Agro
KIIIA1 6.2.1	Speyer, M.	2011	A19786A (PXD/PYR) efficacy trial against Alopecurus and Avena A19786A_10332 Syngenta N/J N 2603598/368853	N	J		Syngenta Agro

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KIIIA1 6.2.1	Carriou, S.	2012	A19786A (PXD/PYR) timing trial against Lolium and dicots A19786A_10414 Syngenta N/J N 2603599/368854	N	J		Syngenta Agro
KIIIA1 6.2.1	Ruppert, R.	2012	A19786A (PXD/PYR) efficacy trial against Bromus and dicots A19786A_10434 Syngenta N/J N 2603600/368855	N	J		Syngenta Agro
KIIIA1 6.2.1	Ruppert, R.	2012	A19786A (PXD/PYR) timing trial against Avena and dicots A19786A_10442 Syngenta N/J N 2603601/368856	N	J		Syngenta Agro
KIIIA1 6.2.1	Piatte, P.	2011	A19786A (PXD/PYR) efficacy trial against Lolium and dicots A19786A_10362 Syngenta N/J N 2603602/368857	N	J		Syngenta Agro
KIIIA1 6.2.1	Gainville, C.	2011	A19786A (PXD/PYR) dose response trial against Avena and dicots A19786A_10330 Syngenta N/J N 2603603/368858	N	J		Syngenta Agro

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KIIIA1 6.2.1	Rigail, J.	2012	A19786A (PXD/PYR) timing trial against Alopecurus A19786A_10328 Syngenta N/J N 2603604/368859	N	J		Syngenta Agro
KIIIA1 6.2.1	Rigail, J.	2012	A19786A (PXD/PYR) dose response trial against Alopecurus A19786A_10350 Syngenta N/J N 2603605/368860	N	J		Syngenta Agro
KIIIA1 6.2.1	Cailliau, B.	2011	A19786A (PXD/PYR) timing trial against Lolium A19786A_10418 Syngenta N/J N 2603606/368861	N	J		Syngenta Agro
KIIIA1 6.2.1	Bourgeois, B.	2012	A19786A (PXD/PYR) dose response trial against Alopecurus and dicots A19786A_10308 Syngenta N/J N 2603607/368862	N	J		Syngenta Agro
KIIIA1 6.2.1	Bourgeois, B.	2011	A19786A (PXD/PYR) dose response trial against Alopecurus and dicots A19786A_10416 Syngenta N/J N 2603608/368863	N	J		Syngenta Agro

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KIIIA1 6.2.1	Reynens, P.	2011	A19786A (PXD/PYR) dose response trial against dicots A19786A_10340 Syngenta N/J N 2603609/368864	N	J		Syngenta Agro
KIIIA1 6.2.1	Ruppert, R.	2011	A19786A (PXD/PYR) efficacy trial against Alopecurus and Bromus A19786A_10446 Syngenta N/J N 2603610/368865	N	J		Syngenta Agro
KIIIA1 6.2.1	Delebarre, O.	2012	A19786A (PXD/PYR) timing trial against Alopecurus and dicots A19786A_10298 Syngenta N/J N 2603611/368866	N	J		Syngenta Agro
KIIIA1 6.2.1	Ponsard, P.	2012	A19786A (PXD/PYR) timing trial against Alopecurus and dicots A19786A_10322 Syngenta N/J N 2603612/368867	N	J		Syngenta Agro
KIIIA1 6.2.1	Largilliere, J.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10156 Syngenta N/J N 2603613/368868	N	J		Syngenta Agro

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KIIIA1 6.2.1	Boudinet, P.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10192 Syngenta N/J N 2603614/368869	N	J		Syngenta Agro
KIIIA1 6.2.1	Montier, L.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10158 Syngenta N/J N 2603615/368870	N	J		Syngenta Agro
KIIIA1 6.2.1	Leger, D.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10166 Syngenta N/J N 2603616/368871	N	J		Syngenta Agro
KIIIA1 6.2.1	Thibault, A.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10212 Syngenta N/J N 2603617/368872	N	J		Syngenta Agro
KIIIA1 6.2.1	Reynens, P.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10176 Syngenta N/J N 2603618/368873	N	J		Syngenta Agro

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KIIIA1 6.2.1	Hooghiemstra, J.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10160 Syngenta N/J N 2603619/368874	N	J		Syngenta Agro
KIIIA1 6.2.1	Schmitt, B.	2012	A19786A (PXD/PYR) dose response trial against Alopecurus and Bromus A19786A_10396 Syngenta N/J N 2603620/368875	N	J		Syngenta Agro
KIIIA1 6.2.1	Largilliere, J.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter triticale A19786A_10152 Syngenta N/J N 2603621/368876	N	J		Syngenta Agro
KIIIA1 6.2.1	Masson, O.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter triticale A19786A_10164 Syngenta N/J N 2603622/368877	N	J		Syngenta Agro
KIIIA1 6.2.1	Delebarre, O.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter triticale A19786A_10182 Syngenta N/J N 2603623/368878	N	J		Syngenta Agro

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KIIIA1 6.2.1	Malbete, A.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter triticale A19786A_10216 Syngenta N/J N 2603624/368879	N	J		Syngenta Agro
KIIIA1 6.2.1	Guichard, J.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter triticale A19786A_10178 Syngenta N/J N 2603625/368880	N	J		Syngenta Agro
KIIIA1 6.2.1	Schmitt, B.	2012	A19786A (PXD/PYR) dose response trial against Alopecurus and Lolium A19786A_10378 Syngenta N/J N 2603626/368881	N	J		Syngenta Agro
KIIIA1 6.2.1	Reisenhofer, A.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10370 Syngenta N/J N 2603627/368882	N	J		Syngenta Agro
KIIIA1 6.2.1	Leger, D.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter rye A19786A_10150 Syngenta N/J N 2603628/368883	N	J		Syngenta Agro

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KIIIA1 6.2.1	Cloix, J.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter rye A19786A_10162 Syngenta N/J N 2603629/368884	N	J		Syngenta Agro
KIIIA1 6.2.1	Cloix, J.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter rye A19786A_10194 Syngenta N/J N 2603630/368885	N	J		Syngenta Agro
KIIIA1 6.2.1	Fluchon, V.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter rye A19786A_10146 Syngenta N/J N 2603631/368886	N	J		Syngenta Agro
KIIIA1 6.2.1	Guichard, J.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter rye A19786A_10198 Syngenta N/J N 2603632/368887	N	J		Syngenta Agro
KIIIA1 6.2.1	Svobodnik, A.	2011	A19786A (PXD/PYR) efficacy trial against Apera and dicots A19786A_10380 Syngenta N/J N 2603633/368888	N	J		Syngenta Agro

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KIIIA1 6.2.1	Janecek, M.	2011	A19786A (PXD/PYR) dose response trial against Avena and dicots A19786A_10342 Syngenta N/J N 2603634/368889	N	J		Syngenta Agro
KIIIA1 6.2.1	Thiel, M.	2012	A19786A (PXD/PYR) dose response trial against Lolium A19786A_10356 Syngenta N/J N 2603635/368890	N	J		Syngenta Agro
KIIIA1 6.2.1	Siegert, E.	2011	A19786A (PXD/PYR) efficacy trial against Apera and dicots A19786A_10286 Syngenta N/J N 2603636/368891	N	J		Syngenta Agro
KIIIA1 6.2.1	Stuebner, B.	2012	A19786A (PXD/PYR) dose response trial against Lolium and dicots A19786A_10458 Syngenta N/J N 2603637/368892	N	J		Syngenta Agro
KIIIA1 6.2.1	Stuebner, B.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10452 Syngenta N/J N 2603638/368893	N	J		Syngenta Agro

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KIIIA1 6.2.1	Stuebner, B.	2011	A19786A (PXD/PYR) efficacy trial against dicots A19786A_10384 Syngenta N/J N 2603639/368894	N	J		Syngenta Agro
KIIIA1 6.2.1	Krueger, D.	2011	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10398 Syngenta N/J N 2603640/368895	N	J		Syngenta Agro
KIIIA1 6.2.1	Krueger, D.	2011	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10386 Syngenta N/J N 2603641/368896	N	J		Syngenta Agro
KIIIA1 6.2.1	Krueger, D.	2012	A19786A (PXD/PYR) timing trial against Apera and dicots A19786A_10428 Syngenta N/J N 2603642/368897	N	J		Syngenta Agro
KIIIA1 6.2.1	Kuhle, B.	2011	A19786A (PXD/PYR) dose response trial against dicots A19786A_10388 Syngenta N/J N 2603643/368898	N	J		Syngenta Agro

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KIIIA1 6.2.1	Kaiser, B.	2011	A19786A (PXD/PYR) dose response trial against Alopecurus and dicots A19786A_10402 Syngenta N/J N 2603644/368899	N	J		Syngenta Agro
KIIIA1 6.2.1	Kaiser, B.	2012	A19786A (PXD/PYR) dose response trial against Alopecurus and dicots A19786A_10292 Syngenta N/J N 2603645/368900	N	J		Syngenta Agro
KIIIA1 6.2.1	Kaiser, B.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10168 Syngenta N/J N 2603646/368901	N	J		Syngenta Agro
KIIIA1 6.2.1	Griehl, T.	2012	A19786A (PXD/PYR) dose response trial against Alopecurus and dicots A19786A_10438 Syngenta N/J N 2603647/368902	N	J		Syngenta Agro
KIIIA1 6.2.1	Griehl, T.	2012	A19786A (PXD/PYR) dose response trial against Alopecurus and dicots A19786A_10426 Syngenta N/J N 2603648/368903	N	J		Syngenta Agro

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KIIIA1 6.2.1	Terhalle, S.	2011	A19786A (PXD/PYR) efficacy trial against Alopecurus and dicots A19786A_10382 Syngenta N/J N 2603649/368904	N	J		Syngenta Agro
KIIIA1 6.2.1	Weigl, A.	2012	A19786A (PXD/PYR) dose response trial against Alopecurus and dicots A19786A_10406 Syngenta N/J N 2603650/368906	N	J		Syngenta Agro
KIIIA1 6.2.1	Terhalle, S.	2012	A19786A (PXD/PYR) dose response trial against Alomy, Apera and dicots A19786A_10460 Syngenta N/J N 2603651/368907	N	J		Syngenta Agro
KIIIA1 6.2.1	Hvid, P.	2011	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10364 Syngenta N/J N 2603652/368909	N	J		Syngenta Agro
KIIIA1 6.2.1	Scott, T.	2011	A19786A (PXD/PYR) dose response trial against Lolium A19786A_10334 Syngenta N/J N 2603653/368910	N	J		Syngenta Agro

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KIIIA1 6.2.1	Fairweather, A.	2011	A19786A (PXD/PYR) efficacy trial against Lolium A19786A_10358 Syngenta N/J N 2603654/368912	N	J		Syngenta Agro
KIIIA1 6.2.1	Scott, T.	2011	A19786A (PXD/PYR) efficacy trial against Bromus A19786A_10302 Syngenta N/J N 2603655/368913	N	J		Syngenta Agro
KIIIA1 6.2.1	Thorpe, A.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10214 Syngenta N/J N 2603656/368914	N	J		Syngenta Agro
KIIIA1 6.2.1	Wielgat, D.	2011	A19786A (PXD/PYR) formulation justification study A19786A_10238 Syngenta N/J N 2603657/368915	N	J		Syngenta Agro
KIIIA1 6.2.1	Poivey, B.	2012	A19786A (PXD/PYR) dose response trial against Lolium and dicots A19786A_10240 Syngenta N/J N 2603658/368916	N	J		Syngenta Agro

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KIIIA1 6.2.1	Poivey, B.	2011	A19786A (PXD/PYR) dose response trial against Lolium and dicots A19786A_10268 Syngenta N/J N 2603659/368917	N	J		Syngenta Agro
KIIIA1 6.2.1	Pietryga, J.	2011	A19786A (PXD/PYR) dose response trial against Alopecurus and dicots A19786A_10244 Syngenta N/J N 2603660/368918	N	J		Syngenta Agro
KIIIA1 6.2.1	Pietryga, J.	2011	A19786A (PXD/PYR) formulation justification study A19786A_10246 Syngenta N/J N 2603661/368919	N	J		Syngenta Agro
KIIIA1 6.2.1	Potocka, E.	2011	A19786A (PXD/PYR) formulation justification study A19786A_10272 Syngenta N/J N 2603662/368920	N	J		Syngenta Agro
KIIIA1 6.2.1	Potocka, E.	2011	A19786A (PXD/PYR) formulation justification study A19786A_10248 Syngenta N/J N 2603663/368921	N	J		Syngenta Agro

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KIIIA1 6.2.1	Potocka, E.	2011	A19786A (PXD/PYR) formulation justification study A19786A_10274 Syngenta N/J N 2603664/368922	N	J		Syngenta Agro
KIIIA1 6.2.1	Idziak, R.	2011	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10250 Syngenta N/J N 2603665/368923	N	J		Syngenta Agro
KIIIA1 6.2.1	Sobiech, L.	2011	A19786A (PXD/PYR) dose response trial against Apera Lolium and dicots A19786A_10252 Syngenta N/J N 2603666/368924	N	J		Syngenta Agro
KIIIA1 6.2.1	Sobiech, L.	2011	A19786A (PXD/PYR) formulation justification study A19786A_10278 Syngenta N/J N 2603667/368925	N	J		Syngenta Agro
KIIIA1 6.2.1	Idziak, R.	2011	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10254 Syngenta N/J N 2603668/368926	N	J		Syngenta Agro

