REGISTRATION REPORT
Part A

Risk Management

Product code: **GF-2540 Milestone**

Active Substances: **propyzamide 500 g/L**
aminopyralid 5.3 g/L
as potassium salt 6.3 g/L

COUNTRY: Germany
Central Zone
Zonal Rapporteur Member State: Germany

NATIONAL ASSESSMENT

Applicant: **Dow AgroScience GmbH**

Date: **01/09/2014**

Table of Contents

PART A – Risk Management

This document describes the acceptable use conditions required for the re-registration/registration of GF-2540 containing propyzamide and aminopyralid in Germany. This evaluation is required subsequent to the inclusion of propyzamide on Annex 1. Aminopyralid is not yet included in Annex I.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-7 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 re-registration/registration by the EU review. It also includes assessment of data and information relating to GF-2450 where that data has not been considered in the EU review. Otherwise assessments for the safe use of GF-2450 have been made using endpoints agreed in the EU review of propyzamide and aminopyralid.

This document describes the specific conditions of use and labelling required for Germany for the registration of GF-2450.

Appendix 1 of this document provides a copy of the final product authorisation Germany.

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 16 of Directive 91/414/EEC.

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

1 Details of the application

1.1 Application background

This application was submitted by Dow AgroSciences GmbH on 20/08/2012.

The application was for approval of the plant protection product GF-2540 containing the active substances propyzamide (500 g a.s./L) and aminopyralid (5.3 g a.s./L). The product is intended to be used as a post-emergence herbicide for the control of annual monocotyledonous and dicotyledonous weeds in winter rape. Due to the fact that the active substance aminopyralid is not yet approved a provisional authorisation is granted.

1.2 Annex I inclusion

Aminopyralid is a new active substance which is undergoing review for Annex I inclusion, with UK Chemicals Regulation Directorate (CRD) serving as the rapporteur. The Draft Assessment Report (DAR) on aminopyralid was issued by the United Kingdom in August 2006, an updated version was distributed for commenting in march 2012. Where appropriate this document refers to the conclusions of the DAR (03/2012) for aminopyralid.

Propyzamide was included on Annex I of Directive 91/414/EEC on 01/04/2004 under Inclusion Directive 2003/39/EC and implemented under Regulation (EU) No 540/2011. The expiry date of the authorisation has been prolonged by Regulation (EU) No 823/2012.

The Annex I Inclusion Directive for propyzamide (2003/29/EC) provides specific provisions 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 on the propyzamide, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 26/02/2003, shall be taken into account. In this overall assessment:

Member States must pay particular attention to the:

- protection of operators and must ensure that conditions of authorisation include risk mitigation measures, where appropriate
- protection of birds and wild mammals in particular if the substance is applied during the breeding season. Conditions of authorisation should include risk mitigation measures, where appropriate

These concerns were all addressed in the submission.

1.3 Regulatory approach

To obtain approval the product GF-2540 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

The applicant claims data protection for the product data submitted in support of the first registration of this product.
For the active substance aminopyralid reference to data owned by Dow AgroSciences was made which were used first for a product authorisation on 18 October 2006.
For the active substance propyzamide the applicant referred to data owned by Dow AgroSciences which were used for an authorisation prior to 16 May 2000.

1.5 Letters of Access

No letter of access required. All data belong to Dow AgroSciences.

2 Details of the authorisation

2.1 Product identity

Product Name	GF-2540
Authorization Number (for re-registration)	007726-00

Function	herbicide
Applicant	Dow AgroSciences GmbH
Composition	500 g/L propyzamide 5.3 g/L aminopyralid (6.3 g/L as potassium salt)
Formulation type	suspension concentrate [Code: SC]
Packaging	0.25 – 20 L bottles (HDPE) 0.25 – 20 L bottles (PET)

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC

The following is proposed in accordance with Directive 99/45/EC in combination with the latest classification and labelling guidance under Directive 67/548/EEC (i.e. in the 18th ATP published as Directive 93/21/EEC):

Symbol(s)/Indication(s) of danger:	
N	dangerous for the environment
Xn	Harmful
Risk phrases:	
R40	Limited evidence of a cancinogenic effect
R50/53	Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
R67	Vapours may cause drowsiness and dizziness
Safety phrases:	
S2	Keep out of the reach of children.
S13	Keep away from food, drink and animal feeding stuffs
S24	Avoid contact with skin.
S35	This material and its container must be disposed of in a safe way.
S36/37	Wear suitable protective clothing and gloves.
S46	If swallowed, seek medical advice immediately and show this container or label.
S57	Use appropriate container to avoid environmental contamination.
Specific labelling requirement:	
To avoid risks to man and the environment, comply with the instructions for use.	
Contains 1.2-Benzisothiazol-3(2H)-one. May produce an allergic reaction.	

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

Hazard classes and categories:	
Aquatic Acute 1 Aquatic Chronic 1	Hazardous to the aquatic environment
	Carc. 2
Hazard symbol:	
GHS09	
Signal word:	
Warning	
Hazard statements:	
H351	Suspected of causing cancer <state route of exposure if it is conclusively proven that no other routs of exposure cause the hazard>.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
Precautionary statetents:	
None.	
Special rule for labelling of PPP:	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
[EUH 208-0098]	Contains 1.2-Benzisothiazol-3(2H)-one. May produce an allergic reaction.
Further labelling statements under Regulation (EC) No 1272/2008:	
None	

2.2.3 R and S phrases under Directive 2003/82/EC (Annex IV and V)

None.

2.2.4 Other phrases

Labelling phrases for human health protection

SB001	Avoid any unnecessary contact with the product. Misuse can lead to health damage.
SB110	The directive concerning requirements for personal protective gear in plant protection, "Personal protective gear for handling plant protection products" of the Federal Office of Consumer rx040Protection and Food Safety must be observed.
SE110	Wear tight fitting eye protection when handling the undiluted 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.
SS2101	Wear a protective suit against pesticides and sturdy shoes (e.g. rubber boots) when handling the undiluted product.
SS610	Wear a rubber apron when handling the undiluted product.

Labelling phrases for fate and ecotoxicology

NW262	The product is toxic for algae.
NW264	The product is toxic for fish and aquatic invertebrates.
NW265	The product is toxic for higher aquatic plants.
NW468	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.

Labelling phrases for sustainable use/IPM

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)
NN1001	The product is classified as non-harmful for populations of relevant beneficial insects.
NN2002	The product is classified as slightly harmful for populations of relevant beneficial predatory mites and spiders.
WMO	Mode of Action (HRAC-Group): O
WMK1	Mode of Action (HRAC-Group): K1

2.2.5 Other phrases linked to specific uses

Labelling phrases for fate and ecotoxicology

All uses:

NW 642-1	The product may not be applied in or in the immediate vicinity of surface or coastal waters. Irrespective of this, the minimum buffer zone from surface waters stipulated by state law must be observed. Violations may be punished by fines of up to 50 000 EUR.
NT 101	In a strip at least 20 m wide which is adjacent to other areas, 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 50 % (except agriculturally or horticulturally used areas, roads, paths and public places). Loss reducing equipment is not 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 or 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.

Labelling phrases for sustainable use/IPM

All uses:

WH9161	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	Damage is possible to the crop.
WP711	Damage is possible to replanted dicotyledonous intermediate crops.
WP740	Take care of adjacent crops, since damage is possible.
WP682-2	Litter, accruing from areas treated with the product, as well as manure, liquid manure or compost from animals, whose litter comes from treated areas, may be used only on the home front.
WP683-2	Manure, liquid manure or compost from animals whose litter accrue from areas treated with the product, may be applied only to grassland, to cereals or maize. All other crops might be damaged.
WP685-1	In early upheaval damage to rotation crops is possible. Only corn, canola and cabbages can be grown.

2.3 Product uses

GAP rev. BVL, date: 2014-03-19

PPP (product name/code)	**GF-2540**	**Formulation type:**	**SC**
active substance 1	**Propyzamid**	**Conc. of as 1:**	**500 g/L**
active substance 2	**Aminopyralid**	**Conc. of as 2:**	**5.3 g/L**
safener	**-**	**Conc. of safener:**	**-**
synergist	**-**	**Conc. of synergist:**	**-**
Applicant:	**DOW AgroSciences GmbH**	**professional use**	☒
Zone(s):	**central/EU**	**non professional use**	☐

Verified by MS: yes

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		
001	DE	winter oil-seed rape (BRSNW)	F	annual monocotyledonous weeds (TTTMS), annual dicotyledonous weeds (TTTDS) (post emergence of weeds)	Spraying	BBCH >14 Late autumn to winter (November to February)	a) 1 b) 1	a) 1.5 b) 1.5	a) Propyzamid 750 g/ha Aminopyralid 7.95 g/ha b) Propyzamid 750 g/ha Aminopyralid 7.95 g/ha	200 - 300	F	NW 642-1 NT101 WH9161 WP734 WP711 WP740 WP682-2 WP683-2 WP685-1

Remarks:

(1) Numeration of uses in accordance with the application/as verified by MS
(2) Member State(s) or zone for which use is applied for
(3) 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)
(4) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(5) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds, developmental stages
(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 of treatment(s) (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 applications possible under practical conditions of use for each single application and per year (permanent crops) or crop (annual crops) must be provided
Min. interval between applications (days) were relevant
(10) The application rate of the product a) max. rate per appl. and b) max. total rate per crop/season must be given in metric units (e.g. kg or L product / ha)
(11) The application rate of the active substance a) max. rate per appl. and b) max. total rate per crop/season must be given in metric units (e.g. g or kg / ha)
(12) The range (min/max) of water volume under practical conditions of use must be given (L/ha)
(13) PHI - minimum pre-harvest interval
(14) Remarks may include: Extent of use/economic importance/restrictions/minor use etc.

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:
All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.
The appearance of the product is that of a brown liquid with a mild odour. It is not explosive and has no oxidising properties, the self ignition temperature is above 400 °C. In aqueous solution, it has a pH value around 7.2. The stability data indicate a shelf life of at least 2 years at ambient temperature. The technical characteristics are acceptable for a suspension concentrate formulation.

Implications for labelling: None

Compliance with FAO specifications:
There are no published FAP specifications for aminopyralid or propyzamide.

Compliance with FAO guidelines:
The product GF-2540 complies with the general requirements of the FAO/WHO manual (2010).

Compatibility of mixtures:
No tank mixes are recommended for Milestone.

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 Milestone 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)

The active substances aminopyralid (a.e.) and propyzamide are dissolved in acetonitril / water and chromatographed on a HPLC reversed phase system with UV-detection and internal calibration.
The method is applicable to the assay of aminopyralid (a.e.) and propyzamide in Milestone.
There are no CIPAC methods available for the determination of propyzamide or aminopyralid.
There are no relevant impurities in the formulation GF-2540. Therefore, no analytical method is required.

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

Adequate analytical methods are available to monitor residues of aminopyralid in food of plant and animal origin, soil, water and air and residues of propyzamide in food of plant origin, soil, water and air.

Analytical methods used to meet the requirements of the Annex to Regulation (EU) No 544/2011, Part A, point 4.2 can be applied for the product.
Aminopyralid residues can be monitored in food of plant and animal origin, soil, water and air by LC-MS/MS. Methods for body fluids and tissues are not required as aminopyralid is not classified as toxic or very toxic.
Propyzamide residues can be monitored in food of plant origin and water by LC-MS/MS. Suitable GC-ECD methods are also available for plants, soil and water. Sufficiently sensitive and selective analytical methods for foodstuff of animal origin are not available. At the latest with the application for renewal of approval for the active substance according to Regulation (EC) No 1107/2009 or in context with the review of the existing MRLs for the active substance according to Article 12 of Regulation (EC) No 396/2005 analytical methods (primary method, ILV and confirmatory method) for the determination of propyzamide residues as sum of propyzamide and all metabolites containing the 3,5-dichlorobenzoic acid, expressed as propyzamide, in milk, meat, fat, eggs, liver and kidney have to be submitted.
Furthermore, acceptable methods for analysis of propyzamide in air were not provided. However, an EU agreed method, which is not protected anymore, is available. Methods for body fluids and tissues are not required as propyzamide is not classified as toxic or very toxic.

3.1.3 Mammalian Toxicology (Part B, Section 3, Point 7)

3.1.3.1 Acute Toxicity (Part B, Section 3, Point 7.1)

Acute toxicity studies for “GF-2540” were not evaluated as part of the EU review of aminopyralid and propyzamide. Therefore, all relevant data were provided and are considered adequate.
“GF-2540”, containing 5.3 g/L aminopyralid and 500 g/L propyzamide, has a low toxicity in respect to acute oral and dermal toxicity and is not irritating to the rabbit eye. It has been found to be not classifiable for irritancy to rabbit skin and is not a skin sensitiser to the guinea pig. Taking into account all submitted data and the labelling of aminopyralid (Xi, R41) and propyzamide (Xn, R40), “GF-2540” should be labelled as harmful, with phrase R40.

3.1.3.2 Operator Exposure (Part B, Section 3, Point 7.3)

Operator exposure to “GF-2540” was not evaluated as part of the EU review of aminopyralid and propyzamide for this submitted rate/crop. Therefore all relevant data and risk assessments have been provided and are considered to be adequate.
Operator exposure was assessed against the AOEL agreed in the EU review (aminopyralid: 0.26 mg/kg bw/d and propyzamide: 0.08 mg/kg bw/d). Data on dermal absorption of “GF-2540” was not provided for aminopyralid. Justification for default values on aminopyralid according to Guidance on Dermal Absorption (EFSA Journal 2012; 10(4):2665) is given and considered acceptable. Proposed endpoint for propyzamide is based on a dermal absorption study on a formulation similar to GF-2540 and is considered acceptable. Operator exposure was modelled using UK OPEX and the German model.
According to the model calculations, it can be concluded that the risk for the operator using “GF-2540” on oilseed rape is acceptable with the use of personal protective equipment.
Given the skin irritating potential of aminopyralid impermeable gloves and eye/face protection should be worn when handling the concentrate. Gloves should also be used for the maintenance of the sprayer during application. Hence, phrase S36/37 should be added to the national standard phrases S2, S13, S24 and S46.

3.1.3.3 Bystander Exposure (Part B, Section 3, Point 7.4)

Bystander exposure to “GF-2540” was not evaluated as part of the EU review of aminopyralid and propyzamide. Therefore, all relevant data and risk assessments have been provided and are considered adequate. It is concluded that there is no undue risk to any bystander after accidental short-term exposure to “GF-2540” This has no labelling implications.

3.1.3.4 Worker Exposure (Part B, Section 3, Point 7.5)

Worker exposure to “GF-2540” was not evaluated as part of the EU review of aminopyralid and propyzamide. Therefore, all relevant data and risk assessments have been provided and are considered adequate. It is concluded that there is no unacceptable risk anticipated for the worker wearing adequate work clothing (but no PPE), when re-entering crops treated with “GF-2540”. As a standard rule, it should be mentioned on the label that treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried.

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

Hazard Symbol: Xn
Indication of danger: Harmful
Risk Phrases: R40
Safety Phrases: S2, 13, 24, 36/37, 46
R and S phrases under Directive 2003/82/EC (Annex IV and V):
SF245-01: Treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried.
Other phrases: -

3.1.4 Residues and Consumer Exposure (Part B, Section 4, Point 8)

3.1.4.1 Residues (Part B, Section 4, Points 8.3 and 8.7)

According to the Commission Decision 2005/778/EC the dossier for inclusion of aminopyralid in Annex I to Directive 91/414/EEC was considered complete. However, the evaluation of the dossier has not been finished. In the context of a procedure for the authorisation of the use of a plant protection product containing aminopyralid on oilseed rape, an application was made in accordance with Article 6(1) of Regulation (EC) No 396/2005 for modification of the existing MRL. The evaluation of this use has been made to establish an EU MRL (EFSA Journal 2012;10(9):2894) and considered the dietary risk assessments appropriate for all EU member states utilising the EFSA model. The MRLs for aminopyralid are published in Annex III of Regulation (EC) No 396/2005 [Reg. (EC) No 251/2013 and Reg. (EC) No 36/2014].
Subsequent to the EU review of propyzamide an evaluation of all uses according to Art. 12 (2) of Reg. (EG) No 396/2005 has been made to establish EU MRLs (Reasoned Opinion, EFSA Journal 2012;10(4):2690), EFSA-Q-2008-615. This evaluation reviewed all the data relevant to establishing MRLs for all supported uses and considered the dietary risk assessments appropriate for all EU member states utilising the EFSA model. The MRLs for propyzamide are published in Annex III of Regulation (EC) No 396/2005 (Reg. (EC) No 149/2008).
The proposed uses of “GF-2540” are within those supported for the EU MRL assessment. Therefore, no further evaluation is required for national re-registration/registration. Application for additional crops or uses should be made by the appropriate process to establish an EU MRL and any additional risk assessment necessary to support additional uses should be submitted via relevant national label extension processes.

3.1.4.2 Consumer exposure (Part B, Section 4, Point 8.10)

The estimated consumer intake levels do not exceed the EU agreed ADI of 0.26 mg/kg bw/day for aminopyralid and of 0.02 mg/kg bw/day for propyzamide. It can therefore be concluded that acceptable margins of safety exist for consumers. A further assessment of consumer intake levels was presented by the notifer. TMDI calculations using the EFSA model PRIMo and NTMDI calculations using the German model NVS II, were performed to take account of all crops to which aminopyralid an d propyzamide may be applied.
With the current models the chronic risk assessment (TMDI) for aminopyralid ranges from 0,0 to 0,5 % of ADI. The diet with the highest TMDI is “DK child” with 0.5 % of ADI. For this diet, the highest contributor is wheat with 0.2 % of ADI. The second diet with the highest TMDI is “NL child” with 0.5 % of ADI where milk and cream is the major contributor with 0.2 % of ADI.
With the current models the chronic risk assessment (TMDI) for propyzamide ranges from 1.1 to 38.0 % of ADI. The diet with the highest TMDI is “UK toddler” with 38.0 % of ADI. For this diet, the highest contributor is sugar beet with 34.3 % of ADI. The second diet with the highest TMDI is “UK infant” with 19.3 % of ADI where sugar beet the major contributor with 15.1 % of ADI.
For aminopyralid the results of the IESTI and NESTI calculations demonstrate that in no case these values are above the acute reference dose (ARfD) of 0.26 mg/kg bw/day including a safety factor of 100. As no acute reference has been set for propyzamide, there is no need to evaluate the acute risk for this active substance.
Thus, the acute risk to the consumer based on the short-term intake of residues of the active substances, is considered to be acceptable.

Based on the different calculations made to estimate the risk for consumer though diet and other means it can be concluded that the use of product “GF-2540” does not lead to unacceptable risk for consumer when applied according to the recommendations.

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

A full exposure assessment for the plant protection product GF-2540 in its intended uses in oil seed rape is documented in detail in the core assessment of the plant protection product GF-2540 dated from 10/2013 performed by zRMS Germany.

The following chapters summarise specific exposure assessment for soil and surface water and the specific risk assessment for groundwater for the authorization of GF-2540 in Germany according to its intended use in oil seed rape (use No. 00-001).

Metabolites
No new study on the fate and behaviour of propyzamide and aminopyralid or GF-2540 has been performed. Hence no potentially new metabolites need to be considered for environmental risk assessment.

Propyzamide
No new study on the fate and behaviour of propyzamide or GF-2540 has been performed. Hence no potentially new metabolites need to be considered.

The risk assessment for these metabolites has not been performed for EU approval (see Review Report 6502/VI/99-final, 9 October 2007). Therefore, risk and exposure assessment are performed for these metabolites in Part B, core assessment.

The risk assessment for groundwater by direct leaching for the application of the plant protection product and its intended uses includes the soil metabolites of propyzamide. Additionally, the soil metabolites of propyzamide were also included in the groundwater risk assessment considering the entry path surface run-off and drainage with subsequent bank filtration.

Aminopyralid
In the Draft Assessment Report (DAR) for the active substance aminopyralid no potentially relevant metabolites were observed. Hence, no metabolites need to be considered in the risk assessment.

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

For the intended use of the plant protection product GF-2540 in oil seed rape according to use No. 001, PECsoil was calculated for the active substances propyzamide and aminopyralid considering a soil depth of 2.5 cm. Due to the fast degradation of the active substance propyzamide and aminopyralid in soil the accumulation potential was not considered.

The results for PEC soil for the active substances and its metabolites were used for the eco-toxicological risk assessment.
PECsoil propyzamide: 3.000 mg/kg
PECsoil aminopyralid: 0.013 mg/kg
PECsoil GF-2540: 6.834 mg/kg

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

1. Direct leaching into groundwater

According to the results of the groundwater simulation with FOCUS-PELMO 5.5.3, a groundwater contamination of the active substance propyzamide in concentrations ≥ 0.1 µg/L is expected for the intended use in winter oilseed rape. For the metabolites RH 24655 and RH 24580 of propyzamide a groundwater concentration ≥ 0.1 µg/L can be excluded for the application in winter oilseed rape according to the results of the groundwater simulation with FOCUS-PELMO 5.5.3. In addition to the PECgw modeling, data from lysimeter studies are used to assess the leaching behaviour of the active substance propyzamide. The experimental data show that the active substance propyzamide and its metabolites RH-24644 and RH-24580 are not expected to penetrate into groundwater at concentrations of ≥ 0.1µg/L assuming applications in winter (January).

Results of modelling with FOCUSPELMO 5.5.3 show that the active substance aminopyralid is not expected to penetrate into groundwater at concentrations of ≥ 0.1µg/L in the intended uses in winter oilseed rape.

2. Ground water contamination by bank filtration due to surface water exposure via run-off and drainage

According to modelling with EXPOSIT 3.01, groundwater contamination at concentrations ≥ 0.1 µg/L by the active substance propyzamide and its soil metabolites RH 24644 and RH 24580 due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

According to modelling with EXPOSIT 3.01, groundwater contamination at concentrations ≥ 0.1 µg/L by the active substance aminopyralid due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

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 use of the plant protection product GF-2540 in oil seed rape according to use No. 001 PECsw was calculated for the active substances propyzamide and aminopyralid considering the two routes of entry (i) spraydrift and volatilization with subsequent deposition and (ii) run-off, drainage separately. 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 propyzamide is between 10^{-5} and 10^{-4} Pa/> 10^{-4} Pa. Hence the active substance is regarded as semivolatile (volatilisation only from plant surfaces). Therefore exposure of surface water by the active substance propyzamide due to deposition following volatilization needs to be considered.

The vapour pressure at 20 °C of the active substance aminopyralid is < 10^{-5} Pa. Hence the active substance is regarded as non-volatile. Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance aminopyralid due to volatilization with subsequent deposition does not need to be considered.

The concentration of the active substances propyzamide and aminopyralid in adjacent ditch due to surface run-off and drainage was calculated using the model EXPOSIT 3.01.

The results for PEC surface water for the active substance and its metabolites were used for the eco-toxicological risk assessment.
PECsw propyzamide (drift and volatilization): 250.000 µg/L (no drift reduction technique)
PECsw aminopyralid (drift and volatilization): 2.65 µg/L (no drift reduction technique)

3.1.5.4 Predicted Environmental Concentration in Air (PEC_{Air}) (Part B, Section 5, Point 9.9)

The vapour pressure at 20 °C of the active substance propyzamide is between 10^{-5} and 10^{-4} Pa/> 10^{-4} Pa. Hence the active substance is regarded as *semivolatile* (volatilisation only from plant surfaces). Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance propyzamide due to volatilization with subsequent deposition should be considered e.g. using the program EVA 2.1.

The vapour pressure at 20 °C of the active substance aminopyralid is < 10^{-5} Pa. Hence the active substance is regarded as *non-volatile*. Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance aminopyralid due to volatilization with subsequent deposition does not need to be considered.

Implications for labelling resulting from environmental fate assessment:

None.

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

A full risk assessment according to the Uniform Principles for the plant protection product GF-2540 in its intended uses in winter oilseed rape is documented in detail in the core assessment of the plant protection product GF-2540 dated from 10/2013 performed by Germany. The intended use of GF-2540 in Germany is generally covered by the uses evaluated in the course of the core assessment by Germany.

The following chapters summarise the specific risk assessment for non-target organisms and hence risk mitigation measures for the authorization of GF-2540 in Germany according to its intended use in winter oilseed rape (use No. 001).

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

The risk assessment for effects on birds and other terrestrial vertebrates was carried out according to the European Food Safety Authority Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438).

Based on the presumptions of the screening step and Tier 1, the calculated TER values for the acute and long-term risk resulting from an exposure of birds to the active substances propyzamide and aminopyralid according to the intended use of the formulation GF-2540 in winter oilseed rape achieve the acceptability criteria TER ≥ 10 and TER ≥ 5, respectively, 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 other terrestrial vertebrates.

Propyzamide Acute LD50 > 6600 mg a.s./kg bw (Coturnix japonica)
Propyzamide Long-term NOAEL = 58.5 mg a.s./kg bw/d (Colinus virginianus)
Aminopyralid Acute LD50 >2250 mg a.s./kg bw (Colinus virginianus)
Aminopyralid Long-term NOEL = 190.23 mg a.s./kg bw/d (Colinus virginianus)

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

Results of aquatic risk assessment for the intended uses of GF-2540 in winter oilseed rape based on FOCUS Surface Water PEC values are presented in the core assessment, Part B, Section 6, chapter 6.4.
For authorization in Germany, exposure assessment of surface water considers the two routes of entry (i) spraydrift and volatilization with subsequent deposition and (ii) run-off/drainage separately in order to allow separate risk mitigation measures for each entry route.

Based on all studies on aquatic toxicity as well as the corresponding safety factors, the relevant endpoint for propyzamide is NOEC = 0.082 mg propyzamide metabolite RH-24-655/L *(Chironomus riparius).* For aminopyralid, the relevant endpoint is NOEC = 0.1 mg aminopyralid/L *(Cyprinodon variegatus*). Risk assessment is predominantly driven by the toxicity of the active substance propyzamide (resp. its metabolite RH-24-655).

1. Exposure by spraydrift and deposition following volatilization

The calculation of PECsw after exposure via spray drift and volatilization with subsequent deposition is performed using the model EVA 2.1. For a single application, the exposure assessment via spray drift is based on the application rate in conjunction with the 90^{th} 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. The vapour pressure of the active substance aminopyralid is < 10^{-5} Pa at 20 °C and the vapour pressure of the active substance propyzamide is > 10^{-5} Pa. Therefore, exposure of surface water due to deposition following volatilization was considered for the active substance propyzamide but not for the active substance aminopyralid. Only one volatilization event following the last use of pesticide is generally considered.

Based on the relevant toxicity data, the calculated TER values for the risk to aquatic organisms resulting from an exposure of surface water by spraydrift deposition following volatilization to GF-2540 according to use No. 001 achieve the acceptability criteria of TER ≥ 10, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. Specific risk mitigation measures do not need to be applied.

2. Exposure by surface run-off and drainage

The concentration of the active substance propyzamide and its metabolites in adjacent ditches due to surface runoff and drainage was calculated using the model EXPOSIT 3.01.

The calculated TER values for the risk to aquatic organisms resulting from an exposure of surface water by the active substances aminopyralid, propyzamide and their metabolites due to run-off and drainage according to use No. 001 achieve the acceptability criteria of TER ≥ 100 or 10 respectively, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. Risk mitigation measures do not need to be applied.

Consequences for authorization:
For the authorization of the plant protection product GF-2540 the following labelling and conditions of use are mandatory:

Required Labelling	
NW 262	Propyzamide: *Selenastrum capricornutum* EbC50 = 0.83 mg/L
NW 264	Propyzamide: *O. mykiss* LD_{50} = 4,7 mg/L; *D. magna* NOEC = 0.6 mg/L
NW 265	Propyzamide: *Lemna gibba* NOEC= 0.56 mg/L
Conditions for use	
GF-2540	NW 468 NW 642-1

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 GF-2540 were not evaluated as part of the EU review of propyzamide. Therefore all relevant data 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.

Table 3.1.6.3-1: Results of laboratory bee toxicity studies

Test substance	Exposure route	LD_{50}	Reference
GF-2540	oral 48 h	> 330.25 µg product/bee	Kling, A. (2010); S09-00693-L1_BLEU
	contact 48 h	> 300 µg product/bee	

Exposure
The recommended use pattern for GF-2540 includes application in oilseed rape at a maximum application rate of up to 1.5 L/ha. This maximum single application rate is equivalent to 1709 g product/ha.

Bees may be exposed to GF-2540 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 hazard quotients for oral and contact exposure according to EPPO (2003) Environmental risk assessment scheme for plant protection products (Chapter 10: Honeybees (PP 3/10(2)). These 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
GF-2540	1709	oral	> 330.25 µg	< 6	50
		contact	> 300 µg	< 6	

Risk assessment
Due to the results of laboratory tests GF-2540 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 and exposure of brood is considered negligible.

Overall conclusion:
It is concluded that GF-2540 will not adversely affect bees or bee colonies when used as recommended.
Label NB6641 is applicable.

Other non-target arthropods

Based on the calculated rates of GF-2540 in in-field and off-field areas, the calculated HQ and TER values describing the potential risk resulting from an exposure of non-target arthropods according to the GAP of the formulation GF-2540 achieve the acceptability criteria HQ ≤ 2 resp. TER ≥ 10 (Tier 1), 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 GF-2540 in winter oilseed rape according to use No. 001.

GF-2540: ER50 *Aphidius rhopalosiphi* 1437 ml Prod./ha
ER50 *Typhlodromus pyri* > 1700 ml Prod./ha

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

The results of the assessment based on the predicted concentrations of aminopyralid / propyzamide / propyzamide metabolites RH-24580 and RH-24644 / GF-2540 in soils, following exposure according to the GAP of the formulation GF-2540 indicate an acceptable risk for soil organisms due to the intended use of GF-2540 in winter oilseed rape according to the label.

GF-2540: Acute LC50 > 500 mg/kg dw soil
Long-term NOEC 26.1 mg/kg dw soil

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

For propyzamide and aminopyralid the max DT_{90} in the field are <365 but >100 (185 and 116.1 d resp.). Effects of both active substances on soil microflora were <25 % and TER_{LT} earthworm was >5. Therefore no tests for assessing effects on organic matter breakdown are considered to be necessary.

For the propyzamide metabolite RH 24580 the DT90 lab was 55.5 (max), so no tests for assessing effects on organic matter breakdown are required. For the RH 24644 the DT90 lab was <365 but >100 (125.8d max) but the TER_{lt} for Earthworms was >5 and effects on soil microflora were <25 %. Hence, for this metabolite no tests for assessing effects on organic matter breakdown are considered to be necessary.

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

For the active ingredients in GF-2540, propyzamide, aminopyralid and the propyzamide metabolite RH-24644, the soil concentrations which caused no deviations greater than ±25% in the activity of the soil microorganisms are at least 10-times higher than the corresponding maximum PEC in soil. For GF-2540 the soil concentrations which caused no deviations greater than ±25% in the activity of the soil microorganisms are 4.8 times higher than the corresponding maximum PEC in soil. Hence, a low risk to soil microflora is concluded.