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KIIIA1 6.2.1	Idziak, R.	2012	A19786A (PXD/PYR) dose response trial against Lolium and dicots A19786A_10280 Syngenta N/J N 2603669/368927	N	J		Syngenta Agro
KIIIA1 6.2.1	Majchrzak, L.	2012	A19786A (PXD/PYR) efficacy trial against Bromus and dicots A19786A_10282 Syngenta N/J N 2603670/368928	N	J		Syngenta Agro
KIIIA1 6.2.1	Sobiech, L.	2011	A19786A (PXD/PYR) dose response trial against Alopecurus and dicots A19786A_10220 Syngenta N/J N 2603671/368929	N	J		Syngenta Agro
KIIIA1 6.2.1	Hvid, P.	2011	A19786A (PXD/PYR) efficacy trial against Alopecurus and dicots A19786A_10222 Syngenta N/J N 2603672/368930	N	J		Syngenta Agro
KIIIA1 6.2.1	Carstens, H.	2011	A19786A (PXD/PYR) efficacy trial against Apera and dicots A19786A_10390 Syngenta N/J N 2603673/368931	N	J		Syngenta Agro

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KIIIA1 6.2.1	Terhalle, S.	2012	A19786A (PXD/PYR) timing trial against Alopecurus, Apera and dicots A19786A_10454 Syngenta N/J N 2603674/368932	N	J		Syngenta Agro
KIIIA1 6.2.1	Dyas, D.	2011	A19786A (PXD/PYR) dose response trial against Lolium A19786A_10336 Syngenta N/J N 2603675/368933	N	J		Syngenta Agro
KIIIA1 6.2.1	Griehl, T.	2012	A19786A (PXD/PYR) timing trial against Alopecurus and dicots A19786A_10432 Syngenta N/J N 2603676/368934	N	J		Syngenta Agro
KIIIA1 6.2.1	Hvid, P.	2011	A19786A (PXD/PYR) efficacy trial against dicots A19786A_10360 Syngenta N/J N 2603677/368935	N	J		Syngenta Agro
KIIIA1 6.2.1	Carstens, H.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10206 Syngenta N/J N 2603678/368936	N	J		Syngenta Agro

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KIIIA1 6.2.1	Carstens, H.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10456 Syngenta N/J N 2603679/368937	N	J		Syngenta Agro
KIIIA1 6.2.1	Griehl, T.	2011	A19786A (PXD/PYR) efficacy trial against Alopecurus and dicots A19786A_10392 Syngenta N/J N 2603680/368938	N	J		Syngenta Agro
KIIIA1 6.2.1	Terhalle, S.	2011	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10404 Syngenta N/J N 2603681/368939	N	J		Syngenta Agro
KIIIA1 6.2.1	Ruppert, R.	2012	A19786A (PXD/PYR) efficacy trial against Bromus A19786A_10450 Syngenta N/J N 2603682/368940	N	J		Syngenta Agro
KIIIA1 6.2.1	Henriksen, K.	2011	A19786A (PXD/PYR) efficacy trial against Bromus A19786A_10368 Syngenta N/J N 2603683/368941	N	J		Syngenta Agro

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KIIIA1 6.2.1	Carstens, H.	2012	A19786A (PXD/PYR) timing trial against Apera and dicots A19786A_10451 Syngenta N/J N 2603684/368942	N	J		Syngenta Agro
KIIIA1 6.2.1	Kuhle, B.	2011	A19786A (PXD/PYR) efficacy trial against Alopecurus and dicots A19786A_10284 Syngenta N/J N 2603685/368943	N	J		Syngenta Agro
KIIIA1 6.2.1	Kuhle, B.	2012	A19786A (PXD/PYR) timing trial against Alopecurus and dicots A19786A_10457 Syngenta N/J N 2603686/368944	N	J		Syngenta Agro
KIIIA1 6.2.1	Terhalle, S.	2011	A19786A (PXD/PYR) dose response trial against Alopecurus and dicots A19786A_10394 Syngenta N/J N 2603687/368945	N	J		Syngenta Agro
KIIIA1 6.2.1	Dyas, D.	2011	A19786A (PXD/PYR) dose response trial against Avena A19786A_10354 Syngenta N/J N 2603688/368946	N	J		Syngenta Agro

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KIIIA1 6.2.1	Carstens, H.	2011	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10400 Syngenta N/J N 2603689/368947	N	J		Syngenta Agro
KIIIA1 6.2.1	Siegert, E.	2011	A19786A (PXD/PYR) efficacy trial against Lolium A19786A_10290 Syngenta N/J N 2603690/368948	N	J		Syngenta Agro
KIIIA1 6.2.1	Hvid, P.	2011	A19786A (PXD/PYR) efficacy trial against Alopecurus and dicots A19786A_10408 Syngenta N/J N 2603691/368949	N	J		Syngenta Agro
KIIIA1 6.2.1	Terhalle, S.	2011	A19786A (PXD/PYR) efficacy trial against Alopecurus and dicots A19786A_10294 Syngenta N/J N 2603692/368950	N	J		Syngenta Agro
KIIIA1 6.2.1	Ehrenschwend, G.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10170 Syngenta N/J N 2603693/368951	N	J		Syngenta Agro

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KIIIA1 6.2.1	Spacilova, V.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10190 Syngenta N/J N 2603694/368952	N	J		Syngenta Agro
KIIIA1 6.2.1	Bernardova, M.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter triticale A19786A_10184 Syngenta N/J N 2603695/368953	N	J		Syngenta Agro
KIIIA1 6.2.1	Stuebner, B.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10459 Syngenta N/J N 2603696/368954	N	J		Syngenta Agro
KIIIA1 6.2.1	Stuebner, B.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10453 Syngenta N/J N 2603697/368955	N	J		Syngenta Agro
KIIIA1 6.2.1	Stuebner, B.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter triticale A19786A_10202 Syngenta N/J N 2603698/368956	N	J		Syngenta Agro

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KIIIA1 6.2.1	Terhalle, S.	2012	A19786A (PXD/PYR) dose response trial against Alopecurus and dicots A19786A_10455 Syngenta N/J N 2603699/368957	N	J		Syngenta Agro
KIIIA1 6.2.1	Pawlak, A.	2012	A19786A (PXD/PYR) dose response trial against Lolium and dicots A19786A_10304 Syngenta N/J N 2603700/368958	N	J		Syngenta Agro
KIIIA1 6.2.1	Kroehnke, J.	2012	A19786A (PXD/PYR) dose response trial against Apera, Avena and dicots A19786A_10270 Syngenta N/J N 2603701/368959	N	J		Syngenta Agro
KIIIA1 6.2.1	Stuebner, B.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter triticale A19786A_10188 Syngenta N/J N 2603702/368960	N	J		Syngenta Agro
KIIIA1 6.2.1	Krueger, D.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter triticale A19786A_10172 Syngenta N/J N 2603703/368961	N	J		Syngenta Agro

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KIIIA1 6.2.1	Carstens, H.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter triticale A19786A_10208 Syngenta N/J N 2603704/368962	N	J		Syngenta Agro
KIIIA1 6.2.1	Kuhle, B.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter triticale A19786A_10174 Syngenta N/J N 2603705/368963	N	J		Syngenta Agro
KIIIA1 6.2.1	Konvalinkova, J.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter rye A19786A_10200 Syngenta N/J N 2603706/368964	N	J		Syngenta Agro
KIIIA1 6.2.1	Krueger, D.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10436 Syngenta N/J N 2603707/368965	N	J		Syngenta Agro
KIIIA1 6.2.1	Kroehnke, J.	2012	A19786A (PXD/PYR) dose response trial against Apera, Avena and dicots A19786A_10242 Syngenta N/J N 2603708/368966	N	J		Syngenta Agro

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KIIIA1 6.2.1	Carstens, H.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter rye A19786A_10186 Syngenta N/J N 2603709/368967	N	J		Syngenta Agro
KIIIA1 6.2.1	Krueger, D.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter rye A19786A_10204 Syngenta N/J N 2603710/368968	N	J		Syngenta Agro
KIIIA1 6.2.1	Kaiser, B.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter rye A19786A_10210 Syngenta N/J N 2603711/368969	N	J		Syngenta Agro
KIIIA1 6.2.1	Krueger, D.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10424 Syngenta N/J N 2603712/368970	N	J		Syngenta Agro
KIIIA1 6.2.1	Krueger, D.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter rye A19786A_10154 Syngenta N/J N 2603713/368971	N	J		Syngenta Agro

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KIIIA1 6.2.1	Terhalle, S.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter rye A19786A_10180 Syngenta N/J N 2603714/368972	N	J		Syngenta Agro
KIIIA1 6.2.1	Psibisauskiene, G.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10232 Syngenta N/J N 2603715/368973	N	J		Syngenta Agro
KIIIA1 6.2.1	Vanaga, I.	2011	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10234 Syngenta N/J N 2603716/368974	N	J		Syngenta Agro
KIIIA1 6.2.1	Vanaga, I.	2011	A19786A (PXD/PYR) formulation justification study A19786A_10264 Syngenta N/J N 2603717/368975	N	J		Syngenta Agro
KIIIA1 6.2.1	Vanaga, I.	2011	A19786A (PXD/PYR) dose response trial against dicots A19786A_10236 Syngenta N/J N 2603718/368976	N	J		Syngenta Agro

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KIIIA1 6.2.1	Vanaga, I.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10266 Syngenta N/J N 2603719/368977	N	J		Syngenta Agro
KIIIA1 6.2.1	Vanaga, I.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10110 Syngenta N/J N 2603720/368978	N	J		Syngenta Agro
KIIIA1 6.2.1	Uminski, P.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10120 Syngenta N/J N 2603721/368979	N	J		Syngenta Agro
KIIIA1 6.2.1	Kroehnke, J.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10130 Syngenta N/J N 2603722/368980	N	J		Syngenta Agro
KIIIA1 6.2.1	Potocka, E.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10124 Syngenta N/J N 2603723/368981	N	J		Syngenta Agro

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KIIIA1 6.2.1	Majchrzak, L.	2011	A19786A (PXD/PYR) dose response trial against Avena A19786A_10276 Syngenta N/J N 2603724/368982	N	J		Syngenta Agro
KIIIA1 6.2.1	Junnila, S.	2011	A19786A (PXD/PYR) dose response trial against Poa and dicots A19786A_10256 Syngenta N/J N 2603725/368983	N	J		Syngenta Agro
KIIIA1 6.2.1	Junnila, S.	2011	A19786A (PXD/PYR) formulation justification study A19786A_10226 Syngenta N/J N 2603726/368984	N	J		Syngenta Agro
KIIIA1 6.2.1	Auskalniene, O.	2011	A19786A (PXD/PYR) formulation justification study A19786A_10262 Syngenta N/J N 2603727/368985	N	J		Syngenta Agro
KIIIA1 6.2.1	Ilumae, E.	2012	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10218 Syngenta N/J N 2603728/368986	N	J		Syngenta Agro

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KIIIA1 6.2.1	Vanaga, I.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10116 Syngenta N/J N 2603729/368987	N	J		Syngenta Agro
KIIIA1 6.2.1	Slowiak, M.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10136 Syngenta N/J N 2603730/368988	N	J		Syngenta Agro
KIIIA1 6.2.1	Auskalniene, O.	2011	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10230 Syngenta N/J N 2603731/368989	N	J		Syngenta Agro
KIIIA1 6.2.1	Auskalniene, O.	2011	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10258 Syngenta N/J N 2603732/368990	N	J		Syngenta Agro
KIIIA1 6.2.1	Auskalniene, O.	2011	A19786A (PXD/PYR) formulation justification study A19786A_10228 Syngenta N/J N 2603733/368991	N	J		Syngenta Agro

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KIIIA1 6.2.1	Junnila, S.	2011	A19786A (PXD/PYR) dose response trial against Avena and dicots A19786A_10224 Syngenta N/J N 2603734/368992	N	J		Syngenta Agro
KIIIA1 6.2.1	Psibisauskiene, G.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10144 Syngenta N/J N 2603735/368993	N	J		Syngenta Agro
KIIIA1 6.2.1	Auskalniene, O.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10114 Syngenta N/J N 2603736/368994	N	J		Syngenta Agro
KIIIA1 6.2.1	Psibisauskiene, G.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter wheat A19786A_10142 Syngenta N/J N 2603737/368995	N	J		Syngenta Agro
KIIIA1 6.2.1	Auskalniene, O.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter triticale A19786A_10138 Syngenta N/J N 2603738/368996	N	J		Syngenta Agro

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KIIIA1 6.2.1	Auskalniene, O.	2011	A19786A (PXD/PYR) dose response trial against Apera and dicots A19786A_10260 Syngenta N/J N 2603739/368997	N	J		Syngenta Agro
KIIIA1 6.2.1	Vanaga, I.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter triticale A19786A_10108 Syngenta N/J N 2603740/368998	N	J		Syngenta Agro
KIIIA1 6.2.1	Kroehnke, J.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter triticale A19786A_10122 Syngenta N/J N 2603741/368999	N	J		Syngenta Agro
KIIIA1 6.2.1	Potocka, E.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter triticale A19786A_10126 Syngenta N/J N 2603742/369000	N	J		Syngenta Agro
KIIIA1 6.2.1	Slowiak, M.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter triticale A19786A_10134 Syngenta N/J N 2603743/369001	N	J		Syngenta Agro