The metabolite Uk1 is formed in relevant amounts in soil (max 24% of AR on day 45) and its toxicity towards soil microorganisms has not been assessed in the EU review of propyzamide. However, the toxicity of this metabolite is considered to be covered in the 56d study with the preparation GF-2540.

Based on the predicted concentrations in soils, the risk to soil microbial processes following exposure to GF-2540 according to the GAP of the formulation GF-2540 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.

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

Terrestrial plants
For the intended use of GF-2540 risk mitigation corresponding to 50% (NT 101) drift reduction has to be applied to achieve an acceptable risk for non-target terrestrial plants according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2.

Based on the predicted rates of GF-2540 in off-field areas, the TER values describing the risk for non-target plants following exposure to GF-2540 according to the GAP of the formulation GF-2540 do not achieve the acceptability criteria TER ≥ 10 according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. Mitigation measures will have to be implemented to reduce the exposure of non-target terrestrial plants to GF-2540 comparable to 5m m in-field buffer strip.

Vegetative vigour GF-2540 210.95 mL product/ha (Lycopersicon esculentum)

Consequences for authorization:
For the authorization of the plant protection product GF-2540 following labelling and conditions of use are mandatory:

Conditions for use
All uses NT101

Implications for labelling resulting from ecotoxicological assessment:

For the authorization of the plant protection product GF-2540 the following labelling and conditions of use are mandatory:

Classification and labelling of the formulation

Relevant toxicity	Acute Active substance propyzamide (content: 50 %) EbC50 = 0.830 mg /L (*Selenastrum capricornutum*), M factor 1 Chronic Active substance propyzamide (content: 50 %) NOEC = 0.082 mg /L (*Lemna gibba*) , M factor 1
Classification and labelling according to Directive 67/548/EC, 78/631/EC and 1999/45/EC	
Hazard symbol	N, dangerous for the environment
Risk phrases	R 50/53
Classification and labelling according to Regulation 1272/2008	

Hazard sysmbol	GHS09
Signal word	No signal word used
Hazard statement	H400, H410

Other labels /conditions for use

Labelling

NW262 The product is toxic for algae.
NW264 The product is toxic for fish and aquatic invertebrates.
NW265 The product is toxic for aquatic plants

Conditions of use:

All uses:

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 642-1 The product may not be applied in or in the immediate vicinity of surface or coastal waters. Irrespective of this, the minimum buffer zone from surface waters stipulated by state law must be observed. Violations may be punished by fines of up to 50 000 EUR.

NT 101 In a strip at least 20 m wide which is adjacent to other areas, 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 50 % (except agriculturally or horticulturally used areas, roads, paths and public places). Loss reducing equipment is not 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 or 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.

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

GF-2540 contains the active substances propyzamide (500 g a.s./L) and aminopyralid (5.3 g a.s./L). The product is intended to be used as a post-emergence herbicide for the control of annual monocotyledonous and dicotyledonous weeds in winter oil seed rape for use from the end of the vegetation period in the year of drilling of oil-seed rape until the start of the vegetation period in the year of oil-seed rape harvest. At application the plants should have grown up to the 4-leaf stage (BBCH 14). The evaluation of the test compound is based on results from field trials conducted in Germany, UK and the northern part of France during the years 2009 to 2010.

Information on the active substances

Propyzamide belongs to the chemical group of benzamides. Mainly, propyzamide is taken up from the soil by plant roots and translocated into the plants. Plant uptake through the leaves is also possible to some extent. In this case only small parts of the substance are translocated within plants. Propyzamide inhibits cell division and photosynthesis. This results in inhibition of the formation of microtubuli and division of cell nucleus. Germination of seed will not be interrupted. After germination, seedlings become chlorotic and die as a consequence of interrupted photosynthesis. Site of action (HRAC-group): K1
Label WMK1 is applicable.

Aminopyralid (4-Amino-3,6-Dichloropyridin-2-carboxylsäure) belongs to the chemical group of pyridine–carboxylic acids. Aminopyralid will mainly be absorbed through green leaves. Uptake through roots is of much less importance. Aminopyralid has systemic properties. Acropetal translocation of aminopyralid in xylem into young meristems and youngest leaves as well as basipetal transport in phloem into roots is possible. It has been shown that aminopyralid is accumulated in meristematic tissue and influences cell division, cell elongation and cell extension as well as RNA synthesis. Consequently, meristematic tissue dies off. The tissues of dicotyledonous plants are destroyed, while monocotyledonous plants are not affected. Typical symptoms of susceptible plants are deformation and curling of young leaves and stems followed by growth stop and necrosis. Site of action (HRAC-group): O.
Label WMO is applicable.

Minimum effective dose

Dose response was assessed in trials treated at post-emergence of weeds. Efficacy data from weeds sprayed in post-emergence support the requested field rate of 1.5 L/ha GF-2540 to control annual monocotyledonous and dicotyledonous weeds in winter oil-seed rape. Reduction of the application rate below the proposed target rate will result in an obvious reduction of weed control performance.

Efficacy

Efficacy tests were conducted in winter oil-seed rape in the maritime EPPO climate zone regarding the control of annual mono- and dicotyledonous weeds. GF-2540 was tested in all trials in comparison to the commercial standard reference products. The trials presented are relevant for judging efficacy of GF-2540 in Germany. They were performed in Germany, UK and the maritime part of France under GEP conditions by GEP certified contractors.
Assessments performed in April/May demonstrated satisfying control levels for the following weed species: ALOMY, APESV, CENCY, LOLMU, MATSS, PAPHR, POAAN, SENVU, STEME, VIOAR and some *Veronica* species. The achieved efficacy is not related to the application timings (early or late winter).
Label WH9161 is applicable.

Yield effects

Even under the extreme conditions of applications of GF-2540 at 2N rate on weed-free sites, no relevant negative impact on yield or 1000 grain weight was found due to the treatment with GF-2540. Applications as recommended on the label will not result in negative impact on yield for the crop.

Phytotoxicity to host crop

Observations for visual phytotoxicity symptoms were performed in a set of specific selectivity trials applied at target rate (N-rate) and double the target rate (2N-rate) as well as in all efficacy trials plus in a variety screen of 6 varieties where GF-2540 was applied at N-rate (758 g a.s./ha).

It can be concluded that phytotoxicity to the host crop is very limited when GF-2540 is applied at 1.5 L/ha (750 g a.s./ha propyzamide + 8 g a.s./ha aminopyralid). However, the label should state that damage is possible to crops.
Label WP734 is applicable.

Succeeding crops
For succeeding crops in a normal rotation, field trials have shown that TRZAW, LOLMU. SINAR, PHCTA, TRFIN, AVESA, TRZAW, ZEAMX, BRSNS, BEAVA, PIBSA, VICFX and SOLTU can be drilled in a normal rotation. For early replacement crops in the case of the failure of a treated oil-seed rape crop, it appeared that the establishment of ZEAMX and BRSNS are secure.
After intensive soil cultivation in fall or spring following the harvest of a treated oil-seed rape crop, there is no restriction in terms of crops to be planted. Catch crops after a treated oil-seed rape might show damage symptoms. In terms of catch crops established after a treated crop phacelia, mustard and grass mixes are possible. Leguminosae (clover, beans, and vetches) should not be used as catch crops.
In the case of early replacement in spring, deep ploughing is required to establish maize, spring oil-seed rape or cabbage crops. It is not possible to establish spring cereals, grasses, beets, potato or crops from the leguminosae or umbellifer group.
It can be concluded that GF-2540 applied at 1.5 L/ha (750 g a.s./ha propyzamide + 8 g a.s./ha aminopyralid), can have a negative impact on catch crops under certain conditions. Most affected are leguminous crops in crop rotation and early replacement after crop failure.
The label should state that damage is possible to succeeding catch crops. Serious damage can occur after early replacement to spring cereals, grasses, beets, potatoes, legume species (peas, beans, lupines, clover, vetches, and lucernes), sunflower, umbellifer (e.g. carrots) and lettuce in spring after crop failure. Maize, spring rape and cabbage species are possible crops.
It is not possible to estimate how aminopyralid residues in fodder (rape straw, pomace) should be assessed concerning the subsequent use of slurry, liquid manure or dung from animals with regard to crop damage following application
Information for herbicides containing aminopyralid:

- Damage cannot be excluded for crops other than grassland, cereals or maize when using slurry, liquid manure, dung or compost from animals whose litter comes from treated areas.
- The use of litter as well as slurry, liquid manure, dung and compost from animals whose litter comes from treated areas represents a hazard when used outside the agricultural business.
- Damage can occur to succeeding crops when breaking the field in the year following application: cereals, fodder grass or maize are possible crops.
- Serious damage can be expected if potatoes, tomatoes, leguminous plants or field vegetable species are replanted within 18 months following treatment.

Labels WP711, WP682-2, WP683-2, WP685-1 are applicable.

Impact on other plants including adjacent crops
GF-2540 is a very effective herbicide; drift at application has to be avoided. Drift to adjacent sensitive crops may cause severe damage. Calculations of TER values showed that a 5 m buffer zone is necessary to protect terrestrial non-target plants due to application of GF-2540. Using nozzles with drift reduction will reduce the risk of plant damage.
Label WP740 is applicable.

Adverse effects on beneficial organisms (other than bees)

GF-2540 is considered to be slightly harmful for the predatory mite *Typhlodromus pyri*, due to effects > 25% in the range of the proposed application rate on a natural substrate. It can be concluded, that the test product is slightly harmful for relevant predatory mites and spiders.
On the basis of the results of valid tests with effects < 25% in the range of the proposed rate, the test product can be classified as not harmful for the insect species *Aphidius rhopalosiphi* and *Chrysoperla carnea*. It can be concluded, that the test product is non-harmful for populations of relevant beneficial insects.
Labels NN2002 and NN1001 are applicable.

Effects on soil quality
There is no indication of any unacceptable adverse effects on soil macro- or soil micro-organisms relevant for the maintenance of soil quality.

Resistance risk
Regarding the low number of weeds showing resistance to the concerned HRAC groups K1 and O in Europe and the fact that no resistance to propyzamide and aminopyralid has been reported in Europe, the general resistance risk of GF-2540 is assessed as being low. The applicant has not provided information on the individual agronomic risk for the concerned Member States in the central zone but has provided some information especially relevant to the UK.

All the data regarding the efficacy of the product have been submitted. These data demonstrate that GF-2540 fulfils all criteria for the authorization of preparations described in Directive 97/57/EC (Uniform Principles, Annex VI to Directive 91/414/EEC), as far as users strictly adhere to the risk mitigation measures outlined in the report.

3.2 Conclusions

With respect to physical, chemical and analytical methods an authorisation can be granted.
With respect to analytical methods (formulation, residues) an authorisation can be granted.

Concerning Efficay/IPM and sustainable use an authorisation can be granted. GF-2540 fulfils all criteria for the authorization of preparations described in Directive 97/57/EC as far as users strictly adhere to the risk mitigation measures outlined in the report.

If used properly and according to the intended conditions of use, adverse health effects for operators, workers, bystanders and residents will not be expected.
The indended use in oilseed rape will not result in residues above the MRLs (LOQ) for aminopyralid and propyzamid set in Regulation (EC) No 396/2005. A risk for consumers through the consumption of food possibly containing residues of these active substances below LOQ is not expected. There is no special risk mitigation necessary which deviate from the existing registration.
As far as consumer health protection is concerned, it is agreed with the authorization of the intended use.

With respect to fate and ecotoxicology an authorisation can be granted. Considering an application in accordance with the evaluated use pattern and good agricultural practice as well as strict observance of the conditions of use no harmful effects on groundwater or adverse effects on the ecosystem are to be apprehended.

In Germany a provisional authorisation can be granted because the active substance aminopyralid is not yet approved.

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

Will be inserted in the final version

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 16 of Directive 91/414/EEC.

Appendix 3 – Letter of Access

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

Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

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

Dow AgroSciences GmbH
Truderingerstraße 15
81677 München

Dr. Dietmar Gottschild
Referent

TELEFON +49 (0)531 299-3512
TELEFAX +49 (0)531 299-3002
E-MAIL dietmar.gottschild@bvl.bund.de

IHR ZEICHEN
IHRE NACHRICHT VOM

AKTENZEICHEN (bitte bei Antwort angeben) 200.22100.007726-00/00.71871

DATUM 10. September 2014

ZN8 007726-00/00

Milestone

Zulassungsverfahren für Pflanzenschutzmittel

Bescheid

Das oben genannte Pflanzenschutzmittel

mit den Wirkstoffen:	500 g/l	Propyzamid
	5,3 g/l	Aminopyralid (als Kalium-Salz 6 g/l)
Zulassungsnummer:	007726-00	
Versuchsbezeichnung:	DOW-02540-H-0-SC	
Antrag vom:	20. August 2012	

wird auf der Grundlage § 15c des Gesetzes zum Schutz der Kulturpflanzen (PflSchG) in der Fassung der Bekanntmachung vom 14. Mai 1998 (BGBl. I. S. 971, 1527, 3512), zuletzt geändert durch Artikel 4 des Gesetzes vom 2. November 2011 (BGBl. I S. 2162), in Verbindung mit Artikel 80 Absatz 5 Buchstabe a 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 10. September 2017.

BVL_FO_05_2021_200_V2.4

Festgesetzte Anwendungsgebiete

Es werden folgende Anwendungsgebiete gemäß § 15 Abs. 2 Nr. 1 des Gesetzes zum Schutz der Kulturpflanzen (PflSchG) in der Fassung der Bekanntmachung vom 14. Mai 1998 (BGBl. I. S. 971, 3512), zuletzt geändert durch Artikel 4 des Gesetzes vom 2. November 2011 (BGBl. I. S. 2162) festgesetzt (siehe Anlage 1):

Schadorganismus/ Zweckbestimmung	**Pflanzen/-erzeugnisse/Objekte**	**Anwendungsnummer**
Einjährige einkeimblättrige Unkräuter, Einjährige zweikeimblättrige Unkräuter	Winterraps	007726-00/00-001

Festgesetzte Anwendungsbestimmungen

Es werden folgende Anwendungsbestimmungen gemäß § 15 Abs. 2 Nr. 2 des Gesetzes zum Schutz der Kulturpflanzen (PflSchG) in der Fassung der Bekanntmachung vom 14. Mai 1998 (BGBl. I. S. 971, 3512), zuletzt geändert durch Artikel 4 des Gesetzes vom 2. November 2011 (BGBl. I. S. 2162) 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:
Aufgrund der Auswirkungen des Wirkstoffs Propyzamid gegenüber aquatischen Organismen (z. B. Propyzamid: Chironomus riparius NOEC = 340 µg/L) besitzt das o.g. Pflanzenschutzmittel einen den Naturhaushalt schädigenden Charakter, so dass jeder weitergehende, d. h. den als Folge der sachgerechten und bestimmungsgemäßen Anwendung des Pflanzenschutzmittels "Milestone" übersteigende Eintrag von Rückständen in Gewässer zu einer erheblichen Gefährdung des Naturhaushaltes führen würde. Angesichts der Umstände, dass ein erheblicher Anteil an Pflanzenschutzmittelfrachten im einzelnen Gewässer auf Einträge aus kommunalen Kläranlagen zurückzuführen ist (vgl. Umweltpolitik - Wasserwirtschaft in Deutschland, 10.5.2 Pestizide, S. 156 ff., BMU, Februar 1998 und Fischer, Bach, Frede: Abschlussbericht zum DBU-Projekt 09931, April 1998), ist es unverzichtbar, der Gefahr, die eine Verbringung von Pflanzenschutzmitteln in Gewässer mit sich bringt, durch die bußgeldbewehrte Anwendungsbestimmung im Sinne der Zweckbestimmung des Pflanzenschutzgesetzes durchsetzbar zu begegnen.

Siehe anwendungsbezogene Anwendungsbestimmungen in Anlage 1, jeweils unter Nr. 4.

Auflagen

Die Zulassung wird mit folgenden Auflagen gemäß § 15 Abs. 4 des Gesetzes zum Schutz der Kulturpflanzen (PflSchG) in der Fassung der Bekanntmachung vom 14. Mai 1998 (BGBl. I. S. 971, 3512), zuletzt geändert durch Artikel 4 des Gesetzes vom 2. November 2011 (BGBl. I. S. 2162) verbunden:

Kennzeichnungsauflagen gemäß § 20 Abs. 2 Nr. 6 PflSchG in Verbindung mit § 15 Abs. 4 des Gesetzes zum Schutz der Kulturpflanzen (PflSchG) in der Fassung der Bekanntmachung vom 14. Mai 1998 (BGBl. I. S. 971, 3512), zuletzt geändert durch Artikel 4 des Gesetzes vom 2. November 2011 (BGBl. I. S. 2162):

(NN2002)
Das Mittel wird als schwach 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.

(SB110)
Die Richtlinie für die Anforderungen an die persönliche Schutzausrüstung im Pflanzenschutz "Persönliche Schutzausrüstung beim Umgang mit Pflanzenschutzmitteln" des Bundesamtes für Verbraucherschutz und Lebensmittelsicherheit ist zu beachten.

(SE110)
Dicht abschließende Schutzbrille tragen beim Umgang mit dem unverdünnten Mittel.

(SF245-01)

Behandelte Flächen/Kulturen erst nach dem Abtrocknen des Spritzbelages wieder betreten.

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

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

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

(WMK1)
Wirkungsmechanismus (HRAC-Gruppe): K1

(WMO)
Wirkungsmechanismus (HRAC-Gruppe): O

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

Sonstige Auflagen:
- keine -

Die Zulassung wird mit folgenden Auflagen gemäß § 36 Abs.1 Verwaltungsverfahrensgesetz verbunden:

- keine -

Vorbehalt

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

Angaben zur Einstufung und Kennzeichnung gemäß § 4 Gefahrstoffverordnung

Gefahrensymbole:	N, Xn
Gefahrenbezeichnungen:	Umweltgefährlich, Gesundheitsschädlich

Gefahrenhinweise (R-Sätze):

R 50/53: Sehr giftig für Wasserorganismen, kann in Gewässern längerfristig schädliche Wirkungen haben.

R 40 : Verdacht auf krebserzeugende Wirkung.

Sicherheitshinweise (S-Sätze):

S 36/37 : Bei der Arbeit geeignete Schutzkleidung und Schutzhandschuhe tragen

S 2 : Darf nicht in die Hände von Kindern gelangen

S 13 : Von Nahrungsmitteln, Getränken und Futtermitteln fernhalten

S 24 : Berührung mit der Haut vermeiden

S 35 : Abfälle und Behälter müssen in gesicherter Weise beseitigt werden

S 46 : Bei Verschlucken sofort ärztlichen Rat einholen und Verpackung oder Etikett vorzeigen

S 57 : Zur Vermeidung einer Kontamination der Umwelt geeigneten Behälter verwenden

Enthält 1,2-Benzisothiazol-3(2H)-on. Kann allergische Reaktionen hervorrufen.

Zur Vermeidung von Risiken für Mensch und Umwelt ist die Gebrauchsanleitung einzuhalten.

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

Signalwort:

(S1) Achtung

Gefahrenpiktogramme:

(GHS09) Umwelt

Gefahrenhinweise (H-Sätze):

(EUH 208-0098)
Enthält 1,2-Benzisothiazol-3(2H)-on. Kann allergische Reaktionen hervorrufen.

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

(H351)
Kann vermutlich Krebs erzeugen <Expositionsweg angeben, sofern schlüssig belegt ist, dass diese Gefahr bei keinem anderen Expositionsweg besteht>.

(H400)
Sehr giftig für Wasserorganismen.

(H410)
Sehr giftig für Wasserorganismen mit langfristiger Wirkung.

Sicherheitshinweise (P-Sätze):
- keine -

Nicht festgesetzte Anwendungsgebiete und nicht vorgesehene Anwendungen

Folgende Anwendungsgebiete werden bei der Zulassung nicht festgesetzt (siehe Anlage 2):
- keine -

Folgende Anwendungen werden bei der Zulassung nicht vorgesehen (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 6.2.8:
Hinweis und Begründung für die Kennzeichnungsauflage zum Wirkungsmechanismus (WMO:Aminopyralid; WMK1: Propyzamid):
Die HRAC-Klassifizierung ist als neutrale Information direkt jedem einzelnen Wirkstoff (hier: Aminopyralid und Propyzamid) zuzuordnen. Die Kennzeichnung erleichtert der Praxis die Bestimmung des Wirkungsmechanismus von Herbiziden und ermöglicht so ein gezieltes Wirkstoffmanagement.

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.

Für folgende Anwendungen ist die Bearbeitung noch nicht abgeschlossen:
- keine -

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. Hans-Gerd Nolting
Abteilungsleiter

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

Anlage

Anlage 1 zugelassene Anwendung: 007726-00/00-001

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung:	Einjährige einkeimblättrige Unkräuter, Einjährige zweikeimblättrige Unkräuter
Pflanzen/-erzeugnisse/Objekte:	Winterraps

2 Einsatzgebiet

Einsatzgebiet:	Ackerbau

3 Kennzeichnungsauflagen

3.1 Angaben zur sachgerechten Anwendung

Anwendungsbereich:	Freiland
- Erläuterungen:	
Anwendung im Haus- und Kleingartenbereich:	Nein
Erläuterung zum Schadorganismus:	
Stadium des Schadorganismus:	
- Erläuterungen:	
Erläuterung zur Kultur:	
Stadium der Kultur:	ab 14
- Erläuterungen:	
Anwendungszeitpunkt:	Nach dem Auflaufen, Spätherbst bis Winter, November bis Februar, nach dem Auflaufen der Unkräuter
- Erläuterungen:	
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	1
- für die Kultur bzw. je Jahr:	1
- Abstand:	
- Erläuterungen Anzahl Behandlungen:	
Mischungspartner:	
- Erläuterungen:	
Anwendungstechnik:	spritzen
- Erläuterungen:	

Aufwand:

- 1,5 l/ha in 200 bis 300 l Wasser/ha

- Erläuterungen:

Sonstige Ergänzungen und Hinweise: - keine -

3.2 Sonstige Kennzeichnungsauflagen

(NW642-1)
Die Anwendung des Mittels in oder unmittelbar an oberirdischen Gewässern oder Küstengewässern ist nicht zulässig. Unabhängig davon ist der gemäß Länderrecht verbindlich vorgegebene Mindestabstand zu Oberflächengewässern einzuhalten. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.

(VV215)
Behandelten Grünraps nicht verfüttern.

(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.

(WP682-2)
Einstreu, das von mit dem Mittel behandelten Flächen stammt, sowie Gülle, Jauche, Mist oder Kompost von Tieren, deren Einstreu von behandelten Flächen stammt, darf nur im eigenen Betrieb verwendet werden.

(WP683-2)
Gülle, Jauche, Mist oder Kompost von Tieren, deren Einstreu von mit dem Mittel behandelten Flächen stammt, darf nur auf Grünland, zu Getreide oder Mais ausgebracht werden. Bei allen anderen Kulturen sind Schädigungen nicht auszuschließen.

(WP685-1)
Bei vorzeitigem Umbruch sind Schäden an nachgebauten Kulturen möglich. Es können nur Mais, Sommerraps und Kohlarten nachgebaut werden.

(WP711)
Schäden an nachgebauten zweikeimblättrigen Zwischenfrüchten möglich.

(WP734)
Schäden an der Kulturpflanze möglich.

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

3.3 Wartezeiten

(F) Freiland: Winterraps
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.

4 Anwendungsbezogene Anwendungsbestimmungen

(NT101)
Die Anwendung des Mittels muss in einer Breite von mindestens 20 m zu angrenzenden Flächen (ausgenommen landwirtschaftlich oder gärtnerisch genutzte Flächen, Straßen, Wege und Plätze) 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 50 % eingetragen ist. Bei der Anwendung des Mittels ist der Einsatz verlustmindernder Technik nicht erforderlich, wenn die Anwendung mit tragbaren Pflanzenschutzgeräten erfolgt oder angrenzende Flächen (z. B. Feldraine, Hecken, Gehölzinseln) weniger als 3 m breit sind oder 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.
Begründung:
Das o.g. Pflanzenschutzmittel weist ein hohes Gefährdungspotenzial für terrestrische Nichtzielpflanzen auf. Bewertungsbestimmend ist hier die ER50 von 210,95 mL Präparat/ha für Lycopersicon esculentum 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 zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen.

REGISTRATION REPORT
Part B

Section 1: Identity, physical and chemical properties, other information
Detailed summary of the risk assessment

Product code:	**GF-2540**	
Active Substances:	**propyzamide**	**500 g/L**
	aminopyralid	**5.3 g/L**
	as potassium salt 6.3 g/L	

Central Zone
Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: **Dow AgroSciences**

Date: **August 2014**

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 GF-2540 containing the active substances propyzamide and aminopyralid.
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	**Aminopyralid** (decision not yet in force)	**Propyzamide** (Reg. (EU) No 540/2011)
Purity of active substance	min 920 g/kg	min 920 g/kg

Appendix 1 of this document contains the list of references included in this document for support of the evaluation. Appendix 2 of this document is the table of intended uses for GF-2540.

Information on the detailed composition of GF-2540 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

[redacted]

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)

Aminopyralid: min 975 g/kg
Relevant impurity: Picloram: max 40 g/kg

Propyzamide: min 920 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: GF-2540

Company code number: GF-2540

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

IIIA 1.4.1 Content of active substance and formulants

GF-2540 was not a representative formulation for the Annex I inclusion of both propyzamide and aminopyralid.

Pure active substance:

content of pure aminopyralid:	5.3 g/L
content of pure aminopyralid potassium:	6.3 g/L
content of pure propyzamide:	500 g/L
limits aminopyralid	4.5 – 6.1 g/L
Limits aminopyralid potassium:	5.36 – 7.25 g/L
limits propyzamide:	475 – 525 g/L

Technical active substance:

content of technical aminopyralid potassium: at minimum purity (92.0 %):	6.85 g/L	(0.60 % w/w)
content of technical propyzamide at minimum purity (92.0 %):	543.4 g/L	(47.46 % w/w)

The active substance aminopyralid is present in the formulation in the form of the potassium salt.

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	Aminopyralid	Propyzamide
1.4.3.2	CAS No.	150114-71-9	23950-58-5
1.4.3.2	EINECS No.	–	245-951-4
1.4.3.2	CIPAC No.	771	315
1.4.3.2	ELINCS	–	–
1.4.3.3	Salt, ester anion or cation present	Potassium salt	–

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

Propyzamide and aminopyralid do not contain any impurities of toxicological or ecotoxicological concern.

IIIA 1.5 Type of Preparation and Code

Type : Suspension Concentrate Code : SC

IIIA 1.6 Function

The product will be used as herbicide.

IIIA 1.7 Other/Special Studies

None.

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

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

The formulation was not a representative formulation for Annex I inclusion.

Tabelle 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	TSN031383-0001 Purity: 0.58% aminopyralid potassium and 43.6% propyzamide	The preparation is a brown liquid with a mild odour.	Y	Rozniak, M., 2010, NAFST-10-159	acceptable
Explosive properties (IIIA 2.2.1)	EEC A 14	TSN031383-0001	Formulation has no explosive properties	Y	Turner, B., 2010, NAFST-10-142	aacceptable. .
Oxidizing properties (IIIA 2.2.2)	EEC A 21	TSN031383-0001	Formulation has no oxidising properties.	Y	Turner, B., 2010, NAFST-10-142	acceptable.
Flash point (IIIA 2.3.1)	EEC A 9	TSN031383-0001	No flash point up to 100 °C.	Y	Rozniak, M., 2010, NAFST-10-159	acceptable.
Flammability (IIIA 2.3.2)	-	-	not required for liquid formulations	-	-	acceptable
Auto-flammability (IIIA 2.3.3)	EEC A 15 EEC A 16	TSN031383-0001	No auto-ignition below 400 °C.		Turner, B., 2010, NAFST-10-142	acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Acidity or alkalinity and pH (IIIA 2.4.1)	-	-	The test was not conducted, because the pH value of the neat product was between 4 and 10.	-	-	acceptable.
pH of a 1% aqueous dilution, emulsion or dispersion (IIIA 2.4.2)	CIPAC MT 75.3	TSN031383-0001	7.20 at 23 °C	Y	Rozniak, M., 2010, NAFST-10-159	acceptable.
		TSN031383-0001 Lot C2241-38-B	deionised water, 20 °C: 7.61 Neat formulation, 20 °C: 7.69 after 2 weeks, 54 °C : deionised water, 20 °C: 7.45 Neat formulation, 20 °C: 7.52	Y	Koors, B., 2010, FOR-09-111	
		TSN031383-0001 Lot C2241-38-B	after two and three years: pH 6.9 – 7.3 (diluted) pH 6.8 – 7.5 (neat formulation)	Y	Stock, M., 2013, FOR-09-114	
Kinematic viscosity (IIIA 2.5.1)	-	-	please refer to 2.5.2	-	-	acceptable.
Dynamic viscosity (IIIA 2.5.2)	OECD 114	TSN031383-0001	421 mPa s at 19.8 °C 328 mPa s at 40 °C nNon-Newtonian fluid	Y	Rozniak, M., 2010, NAFST-10-159	acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Surface tension (IIIA 2.5.3)	EEC A 5	TSN031383-0001	0.5 %, purified water, 20 °C: 34.0 mN/m 0.85 %, purified water, 20 °C: 32.5 mN/m	Y	Turner, B., 2010, NAFST-10-142	acceptable.
Relative density (IIIA 2.6.1)	EEC A 3	TSN031383-0001	d_4^{20} = 1.139	Y	Rozniak, M., 2010, NAFST-10-159	acceptable.
Bulk or tap density (IIIA 2.6.2)	-	-	not relevant for liquid formulations	-	-	acceptable
Storage Stability after 14 days at 54º C (IIIA 2.7.1)	CIPAC MT 46.3	TSN031383-0001 Lot C2241-38-B	storage material: glass The content of the active substances does not decrease > 5 %.. Content of aminopyralid potassium: before storage: 0.54 wt% after storage: 0.54 wt% Content of propyzamide: before storage: 43.0 wt% after storage: 43.1 wt% The changes of appearance (after hand shaking), pH, persistent foaming, wet sieve test, suspensibility, spontaneity of dispersion and pourability are	Y	Koors, B., 2010, FOR-09-111	acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
			negligible			
Stability after storage for other periods and/or temperatures (IIIA 2.7.2)	CIPAC MT 46.3 storage conditions: 8 weeks at 40 °C	TSN031383-0001 Lot C2241-38-B	Storage material: PET and HDPE (1 L bottle) The content of the active substances does not decrease > 5 %. Content of aminopyralid potassium: before storage: 0.54 wt% after storage: 0.56 wt% Content of propyzamide: before storage: 43.0 wt% after storage: 43.2 / 43.3 wt% The changes of appearance, pH, persistent foaming, wet sieve test, suspensibility, spontaneity of dispersion and pourability are negligible. Both bottle types showed no evidence of corrosion.	Y	Koors, B., 2010, FOR-09-112	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	CIPAC MT 39.3	TSN031383-0001 Lot C2241-38-B	Storage material: glass No separated material,	Y	Koors, B., 2010, FOR-09-111	acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
stability (IIIA 2.7.4)			homogeneous liquid. The product shows good low temperature stability, the effects on wet sieve test and suspensibility are negligible.			
Ambient temperature shelf life (IIIA 2.7.5)	GIFAP Monograph No. 17	TSN031383-0001 Lot C2241-38-B	Storage material: HDPE and PET 1 L bottles; samples were stored for two and three years, the temperature range was -9 to 49 °C. The content of the active substances does not decrease > 5 %. Content of aminopyralid potassium: before storage: 0.54 wt% after storage: 0.53 – 0.55 wt% Content of propyzamide: before storage: 43.0 wt% after storage: 43.1 – 44.2 wt% The changes of appearance (after hand shaking), pH, persistent foaming, wet sieve test, suspensibility, spontaneity of dispersion and pourability are negligible. HDPE bottles were unchanged after three years, no weight loss was	Y	Stock, M., 2013, FOR-09-114	acceptable. The preparation is stable for two years at ambient temperature in HDPE and PET. After three years the HDPE packaging were unchanged, but the PET packaging was severely panelled.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
			detected. The PET bottles were in good condition after two years, after three years they were severely panelled and a weight loss of 1.7 % was observed.			
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	TSN031383-0001 Lot C2241-38-B	CIPAC water D, 5.0 %: Before storage 10s: 36 mL 1 min: 8 mL 3 min: 0 mL 12 min: 0 mL 2 weeks, 54 °C 10s: 37 mL 1 min: 1 mL 3 min: 0 mL 12 min: 0 mL	Y	Koors, B., 2010, FOR-09-111	acceptable.
		TSN031383-0001 Lot C2241-38-B	after 2 years in HDPE, 3 years in HDPE, 2 years in PET and three years in PET: 10 s: 32 / 18 / 26 / 18 mL 1 min: 8 / 0 / 0 / 0 mL 3 min: 0 / 0 / 0 / 0 mL	Y	Stock, M., 2013, FOR-09-114	