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KIIIA1 6.2.1	Kroehnke, J.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter rye A19786A_10128 Syngenta N/J N 2603744/369002	N	J		Syngenta Agro
KIIIA1 6.2.1	Ilumae, E.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter rye A19786A_10140 Syngenta N/J N 2603745/369003	N	J		Syngenta Agro
KIIIA1 6.2.1	Auskalniene, O.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter rye A19786A_10112 Syngenta N/J N 2603746/369004	N	J		Syngenta Agro
KIIIA1 6.2.1	Slowiak, M.	2011	A19786A (PXD/PYR) crop safety trial with yield in winter rye A19786A_10132 Syngenta N/J N 2603747/369005	N	J		Syngenta Agro
KIIIA1 6.2.1	Vanaga, I.	2012	A19786A (PXD/PYR) crop safety trial with yield in winter rye A19786A_10118 Syngenta N/J N 2603748/369006	N	J		Syngenta Agro

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KIIIA1 6.2.6	Fullick, K., Murdock J.	2013	Evaluation of the carryover potential of EAME BOLD formulations in GH A19786A_10105 Syngenta N/N N 2603749/369007	N	J		Syngenta Agro
KIIIA1 6.2.6	Butz, P.	2012	BOLT projects- carry over effect A19786A_10103 Syngenta N/N N 2603750/369008	N	J		Syngenta Agro
KIIIA1 6.2.6	Doerig, B.	2012	BOLT projects- carry over effect A19786A_10099 Syngenta N/N N 2603751/369009	N	J		Syngenta Agro
KIIIA1 6.2.6	Speyer, M.	2012	HDWW75 : BOLT projects- carry over effect A19786A_10101 Syngenta N/J N 2603752/369010	N	J		Syngenta Agro
KIIIA1 6.2.6	Derrico, M.	2012	BOLT projects- carry over effect A19786A_10097 Syngenta N/J N 2603753/369011	N	J		Syngenta Agro

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MIIIA1 Sec 1	Syngenta Agro GmbH	2013	dRR - B1 - core assess. - DE - 008178-00/00 - A19786A A19786A_10091 Syngenta N/N N 2603754/369012	N	N		Syngenta Agro
MIIIA1 Sec 1	Syngenta Agro GmbH	2013	dRR - B1 - core assess. - DE - 008178-00/00 - A19786A A19786A_10091 Syngenta N/N N 2603755/369013	N	N		Syngenta Agro
MIIIA1 Sec 6	Syngenta Agro GmbH	2013	dRR - B6 - core assess. - DE - 008178-00/00 - A19786A A19786A_10047 Syngenta European Product Registration, Basel, Switzerland N/N N 2603778/369024	N	N		Syngenta Agro
MIIIA1 Sec 6	Syngenta Agro GmbH	2013	dRR - B6 - core assess. - DE - 008178-00/00 - A19786A A19786A_10047 Syngenta European Product Registration, Basel, Switzerland N/N N 2603779/369025	N	N		Syngenta Agro
MIIIA1 Sec 6	Syngenta Agro GmbH	2013	dRR - B6 - nat. add. - DE - 008178-00/00 - A19786A A19786A_10048 Syngenta European Product Registration, Basel, Switzerland N/N N 2603780/369026	N	N		Syngenta Agro

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MIIIA1 Sec 6	Syngenta Agro GmbH	2013	dRR - B6 - nat. add. - DE - 008178-00/00 - A19786A A19786A_10048 Syngenta European Product Registration, Basel, Switzerland N/N N 2603781/369027	N	N		Syngenta Agro
MIIIA1 Sec 7	Syngenta Agro GmbH	2014	dRR - B7 - core assess. - DE - 008178-00/00 - A19786A A19786A_10479 Syngenta N/N N 2603784/369030	N	N		Syngenta Agro
MIIIA1 Sec 7	Syngenta Agro GmbH	2014	dRR - B7 - core assess. - DE - 008178-00/00 - A19786A A19786A_10479 Syngenta N/N N 2603785/369031	N	N		Syngenta Agro
Document N	Syngenta Agro GmbH	2013	dRR - A - DE - 008178-00/00 - A19786A A19786A_10030 Syngenta Crop Protection AG, Basel, Switzerland N/N N 2603798/369044	N	N		Syngenta Agro
Document N	Syngenta Agro GmbH	2013	dRR - A - DE - 008178-00/00 - A19786A A19786A_10030 Syngenta Crop Protection AG, Basel, Switzerland N/N N 2603799/369045	N	N		Syngenta Agro

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Document N	Syngenta	2014	A19786A Germany Part A Appendix 3 A19786A_10472 Syngenta Crop Protection AG, Basel, Switzerland N/N N 2603800/369046	N	N		Syngenta Agro
Document N	Syngenta	2014	Attachment: A19786A Germany Part A Appendix 3 A19786A_10472 Syngenta Crop Protection AG, Basel, Switzerland N/N N 2603801/369047	N	N		Syngenta Agro
Document N	Anonymous	2013	Form to notify intended zonal applications under Regulation (EC) No 1107/2009 O/O N 2611940/369068	N	O		Syngenta Agro
KIIIA1 3.9	Anonymous	2014	Vorläufige Gebrauchsanleitung O/O N 2611942/369069	N	J		Syngenta Agro
KIIIA1 10.8.1.2	Sutton, P., Spatz, R.	2015	A19786A: Comment on the divergent results for Avena sativa from two vegetative vigour tests A19786A_10527 ! 20150702 RSp Syngenta Crop Protection AG, Basel, Switzerland N/N N 3015236/430610	N	J		Syngenta Agro

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KIIIA1 6	Pflughoeft, O., Weber, C.	2015	Biological Assessment Dossier A19786A (Pyroxsulam, Pinoxaden, Cloquintocet-Mexyl) A19786A_10465 Syngenta N/N N 3015237/430611	N	J		Syngenta Agro
KIIIA1 6.2.6	Watkins, M.	2014	Biological evaluation of the phytotoxicity of A19786A (pinoxaden/pyroxsulam EC41.66) after soil Pre-Plant Incorporation (PPI) A19786A_10529 ! GBJH2H7012014 Syngenta N/N N 3015238/430612	N	J		Syngenta Agro
KIIIA1 6.2.8	Petersen, J.	2013	A19786A resistance monitoring of ALOMY in Germany - University Bingen 2013 A19786A_10530 Syngenta N/N N 3015239/430613	N	J		Syngenta Agro
KIIIA1 6.2.8	Petersen, J.	2014	A19786A resistance monitoring of ALOMY in Germany - University Bingen 2014 A19786A_10531 Syngenta N/N N 3015240/430614	N	J		Syngenta Agro
KIIIA1 6.2.8	Rosenhauer, M., Petersen, J.	2012	A19786A APESV-Resistenzmonitoring - University Bingen 2012 A19786A_10532 Syngenta N/N N 3015241/430615	N	J		Syngenta Agro

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KIIIA1 6.2.8	Petersen, J.	2013	A19786A resistance monitoring of APESV - University Bingen 2013 A19786A_10533 Syngenta N/N N 3015242/430616	N	J		Syngenta Agro
KIIIA1 6.2.8	Petersen, J., Sche-liga, M.	2014	A19786A resistance monitoring of APESV in Germany, Austria, Czech-Republic and Poland - University Bingen 2014 A19786A_10534 Syngenta N/N N 3015243/430617	N	J		Syngenta Agro
MIIIA1 Sec 7	Syngenta - update 09.11.2015 (pdf)	2015	dRR - B7 - core assess. - DE - 008178-00/00 - A19786A A19786A_10479 Syngenta N/N N 3015271/430618	N	N		Syngenta Agro
Document N	Syngenta (pdf)	2015	dRR - B8 - nat.add. - DE - 008178-00/00 - A19786A A19786A_10528 Syngenta Crop Protection AG, Basel, Switzerland N/N N 3015272/430619	N	N		Syngenta Agro
Document N	Syngenta (word)	2015	dRR - B8 - nat.add. - DE - 008178-00/00 A19786A A19786A_10528 Syngenta Crop Protection AG, Basel, Switzerland N/N N 3015273/430620	N	N		Syngenta Agro

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIIA1 6.2.8	Petersen, J., Rosenhauer, M.	2012	RESISTANCE MONITORING OF ALOPECURUS MYOSUROIDES - Trial Report 2012 A19786A_10093 N/N N 3018531/430621	N	J		Syngenta Agro
KIIIA1 6	Pflughöft, O., Weber, C.	2015	Updated BAD A19786A (word) A19786A_10465 N/N N 3018606/430622	N	J		Syngenta Agro
MIIIA1 Sec 7	Pflughöft, O., Weber, C.	2015	Updated dRR - B7 - core assess. - DE - A19786A A19786A_10479 O/O N 3018801/430624	N	J		Syngenta Agro
KIIIA1 3.9	Anonymous	2017	Gebrauchsanleitung O/O N 3403196/510046	N	J		Syngenta Agro GmbH Maintal

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed Y/N	Justification if data protection is claimed	Owner

List of data relied on and not submitted by the applicant but necessary for evaluation

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed Y/N	Justification if data protection is claimed	Owner

List of data submitted by the applicant and not relied on

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed Y/N	Justification if data protection is claimed	Owner

Appendix 2: GAP table

GAP-Table of intended uses for Germany

Reg.-No.	008178-00/00		GAP rev.1, date: 2017-10-26
PPP (product name/code):	AVOXA	Formulation type:	EC (a, b)
Safener 1:	Cloquintocet	Conc. of as 1:	8.33 g/L (c)
Active substance 2:	Pinoxaden	Conc. of as 2:	33.30 g/L (c)
Active substance 3:	Pyroxsulam	Conc. of as 3:	8.33 g/L (c)
Applicant:	Syngenta Agro GmbH	Professional use:	Yes
Zone(s):	central/interzonal (d)	Non professional use:	No
Verified by MS:	Yes	Field of use:	Herbicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-	**Member**	**Crop and/**	**F,**	**Pests or Group of**	**Application**				**Application rate**			**PHI**	**Remarks:**	**Conclusion**

No. (e)	**state(s)**	**or situation** **(crop destination / purpose of crop)**	**Fn, Fpn G, Gn, Gpn or I**	**pests controlled** (additionally: developmental stages of the pest or pest group)	Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max	(days)	e.g. g safener/synergist per ha (f)	**(efficacy)**
001	DE	winter soft wheat (TRZAW), winter triticale (TTLWI), winter rye (SECCW)	F	*Alopecurus myosuroides* (ALOMY), *Bromus sp.* (BROSS), *Galium aparine* (GALAP)	spraying	After emergence, spring 10 to 32	a) 1 b) 1		a) 1.8 L/ha b) 1.8 L/ha	a) a.s.1: 0.01499 kg/ha a.s.2: 0.05994 kg/ha a.s.3: 0.01499 kg/ha b) 0.01499 kg/ha 0.05994 kg/ha 0.01499 kg/ha	200 - 400 L/ha	-		
002	DE	winter soft wheat (TRZAW), winter triticale (TTLWI), winter rye (SECCW)	F	*Apera spica-venti* (APESV), *Lolium species* (LOLSS), annual dicotyledonous weeds (TTTDS)	spraying	After emergence, spring 10 to 32	a) 1 b) 1		a) 1.35 L/ha b) 1.35 L/ha	a) a.s.1: 0.01125 kg/ha a.s.2: 0.04496 kg/ha a.s.3: 0.01125 kg/ha b) 0.01125 kg/ha 0.04496 kg/ha 0.01125 kg/ha	200 - 400 L/ha	-		

GAP-Table of intended uses for all cMS (without Germany), not verified by zRMS

GAP rev. (No), date: 2014-07-01

PPP (product name/code) **A19786A**
active substance 1 **pinoxaden**
active substance 2 **pyroxsulam**

safener cloquintocet-mexyl

Applicant: **Syngenta Agro GmbH**
Zone(s):northern/central/southern/EU

Verified by MS: no

Formulation type: **EC**
Conc. of a.s. 1: **33.3 g/L**
Conc. of a.s. 2: **8.33 g/La**

Conc. of safener: **8.33 g/L**

professional use **X**
non professional use

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**			**Application rate**			**PHI** (days)	**Remarks:** e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
1a	S-EU: FR C-EU AT BE CZ LU NL PL SK	Winter wheat	F	*Apera* only	Foliar Spray	BBCH 10-32 (spring application only)	a) 1 b) 1	a) 1.35 b) 1.35	a) 45 g/ha pinoxaden 11.3 g/ha pyroxsulam b) 45 g/ha pinoxaden 11.3 g/ha pyroxsulam	100 - 300	nr	Also includes safener at 11.3 g cloquintocet-mexyL/ha

	N-EU EE LV LT											
1b	S-EU: FR C-EU AT BE CZ LU NL PL SK N-EU EE LV LT	Winter wheat	F	*Apera*, *Alopecurus*, *Avena*, *Lolium*, other grasses and dicots	Foliar Spray	BBCH 10-32 (spring application only)	a) 1 b) 1	a) 1.8 b) 1.8	a) 59.9 g/ha pinoxaden 15 g/ha pyroxsulam b) 59.9 g/ha pinoxaden 15 g/ha pyroxsulam	100 - 300	nr	Also includes safener at 15 g cloquintocet-mexyL/ha
2a	S-EU: FR C-EU AT BE CZ LU NL PL SK N-EU EE LV LT	Winter rye	F	*Apera* only	Foliar Spray	BBCH 10-32 (spring application only)	a) 1 b) 1	a) 1.35 b) 1.35	a) 45 g/ha pinoxaden 11.3 g/ha pyroxsulam b) 45 g/ha pinoxaden 11.3 g/ha pyroxsulam	100 - 300	nr	Also includes safener at 11.3 g cloquintocet-mexyL/ha