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)	CIPAC MT 161	TSN031383-0001 Purity: 0.58% aminopyralid potassium and 43.6% propyzamide	CIPAC water D, 0.1 %: before storage aminopyralid potassium: 101 % propyzamide: 98 % after 2 weeks, 54 °C aminopyralid potassium: 101 % propyzamide : 95 % after 7 days, 0 °C aminopyralid potassium: 101 % propyzamide : 97 % CIPAC water D, 5.7 %: before storage aminopyralid potassium: 102 % propyzamide: 94 % after 2 weeks, 54 °C aminopyralid potassium: 101 % propyzamide : 91 % after 7 days, 0 °C aminopyralid potassium: 103 % propyzamide : 97 %	Y	Koors, B., 2010, FOR-09-111	acceptable.
	CIPAC MT 161	TSN031383-0001 Lot C2241-38-B	after three years in HDPE: 100 % aminopyralid, > 98 % propyzamide. after three years in PET:	Y	Stock, M., 2013, FOR-09-114	

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
			100 % aminopyralid, > 96 % propyzamide.			
Spontaneity of dispersion (IIIA 2.8.3.2)	CIPAC MT 160	TSN031383-0001	CIPAC water D, 5 %: before storage aminopyralid potassium: 100 % propyzamide: 98 % after 2 weeks, 54 °C aminopyralid potassium: 100 % propyzamide : 97 %	Y	Koors, B., 2010, FOR-09-111	acceptable.
	CIPAC MT 160	TSN031383-0001 Lot C2241-38-B	after three years in HDPE: 94 % after three years in PET: 89-90 %	Y	Stock, M., 2013, FOR-09-114	
Dilution stability (IIIA 2.8.4)	-	-	not required for SC formulations	-	-	acceptable
Dry sieve test (IIIA 2.8.5.1)	-	-	not required for SC formulations	-	-	acceptable
Wet sieve test (IIIA 2.8.5.2)	CIPAC MT 59.3	TSN031383-0001 Purity: 0.58% aminopyralid potassium and 43.6% propyzamide	Before storage 0.0 % on 75 µm sieve After 2 weeks, 54 °C 0.05 % on 75 µm sieve After 7 days, 0 °C 0.05 % on 75 µm sieve	Y	Koors, B., 2010, FOR-09-111	acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
	CIPAC MT 185	TSN031383-0001 Lot C2241-38-B	after three years in HDPE and PET: 0.0 % on 75 µm sieve	Y	Stock, M., 2013, FOR-09-114	
Particle size distribution (IIIA 2.8.6.1)	-	-	-	-	-	acceptable, based on the results of the wet-sieve test
Nominal size range of granules (IIIA 2.8.6.2)	-	-	not required for liquid formulations	-	-	acceptable
Dust content (IIIA 2.8.6.3)	-	-	not required for liquid formulations	-	-	acceptable
Particle size of dust (IIIA 2.8.6.4)	-	-	not required for liquid formulations	-	-	acceptable
Friability and attrition (IIIA 2.8.6.5)	-	-	not required for liquid formulations	-	-	acceptable
Emulsifiability (IIIA 2.8.7.1)	-	-	not required for SC formulations	-	-	acceptable
Dispersibility (IIIA 2.8.7.1)	-	-	not required for SC formulations	-	-	acceptable
Flowability (IIIA 2.8.8.1)	-	-	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
Pourability (including rinsed residue) (IIIA 2.8.8.2)	CIPAC MT 148	TSN031383-0001 Lot C2241-38-B	before storage: residue: 2.40 % residue after rinsing: 0.15 % after 2 weeks, 54 °C: residue: 2.16 % residue after rinsing: 0.13 %	Y	Koors, B., 2010, FOR-09-111	acceptable.
		TSN031383-0001 Lot C2241-38-B	after two and three years: residue: 1.69 – 1.97 % residue after rinsing: 0.12 – 0.15 %	Y	Stock, M., 2013, FOR-09-114	
Dustability following accelerated storage (IIIA 2.8.8.3)	-	-	not required for SC formulations	-	-	acceptable
Physical compatibility of tank mixes (IIIA 2.9.1)	-	-	no tank mixes are recommended	-	-	acceptable.
Chemical compatibility of tank mixes (IIIA 2.9.2)	-	-	no tank mixes are recommended	-	-	acceptable.
Distribution to seed (IIIA 2.10.1)	-	-	not intended for seed treatment	-	-	acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Adhesion to seeds (IIIA 2.10.2)	-	-	not intended for seed treatment	-	-	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.

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

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of a brown liquid, with a mild odour. It is not explosive and has no oxidising properties, the self ignition temperature is above 400 °C. In aqueous solution, it has a pH value around 7.2. The stability data indicate a shelf life of at least 2 years at ambient temperature. The technical characteristics are acceptable for a suspension 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

GF-2540 contains the active substances propyzamide (500 g a.s./L) and aminopyralid (5.3 g a.s./L). The product is intended to be used as a post-emergence herbicide for the control of annual monocotyledonous and dicotyledonous weeds in winter oil seed rape.

IIIA 3.2 Nature of the Effects on Harmful Organisms

Propyzamide inhibits cell division and photosynthesis. This results in inhibition of the formation of microtubuli and division of cell nucleus. Germination of seed will not be interrupted. After germination, seedlings become chlorotic and die as a consequence of interrupted photosynthesis. Site of action (HRAC-group): K1

Aminopyralid accumulates in meristematic tissue and influences cell division, cell elongation and cell extension as well as RNA synthesis. Consequently, meristematic tissue dies off. The tissues of dicotyledonous plants are destroyed, while monocotyledonous plants are not affected. Typical symptoms of susceptible plants are deformation and curling of young leaves and stems followed by growth stop and necrosis. Site of action (HRAC-group): O.

IIIA 3.3 Details of Intended Use

IIIA 3.3.1 Details of existing and intended uses

Please refer to Appendix 2.

IIIA 3.3.2 Details of harmful organisms against which protection is afforded

Please refer to 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.

IIIA 3.5 Concentration of the Active Substance in the Material Used

Please refer to Appendix 2.

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

Please refer to Appendix 2.

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.

IIIA 3.7.2 Growth stages of crops or plants to be protected

Please refer to Appendix 2. For further information please refer to Part B Section 7.

IIIA 3.7.3 Development stages of the harmful organism concerned

Please refer to Appendix 2. For further information please refer to Part B Section 7.

IIIA 3.7.4 Duration of protection afforded by each application

For further information please refer to Part B Section 7.

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

For further information 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 are considered to be acceptable.

IIIA 4.1.1 Description and specification of the packaging

0.25, 0.5, 1.0, 2.0 litre bottles:	material:	PET or HDPE
	shape/size:	no data
	opening:	45 mm inner diameter
	closure:	screw cap
	seal:	induction seal
3.0 and 5.0 litre bottles:	material:	PET or HDPE
	shape/size:	no data
	opening:	63 mm inner diameter
	closure:	screw cap
	seal:	Induction seal
10 and 20 litre bottles:	material:	PET or HDPE
	shape/size:	no data
	opening:	no data
	closure:	no data
	seal:	no data

Remarks by zRMS:

In the submitted dRR only packaging made of PET is mentioned.

The 10 L and 20 L packages are only mentioned in the application form for Germany.

IIIA 4.1.2 Suitability of the packaging and closures

Report:	Koors, B., 2010
Title:	Eight-Week Accelerated Storage Stability and Package Corrosion Characteristics of GF-2540 in 1-L PET and 1-L HDPE Bottles
Document No:	FOR-09-112
Guidelines:	ADR/RID
GLP	Yes

The packaging complies with ADR regulations having been tested using the ADR test methods appropriate to the pack type and material and classification of the contents and an appropriate UN certificate issued.

IIIA 4.1.3 Resistance of the packaging material to its contents

Report:	Koors, B., 2010
Title:	Eight-Week Accelerated Storage Stability and Package Corrosion Characteristics of GF-2540 in 1-L PET and 1-L HDPE Bottles
Document No:	FOR-09-112
Guidelines:	ADR/RID
GLP	Yes

An 8 week storage stability study at 40°C has been performed with GF-2540 and showed no significant physical changes and all performance properties were within acceptable limits. GF-2540 is chemically and physically compatible with HDPE and PET.

Weight loss after 24 month: no significant weight loss for HDPE packaging. For PET packaging a weight loss of 0.7 % after two years and 1.7 % after 3 years was determined.

Package: 0.25, 0.5, 1.0, 2.0, 3.0, 10, 20 L PET and HDPE bottles.

IIIA 4.2 Procedures for Cleaning Application Equipment

IIIA 4.2.1 Procedures for cleaning application equipment and protective clothing

To avoid subsequent injury to crops other than propyzamide and aminopyralid approved uses, all spraying equipment must be thoroughly cleaned both inside and out:

1. Immediately after spraying, drain tank completely. Any contamination on the outside of the spraying equipment should be removed by washing with clean water.

2. Rinse inside of tank with clean water and flush through booms and hoses using at least one tenth of the spray tank volume. Drain tank completely.

3. Half fill tank with clean water. Agitate and then briefly flush the boom and hoses. Top up with water making sure the tank is completely full and allow to stand for 15 minutes with agitation. Flush the boom and hoses and drain tank completely.

4. Nozzles and filters should be cleaned separately and removed if necessary.

5. For disposal of washings, follow local regulations. Do not spray onto sensitive crop or land intended for cropping with sensitive crop.

Note: If it is not possible to drain the tank completely, step 3 must be repeated before going onto step 4.

IIIA 4.2.2 Effectiveness of the cleaning procedures

See point 4.2.1.

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

Report:	Dow Agro Sciences
Title:	Safety data sheet in Registration Report Part C GF-2540
Document No:	-
Guidelines:	EEC 1907/2006
GLP	No, not subject to GLP regulations

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

IIIA 4.4.1 Warehouse storage

Refer to the safety data sheet for GF-2540.

IIIA 4.4.2 User level storage

Refer to the safety data sheet for GF-2540.

IIIA 4.4.3 Transport

Refer to the safety data sheet for GF-2540.

IIIA 4.4.4 Fire

Refer to the safety data sheet for GF-2540.

IIIA 4.4.5 Nature of protective clothing proposed

Refer to the safety data sheet for GF-2540.

IIIA 4.4.6 Characteristics of protective clothing proposed

Refer to the safety data sheet for GF-2540.

IIIA 4.4.7 Suitability and effectiveness of protective clothing and equipment

Refer to the safety data sheet for GF-2540.

IIIA 4.4.8 Procedures to minimise the generation of waste

Refer to the safety data sheet for GF-2540.

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

Refer to the safety data sheet for GF-2540.

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

Refer to the safety data sheet for GF-2540.

IIIA 4.5.1 Containment of spillages

Refer to the safety data sheet for GF-2540.

IIIA 4.5.2 Decontamination of areas, vehicles and buildings

Refer to the safety data sheet for GF-2540.

IIIA 4.5.3 Disposal of damaged packaging, adsorbents and other materials

Refer to the safety data sheet for GF-2540.

IIIA 4.5.4 Protection of emergency workers and bystanders

Refer to the safety data sheet for GF-2540.

IIIA 4.5.5 First aid measures

Refer to the safety data sheet for GF-2540.

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

GF-2540 does not require specific neutralisation. Any spilt material should be absorbed onto dry, inert material (e.g. sand) and swept up into labelled containers for disposal.

IIIA 4.6.1 Details of proposed procedures for small quantities

Not applicable, no neutralization procedures are proposed

IIIA 4.6.2 Evaluation of products of neutralization (small quantities)

Not applicable, no neutralization procedures are proposed

IIIA 4.6.3 Procedures for disposal of small quantities of neutralized waste

Not applicable, no neutralization procedures are proposed

IIIA 4.6.4 Details of proposed procedures for large quantities

Not applicable, no neutralization procedures are proposed

IIIA 4.6.5 Evaluation of products of neutralization (large quantities)

Not applicable, no neutralization procedures are proposed

IIIA 4.6.6 Procedures for disposal of large quantities of neutralized waste

Not applicable, no neutralization procedures are proposed

IIIA 4.7 Pyrolytic Behaviour of the Active Substance

As the halogen content of propyzamide and aminopyalid are less than 60%, there is no need for a pyrolysis study.

IIIA 4.8 Disposal Procedures for the Plant Protection Product

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

If destruction is necessary then incineration is recommended, however contact with the supplier should be made to evaluate the return of excess material before destruction is undertaken. Incineration (minimum 1220°C for 2 seconds) must take place in a facility approved to handle chemical waste. As the halogen content is <60% there is no need for a pyrolysis study.

Container and washings must be disposed of safely and in accordance with applicable regulations. The preferred options are to send to a licensed reclaimer or to permitted incinerators. Do not re-use the container for any purpose. No other data is available to assess the safety and effectiveness of these procedures.

IIIA 4.8.2 Methods other than controlled incineration for disposal

No additional disposal methods are recommended

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

Proposals for classification and labelling of BAS 512 16 F in accordance with the EC Directive on dangerous preparations 1999/45/EC and Directive 2001/59/EC (as amended) are presented below:

Physico-chemical properties

Table 11.3-1 Physico-chemical properties

Study Type	Findings (triggered risk phrase)	Reference

Table 11.3-1 Physico-chemical properties

Study Type	Findings (triggered risk phrase)	Reference
Explosivity	Not explosive (-)	Turner, B., 2010, NAFST-10-142
Oxidizing properties	Not oxidizing (-)	Turner, B., 2010, NAFST-10-142
Flammability	Auto-ignition temperature below 400°C	Turner, B., 2010, NAFST-10-142
Content of hydrocarbon	< 10 % w/w	
Viscosity (dynamic)	40 °C, 328 mPa s, non-Newtonian liquid	Rozniak, M., 2010, NAFST-10-159
Surface tension	0.5 %, purified water, 20 °C: 34.0 mN/m 0.85 %, purified water, 20 °C: 32.5 mN/m	Turner, B., 2010, NAFST-10-142

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), Published or not	**Data protection claimed**	**Owner**	**How considered in dRR** Study-Status / Usage*
KIIIA1 2.1, 2.3.1, 2.5.2, 2.6.1	Rozniak, M.	2010	Determination of odor, color, physical state, oxydising and reducing action, flash point, pH, viscosity and density of GF-2540, an end use product containing aminopyralid potassium and propyzamide under GLP. NAFST-10-159, GLP, unpublished	Y	DOW	1
KIIIA1 2.2.1, 2.2.2, 2.3.3, 2.5.3	Turner, B.	2010	Determination of surface tension, explosive property, auto ignition temperature and oxydising properties. NAFST-10-142, GLP, unpublished	Y	DOW	1
KIIIA1 2.4.2, 2.7.1, 2.7.4, 2.8.2, 2.8.3.1, 2.8.3.2, 2.8.5.2, 2.8.8.3	Koors, B.	2010	GF-2540 one week low temperature and two weeks accelerated storage stability in glass. FOR-09-111 GLP, unpublished	Y	DOW	1
KIIIA1 2.7.2, 4.1.1, 4.1.2, 4.1.3	Koors, B.	2010	Eight week accelerated storage stability and package corrosion characteristics of Gf-2540 in 1L PET and 1L HDPE bottles. FOR-09-112, GLP, unpublished	Y	DOW	1
KIIIA1 2.7.5	Stock, M.	2013	Storage stability and package corrosion characteristics of GF-2540 in HDPE and PET bottles; two year and three year ambient study FOR-09-114 GLP, unpublished	Y	DOW	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

GAP rev. BVL, date: 2014-03-19

PPP (product name/code)	**GF-2540**	**Formulation type:**	**SC**
active substance 1	**Propyzamid**	**Conc. of as 1:**	**500 g/L**
active substance 2	**Aminopyralid**	**Conc. of as 2:**	**5.3 g/L**
safener -		**Conc. of safener:**	**-**
synergist	**-**	**Conc. of synergist:**	**-**
Applicant:	**DOW AgroSciences GmbH**	**professional use**	☒
Zone(s): central/EU		**non professional use**	☐

Verified by MS: yes

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		
001	DE	winter oil-seed rape (BRSNW)	F	annual monocotyledonous weeds (TTTMS), annual dicotyledonous weeds (TTTDS) (post emergence of weeds)	Spraying	BBCH >14 Late autumn to winter (November to February)	a) 1 b) 1	a) 1.5 b) 1.5	a) Propyzamid 750 g/ha Aminopyralid 7.95 g/ha b) Propyzamid 750 g/ha Aminopyralid 7.95 g/ha	20 0 - 300		NW 642-1 NT101 WH9161 WP734 WP711 WP740 WP682-2 WP683-2

Remarks:

(1) Numeration of uses in accordance with the application/as verified by MS
(2) Member State(s) or zone for which use is applied for
(3) 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)
(4) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(5) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds, developmental stages
(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 of treatment(s) (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 applications possible under practical conditions of use for each single application and per year (permanent crops) or crop (annual crops) must be provided
Min. interval between applications (days) were relevant
(10) The application rate of the product a) max. rate per appl. and b) max. total rate per crop/season must be given in metric units (e.g. kg or L product / ha)
(11) The application rate of the active substance a) max. rate per appl. and b) max. total rate per crop/season must be given in metric units (e.g. g or kg / ha)
(12) The range (min/max) of water volume under practical conditions of use must be given (L/ha)
(13) PHI - minimum pre-harvest interval
(14) Remarks may include: Extent of use/economic importance/restrictions/minor use etc.

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, suspensibility, particle size distribution (laser diffraction) and pourability incl. rinsed residue.

Some deviations from the data submitted by the applicant were detected for surface tension and foam volume after 10 s, but these deviations are not considered as critical.

The formulation complies with the chemical, physical and technical criteria which are stated for this type of formulation in the FAO/WHO manual (2010).

REGISTRATION REPORT
Part B

Section 2: Analytical Methods
Detailed summary of the risk assessment

Product code:	**GF-2540**
Active Substances:	**propyzamide 500 g/L**
	aminopyralid 5.3 g/L
	as potassium salt 6.3 g/L

Central Zone
Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant:	**Dow AgroSciences**
Date:	**01/09/2014**

Table of Contents

IIIA 5 METHODS OF ANALYSIS

This document summarises the information related to the analytical methods for the product GF-2540 containing the active substances propyzamide and aminopyralid.

Propyzamide is approved according to Regulation (EC) No 1107/2009.
Aminopyralid is a new active substance which is undergoing review for Annex I inclusion, with UK Chemicals Regulation Directorate (CRD) serving as the rapporteur. The Draft Assessment Report (DAR) on aminopyralid was issued by the United Kingdom in August, 2006, with a recommendation for inclusion of the active substance in Annex I. The public version of the DAR was published by EFSA on 16 January 2008. Provisional authorisations of aminopyralid formulations have been granted in 18 member states.

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 BAS 512 16 F 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 for the active substances 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

There are no relevant impurities in the formulation GF-2540

IIIA 5.2 Methods for the Analysis of the Plant Protection Product

Analytical methods for the determination of propyzamide and aminopyralid and their impurities and relevance of CIPAC methods were evaluated as part in the EU review. The respective data are considered adequate and are not included in this submission. Additional studies to support the registration of GF-2540 not previously assessed are given below. 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 GF-2540 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

The following analytical method for the determination of the active substances in the plant protection product performed on GF-2540 has not previously been reviewed.

Report:	5.2.2/1 Jones, J., 2009
Title:	Analytical Method and Validation for the Determination of Aminopyralid and Propyzamide in GF-2540 Formulation
Document No:	DAS-AM-G-09-24
Guidelines:	SANCO/303/99 rev. 4
GLP	Yes

Method description
Approximately 300 mg of GF-2540 were accurately weighed into a glass jar. To each jar, 5 mL of water and 5 mL internal standard solution were added. Using a graduated cylinder 90 mL of acetonitrile was added. The jars were mixed well, and the solutions were analyzed using the conditions given
Determination was conducted using reversed phase high pressure liquid chromatography with a 4.6 x 250 mm x 5 µm Zorbax SB-phenyl column. The detector was ultra-violet set at a wavelength of 290 nm. Quantification was done by internal standard calibration using diethyl phthalate.

Method validation
The method is applicable to the assay of aminopyralid (a.e.) and propyzamide in GF-2540 formulation over the range of 0.28% to 1.39% and 20.0% to 86.8% propyzamide by weight, respectively.

Table containing the methods and validation of the methods (formulation GF-2540)

Analyte	Linearity n = 7	Accuracy n = 5 Mean [%]	Repeatability n = 5 [% RSD]	Specificity/Inteferences
aminopyralid(a.e.)	0.28 % to 1.39 % by weight r = 1.0000	98.7 ´%	1.77 % acceptable acc. modified Horwitz-eqn: 2.93 %	Interferences were observed in the formulation blank of 2.3 % of the aminopyralid peak. Chromatograms of solvent blank, formulation blank, internal standard, aminopyralid test substance, and propyzamide test substance were submitted.
propyzamide	20.0 % to 86.8 % by weight	98.6 %	0.41 % acceptable acc.	no interferences were observed

	r = 0.9998		modified Horwitz-eqn: 1.52 %	

Summary

The active substances aminopyralid (a.e.) and propyzamide are dissolved in acetonitril / water and chromatographed on a HPLC reversed phase system with UV-detection and internal calibration.
The method is applicable to the assay of aminopyralid (a.e.) and propyzamide in GF-2540 formulation.

IIIA 5.2.3 Applicability of existing CIPAC methods

There are no CIPAC methods available for the determination of propyzamide or aminopyralid.

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

There are no relevant impurities in the formulation GF-2540. Therefore, no analytical method is required.

IIIA 5.2.5 Description of analytical methods for the determination of formulants

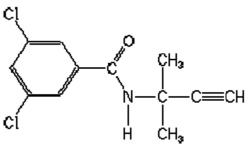
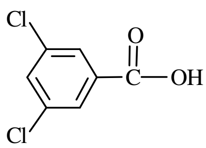
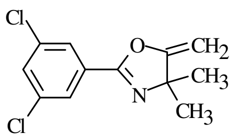
No formulants with toxicological or ecotoxicological relevant compounds are present in the formulation. Therefore, no analytical methods for the determination of formulants are necessary.

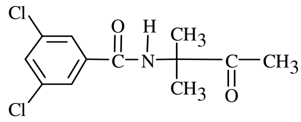
IIIA 5.3 Description of Analytical Methods for the Determination of Residues

IIIA 5.3.1 Evaluation of propyzamide

The conclusion regarding the peer review of the analytical methods for residues of propyzamide are summarized in Review Report 6502/VI/99-final.

Table 5.3-1: Information on the active substance propyzamide

Name of component of residue definiton substance code IUPAC name formula	**Structural formula**
Propyzamide, RH-23315, RH-3315 3,5-Dichloro-N-(1,1-dimethyl-prop-2-ynyl)-benzamide $C_{12}H_{11}Cl_2NO$	
3,5-Dichlorobenzoic acid, 3,5-DCBA $C_7H_4Cl_2O_2$	
RH-24644, RH-4644 2-(3,5-Dichlorophenyl)-4,4-dimethyl-5-methylene-oxazoline $C_{12}H_{11}Cl_2NO$	

RH-24580, RH-4580, propyzamide-ketone N-(1,1-Dimethylacetonyl)-3,5-dichlorobenzamide $C_{12}H_{13}Cl_2NO_2$	

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

Compared to the residue definition proposed in the Draft Assessment Report (incl. its addenda) the current legal residue definition is identical.

Table 5.3-2: Relevant residue definitions

Matrix	Relevant residue	Reference Remarks
Plant material	Propyzamide	Regulation (EC) No 149/2008, annex II, annex III part B
Foodstuff of animal origin	Sum of propyzamide and all metabolites containing the 3,5-dichlorobenzoic acid fraction, expressed as propyzamide	Regulation (EC) No 149/2008, annex II, annex III part B
Soil	Propyzamide, RH-24644 and RH-24580	DAR, vol. 1, list of endpoints, 01/2003, ASB2010-10283
Surface water	Propyzamide	DAR, vol. 1, list of endpoints, 01/2003, ASB2010-10283
Drinking/ground water	Propyzamide	DAR, vol. 1, list of endpoints, 01/2003, ASB2010-10283
Air	Propyzamide	Generally defined
Body fluids/tissue	Not residue relevant	Not classified as T / T+

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 149/2008, annex II, annex III part B
Plant, acidic commodities	0.02 mg/kg	Regulation (EC) No 149/2008, annex II, annex III part B
Plant, dry commodities	0.02 mg/kg	Regulation (EC) No 149/2008, annex II, annex III part B
Plant, high oil content	0.02 mg/kg	Regulation (EC) No 149/2008, annex II, annex III part B
Plant, difficult matrices (hops, spices, tea)	0.05 mg/kg	Regulation (EC) No 149/2008, annex II, annex III part B
Meat	0.02 mg/kg	Regulation (EC) No 149/2008, annex II, annex III part B
Milk	0.01 mg/kg	Regulation (EC) No 149/2008, annex II, annex III part B

Eggs	0.02 mg/kg	Regulation (EC) No 149/2008, annex II, annex III part B
Fat	0.05 mg/kg	Regulation (EC) No 149/2008, annex II, annex III part B
Liver, kidney	0.05 mg/kg	Regulation (EC) No 149/2008, annex II, annex III part B
Soil	0.05 mg/kg	Common limit
Drinking/ground water	0.1 µg/L	General limit for drinking water
Surface water	600 µg/L	NOEC *Daphnia magna*; EC Review-Report SANCO 6502/VI/99-final, 2007; ASB2013-5446
Air	24 µg/m^3	AOEL sys: 0.08 mg/kg bw/d, EC Review-Report SANCO 6502/VI/99-final, 2007 ASB2013-5446
Tissue (meat or liver)	Not required	Not classified as T / T+
Body fluids	Not required	Not classified as T / T+

IIIA 5.3.1.2 Description of Analytical Methods for the Determination of Residues of Propyzamide in Plant Matrices

An overview of the acceptable methods and possible data gaps for analysis of propyzamide in plant matrices is given in the following tables. Analytical methods were presented in the DAR and were considered as acceptable. Nevertheless according to the latest SANCO/825/00 rev. 8.1 guidance documents the extent of validation is not sufficient. Therefore, additional methods are given in Appendix 2.

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	Anonymous/ 2008	Anonymous/ 2008	Anonymous, 2010
Acidic	Anonymous/ 2008	Anonymous/ 2008	Anonymous, 2010
Fatty	Anonymous/ 2013	Anonymous/ 2013	Anonymous, 2010
Dry	Anonymous/ 2008	Anonymous/ 2008	Anonymous, 2010
Difficult	Not required for the intende GAP	Not required for the intende GAP	Not required for the intende GAP

Table 5.3-5: Statement on extraction efficiency

	Method for products of plant origin
Required, available from:	DAR, vol. 3, B.6.1
Not required, because:	

In the DAR metabolism studies in lettuce and alfalfa are described. The majority of TRR (> 88 %) is extractable by organic solvent (methanol).

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 section
Anonymous, 2008 <u>ASB2008-5464</u>	High water content, dry, acidic, high sugar content	0.01 mg/kg	LC-MS/MS, RP column, ESI+, m/z 256→173	ILV included; EN 15662:2008 (QuEChERS)	Appendix 2
Anonymous, 2013 <u>ASB2013-7593</u>	fatty	0.01 mg/kg	LC-MS/MS, RP column, ESI+, m/z 256→173	ILV included, QuEChERS method for fatty matrix (QuOiL)	Appendix 2
Anonymous, 2010 <u>ASB2013-8342</u>	High water content, dry, acidic, fatty	0.01 mg/kg	GC-ECD	L .00.00-34 multiresidue method	Appendix 2

IIIA 5.3.1.3 Description of Analytical Methods for the Determination of Residues of Propyzamide in Animal Matrices

In the DAR several studies were described for the quantification of propyzamide in animal matrices. Nevertheless, according to the latest SANCO/825/00 rev. 8.1 guidance document the extent of validation and the performance of the methods are not sufficient. E.g. the number of fortified samples per level is not sufficient and mean recoveries per level were not reported. Chromatograms of fortified samples and standard are missing. The method uses GC-ECD with packed column which is not state-of-the-art. New studies were not provided.

Table 5.3-7: 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	missing	missing	missing
eggs	missing	missing	missing
meat	missing	missing	missing
fat	missing	missing	missing
kidney, liver	missing	missing	missing

Table 5.3-8: Statement on extraction efficiency

	Method for products of animal origin
Required, available from:	open
Not required, because:	

IIIA 5.3.1.4 Description of Methods for the Analysis of Propyzamide in Soil

An overview of the acceptable methods and possible data gaps for analysis of propyzamide in soil is given in the following tables. New studies were not provided.

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

Component(s) of residue definition	Primary method	Confirmatory method
Propyzamide	Chamberlin, 1997	Chamberlin, 1997

Table 5.3-10: Methods for soil

Author(s), year	Method LOQ	Principle of method	Comment	Evaluated in
Chamberlin, 1997 (MET2000-164)	0.01 mg/kg	GC-ECD, RTX-5 column	Confirmation by RTX-200 column included	Review Report, 6502/VI/99 final, 2003, Appendix IIIA *)

* EU agreed method

IIIA 5.3.1.5 Description of Methods for the Analysis of Propyzamide in Water

An overview of the acceptable methods and possible data gaps for analysis of propyzamide in surface and drinking water is given in the following table. A published study for quantification of propyzamide in drinking water by LC-MS/MS is available. The method quantifies the residues with LC-MS/MS after direct injection. Because the required limit for surface water is more than 3000 fold higher than the LOQ, the method is also accepted for surface water. For the detailed evaluation of the additional study it is referred to Appendix 2.