2b	S-EU: FR C-EU AT BE CZ LU NL PL SK N-EU EE LV LT	Winter rye	F	*Apera*, *Alopecurus*, *Avena*, *Lolium*, other grasses and dicots	Foliar Spray	BBCH 10-32 (spring application only)	a) 1 b) 1	a) 1.8 b) 1.8	a) 59.9 g/ha pinoxaden 15 g/ha pyroxsulam b) 59.9 g/ha pinoxaden 15 g/ha pyroxsulam	100 - 300	nr	Also includes safener at 15 g cloquintocet-mexyL/ha
3a	S-EU: FR C-EU AT BE CZ LU NL PL SK N-EU EE LV LT	Winter triticale	F	*Apera* only	Foliar Spray	BBCH 10-32 (spring application only)	a) 1 b) 1	a) 1.35 b) 1.35	a) 45 g/ha pinoxaden 11.3 g/ha pyroxsulam b) 45 g/ha pinoxaden 11.3 g/ha pyroxsulam	100 - 300	nr	Also includes safener at 11.3 g cloquintocet-mexyL/ha
3b	S-EU: FR C-EU AT	Winter triticale	F	*Apera*, *Alopecurus*, *Avena*, *Lolium*, other grasses and dicots	Foliar Spray	BBCH 10-32 (spring application only)	a) 1 b) 1	a) 1.8 b) 1.8	a) 59.9 g/ha pinoxaden 15 g/ha	100 - 300	nr	Also includes safener at 15 g cloquintocet-mexyL/ha

	BE CZ LU NL PL SK N-EU EE LV LT								pyroxsulam b) 59.9 g/ha pinoxaden 15 g/ha pyroxsulam			

REGISTRATION REPORT
Part B

Section 8: Assessment of the relevance of metabolites in groundwater

Detailed summary of the risk assessment

Product code: A19786A

Active Substances:

Cloquintocet-mexyl 8.33 g/L

Pinoxaden 33.3 g/L

Pyroxsulam 8.33 g/L

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Syngenta Agro GmbH

Date: June 2017

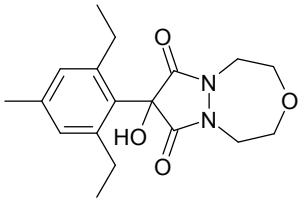
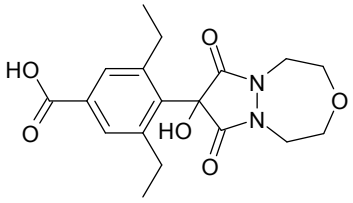
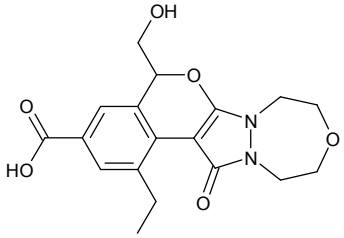
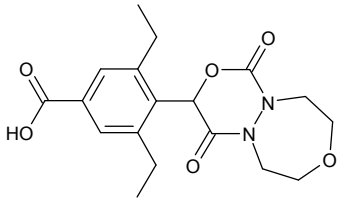
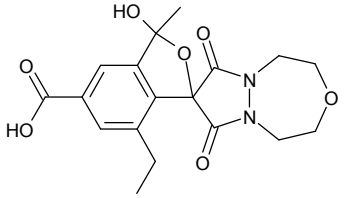
Table of Contents

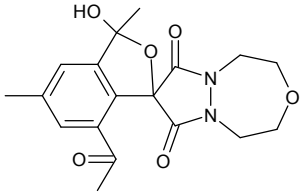
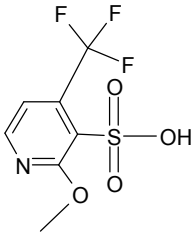
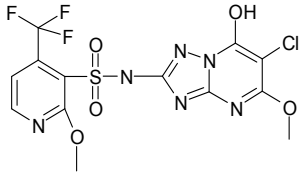
8 RELEVANCE OF METABOLITES IN GROUNDWATER

8.1 General information

The pinoxaden metabolites M3, M11, M52, M54, M55 and M56 and the pyroxsulam metabolites PSA and 6-Cl-7-OH are predicted to occur in groundwater at concentrations above 0.1 µg/L. Assessment of the relevance of these metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is therefore required.
General information on the metabolites is provided in Table 8.1-1. The impact of the relevance assessment on whether a particular GAP use leads to acceptable risk or not is presented in the summary of the cGAP evaluation in chapter 5.7 of the dRR Part B, Section 5 (Environmental fate and behaviour).

Table 8.1-1: General information on the metabolite(s)

Metabolite name and code	Structural/molecular formula	Name of parent active substance	Trigger for relevance assessmnent	
M3 (NOA 447204) (CSAA783052)		pinoxaden	Max PECgw Based on:	10.413 µg/L FOCUS PELMO 5.5.3 / Jokioinen 0.218 µg/L Lysimeter
M11 (SYN 504574) (CSCC204395)		pinoxaden	Max PECgw Based on:	1.123 µg/L FOCUS PELMO 5.5.3 / Jokioinen 0.263 µg/L Lysimeter
M52 (SYN546105) (CSCD704931)		pinoxaden	Max PECgw Based on:	0.150 µg/L Lysimeter
M54 (SYN546106) (CSCD704932)		pinoxaden	Max PECgw Based on:	0.698 µg/L FOCUS PELMO 5.5.3 / Jokioinen 0.173 µg/L Lysimeter
M55 (SYN546107) (CSCD704933)		pinoxaden	Max PECgw Based on:	1.582 µg/L FOCUS PELMO 5.5.3 / Jokioinen 0.161 µg/L Lysimeter

M56 (SYN546108)		pinoxaden	Max PECgw Based on:	5.635 µg/L FOCUS PELMO 5.5.3 /Châteaudun 0.307 µg/L Lysimeter
PSA PSA (XDE-742 sulfonic acid) = Pyridin-sulfonic acid)		pyroxsulam	Max PECgw Based on:	0.353 µg/L FOCUS PELMO 5.5.3 / Jokioinen
6-Cl-7-OH (6-Cl-7-OH-XDE-742)		pyroxsulam	Max PECgw Based on:	0.185 µg/L FOCUS PELMO 5.5.3 / Kremsmünster

8.2 Relevance assessment of M3 (NOA 447204)

Summary:

The relevance of the groundwater metabolite M3 (NOA 447204) has already been assessed at EU level (see EFSA Journal 2013;11(8):3269). For pinoxaden a classification with H361d (Repr. Cat. 2) was proposed in the Conclusion on the peer review. According to EFSA the metabolite M3 should be considered relevant if ECHA confirms H361d proposed for pinoxaden.
The classification for pinoxaden with H361d was confirmed by ECHA (CLH-O-0000001412-86-127/F; 16 September 2016). It is thus be mandatory to allocate that the groundwater metabolite M3 doesn't share the toxic properties for reproduction of the parent compound. Otherwise the metabolite M3 must be considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 – rev.10.
According to Implementing Regulation (EU) 2016/370 of 15 March 2016 the applicant shall submit confirmatory information as regards the relevance of the metabolite M3 and the corresponding groundwater risk assessment, if pinoxaden is classified under Regulation (EC) No 1272/2008 as H361d (suspected of damaging the unborn child). The applicant shall submit to the Commission, the Member States and the Authority the relevant information within six months from the notification of the classification decision under Regulation (EC) No 1272/2008.
A summary of the relevance assessment for M3 (NOA 447204) is given in the following table.

Table 8.2-1: Summary of the relevance assessment for M3 (NOA 447204)

	Assessment step	**Result of assessment**	
	STEP 1	Metabolite of no concern?	no

Quantification of groundwater contamination	STEP 2		Max PEC_{gw} Based on	10.413 µg/L FOCUS PELMO 5.5.3 / Jokioinen 0.218 µg/L Lysimeter
Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	No
		Stage 2	Genotoxic properties of metabolite	Non-genotoxic
		Stage 3	Toxic properties of metabolite;	
			Classification of parent	Not listed. Proposal of EU peer review (see EFSA Journal 2013;11(8):3269): H315, H317, H319, H332, H335, H361d RAC-Opinion(CLH-O-0000001412-86-127/F; 16 September 2016): H317, H319, H332, H335, H361d
			Classification of metabolite	not listed
Consumer health risk assessment	STEP 4		Estimated consumer exposure via drinking water and other sources; threshold of concern approach	Acceptable if the metabolite doesn't share the toxic properties for reproduction of the parent compound.
	STEP 5		Refined risk assessment	Acceptable if the metabolite doesn't share the toxic properties for reproduction of the parent compound.
			Predicted exposure (% of ADI)	0.062%*
			ADI based on	A specific ADI of 0.01 mg/kg bw/day, based on 10-fold higher toxicity than parent substance in short term toxicological studies*

* Since the metabolite concentration is in this case < 0.75 µg/L, a refined assessment according to Steps 4 and 5 is not necessary, but is included here for the purposes of information only.

8.2.1 STEP 1: Exclusion of degradation products of no concern

Metabolite M3 does not meet the criteria for products of no concern as defined in step 1 of the guidance and therefore needs further assessment.

8.2.2 STEP 2: Quantification of potential groundwater contamination

PEC_{gw} calculations after leaching from soil for M3 were performed using the simulation model FOCUS PELMO 5.5.3 (see Part B, Section 5, chapter 5.7). The metabolite M3 by far exceeds the trigger value of 0.1 µg/L in all scenarios and exceeds the orientation value of 10 µg/L for Jokionen. However, these results might be an overestimation as confirmed by lysimeter data, in which a concentration of 0.218 µg/L was measured. A relevance assessment has to be performed for the metabolite.

Metabolite M3 is relevant according to Step 2 of this assessment.

8.2.3 STEP 3: Hazard assessment – identification of relevant metabolites

8.2.3.1 STEP 3, Stage 1: screening for biological activity

The metabolites M3, M11, M52, M54, M55 and M56 have been evaluated in the peer review in view of the Annex I inclusion of Pinoxaden. The metabolites M3, M11, M52, M54, M55 and M56 have no biological activity as compared to the parent compound (EFSA Journal 2013;11(8):3269).

8.2.3.2 STEP 3, Stage 2: screening for genotoxicity

Metabolite M3 was evaluated in a battery of three in vitro and two in vivo genotoxicity studies (see Table 8.2-2) as required in the EC guidance document SANCO/221/2000 –rev.10. The results of all five studies were negative. Therefore, it can be concluded that metabolite M3 does not have genotoxic potential. The metabolite M3 is not considered relevant at this step of the assessment.

Table 8.2-2: Summary of the evaluation of the genotoxicity studies for NOA 447204 (M3)

Type of test, species (Guideline)	Result	Acceptability	Reference*
Bacterial Reverse Mutation Assay (OECD 471)	negative	Yes	Callander, R., 2003* TOX2004-2737
In vitro chromosome aberration test in Human lymphocytes (OECD 473)	weakly clastogenic in presence and absence of S9-mix	Yes	Fox, V., 2003* TOX2004-2738
Cell mutation assay in Mouse Lymphoma Cells in vitro (OECD 476)	negative	Yes	Clay, P., 2003* TOX2004-2739
Micronucleus test in mouse	negative	Yes	Fox, V., 2003* TOX2004-2740
In vivo Rat liver UDS test (OECD 486)	negative	Yes	Fox, V., 2003* TOX2004-2741

*indicates that a study was reviewed at EU level

8.2.3.3 STEP 3, Stage 3: screening for toxicity

The parent substance pinoxaden and the groundwater metabolite M3 are currently not classified for carcinogenicity, mutagenicity or reproductive toxicity.
However, for pinoxaden a classification with H361d was proposed in the Conclusion on the peer review (EFSA Journal 2013;11(8):3269). According to EFSA the metabolite M3 should be considered relevant if ECHA confirms H361d proposed for pinoxaden.
The classification for pinoxaden with H361d was confirmed by ECHA (CLH-O-0000001412-86-127/F; 16 September 2016). It is thus be mandatory to allocate that the groundwater metabolite M3 doesn't share the toxic properties for reproduction of the parent compound. Otherwise the metabolite M3 must be considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 – rev.10.
According to Implementing Regulation (EU) 2016/370 of 15 March 2016 the applicant shall submit confirmatory information as regards the relevance of the metabolite M3 and the corresponding groundwater risk assessment, if pinoxaden is classified under Regulation (EC) No 1272/2008 as H361d (suspected of damaging the unborn child). The applicant shall submit to the Commission, the Member States and the Authority the relevant information within six months from the notification of the

classification decision under Regulation (EC) No 1272/2008.

8.2.4 STEP 4: Exposure assessment – threshold of concern approach

According to the EC guidance document SANCO/221/2000 –rev.10 a threshold can be accepted if the metabolite M3 does not exceed a concentration in groundwater of 0.75 µg/L provided the metabolite doesn't share the toxic properties for reproduction of the parent compound. The level of estimated concentration of metabolite M3 in groundwater is 0.218 µg/L. Therefore, in this case, no further data are required and a refined risk assessment is not necessary.
The studies reviewed at EU level are listed in the following table solely for the purpose of information.