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

Component(s) of residue definition	Matrix	Primary method	Confirmatory method
Propyzamide	Drinking water, surface water	Müller-Kallert/ 1994	Greulich/ 2006

Table 5.3-12: Methods for drinking water and surface water

Author(s), year	Method LOQ	Principle of method	Comment	Evaluated in
Müller-Kallert, 1994 (MET2000-166)	0.05 µg/L (drinking water) 0.1 µg/L (surface water)	GC-ECD, DB-5 column		DAR, vol. 3, B.4.3.2 *)
Greulich/ 2006 (ASB2011-8450)	0.1 µg/L (drinking water)	LC-MS/MS, RP18 column, ESI+, m/z 256→190, 256→173	Confirmation included, also accepted for surface water	Appendix 2

* EU agreed method

IIIA 5.3.1.6 Description of Methods for the Analysis of Propyzamide in Air

Acceptable methods for analysis of propyzamide in air are not provided.

IIIA 5.3.1.7 Description of Methods for the Analysis of Propyzamide in Body Fluids and Tissues

Methods for body fluids and tissues are not required, because propyzamide 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).

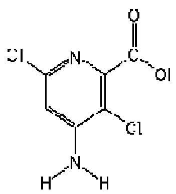
IIIA 5.3.1.8 Other Studies/ Information

Other studies were not provided.

IIIA 5.3.2 Evaluation of Aminopyralid

The conclusion regarding the peer review of the analytical methods for residues of aminopyralid are summarized in EFSA Journal 2013;11(9):3352.

Table 5.3-13: Information on the active substance aminopyralid

Name of component of residue definiton **substance code** **IUPAC name** **formula**	**Structural formula**
Aminopyralid, XDE-750 4-Amino-3,6-dichloropyridine-2-carboxylic acid $C_6 H_4 Cl_2 N_2 O_2$	

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

The current legal residue definition for plant material is not identical to the residue definition proposed in the Draft Assessment Report (incl. its addenda). Whereas the active ingredient is defined as relevant residue in Regulation (EC) No 251/2013, the EFSA proposes the inclusion of aminopyralid conjugates in the residue definition. The proposed analytical methods for monitoring include a hydrolysis step releasing the conjugates. Therefore, the residue analytical methods could result in an overestimation of the currently regulated residue definition.

Table 5.3-14: Relevant residue definitions

Matrix	Relevant residue	Reference Remarks
Plant material	Aminopyralid	Regulation (EC) No 251/2013,annex III part A
Plant material	Sum of aminopyralid and its conjugates expressed as aminopyralid	EFSA conclusion on pesticide peer review, EFSA Journal 2013;11(9):3352; ASB2013-11899
Foodstuff of animal origin	Aminopyralid	Regulation (EC) No 251/2013,annex III part A EFSA conclusion on pesticide peer review, EFSA Journal 2013;11(9):3352; ASB2013-11899
Soil	Aminopyralid	EFSA conclusion on pesticide peer review, EFSA Journal 2013;11(9):3352; ASB2013-11899
Surface water	Aminopyralid	EFSA conclusion on pesticide peer review, EFSA Journal 2013;11(9):3352; ASB2013-11899
Drinking/ground water	Aminopyralid	EFSA conclusion on pesticide peer review, EFSA Journal 2013;11(9):3352; ASB2013-11899
Air	Aminopyralid	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 251/2013, annex III part A
Plant, acidic commodities	0.01mg/kg	Regulation (EC) No 251/2013,, annex III part A
Plant, dry commodities	0.02 mg/kg	Regulation (EC) No 251/2013, annex III part A
Plant, high oil content	0.01 mg/kg	Regulation (EC) No 251/2013, annex III part A
Plant, difficult matrices (hops, spices, tea)	0.02 mg/kg	Regulation (EC) No 251/2013, annex III part A
Meat	0.01 mg/kg	Regulation (EC) No 251/2013, annex III part A
Milk	0.02 mg/kg	Regulation (EC) No 251/2013, annex III part A
Eggs	0.01 mg/kg	Regulation (EC) No 251/2013, annex III part A
Fat	0.02 mg/kg	Regulation (EC) No 251/2013, annex

Matrix	MRL	Reference for MRL/level Remarks
		III part A
Liver, kidney	0.02 mg/kg	Regulation (EC) No 251/2013, annex III part A
Soil	0.05 mg/kg	Common limit
Drinking/ground water	0.1 µg/L	General limit for drinking water
Surface water	100 µg/L	NOEC *Cyprinodon variegatus*, EFSA conclusion on pesticide peer review, EFSA Journal 2013;11(9):3352; ASB2013-11899
Air	78 µg/m^3	AOEL sys: 0.26 mg/kg bw/d; EFSA conclusion on pesticide peer review, EFSA Journal 2013;11(9):3352; ASB2013-11899
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 Aminopyralid in Plant Matrices

An overview of the acceptable methods and possible data gaps for analysis of aminopyralid in plant matrices is given in the following tables. Analytical methods were presented in the DAR and were considered as acceptable.

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	Wendelburg, 2008	Beck, 2008	Wendelburg, 2012
Acidic	Wendelburg, 2008	Not necessary	Wendelburg, 2012
Fatty	Wendelburg, 2008	Not necessary	Wendelburg, 2012
Dry	Wendelburg, 2008	Beck, 2008	Wendelburg, 2012
Difficult	Not required for the intended GAP	Not required for the intended GAP	Not required for the intended GAP

Table 5.3-17: Statement on extraction efficiency

	Method for products of plant origin
Required, available from:	DAR, vol. 3, B.7.1.2
Not required, because:	

The analytical methods for monitoring used alkaline hydrolysis followed by acidic hydrolysis for releasing acid and base labile conjugates. The metabolism study of Graper, 2003 (RIP2004-985) cited in the DAR used the same hydrolytic conditions resulting in an extraction efficiency of 75-98.7 % TRR.

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 section
Wendelburg, 2008 & 2012 (ASB2009-3077, ASB2013-1135)	High water content, acid, dry, fatty	0.01 mg/kg	LC-MS/MS, RP8 column, ESI+, m/z 263→189, 263→134 as butyl ester	$^{13}C_2{}^{15}N$-amino-pyralid as internal standard, confirmation included	DAR, addendum 2, vol. 3, B5.2.2 *)
Beck, 2008 (ASB2009-3078)	High water content, dry	0.01 mg/kg	LC-MS/MS, RP8 column; ESI+, m/z 263→189 as butyl ester	ILV of Wendelburg, 2008	DAR, addendum 2, vol. 3, B5.2.2 *)

*) EU Agreed method

IIIA 5.3.2.3 Description of Analytical Methods for the Determination of Residues of Aminopyralid in Animal Matrices

An overview of the acceptable methods and possible data gaps for analysis of aminopyralid in animal matrices is given in the following tables. Analytical methods were presented in the DAR and were considered as acceptable.

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	Wendelburg, 2008	Beck, 2008	Wendelburg, 2012
Eggs	Wendelburg, 2008	Not necessary	Wendelburg, 2012
Meat	Wendelburg, 2008	Not necessary	Wendelburg, 2012
Fat	Wendelburg, 2008	Not necessary	Wendelburg, 2012
Kidney, liver	Wendelburg, 2008	Beck, 2008	Wendelburg, 2012

Table 5.3-20: Statement on extraction efficiency

	Method for products of animal origin
Required, available from:	DAR, Vol. 3, B.7.2.2
Not required, because:	

The metabolism study of Macpherson, 2003 (RIP2004-986, see also DAR, vol. 3, B.7.2.2) used an initial extraction with methanol resulting in an extraction efficiency of 72.5 % for milk, 75.6 % for liver and 95.5 % for kidney. The proposed enforcement method of Wendelburg, 2008 & 2012 extracted the residues by means of methanol as well. Therefore, acceptable extraction efficiency is proven.

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
Wendelburg, 2008 & 2012 (ASB2009-3080	Milk, eggs, meat, fat, liver, kidney	0.01 mg/kg	LC-MS/MS, RP8 column, ESI+, m/z 263→189,	$^{13}C_2{}^{15}N$-amino-pyralid as internal standard,	DAR, addendum 2, vol. 3, B5.2.3 *)

Author(s), year	Matrix group	Method LOQ	Principle of method	Comment	Evaluated in section
ASB2013-1135)			263→134 as butyl ester	confirmation included	
Beck, 2008 (ASB2009-3081)	Milk, kidney	0.01 mg/kg	LC-MS/MS, RP8 column; ESI+, m/z 263→189, 263→134 as butyl ester	ILV of Wendelburg, 2008	DAR, addendum 2, vol. 3, B5.2.3 *)

*) EU Agreed method

IIIA 5.3.2.4 Description of Methods for the Analysis of Aminopyralid in Soil

An overview of the acceptable methods and possible data gaps for analysis of aminopyralid in soil is given in the following tables. Analytical methods were presented in the DAR and were considered as acceptable.

Table 5.3-21: Overview of suitable primary and confirmatory methods for soil

Component(s) of residue definition	Primary method	Confirmatory method
Aminopyralid	Wendelburg, 2008 Beck, 2008 (ILV)	Wendelburg, 2012

Table 5.3-22: Methods for soil

Author(s), year	Method LOQ	Principle of method	Comment	Evaluated in
Wendelburg, 2008 & 2012 (ASB2009-3083 ASB2013-1135)	0.001 mg/kg	LC-MS/MS, RP8 column, ESI+, m/z 263→134, 263→189as butyl ester	$^{13}C_2{}^{15}N$-amino-pyralid as internal standard, confirmation included	DAR, addendum 2, vol. 3, B.5.3.1 *)
Beck, 2008 (ASB2009-3084)	0.001 mg/kg	LC-MS/MS, RP8 column, ESI+, m/z 263→134 as butyl ester	ILV of Wendelburg, 2008	DAR, addendum 2, vol. 3, B.5.3.1 *)

*) EU agreed method

IIIA 5.3.2.5 Description of Methods for the Analysis of Propyzamide in Water

An overview of the acceptable methods and possible data gaps for analysis of aminopyralid in surface and drinking water is given in the following table. Analytical methods were presented in the DAR and were considered as acceptable.

Table 5.3-23: Overview of suitable primary and confirmatory methods for water

Component(s) of residue definition	Matrix	Primary method	Confirmatory method
Aminopyralid	Drinking water ground water surface water	Wendelburg, 2008 Beck, 2008 (ILV)	Wendelburg, 2012

Table 5.3-24: Methods for drinking water and surface water

Author(s), year	Method LOQ	Principle of method	Comment	Evaluated in
Wendelburg, 2008 & 2012 (ASB2009-3085 ASB2013-1135)	0.05 µg/L	LC-MS/MS, RP8 column, ESI+, m/z 263→189, 263→134 as butyl ester	$^{13}C_2{}^{15}N$-aminopyralid as internal standard confirmation included	DAR, addendum 2, vol. 3, B.5.3.2 *)
Beck, 2008 (ASB2009-3086)	0.05 µg/L	LC-MS/MS, RP8 column, ESI+, m/z 263→189 as butyl ester	ILV of Wendelburg, 2008	DAR, addendum 2, vol. 3, B.5.3.2 *)

* EU agreed method

IIIA 5.3.2.6 Description of Methods for the Analysis of Aminopyralid in Air

An overview of the acceptable methods and possible data gaps for analysis of aminopyralid in air is given in the following table. Analytical methods were presented in the DAR and were considered as acceptable.

Table 5.3-25: Overview of suitable primary and confirmatory methods for air

Component(s) of residue definition	Primary method	Confirmatory method
Aminopyralid	Class, 2004	Not required

Table 5.3-26: Methods for air

Author(s), year	Method LOQ	Principle of method	Comment	Evaluated in
Class, 2004 (MET2004-399)	1.4 µg/m³	LC-MS/MS, RP18 column, ESI+, m/z 207→134		DAR, vol. 3, B.5.3.3 *)

*) EU agreed method

IIIA 5.3.2.7 Description of Methods for the Analysis of Aminopyralid in Body Fluids and Tissues

Methods for body fluids and tissues are not required, because aminopyralid 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

Other studies were not provided.

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

Propyzamid

Sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions except for foodstuff of animal origin.

Noticed data gaps, which at the latest with the application for renewal of approval for the active substance according to Regulation (EC) No 1107/2009 or in context with the review of the existing MRLs for the active substance according to Article 12 of Regulation (EC) No 396/2005 have to be submitted, are:

- An analytical method (primary method, ILV and confirmatory method) for propyzamide residues as sum of propyzamide and all metabolites containing the 3,5-dichlorobenzoic acid, expressed as propyzamide, in milk, meat, fat, eggs, liver and kidney is missing.
- An analytical method for propyzamide in air is missing. This data gap could be filled with the EU agreed method of Müller-Kallert, 1994 (MET2000-177) but the study has not been submitted by the applicant.

Aminopyralid

Sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions.

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 Authority registration No	**Data protection claimed**	**Owner**	**How considered in dRR** Study-Status / Usage*
KIIIA1 5.2.2	Jones, J.	2009	Analytical Method and Validation for the Determination of Aminopyralid and Propyzamide in GF-2540 Formulation DAS-AM-G-09-24, GLP, unpublished	Y	DOW	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 ***
	Anon.	2008	European Standard EN 15662:2008 - Foods of plant origin - Determination of pesticide residues using GC-MS and/or LC-MS(/MS) following acetonitrile extraction/partitioning and cleanup by dispersive SPE-QuEChERS-method // Pflanzliche Lebensmittel - Bestimmung von Pestizidrückständen mit GC-MS und/oder LC-MS/MS nach Acetonitril-Extraktion/Verteilung und Reinigung mit dispersiver SPE - QuEChERS-Verfahren EN 15662:2008 GLP: Open (1) No (12) Published: Yes (12) Open (1) BVL-1891180, BVL-1916668, BVL-1928802, BVL-1977903, BVL-2121949, BVL-2121995, BVL-2193372, BVL-2203046, BVL-2203046, BVL-2231017, BVL-2234627, BVL-2255528, BVL-2340307, ASB2008-5464			Add
	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