Table 8.2-3: Summary of evaluation of the toxicity studies for NOA 447204 (M3)

Type of test, species (Guideline)	Result	Acceptability	Reference*
Acute oral toxicity (up & down), Rat (OECD 425)	Rat LD50 oral: 1098 mg/kg bw	Yes	Johnson, I.R., 2002* TOX2004-2734
28 day oral toxicity, Rat (OECD 407)	NOAEL: 65 mg/kg bw/day (500 ppm)	Yes	Twomey, K., 2003* TOX2004-2735
90 day oral toxicity, Rat (OECD 407)	NOAEL: 99 mg/kg bw/day (1000 ppm)	Yes	Twomey, K., 2003* TOX2004-2736

*indicates that a study was reviewed at EU level

8.2.5 STEP 5: Refined risk assessment

N/A

8.3 Relevance assessment of M11 (SYN 504574)

Summary:

The relevance of the groundwater metabolite M11 (SYN 504574) has already been assessed at EU level (see EFSA Journal 2013;11(8):3269). For pinoxaden a classification with H361d (Repr. Cat. 2) was proposed in the Conclusion on the peer review. According to EFSA the metabolite M11 should be considered relevant if ECHA confirms H361d proposed for pinoxaden.
The classification for pinoxaden with H361d was confirmed by ECHA (CLH-O-0000001412-86-127/F; 16 September 2016). It is thus be mandatory to allocate that the groundwater metabolite M11 doesn't share the toxic properties for reproduction of the parent compound. Otherwise the metabolite M11 must be considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10.
According to Implementing Regulation (EU) 2016/370 of 15 March 2016 the applicant shall submit confirmatory information as regards the relevance of the metabolite M11 and the corresponding groundwater risk assessment, if pinoxaden is classified under Regulation (EC) No 1272/2008 as H361d (suspected of damaging the unborn child). The applicant shall submit to the Commission, the Member States and the Authority the relevant information within six months from the notification of the classification decision under Regulation (EC) No 1272/2008.
A summary of the relevance assessment for M11 is given in the following table.

Table 8.3-1: Summary of the relevance assessment for M11 (SYN 504574)

	Assessment step	Result of assessment

	STEP 1		Metabolite of no concern?	no
Quantification of groundwater contamination	STEP 2		Max PEC_{gw} Based on	1.123 µg/L FOCUS PELMO 5.5.3 / Jokioinen 0.263 µg/L Lysimeter
Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	no
		Stage 2	Genotoxic properties of metabolite	Non-genotoxic
		Stage 3	Toxic properties of metabolite;	
			Classification of parent	Not listed. Proposal of EU peer review (see EFSA Journal 2013;11(8):3269): H315, H317, H319, H332, H335, H361d RAC-Opinion(CLH-O-0000001412-86-127/F; 16 September 2016): H317, H319, H332, H335, H361d
			Classification of metabolite	Not listed
Consumer health risk assessment	STEP 4		Estimated consumer exposure via drinking water and other sources; threshold of concern approach	Acceptable if the metabolite doesn't share the toxic properties for reproduction of the parent compound.
	STEP 5		Refined risk assessment	N/A
			Predicted exposure (% of ADI)	N/A
			ADI based on	N/A

N/A: not applicable

8.3.1 STEP 1: Exclusion of degradation products of no concern

Metabolite M11 does not meet the criteria for products of no concern as defined in step 1 of the guidance and therefore needs further assessment.

8.3.2 STEP 2: Quantification of potential groundwater contamination

PEC_{gw} calculations after leaching from soil for M11 were performed using the simulation model FOCUS PELMO 5.5.3 (see Part B, Section 5, chapter 5.7). The metabolite M11 exceeds the trigger value of 0.1 µg/L in all scenarios except for Sevilla and Thiva. However, these results might be an overestimation as confirmed by lysimeter data, in which a concentration of 0.263 µg/L was measured. A relevance assessment has to be performed for the metabolite.
Metabolite M11 is relevant according to Step 2 of this assessment.

8.3.3 STEP 3: Hazard assessment – identification of relevant metabolites

8.3.3.1 STEP 3, Stage 1: screening for biological activity

The metabolites M3, M11, M52, M54, M55 and M56 have been evaluated in the peer review in view of the Annex I inclusion of Pinoxaden. The metabolites M3, M11, M52, M54, M55 and M56 have no biological activity as compared to the parent compound (EFSA Journal 2013;11(8):3269).

8.3.3.2 STEP 3, Stage 2: screening for genotoxicity

Metabolite M11 was evaluated in a battery of three in vitro genotoxicity studies (see Table 8.3-2) as required in the EC guidance document SANCO/221/2000 –rev.10. The results of all three studies were negative. Therefore, it can be concluded that metabolite M11 does not have genotoxic potential. The metabolite M11 is not considered relevant at this step of the assessment.

Table 8.3-2: Genotoxicity testing with metabolite M11

Type of test, species (Guideline)	Result	Acceptability	Reference
Bacterial Reverse Mutation Assay (OECD 471)	negative	Yes	Sokolowski, A., 2010a* ASB2014-5432
Cell mutation assay in Mouse Lymphoma Cells in vitro (OECD 476)	negative	Yes	Wollny, H-E., 2010* ASB2014-5433
Micronucleus test in mouse	negative	Yes	Merker, M., 2011a* ASB2014-5434

*indicates that a study was reviewed at EU level

8.3.3.3 STEP 3, Stage 3: screening for toxicity

The parent substance pinoxaden and the groundwater metabolite M11 are currently not classified for carcinogenicity, mutagenicity or reproductive toxicity.
However, for pinoxaden a classification with H361d was proposed in the Conclusion on the peer review (EFSA Journal 2013;11(8):3269). According to EFSA the metabolite M11 should be considered relevant if ECHA confirms H361d proposed for pinoxaden.
The classification for pinoxaden with H361d was confirmed by ECHA (CLH-O-0000001412-86-127/F; 16 September 2016). It is thus be mandatory to allocate that the groundwater metabolite M11 doesn't share the toxic properties for reproduction of the parent compound. Otherwise the metabolite M11 must be considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10.
According to Implementing Regulation (EU) 2016/370 of 15 March 2016 the applicant shall submit confirmatory information as regards the relevance of the metabolite M11 and the corresponding groundwater risk assessment, if pinoxaden is classified under Regulation (EC) No 1272/2008 as H361d (suspected of damaging the unborn child). The applicant shall submit to the Commission, the Member States and the Authority the relevant information within six months from the notification of the classification decision under Regulation (EC) No 1272/2008.

8.3.4 STEP 4: Exposure assessment – threshold of concern approach

According to the EC guidance document SANCO/221/2000 –rev.10 a threshold can be accepted if the metabolite M11 does not exceed a concentration in groundwater of 0.75 µg/L provided the metabolite

doesn't share the toxic properties for reproduction of the parent compound. The level of estimated concentration of metabolite M11 in groundwater is 0.263 µg/L. Therefore, no further data are required and a refined risk assessment is not necessary.

8.3.5 STEP 5: Refined risk assessment

N/A

8.4 Relevance assessment of M52 (SYN 546105)

Summary:

The relevance of the groundwater metabolite M52 (SYN 546105) has already been assessed at EU level (see EFSA Journal 2013;11(8):3269). For pinoxaden a classification with H361d (Repr. Cat. 2) was proposed in the Conclusion on the peer review. According to EFSA the metabolite M52 should be considered relevant if ECHA confirms H361d proposed for pinoxaden.
The classification for pinoxaden with H361d was confirmed by ECHA (CLH-O-0000001412-86-127/F; 16 September 2016). It is thus be mandatory to allocate that the groundwater metabolite M52 doesn't share the toxic properties for reproduction of the parent compound. Otherwise the metabolite M52 must be considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10.
According to Implementing Regulation (EU) 2016/370 of 15 March 2016 the applicant shall submit confirmatory information as regards the relevance of the metabolite M52 and the corresponding groundwater risk assessment, if pinoxaden is classified under Regulation (EC) No 1272/2008 as H361d (suspected of damaging the unborn child). The applicant shall submit to the Commission, the Member States and the Authority the relevant information within six months from the notification of the classification decision under Regulation (EC) No 1272/2008.

A summary of the relevance assessment for M52 is given in the following table.

Table 8.4-1: Summary of the relevance assessment for M52 (SYN546105)

	Assessment step		Result of assessment	
	STEP 1		Metabolite of no concern?	no
Quantification of groundwater contamination	STEP 2		Max PEC_{gw} Based on	0.150 µg/L Lysimeter
Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	no
		Stage 2	Genotoxic properties of metabolite	Non-genotoxic
		Stage 3	Toxic properties of metabolite;	
			Classification of parent	Not listed. Proposal of EU peer review (see EFSA Journal 2013;11(8):3269): H315, H317, H319, H332, H335, H361d RAC-Opinion(CLH-O-0000001412-86-127/F; 16 September 2016): H317, H319, H332, H335, H361d
			Classification of metabolite	Not listed
Consumer health risk assessment	STEP 4		Estimated consumer exposure via drinking water and other sources; threshold of concern approach	Acceptable if the metabolite doesn't share the toxic properties for reproduction of the parent compound.
	STEP 5		Refined risk assessment	N/A
			Predicted exposure (% of ADI)	N/A
			ADI based on	N/A

N/A: not applicable

8.4.1 STEP 1: Exclusion of degradation products of no concern

Metabolite M52 does not meet the criteria for products of no concern as defined in step 1 of the guidance and therefore needs further assessment.

8.4.2 STEP 2: Quantification of potential groundwater contamination

PEC_{gw} calculations after leaching from soil for M52 were performed using the simulation model FOCUS PELMO 5.5.3 (see Part B, Section 5, chapter 5.7). The metabolite M52 do not exceeds the trigger value of 0.1 µg/L in all scenarios. However, metabolite M52 was probably underestimated in the simulations, because lysimeter data show a concentration of 0.150 µg/L, which clearly exceeds the trigger value. A relevance assessment has to be performed for the metabolite.
Metabolite M52 is relevant according to Step 2 of this assessment.

8.4.3 STEP 3: Hazard assessment – identification of relevant metabolites

8.4.3.1 STEP 3, Stage 1: screening for biological activity

The metabolites M3, M11, M52, M54, M55 and M56 have been evaluated in the peer review in view of the Annex I inclusion of Pinoxaden. The metabolites M3, M11, M52, M54, M55 and M56 have no biological activity as compared to the parent compound (EFSA Journal 2013;11(8):3269).

8.4.3.2 STEP 3, Stage 2: screening for genotoxicity

Metabolite M52 was evaluated in a battery of three in vitro genotoxicity studies (see Table 8.4-2) as required in the EC guidance document SANCO/221/2000 –rev.10. The results of all three studies were negative. Therefore, it can be concluded that metabolite M52 does not have genotoxic potential. The metabolite M52 is not considered relevant at this step of the assessment.

Table 8.4-2: Genotoxicity testing with metabolite M52

Type of test, species (Guideline)	Result	Acceptability	Reference
Bacterial Reverse Mutation Assay (OECD 471)	negative	Yes	Sokolowski, A., 2010c* ASB2014-5435
Cell mutation assay in Mouse Lymphoma Cells in vitro (OECD 476)	negative	Yes	Wollny, H.-E., 2011b* ASB2014-5436
Micronucleus test in mouse (OECD 474)	negative	Yes	Vogel, J., 2011a* ASB2014-5437

*indicates that a study was reviewed at EU level

8.4.3.3 STEP 3, Stage 3: screening for toxicity

The parent substance pinoxaden and the groundwater metabolite M52 are currently not classified for carcinogenicity, mutagenicity or reproductive toxicity.
However, for pinoxaden a classification with H361d was proposed in the Conclusion on the peer review (EFSA Journal 2013;11(8):3269). According to EFSA the metabolite M52 should be considered relevant if ECHA confirms H361d proposed for pinoxaden.
The classification for pinoxaden with H361d was confirmed by ECHA (CLH-O-0000001412-86-127/F; 16 September 2016). It is thus be mandatory to allocate that the groundwater metabolite M52 doesn't share the toxic properties for reproduction of the parent compound. Otherwise the metabolite M52 must be considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10.
According to Implementing Regulation (EU) 2016/370 of 15 March 2016 the applicant shall submit confirmatory information as regards the relevance of the metabolite M52 and the corresponding

groundwater risk assessment, if pinoxaden is classified under Regulation (EC) No 1272/2008 as H361d (suspected of damaging the unborn child). The applicant shall submit to the Commission, the Member States and the Authority the relevant information within six months from the notification of the classification decision under Regulation (EC) No 1272/2008.

8.4.4 STEP 4: Exposure assessment – threshold of concern approach

According to the EC guidance document SANCO/221/2000 –rev.10 a threshold can be accepted if the metabolite M52 does not exceed a concentration in groundwater of 0.75 µg/L provided the metabolite doesn't share the toxic properties for reproduction of the parent compound. The level of estimated concentration of metabolite M52 in groundwater is 0.150 µg/L. Therefore, no further data are required and a refined risk assessment is not necessary.

8.4.5 STEP 5: Refined risk assessment

N/A

8.5 Relevance assessment of M54 (SYN 546106)

Summary:

The relevance of the groundwater metabolite M54 (SYN 546106) has already been assessed at EU level (see EFSA Journal 2013;11(8):3269). For pinoxaden a classification with H361d (Repr. Cat. 2) was proposed in the Conclusion on the peer review. According to EFSA the metabolite M54 should be considered relevant if ECHA confirms H361d proposed for pinoxaden.
The classification for pinoxaden with H361d was confirmed by ECHA (CLH-O-0000001412-86-127/F; 16 September 2016). It is thus be mandatory to allocate that the groundwater metabolite M54 doesn't share the toxic properties for reproduction of the parent compound. Otherwise the metabolite M54 must be considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10.
According to Implementing Regulation (EU) 2016/370 of 15 March 2016 the applicant shall submit confirmatory information as regards the relevance of the metabolite M54 and the corresponding groundwater risk assessment, if pinoxaden is classified under Regulation (EC) No 1272/2008 as H361d (suspected of damaging the unborn child). The applicant shall submit to the Commission, the Member States and the Authority the relevant information within six months from the notification of the classification decision under Regulation (EC) No 1272/2008.
A summary of the relevance assessment for M54 is given in the following table.

Table 8.5-1: Summary of the relevance assessment for M54 (SYN546106)

	Assessment step		Result of assessment	
	STEP 1		Metabolite of no concern?	no
Quantification of groundwater contamination	STEP 2		Max PEC_{gw} Based on	0.698 µg/L FOCUS PELMO 5.5.3 / Jokioinen 0.173 µg/L Lysimeter
Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	no
		Stage 2	Genotoxic properties of metabolite	Non-genotoxic
		Stage 3	Toxic properties of metabolite;	
			Classification of parent	Not listed. Proposal of EU peer review (see EFSA Journal 2013;11(8):3269): H315, H317, H319, H332, H335, H361d RAC-Opinion(CLH-O-0000001412-86-127/F; 16 September 2016): H317, H319, H332, H335, H361d
			Classification of metabolite	Not listed
Consumer health risk assessment	STEP 4		Estimated consumer exposure via drinking water and other sources; threshold of concern approach	Acceptable if the metabolite doesn't share the toxic properties for reproduction of the parent compound.
	STEP 5		Refined risk assessment	N/A
			Predicted exposure (% of ADI)	N/A
			ADI based on	N/A

N/A: not applicable

8.5.1 STEP 1: Exclusion of degradation products of no concern

Metabolite M54 does not meet the criteria for products of no concern as defined in step 1 of the guidance and therefore needs further assessment.

8.5.2 STEP 2: Quantification of potential groundwater contamination

PEC_{gw} calculations after leaching from soil for M54 were performed using the simulation model FOCUS PELMO 5.5.3 (see Part B, Section 5, chapter 5.7). The metabolite M54 exceeds the trigger value of 0.1 µg/L in all scenarios except for Sevilla and Thiva. However, these results might be an overestimation as

confirmed by lysimeter data, in which a concentration of 0.173 µg/L was measured. A relevance assessment has to be performed for the metabolite.
Metabolite M54 is relevant according to Step 2 of this assessment.

8.5.3 STEP 3: Hazard assessment – identification of relevant metabolites

8.5.3.1 STEP 3, Stage 1: screening for biological activity

The metabolites M3, M11, M52, M54, M55 and M56 have been evaluated in the peer review in view of the Annex I inclusion of Pinoxaden. The metabolites M3, M11, M52, M54, M55 and M56 have no biological activity as compared to the parent compound (EFSA Journal 2013;11(8):3269).

8.5.3.2 STEP 3, Stage 2: screening for genotoxicity

Metabolite M54 was evaluated in a battery of three in vitro genotoxicity studies (see Table 8.5-2) as required in the EC guidance document SANCO/221/2000 –rev.10. The results of all three studies were negative.
Therefore, it can be concluded that metabolite P54 does not have genotoxic potential. The metabolite M54 is not considered relevant at this step of the assessment.

Table 8.5-2: Genotoxicity testing with metabolite M54

Type of test, species (Guideline)	Result	Acceptability	Reference
Bacterial Reverse Mutation Assay (OECD 471)	negative	Yes	Sokolowski, A., 2010b* ASB2014-5438
Cell mutation assay in Mouse Lymphoma Cells in vitro (OECD 476)	negative	Yes	Wollny, H.-E., 2011a* ASB2014-5439
Micronucleus test in mouse (OECD 474)	negative	Yes	Merker, M., 2011b* ASB2014-5440

*indicates that a study was reviewed at EU level

8.5.3.3 STEP 3, Stage 3: screening for toxicity

The parent substance pinoxaden and the groundwater metabolite M54 are currently not classified for carcinogenicity, mutagenicity or reproductive toxicity.
However, for pinoxaden a classification with H361d was proposed in the Conclusion on the peer review (EFSA Journal 2013;11(8):3269). According to EFSA the metabolite M54 should be considered relevant if ECHA confirms H361d proposed for pinoxaden.
The classification for pinoxaden with H361d was confirmed by ECHA (CLH-O-0000001412-86-127/F; 16 September 2016). It is thus be mandatory to allocate that the groundwater metabolite M54 doesn't share the toxic properties for reproduction of the parent compound. Otherwise the metabolite M54 must be considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10.
According to Implementing Regulation (EU) 2016/370 of 15 March 2016 the applicant shall submit confirmatory information as regards the relevance of the metabolite M54 and the corresponding groundwater risk assessment, if pinoxaden is classified under Regulation (EC) No 1272/2008 as H361d (suspected of damaging the unborn child). The applicant shall submit to the Commission, the Member States and the Authority the relevant information within six months from the notification of the classification decision under Regulation (EC) No 1272/2008.

8.5.4 STEP 4: Exposure assessment – threshold of concern approach

According to the EC guidance document SANCO/221/2000 –rev.10 a threshold can be accepted if the metabolite M54 does not exceed a concentration in groundwater of 0.75 µg/L provided the metabolite doesn't share the toxic properties for reproduction of the parent compound. The level of estimated concentration of metabolite M54 in groundwater is 0.173 µg/L. Therefore, no further data are required and a refined risk assessment is not necessary.

8.5.5 STEP 5: Refined risk assessment

N/A

8.6 Relevance assessment of M55 (SYN 546107)

Summary:

The relevance of the groundwater metabolite M55 (SYN 546107) has already been assessed at EU level (see EFSA Journal 2013;11(8):3269). For pinoxaden a classification with H361d (Repr. Cat. 2) was proposed in the Conclusion on the peer review. According to EFSA the metabolite M55 should be considered relevant if ECHA confirms H361d proposed for pinoxaden.
The classification for pinoxaden with H361d was confirmed by ECHA (CLH-O-0000001412-86-127/F; 16 September 2016). It is thus be mandatory to allocate that the groundwater metabolite M55 doesn't share the toxic properties for reproduction of the parent compound. Otherwise the metabolite M55 must be considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10.
According to Implementing Regulation (EU) 2016/370 of 15 March 2016 the applicant shall submit confirmatory information as regards the relevance of the metabolite M55 and the corresponding groundwater risk assessment, if pinoxaden is classified under Regulation (EC) No 1272/2008 as H361d (suspected of damaging the unborn child). The applicant shall submit to the Commission, the Member States and the Authority the relevant information within six months from the notification of the classification decision under Regulation (EC) No 1272/2008.
A summary of the relevance assessment for M55 is given in the following table.

Table 8.6-1: Summary of the relevance assessment for M55 (SYN546107)

	Assessment step		Result of assessment	
	STEP 1		Metabolite of no concern?	no
Quantification of groundwater contamination	STEP 2		Max PEC_{gw} Based on	1.582 µg/L FOCUS PELMO 5.5.3 / Jokioinen 0.161 µg/L Lysimeter
Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	no
		Stage 2	Genotoxic properties of metabolite	Non-genotoxic
		Stage 3	Toxic properties of metabolite;	
			Classification of parent	Not listed. Proposal of EU peer review (see EFSA Journal 2013;11(8):3269): H315, H317, H319, H332, H335, H361d RAC-Opinion(CLH-O-0000001412-86-127/F; 16 September 2016): H317, H319, H332, H335, H361d
			Classification of metabolite	Not listed
Consumer health risk assessment	STEP 4		Estimated consumer exposure via drinking water and other sources; threshold of concern approach	Acceptable if the metabolite doesn't share the toxic properties for reproduction of the parent compound.
	STEP 5		Refined risk assessment	N/A
			Predicted exposure (% of ADI)	N/A
			ADI based on	N/A

N/A: not applicable

8.6.1 STEP 1: Exclusion of degradation products of no concern

Metabolite M55 does not meet the criteria for products of no concern as defined in step 1 of the guidance and therefore needs further assessment.

8.6.2 STEP 2: Quantification of potential groundwater contamination

PEC_{gw} calculations after leaching from soil for M55 were performed using the simulation model FOCUS PELMO 5.5.3 (see Part B, Section 5, chapter 5.7). The metabolite M55 exceeds the trigger value of 0.1 µg/L in all scenarios. However, these results might be an overestimation as confirmed by lysimeter data,

in which a concentration of 0.173 µg/L was measured. A relevance assessment has to be performed for the metabolite.
Metabolite M55 is relevant according to Step 2 of this assessment.

8.6.3 STEP 3: Hazard assessment – identification of relevant metabolites

8.6.3.1 STEP 3, Stage 1: screening for biological activity

The metabolites M3, M11, M52, M54, M55 and M56 have been evaluated in the peer review in view of the Annex I inclusion of Pinoxaden. The metabolites M3, M11, M52, M54, M55 and M56 have no biological activity as compared to the parent compound (EFSA Journal 2013;11(8):3269).

8.6.3.2 STEP 3, Stage 2: screening for genotoxicity

Metabolite M55 was evaluated in a battery of three in vitro genotoxicity studies and one in vivo genotoxicity study (see Table 8.6-2) as required in the EC guidance document SANCO/221/2000 –rev.10. The results of two in vitro studies were negative. However, a positive result was found in the bacterial reverse mutation assay. Therefore, an additional in vivo rat liver unscheduled DNA synthesis test was performed. The result of this study was negative. Overall, groundwater metabolite M55 is considered to be non-genotoxic. The metabolite M55 is not considered relevant at this step of the assessment.

Table 8.6-2: Genotoxicity testing with metabolite M55

Type of test, species (Guideline)	Result	Acceptability	Reference
Bacterial Reverse Mutation Assay (OECD 471)	positive	Yes	Sokolowski, A., 2011a* ASB2014-5441
Cell mutation assay in Mouse Lymphoma Cells in vitro (OECD 476)	negative	Yes	Wollny, H.-E., 2011d* ASB2014-5442
Micronucleus test in mouse (OECD 474)	negative	Yes	Vogel, J., 2011b* ASB2014-5443
In vivo Rat liver UDS test (OECD 486)	negative	Yes	Merker, M., 2011c* ASB2016-2672

*indicates that a study was reviewed at EU level

8.6.3.3 STEP 3, Stage 3: screening for toxicity

The parent substance pinoxaden and the groundwater metabolite M55 are currently not classified for carcinogenicity, mutagenicity or reproductive toxicity.
However, for pinoxaden a classification with H361d was proposed in the Conclusion on the peer review (EFSA Journal 2013;11(8):3269). According to EFSA the metabolite M55 should be considered relevant if ECHA confirms H361d proposed for pinoxaden.
The classification for pinoxaden with H361d was confirmed by ECHA (CLH-O-0000001412-86-127/F; 16 September 2016). It is thus be mandatory to allocate that the groundwater metabolite M55 doesn't share the toxic properties for reproduction of the parent compound. Otherwise the metabolite M55 must be considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10.
According to Implementing Regulation (EU) 2016/370 of 15 March 2016 the applicant shall submit confirmatory information as regards the relevance of the metabolite M55 and the corresponding groundwater risk assessment, if pinoxaden is classified under Regulation (EC) No 1272/2008 as H361d (suspected of damaging the unborn child). The applicant shall submit to the Commission, the Member States and the Authority the relevant information within six months from the notification of the classification decision under Regulation (EC) No 1272/2008.

8.6.4 STEP 4: Exposure assessment – threshold of concern approach

According to the EC guidance document SANCO/221/2000 –rev.10 a threshold can be accepted if the metabolite M55 does not exceed a concentration in groundwater of 0.75 µg/L provided the metabolite doesn't share the toxic properties for reproduction of the parent compound. The level of estimated concentration of metabolite M55 in groundwater is 0.161 µg/L. Therefore, no further data are required and a refined risk assessment is not necessary.

8.6.5 STEP 5: Refined risk assessment

N/A

8.7 Relevance assessment of M56 (SYN 546108)

Summary:

The relevance of the groundwater metabolite M56 (SYN 546108) has already been assessed at EU level (see EFSA Journal 2013;11(8):3269). For pinoxaden a classification with H361d (Repr. Cat. 2) was proposed in the Conclusion on the peer review. According to EFSA the metabolite M56 should be considered relevant if ECHA confirms H361d proposed for pinoxaden.
The classification for pinoxaden with H361d was confirmed by ECHA (CLH-O-0000001412-86-127/F; 16 September 2016). It is thus be mandatory to allocate that the groundwater metabolite M56 doesn't share the toxic properties for reproduction of the parent compound. Otherwise the metabolite M56 must be considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10.
According to Implementing Regulation (EU) 2016/370 of 15 March 2016 the applicant shall submit confirmatory information as regards the relevance of the metabolite M56 and the corresponding groundwater risk assessment, if pinoxaden is classified under Regulation (EC) No 1272/2008 as H361d (suspected of damaging the unborn child). The applicant shall submit to the Commission, the Member States and the Authority the relevant information within six months from the notification of the classification decision under Regulation (EC) No 1272/2008.
A summary of the relevance assessment for M56 is given in the following table.

Table 8.7-1: Summary of the relevance assessment for M56 (SYN546108)

	Assessment step		Result of assessment	
	STEP 1		Metabolite of no concern?	no
Quantification of groundwater contamination	STEP 2		Max PEC_{gw} Based on	5.635 µg/L FOCUS PELMO 5.5.3 /Châteaudun 0.307 µg/L Lysimeter
Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	no
		Stage 2	Genotoxic properties of metabolite	Non-genotoxic
		Stage 3	Toxic properties of metabolite;	
			Classification of parent	Not listed. Proposal of EU peer review (see EFSA Journal 2013;11(8):3269): H315, H317, H319, H332, H335, H361d RAC-Opinion(CLH-O-0000001412-86-127/F; 16 September 2016): H317, H319, H332, H335, H361d
			Classification of metabolite	Not listed
Consumer health risk assessment	STEP 4		Estimated consumer exposure via drinking water and other sources; threshold of concern approach	Acceptable if the metabolite doesn't share the toxic properties for reproduction of the parent compound.
	STEP 5		Refined risk assessment	N/A
			Predicted exposure (% of ADI)	N/A
			ADI based on	N/A

N/A: not applicable

8.7.1 STEP 1: Exclusion of degradation products of no concern

Metabolite M56 does not meet the criteria for products of no concern as defined in step 1 of the guidance and therefore needs further assessment.

8.7.2 STEP 2: Quantification of potential groundwater contamination

PEC_{gw} calculations after leaching from soil for M54 were performed using the simulation model FOCUS PELMO 5.5.3 (see Part B, Section 5, chapter 5.7). The metabolite M54 exceeds the trigger value of 0.1 µg/L in all scenarios. However, these results might be an overestimation as confirmed by lysimeter data,

in which a concentration of 0.307 µg/L was measured. A relevance assessment has to be performed for the metabolite.
Metabolite M54 is relevant according to Step 2 of this assessment.

8.7.3 STEP 3: Hazard assessment – identification of relevant metabolites

8.7.3.1 STEP 3, Stage 1: screening for biological activity

The metabolites M3, M11, M52, M54, M55 and M56 have been evaluated in the peer review in view of the Annex I inclusion of Pinoxaden. The metabolites M3, M11, M52, M54, M55 and M56 have no biological activity as compared to the parent compound (EFSA Journal 2013;11(8):3269).

8.7.3.2 STEP 3, Stage 2: screening for genotoxicity

Metabolite M56 was evaluated in a battery of three in vitro genotoxicity studies (see Table 8.7-2) as required in the EC guidance document SANCO/221/2000 –rev.10. The results of all three studies were negative. Therefore, it can be concluded that metabolite P56 does not has genotoxic potential. The metabolite M56 is not considered relevant at this step of the assessment. For a detailed review of these studies it is referred to A.2.11 of Section B.3 of the dRR.

Table 8.7-2: Genotoxicity testing with metabolite M56

Type of test, species (Guideline)	Result	Acceptability	Reference
Bacterial Reverse Mutation Assay (OECD 471)	negative	Yes	Sokolowski, A., 2011b ASB2013-397
Cell mutation assay in Mouse Lymphoma Cells in vitro (OECD 476)	negative	Yes	Wollny, H.-E., 2011c ASB2013-396
Micronucleus test in mouse (OECD 474)	negative	Yes	Merker, M., 2011d ASB2013-398

8.7.3.3 STEP 3, Stage 3: screening for toxicity

The parent substance pinoxaden and the groundwater metabolite M56 are currently not classified for carcinogenicity, mutagenicity or reproductive toxicity.
However, for pinoxaden a classification with H361d was proposed in the Conclusion on the peer review (EFSA Journal 2013;11(8):3269). According to EFSA the metabolite M56 should be considered relevant if ECHA confirms H361d proposed for pinoxaden.
The classification for pinoxaden with H361d was confirmed by ECHA (CLH-O-0000001412-86-127/F; 16 September 2016). It is thus be mandatory to allocate that the groundwater metabolite M56 doesn't share the toxic properties for reproduction of the parent compound. Otherwise the metabolite M56 must be considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10.
According to Implementing Regulation (EU) 2016/370 of 15 March 2016 the applicant shall submit confirmatory information as regards the relevance of the metabolite M56 and the corresponding groundwater risk assessment, if pinoxaden is classified under Regulation (EC) No 1272/2008 as H361d (suspected of damaging the unborn child). The applicant shall submit to the Commission, the Member States and the Authority the relevant information within six months from the notification of the classification decision under Regulation (EC) No 1272/2008.

8.7.4 STEP 4: Exposure assessment – threshold of concern approach

According to the EC guidance document SANCO/221/2000 –rev.10 a threshold can be accepted if the metabolite M56 does not exceed a concentration in groundwater of 0.75 µg/L provided the metabolite doesn't share the toxic properties for reproduction of the parent compound. The level of estimated concentration of metabolite M56 in groundwater is 0.307 µg/L. Therefore, no further data are required and a refined risk assessment is not necessary.

8.7.5 STEP 5: Refined risk assessment

N/A

8.8 Relevance assessment of PSA

Summary:

The relevance of the pyroxsulam groundwater metabolite PSA has already been assessed at EU level. PSA did not show a genotoxic potential in three *in vitro* genotoxicity studies. However, a final conclusion on the toxicological relevance was not drawn because an additional acute oral toxicity study was needed (data gap; see EFSA Journal 2013;11(4):3182).
In the meantime the required acute toxicity study is available. According to the results of this study a classification of PSA as acute toxic of very toxic is not justified.
The groundwater metabolite PSA is not considered as relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10.
A summary of the relevance assessment for PSA is given in the following table.

Table 8.8-1: Summary of the relevance assessment for PSA

	Assessment step		Result of assessment	
	STEP 1		Metabolite of no concern?	no
Quantification of groundwater contamination	STEP 2		Max PEC_{gw} Based on	0.353 µg/L FOCUS PELMO 5.5.3 / Jokioinen
Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	no
		Stage 2	Genotoxic properties of metabolite	Non genotoxic
		Stage 3	Toxic properties of metabolite;	
			Classification of parent	Not listed Proposal of EU peer review (see EFSA Journal 2013;11(4):3182): H317 RAC-Opinion(CLH-O-0000001412-86-102/F; 10 March 2016): H317
			Classification of metabolite	Not listed
Consumer health risk assessment	STEP 4		Estimated consumer exposure via drinking water and other sources; threshold of concern approach	acceptable
	STEP 5		Refined risk assessment	N/A
			Predicted exposure (% of ADI)	N/A
			ADI based on	N/A

N/A: not applicable

8.8.1 STEP 1: Exclusion of degradation products of no concern

Metabolite PSA does not meet the criteria for products of no concern as defined in step 1 of the guidance and therefore needs further assessment.

8.8.2 STEP 2: Quantification of potential groundwater contamination

PEC_{gw} calculations after leaching from soil for PSA were performed using the simulation model FOCUS PELMO 5.5.3 (see Part B, Section 5, chapter 5.7). The metabolite PSA exceeds the trigger value of 0.1 µg/L in all scenarios. A relevance assessment has to be performed for the metabolite.
Metabolite M54 is relevant according to Step 2 of this assessment.

8.8.3 STEP 3: Hazard assessment – identification of relevant metabolites

8.8.3.1 STEP 3, Stage 1: screening for biological activity

The metabolites 6-Cl-7-OH and PSA have been evaluated in the peer review in view of the Annex I inclusion of Pyroxsulam. The metabolites 6-Cl-7-OH and PSA have no biological activity as compared to the parent compound (EFSA Journal 2013;11(4):3182).

8.8.3.2 STEP 3, Stage 2: screening for genotoxicity

PSA was evaluated in a battery of three in vitro genotoxicity studies (see Table 8.8-2) as required in the EC guidance document SANCO/221/2000 –rev.10. All three studies were already assessed at EU level (see EFSA Journal 2013;11(4):3182). The results of all three studies were negative. Therefore, it can be concluded that metabolite PSA does not has genotoxic potential. The metabolite PSA is not considered relevant at this step of the assessment.

Table 8.8-2: Genotoxicity testing with metabolite PSA

Study	Result	Acceptability	Reference
Salmonella-escherichia coli/ mammalian-microsome reverse mutation assay	negative	Yes	Mecchi, M.S. (2008)* (ASB2010-6431)
CHO HGPRT forward mutation assay	negative	Yes	Stankowski, L.F. (2008)* (ASB2010-6433)
In vitro chromosome aberration assay in rat lymphocytes	negative	Yes	Schisler, M.R., Kleinert, K.M. (2007)* (ASB2010-6435)

* DAR, Pyroxsulam - Volume 3, Annex B.6 : Toxicology and Metabolism, January 2012

8.8.3.3 STEP 3, Stage 3: screening for toxicity

The parent substance pyroxsulam and the groundwater metabolite PSA are currently not classified for carcinogenicity, mutagenicity of reproductive toxicity. Furthermore, no classification for carcinogenicity, mutagenicity of reproductive toxicity was proposed for pyroxsulam in result of the assessment at EU level (see EFSA Journal 2013;11(4):3182).
However, an additional study on acute oral toxicity was demanded at EU level (see EFSA Journal 2013;11(4):3182). In the meantime, an acute oral toxicity study in female rats is available (see Table 8.8-3). The oral LD_{50} in female rats was >612 mg/kg bw. Therefore, based on this study no classification as toxic or very toxic is necessary. The metabolite PSA is not considered relevant at this step of the assessment. A summary of the study is provided in A.2.11 of Section B.3 of the dRR.

Table 8.8-3: Summary of the acute oral toxicity study for PSA

Type of test, species (Guideline)	Result	Acceptability	Reference
Acute oral toxicity, rat	LD50 > 612 mg/kg bw	Yes	Murphy et al., 2014 ASB2015-4380

8.8.4 STEP 4: Exposure assessment – threshold of concern approach

According to the EC guidance document SANCO/221/2000 –rev.10 a threshold can be accepted if the metabolite PSA does not exceed a concentration in groundwater of 0.75 µg/L. The level of estimated concentration of PSA in groundwater is 0.20 µg/L. Therefore, no further data are required and a refined risk assessment is not necessary.

8.8.5 STEP 5: Refined risk assessment

N/A

8.9 Relevance assessment of 6-Cl-7-OH

Summary:

The relevance of the pyroxsulam groundwater metabolite 6-Cl-7-OH has already been assessed at EU level. 6-Cl-7-OH gave a negative response in the Ames test. However, a full *in vitro* genotoxicity data package is needed to conclude on the genotoxic potential of this metabolite (data gap). Regarding the acute toxicity, no further data would be necessary due to the structure similarities with the parent and the lack of structural alerts (see EFSA Journal 2013;11(4):3182).
In the meantime the required genotoxicity studies are available. According to the results of these studies the metabolite 6-Cl-7-OH did not show a genotoxic potential.
The groundwater metabolite 6-Cl-7-OH is not considered as relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10.
A summary of the relevance assessment for 6-Cl-7-OH is given in the following table.

Table 8.9-1: Summary of the relevance assessment for 6-Cl-7-OH

	Assessment step		Result of assessment	
	STEP 1		Metabolite of no concern?	no
Quantification of groundwater contamination	STEP 2		Max PEC_{gw} Based on	0.185 µg/L FOCUS PELMO 5.5.3 / Kremsmünster
Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	no
		Stage 2	Genotoxic properties of metabolite	Non-genotoxic
		Stage 3	Toxic properties of metabolite;	
			Classification of parent	Not listed Proposal of EU peer review (see EFSA Journal 2013;11(4):3182): H317 RAC-Opinion(CLH-O-0000001412-86-102/F; 10 March 2016): H317
			Classification of metabolite	Not listed
Consumer health risk assessment	STEP 4		Estimated consumer exposure via drinking water and other sources; threshold of concern approach	acceptable
	STEP 5		Refined risk assessment	N/A
			Predicted exposure (% of ADI)	N/A
			ADI based on	N/A

N/A: not applicable

8.9.1 STEP 1: Exclusion of degradation products of no concern

Metabolite 6-Cl-7-OH does not meet the criteria for products of no concern as defined in step 1 of the guidance and therefore needs further assessment.

8.9.2 STEP 2: Quantification of potential groundwater contamination

PEC_{gw} calculations after leaching from soil for 6-Cl-7-OH were performed using the simulation model FOCUS PELMO 5.5.3 (see Part B, Section 5, chapter 5.7). The metabolite 6-Cl-7-OH exceeds the trigger value of 0.1 µg/L in scenarios Kremsmünster and Piacenza. A relevance assessment has to be performed for the metabolite.
Metabolite M54 is relevant according to Step 2 of this assessment.

8.9.3 STEP 3: Hazard assessment – identification of relevant metabolites

8.9.3.1 STEP 3, Stage 1: screening for biological activity

The metabolites 6-Cl-7-OH and PSA have been evaluated in the peer review in view of the Annex I inclusion of Pyroxsulam. The metabolites 6-Cl-7-OH and PSA have no biological activity as compared to the parent compound (EFSA Journal 2013;11(4):3182).

8.9.3.2 STEP 3, Stage 2: screening for genotoxicity

The relevance of the pyroxsulam groundwater metabolite 6-Cl-7-OH was already assessed at EU level.
6-Cl-7-OH did not show a genotoxic potential in an Ames test. However, a final conclusion on the relevance was not drawn because a full genotoxicity data package was needed (see EFSA Journal 2013;11(4):3182).
In the meantime the required three in vitro genotoxicity studies according to the EC guidance document SANCO/221/2000 –rev.10 are available. The results of all genotoxicity studies were negative (see Table 8.9-2)
Therefore, it can be concluded that metabolite 6-CL-7-OH does not have genotoxic potential. The groundwater metabolite 6-Cl-7-OH is not considered as relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10. For a detailed review of those studies not yet reviewed at EU level it is referred to A.2.11 of Section B.3 of the dRR.

Table 8.9-2: Genotoxicity testing with metabolite 6-Cl-7-OH

Study	Result	Acceptability	Reference
Bacterial reverse mutation test using S. typhimurium	negative	Yes	Pillai, R.R. (2011)* (ASB2015-4381)
In vitro CHO HGPRT forward mutation assay	negative	Yes	Tendulkar, K.E. (2014a) (ASB2015-4379)
In vitro chromosome aberration assay in human lymphocytes	negative	Yes	Tendulkar, K.E. (2014b) (ASB2015-4378)

* assessed at EU level

8.9.3.3 STEP 3, Stage 3: screening for toxicity

The parent substance pyroxsulam and the groundwater metabolite 6-Cl-7-OH are currently not classified for carcinogenicity, mutagenicity of reproductive toxicity. Furthermore, no classification for carcinogenicity, mutagenicity of reproductive toxicity was proposed for pyroxsulam in result of the assessment at EU level (see EFSA Journal 2013;11(4):3182).
Regarding the acute toxicity, no further data would be necessary due to the structure similarities with the parent and the lack of structural alerts (see EFSA Journal 2013;11(4):3182).
The metabolite 6-Cl-7-OH is not considered relevant at this step of the assessment.

8.9.4 STEP 4: Exposure assessment – threshold of concern approach

According to the EC guidance document SANCO/221/2000 –rev.10 a threshold can be accepted if the metabolite 6-Cl-7-OH does not exceed a concentration in groundwater of 0.75 µg/L. The level of estimated concentration of 6-Cl-7-OH in groundwater is 0.185 µg/L. Therefore, no further data are required and a refined risk assessment is not necessary.

8.9.5 STEP 5: Refined risk assessment

N/A

Appendix 1 List of data considered in support of the evaluation

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
KIIA 5.8	Callander, R.	2003	NOA 447204 (Metabolite of NOA 407855): Bacterial mutation assay in S.typhimurium and E.coli YV6168 ! NOA447204/0019 ! HAES0149 ! CTL/YV/REG/REPT Syngenta Crop Protection AG, Basel, Switzerland GLP: Open (1) Yes (2) Published: No (2) Open (1) BVL-1855018, BVL-3015247, BVL-3015247, TOX2004-2737	Yes	Syngenta Agro	Y
KIIA 5.8	Clay, P.	2003	NOA 447204 (Metabolite of NOA 407855): L5178Y TK +/- mouse lymphona mutation assay VV0281 ! NOA447204/0020 ! H407855GBL001A-157 Syngenta Crop Protection AG, Basel, Switzerland GLP: Open (1) Yes (2) Published: No (2) Open (1) BVL-1855020, BVL-3015249, BVL-3015249, TOX2004-2739	Yes	Syngenta Agro	Y
KIIA 5.8	Fox, V.	2003	NOA 447204 (Metabolite of NOA 407855) : Mouse bone marrow micronucleus test SM1188 ! NOA447204/0022 ! HAES03004 Syngenta Crop Protection AG, Basel, Switzerland GLP: Open (1) Yes (2) Published: No (2) Open (1) BVL-1855021, BVL-3015250, BVL-3015250, TOX2004-2740	Yes	Syngenta Agro	Y
KIIA 5.8	Fox, V.	2003	NOA 447204 (Metabolite of NOA 407855) : In vivo rat liver unscheduled DNA synthesis assay SR1189 ! NOA447204/0021 ! HAES03004 Syngenta Crop Protection AG, Basel, Switzerland GLP: Open (1) Yes (2) Published: No (2) Open (1) BVL-1855022, BVL-3015251, BVL-3015251, TOX2004-2741	Yes	Syngenta Agro	Y
KIIA 5.8	Fox, V.	2003	NOA 447204 (Metabolite NOA 407855): In vitro cytogenetic assay in human lymphocytes SV1135 ! NOA447204/0018 ! HAES0149 Syngenta Crop Protection AG, Basel, Switzerland GLP: Open (1) Yes (2) Published: No (2) Open (1) BVL-1855019, BVL-3015248, BVL-3015248, TOX2004-2738	Yes	Syngenta Agro	Y
KIIA 5.8	Johnson, I. R.	2002	NOA 447204: Acute oral toxicity study in the rat - up and down procedure NOA447204/0011 ! AR7150 ! HAES0149 Syngenta Crop Protection AG, Basel, Switzerland GLP: Open (1) Yes (2) Published: No (2) Open (1) BVL-1855015, BVL-3015268, BVL-3015268, TOX2004-2734	Yes	Syngenta Agro	Y

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
KIIA 5.8	Mecchi, M. S.	2008	Salmonella-escherichia coli/mammalian-microsome reverse mutation assay preincubation method with a confirmatory assay with Sulfonic Acid metabolite of XDE-742 071141.SPT ! 6736-197.SPT GLP: Yes Published: No BVL-2067329, ASB2010-6431	Yes	DOW	Y
KIIA 5.8	Merker, M.	2011a	SYN504574: Micronucleus assay in bone marrow cells of the mouse 1323603 ! SYN504574_10002 ! TK0004425 Syngenta - Jealott's Hill, Bracknell, United Kingdom GLP: Open (1) Yes (2) Published: No (2) Open (1) BVL-2599134, BVL-3015254, BVL-3015254, ASB2014-5434	Yes	Syngenta Agro	Y
KIIA 5.8	Merker, M.	2011b	SYN546106: Micronucleus assay in bone marrow cells of the mouse 1349703 ! SYN546106_10002 ! TK0004421 Syngenta - Jealott's Hill, Bracknell, United Kingdom GLP: Open (1) Yes (2) Published: No (2) Open (1) BVL-2599390, BVL-3015260, BVL-3015260, ASB2014-5440	Yes	Syngenta Agro	Y
KIIA 5.8	Merker, M.	2011c	SYN546107 - in vivo unscheduled DNA synthesis in rat hepatocytes 1390900 ! SYN546107_10003 ! TK0055127 Syngenta - Jealott's Hill, Bracknell, United Kingdom GLP: Yes Published: No BVL-3015264, BVL-3015264, ASB2016-2672	Yes	Syngenta Agro	Y
KIIA 5.8	Merker, M.	2011d	SYN546108: Micronucleus assay in bone marrow cells of the mouse SYN546108_10001 ! 1422502 ! TK0060522 GLP: Open (1) Yes (2) Published: No (2) Open (1) BVL-2600064, BVL-3015267, BVL-3015267, ASB2013-398	Yes	Syngenta Agro	Y
KIIA 5.8	Murphy, L. A.; Marshall, V. A.; Sura, R.	2014	XDE-742 Sulfonic Acid: Acute oral toxicity study in F344/DuCrl rats 141089 GLP: Yes Published: No BVL-2797976, ASB2015-4380	Yes	DOW	Add
KIIA 5.8	Pillai, R. R.	2011	6-CL-7-OH metabolite bacterial reverse mutation test of using Salmonella typhimurium 101870 ! DR-0401-9221-007 GLP: Yes Published: No BVL-2797980, ASB2015-4381	Yes	DOW	Add
KIIA 5.8	Schisler, M. R.; Kleinert, K. M.	2007	Evaluation of Sulfonic Acid metabolite of XDE-742 in an in-vitro chromosomal aberration assay utilizing rat lymphocytes 071149 GLP: Open (1) Yes (1) Published: No (1) Open (1) BVL-1954723, BVL-2067331, ASB2010-6435	Yes	DOW	Y

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
KIIA 5.8	Sokolowski, A.	2010a	SYN504574: Salmonella typhimurium and escherichia coli reverse mutation assay 1323601 ! SYN504574_10000 ! TK0004428 Syngenta - Jealott's Hill, Bracknell, United Kingdom GLP: Open (1) Yes (2) Published: No (2) Open (1) BVL-2598091, BVL-3015252, BVL-3015252, ASB2014-5432	Yes	Syngenta Agro	Y
KIIA 5.8	Sokolowski, A.	2010b	SYN546106: Salmonella typhimurium and escherichia coli reverse mutation assay 1349701 ! SYN546106_10000 ! TK0004424 Syngenta - Jealott's Hill, Bracknell, United Kingdom GLP: Open (1) Yes (2) Published: No (2) Open (1) BVL-2599319, BVL-3015258, BVL-3015258, ASB2014-5438	Yes	Syngenta Agro	Y
KIIA 5.8	Sokolowski, A.	2010c	SYN546105: Salmonella typhimurium and escherichia coli reverse mutation assay 1371901 ! SYN546105_10000 ! TK0004420 Syngenta - Jealott's Hill, Bracknell, United Kingdom GLP: Open (1) Yes (2) Published: No (2) Open (1) BVL-SYNGB165-01.00 IDD0000285019, BVL-3015255, BVL-3015255, ASB2014-5435	Yes	Syngenta Agro	Y
KIIA 5.8	Sokolowski, A.	2011a	SYN546107: Salmonella typhimurium and Escherichia coli reverse mutation assay SYN546107_10001 ! TK0004416 GLP: Open (1) Yes (2) Published: No (2) Open (1) BVL-SYNGB165-01.00; BVL-2599424; BVL-3015261 ASB2014-5441	Open (2) Yes (1)	Syngenta Agro	Y
KIIA 5.8	Sokolowski, A.	2011b	SYN546108: Salmonella typhimurium and Escherichia coli reverse mutation assay SYN546108_10000 ! 1422501 ! TK0060521 GLP: Open (1) Yes (2) Published: No (2) Open (1) BVL-2599895, BVL-3015265, BVL-3015265, ASB2013-397	Open (2) Yes (1)	Syngenta Agro	Y
KIIA 5.8	Stankowski, L. F.	2008	CHO HGPRT forward mutation assay with a confirmatory assay and duplicate cultures with XDE-742 Sulfonic Acid metabolite 071148 ! 6736-194 ! 29403-0-435OECD GLP: Open (1) Yes (1) Published: No (1) Open (1) BVL-1954731, BVL-2067332, ASB2010-6433	Yes	DOW	Y
KIIA 5.8	Tendulkar, K. E.	2014a	In vitro Mammalian chromosome aberration test of 6-Cl-7-0H-742 metabolite in human peripheral blood lymphocytes 140428 ! 488-1-06-8448 GLP: Open Published: No BVL-2797972, ASB2015-4378	Open	DOW	Add

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
KIIA 5.8	Tendulkar, K. E.	2014b	In vitro mammalian cell gene forward mutation test at the hgprt locus of the chinese hamster ovary (CHO)-Kl cell line using 6-CI-7-0H-742 metabolite 140429 ! 482-1-06-8449 GLP: Yes Published: No BVL-2797981, ASB2015-4379	Yes	DOW	Add
KIIA 5.8	Twomey, K.	2003	NOA 447204 (Metabolite of NOA 407855): 90-day dietary toxicity study in rats NOA447204/0023 ! PR1253 ! H407855GBL001A-271 ! HAES0149 Syngenta Crop Protection AG, Basel, Switzerland GLP: Open (1) Yes (2) Published: No (2) Open (1) BVL-1855017, BVL-3015270, BVL-3015270, TOX2004-2736	Yes	Syngenta Agro	Y
KIIA 5.8	Twomey, K.	2003	NOA 447204 (Metabolite of NOA 407855): 28-day dietary toxicity study in rats NOA447204/0024 ! KR1494 ! HAES0149 Syngenta Crop Protection AG, Basel, Switzerland GLP: Open (1) Yes (2) Published: No (2) Open (1) BVL-1855016, BVL-3015269, BVL-3015269, TOX2004-2735	Yes	Syngenta Agro	Y
KIIA 5.8	Vogel, J.	2011a	SYN546105: Micronucleus assay in bone marrow cells of the mouse 1371903 ! SYN546105_10002 ! TK0004417 Syngenta - Jealott's Hill, Bracknell, United Kingdom GLP: Open (1) Yes (2) Published: No (2) Open (1) BVL-2599300, BVL-3015257, BVL-3015257, ASB2014-5437	Yes	Syngenta Agro	Y
KIIA 5.8	Vogel, J.	2011b	SYN546107: Micronucleus assay in bone marrow cells of the mouse 1371903 ! SYN546107_10002 ! TK0004413 Syngenta - Jealott's Hill, Bracknell, United Kingdom GLP: Open (1) Yes (2) Published: No (2) Open (1) BVL-285021, BVL-2599822, BVL-3015263, ASB2014-5443	Yes	Syngenta Agro	Y
KIIA 5.8	Wollny, H. E.	2010	SYN504574: Cell mutation assay at the thymidine kinase locus (TK +/-) in mouse lymphoma L5178Y cells 1323602 ! SYN504574_10001 ! TK0004427 GLP: Open Published: Open BVL-2598104, ASB2014-5433	Yes	Syngenta Agro	Y
KIIA 5.8	Wollny, H.-E.	2011a	SYN546106: Cell mutation assay at the thymidine kinase locus (TK+/-) in mouse lymphoma L5178Y cells 1349702 ! SYN546106_10001 ! TK0004423 Syngenta - Jealott's Hill, Bracknell, United Kingdom GLP: Open (1) Yes (2) Published: No (2) Open (1) BVL-2599344, BVL-3015259, BVL-3015259, ASB2014-5439	Yes	Syngenta Agro	Y

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
KIIA 5.8	Wollny, H.-E.	2011b	SYN546105: Cell mutation assay at the thymidine locus (TK+/-) in mouse lymphoma L5178Y cells 1371902 ! SYN546105_10001 ! TK0004419 Syngenta - Jealott's Hill, Bracknell, United Kingdom GLP: Open (1) Yes (2) Published: No (2) Open (1) BVL-2599276, BVL-3015256, BVL-3015256, ASB2014-5436	Yes	Syngenta Agro	Y
KIIA 5.8	Wollny, H.-E.	2011c	SYN546108: Cell mutation assay at the thymidine kinase locus (TK +/-) in mouse lymphoma L5178Y cells SYN546108_10002 ! 1422503 ! TK0060523 GLP: Open (1) Yes (2) Published: No (2) Open (1) BVL-2600026, BVL-3015266, BVL-3015266, ASB2013-396	Yes	Syngenta Agro	Y
KIIA 5.8	Wollny, H.-E.	2011d	SYN546107: Cell mutation assay at the thymidine kinase locus (TK +/-) in mouse lymphoma L5178Y cells SYN546107_10000 ! 1378902 ! TK0004415 GLP: Open (1) Yes (2) Published: No (2) Open (1) BVL-SYNGB165-01.00, BVL-2599501, BVL-3015262, ASB2014-5442	Yes	Syngenta Agro	Y

* Y: Yes, relied on
N: No, not relied on
Add: Relied on, study not submitted by applicant but necessary for evaluation