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
	Anon.	2013	Untersuchung von Lebensmitteln - Multimethode zur Bestimmung von Pflanzenschutzmittelrückständen in pflanzlichen Ölen mittels LC-MS(/MS) (QUOIL) - nach §64 LFGB ASB2013-7593			Add
	EFSA	2013	Conclusion on the peer review of the pesticide risk assessment of the active substance Aminopyralid EFSA Journal 2013;11(9):3352 ! EFSA-Q-2009-00330 ASB2013-11899			Add
	European Commission	2007	Review report for the active substance Propyzamide 6502/VI/99-final ASB2013-5446			Add
	Greulich, K.; Alder, L.	2006	Fast multi residue screening of 300 pesticides in drinking water BfR-IX-2005 GLP: Yes Published: Yes BVL-2066681, ASB2011-8450			Add
	Sweden	1998	Propyzamide: (Monograph) Vol. 1-3 GLP: Open Published: Yes ASB2010-10283			Add
	Wendelburg, B. M.; Olberding, E. L.;	2012	Validation Report for Methods GRM 07.07.R1 - Determination of Residues of Aminopyralid in Agricultural Commodities by Liquid Chromatography with Tandem Mass Spectrometric Detection, GRM 07.08.R1 - Determination of Residues of Aminopyralid in Bovine and Poultry Tissues, Milk, and Eggs by Liquid Chromatography with Tandem Mass Spectrometric Detection, GRM 07.09.R1 - Determination of Residues of Aminopyralid in Soil by Liquid Chromatography with Tandem Mass Spectrometric Detection, and GRM 07.10.R1 - Determination of Residues of Aminopyralid in Drinking Water, Ground Water, and Surface Water by Liquid Chromatography with Tandem Mass Spectrometric Detection. Amended report 071121 ! GRM 07.10.R1 ! GRM 07.09.R1 ! GRM 07.08.R1 ! GRM 07.07.R1 ASB2013-1135			Add
KIIA 4.3	Adler, I. L.; Gordon, C. F.; Haines, L. D. et al.	1972	Determination of residues from herbicide N-(1,1-Dimethylpropynyl)-3,5-dichlorobenzamide by Electron Capture gas liquid chromatography ER 17.4 ! Jaoac 55 ! page 802-805 GLP: Open Published: Open BVL-1988497, MET2000-169			N
KIIA 4.3	Hofmann, C. K.; Brackett, C. K.	1994	Analytical method for the determination of Kerb® residues in goat liver 34-91-68 ! ER 44.10 GLP: Open Published: Open BVL-1988496, MET2000-150			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	Olberding, E. L.; Hastings, M. J.	2004	Validation report for method GRM 02.31- determination of residues of Aminopyralid in agricultural commodities by liquid chromotography with tandem mass spectrometry detection. 137142 ! 998010-5002-1 GLP: Open Published: Open BVL-1938688, MET2004-393			N
KIIA 4.3	Reed, R. L.	2004	Independent Laboratory Validation of Dow AgroSciences LLC method GRM 02.31- determination of residues of Aminopyralid in agricultural commodities by liquid chromotography with tandem mass spectrometry detection 020157 ! ML03-1110-DOW GLP: Open Published: Open BVL-1938681, MET2004-394			N
KIIA 4.3	Reed, R. L.	2004	Independent Laboratory Validation of Dow Agrosciences LLC method GRM 03.18 - Determination of residues of Aminopyralid in bovine tissues by liquid chromotography with tandem mass spectrometry 030098 ! ML03-1122-DOW GLP: Open Published: Open BVL-1938682, MET2004-396			N
KIIA 4.3	Rutherford, L. A.; Hastings, M. J.	2003	Method validation report for the determination of residues of Aminopyralid in bovine tissues by liquid chromotography with tandem mass spectrometry using Dow Agrosciences LLC Method GRm 03.18 137355 ! 021327 ! 998010-5007-1 GLP: Open Published: Open BVL-1938683, MET2004-395			N
KIIA 4.3	Wendelburg, B. M.; Olberding, E. L.	2008	Determination of residues of Aminopyralid in agricultural commodities by liquid chromatography with tandem mass spectrometric detection GRM 07.07 GLP: Open Published: Open BVL-1938690, ASB2009-3077			Y
KIIA 4.3	Wendelburg, B. M.; Olberding, E. L.	2008	Determination of residues of Aminoclopyralid in bovine and poultry tissues, milk, and eggs by liquid chromatography with tandem mass spectrometric detection GRM 07.08 GLP: Open Published: Open BVL-1938692, ASB2009-3080			Y
KIIA 4.3, KIIA 4.4	Class, T.	2003	Assessment of multi-residue enforcement Method (s) for the determination of XDE-750 (Aminopyralid) in plant material, in foodstuffs of animal origin, and in soil. 135070 ! 998010-5010-1 GLP: Open Published: Open BVL-1938680, BVL-1938689, MET2004-392			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, KIIA 4.4	Weinmann, W. D.; Nolting, H. G.	1994	DFG Method 350, Propyzamide - Gas chromatographic determination; Übersetzung (MBL-3712) ER 44.5 GLP: Open Published: Open BVL-1988499, BVL-1988549, MET2000-86			N
KIIA 4.3, KIIA 4.4, KIIA 4.5	Anon.	2009	Erklärung zu einer kommerziellen Bezugsquelle für 13C2 15N-Aminopyralid - Anlage zu KIIA Nr. 4.3/4.4/4.5 (Aminopyralid) Simplex GLP: Open Published: Open BVL-1938698, BVL-1939040, BVL-1939042, ASB2009-3082			N
KIIA 4.3, KIIA 4.4, KIIA 4.5	Nolting, H. G.; Weinmann, W. D.	1978	Analysenmethode zur Bestimmung von Propyzamidrückständen in verschiedenen Lebensmitteln, Wasser und Boden ER 37.4 ! page 137-140 GLP: Open Published: Open BVL-1988498, BVL-1988503, BVL-1991387, MET2000-171			N
KIIA 4.3, KIIIA1 5.3.1	Beck, I. C.; Class, T.	2008	Independent laboratory validation of Dow AgroSciences LLC Method GRM 07.07 - Determination of residues of Aminopyralid in Agricultural Commodities by liquid chromatography with tandem mass spectrometric detection 080117 ! P 1466 G GLP: Open Published: Open (1) No (2) BVL-1938691, BVL-2348300, BVL-2348372, ASB2009-3078			Y
KIIA 4.3, KIIIA1 5.3.1	Beck, I. C.; Class, T.	2008	Independent laboratory validation of Dow AgroSciences LLC Method GRM 07.08 - Determination of residues of Aminopyralid in bovine and poultry tissues, milk, and eggs by liquid chromatography with tandem mass spectrometric detection 080118 ! P 1467 G GLP: Open Published: Open (1) No (2) BVL-1938693, BVL-2348314, BVL-2348373, ASB2009-3081			Y
KIIA 4.3, KIIIA1 5.3.1	Wendelburg, B. M.; Olberding, E. L.	2008	Method validation study for the determination of residues of Aminopyralid in agricultural commodities, animal tissues, soil, and water by high performance liquid chromatography with tandem mass spectrometry 071121 GLP: Open Published: No BVL-2348296, BVL-2348371, ASB2012-14212			N
KIIA 4.4	Chamberlin, W. E.; O?Donnell, A.; Choo, D.	1997	Method validation for residue analytical method for terminal Pronamide in soil 34-96-49 ! ER 53.7 GLP: Open Published: Open BVL-1988501, MET2000-164			Y
KIIA 4.4	Hofmann, C. K.; Kurilla, K.; Zogorski, W. J.	1995	Terminal Pronamid preliminary residue analytical method for soil 34-95-34 ! ER 53.7b GLP: Open Published: Open BVL-1988502, MET2000-151			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	Lindsey, A. E.; Hastings, M. J.	2004	Method validation report for the determination of residues of Aminopyralid in soil by liquid chromotography with tandem mass spectrometry detection using Dow AgroSciences Method GRM 02.34 137273 ! 998010-5003-1 ! GRM 02.34 ! O56 GLP: Open Published: Open BVL-1938684, MET2004-397			N
KIIA 4.4	Wendelburg, B. M.; Olberding, E. L.	2008	Determination of residues of Aminopyralid in soil by liquid chromatography with tandem mass spectrometric detection GRM 07.09 GLP: Open Published: Open BVL-1938694, ASB2009-3083			Y
KIIA 4.4	Xu, B.	1997	Method validation for "Residue analytical method for terminal Pronamide RH-23315 in soil (TR 34-95-34)" 34-96-51 ! ER 53.7 GLP: Open Published: Open BVL-1988500, MET2000-165			N
KIIA 4.4, KIIIA1 5.4	Beck, I. C.; Class, T.	2008	Independent laboratory validation of Dow AgroSciences LLC Method GRM 07.09 - Determination of residues of Aminopyralid in soil by liquid chromatography with tandem mass spectrometric detection 080115 ! P 1465 G GLP: Open Published: Open (1) No (2) BVL-1938695, BVL-2348321, BVL-2348374, ASB2009-3084			Y
KIIA 4.5	Hastings, M. J.	2003	Method validation report for the determination of residues of Aminopyralid in water by liquid chromotography with tandem mass spectrometry detection using Dow AgroSciences Method GRM 01.32 136924 ! 998010-5004-1 ! O57 ! GRM 01.32 GLP: Open Published: Open BVL-1938685, MET2004-398			N
KIIA 4.5	Müller-Kallert, H.-M.	1994	Development and validation of an analytical method for the determination of Propyzamid (RH-23315, Pronamide) and its main metabolites in water 346590 ! RHD 94/10099 GLP: Open Published: Open BVL-1988504, MET2000-166			Y
KIIA 4.5	Müller-Kallert, H.-M.	1994	Development and validation of an analytical method for the determination of Propyzamid (RH-23315, Pronamide) and its main metabolites in water - First amendment to report RHD 94/10146 ! 346590 GLP: Open Published: Open BVL-1989373, MET2000-167			N
KIIA 4.5	Wendelburg, B. M.; Olberding, E. L.	2008	Determination of residues of Aminopyralid in drinking water, ground water and surface water by liquid chromatography with tandem mass spectrometric detection GRM 07.10 GLP: Open Published: Open BVL-1938696, ASB2009-3085			Y

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
KIIA 4.5, KIIIA1 5.6	Beck, I. C.; Class, T.	2008	Independent laboratory validation of Dow AgroSciences LLC method GRM 07.10 - Determination of residues of Aminopyralid in drinking water, ground water and surface water by liquid chromatography with tandem mass spectrometric detection 080116 ! P 1464 G GLP: Open Published: Open (1) No (2) BVL-1938697, BVL-2348323, BVL-2348375, ASB2009-3086			Y
KIIA 4.7	Class, T.	2004	The development and validation of a method for the analysis (or determination) of Aminopyralid in air 144631 ! 998010-5154-1 ! B 722 G GLP: Open Published: Open BVL-1938687, MET2004-399			Y
KIIA 4.7	Wais, A.	1998	Method for the determination of Propyzamid and its metabolite RH-24644 in air - Third amendment to report 34-97-163 ! 345420 ! RHD 98/10007 GLP: Open Published: Open BVL-1988506, MET2000-178			N
KIIA 4.7, KIIIA1 5.7	Bacher, R.	2009	The Development and Validation of a Method for the Determination of Aminopyralid in Air P 1645 G, 091020 GLP: Open Published: No BVL-2348365, BVL-2348376, ASB2012-9127			N
KIIA 4.8	Mollica, J.; West, S. D	2003	Method validation for the analysis of XDE-750 (Aminopyralid) in human blood and urine 134426 ! 15385039-5716-1 ! DOW-1419/03/031005 GLP: Open Published: Open BVL-1938686, MET2004-400			N
KIIA 6.2.1	Graper, L. K.; Smith, K. P.; Hilla, S.	2003	A nature of the residue study with 14C-labelled XDE-750 applied to spring wheat 020022 ! 98010-5051-2 ! 136893 GLP: Open Published: Open BVL-1954911, RIP2004-985			Y
KIIA 6.2.3	Macpherson, D.; Gedek, L.	2003	The distribution and metabolism of [14C]- XDE-750 in the lactating goat 998010-5049-1 ! 010079 ! 138360 GLP: Open Published: Open BVL-1954914, RIP2004-986			Y
KIIIA1 8.3	Devine, H. C.	2006	Residues of Clopyralid, Picloram and Aminopyralid in oil seed rape at intervals and at harvest following a single application of GF-1634, Germany, Poland and Hungary - 2005 GHE-P-11273 ! N238 ! CEMS-2698 GLP: Yes Published: No BVL-2355600, ASB2010-7658			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 propyzamide

A 1.1.1 Methods for enforcement of residues in food and feed of plant origin

A 1.1.1.1 Analytical method 1

Reference: KIIIA, 4.3

Report: European Standard EN 15662:2008 - Foods of plant origin - Determination of pesticide residues using GC-MS and/or LC-MS(/MS) following acetonitrile extraction/partitioning and cleanup by dispersive SPE-QuEChERS-method, Anonymous, 2008, ASB2008-5464

Guideline(s): No

Deviations: Not applicable

GLP: Not applicable

Acceptability: Yes

Materials and methods

Dry crops (wheat grain), acidic commodities (lemon), high water content commodities (cucumber), and commodities with high sugar content (raisins) and fatty commodities (olive oil) are analyzed according to the multiresidue method EN 15662:2008 (QuEChERS method). The sample material is extracted by shaking with acetonitrile, sodium citrate, sodium hydrogencitrate sesquihydrate, magnesium sulfate and sodium chloride. After centrifugation, the acetonitrile layer is shaking with primary secondary amine (PSA) and magnesium sulfate. The extracts are centrifuged and diluted. Final quantification is done by LC-MS/MS using a C18 column, electrospray ionization in positive mode and monitoring of the MS/MS transition m/z 256→173.

Results and discussions

Table A 1: Recovery results from method validation of high water content matrix (cucumber) using the analytical method. Standards were prepared in blank matrix extract.

Matrix	Fortification level (mg/kg)	No of samples per fortification level	Mean recovery	RSD (%)	Comments
Cucumber	0.01	54	101	8.1	Validated in 8 labs
Cucumber	0.1	57	101	6.3	Validated in 8 labs

Table A 2: Recovery results from method validation of high sugar content matrix (raisin) using the analytical method. Standards were prepared in blank matrix extract.

Matrix	Fortification level (mg/kg)	No of samples per fortifica-	Mean recovery	RSD (%)	Comments

		tion level			
Raisin	0.01	46	102	10.7	Validated in 8 labs
Raisin	0.1	51	104	9.7	Validated in 8 labs

Table A 3: Recovery results from method validation of acidic matrix (lemon) using the analytical method. Standards were prepared in blank matrix extract.

Matrix	**Fortification level (mg/kg)**	**No of samples per fortifica-tion level**	**Mean recovery**	**RSD (%)**	**Comments**
Lemon	0.01	48	97	8.7	Validated in 8 labs
Lemon	0.1	52	101	7.1	Validated in 8 labs

Table A 4: Recovery results from method validation of dry matrix (wheat flour) using the analytical method. Standards were prepared in blank matrix extract.

Matrix	**Fortification level (mg/kg)**	**No of samples per fortifica-tion level**	**Mean recovery**	**RSD (%)**	**Comments**
Wheat flour	0.01	40	101	8.5	Validated in 6 labs
Wheat flour	0.1	45	100	9.1	Validated in 6 labs

Table A 5: Characteristics for the analytical method used for the quantitation of propyzamide in high water content matrix, high sugar content matrix, dry crops and acidic matrix

	Propyzamide	
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 multi-residue method EN15662:2008 (QuEChERS method) is validated for the quantification of propyzamide in dry, acidic, high water content and high sugar content using MS/MS detection with a limit of quantification of 0.01 mg/kg. The applicability of the method is proven by proficiency tests in 6-8 labs.

Comments of zRMS:	Acceptable as primary method and ILV.

A 1.1.1.2 Confirmatory method

Reference: KIIIA, 4.5

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 64 of the German Federal Food Act), Anonymous, 2001, revised 2010, ASB2013-8342

Guideline(s): No

Deviations: Not applicable

GLP: Not applicable

Acceptability: Yes

Materials and methods

Dry crops (cereal grain), acidic commodities (grapes), high water content commodities (cucumber), and fatty commodities (hazelnut) are analyzed according to the multiresidue method EN 12393 (DFG S19, L 00.00-34). Dry crops are extracted with acetone/water (2/1, v/v) followed by partition with ethyl acetate/cyclohexane (1/1, v/v) (module E2). Commodities with high water content (cucumber) and acidic matrices (kiwi) are extracted with acetone/water (2/1, v/v) followed by partition with ethyl acetate/cyclohexane (1/1, v/v) (module E1). Commodities with high fat content (hazelnut) are extracted according to module E7 with acetonitrile/acetone (225/25, v/v). After filtration the solution is evaporated to a small volume and dissolved in ethyl acetate/cyclohexane (1/1).
For all commodities a clean-up by GPC is performed. Final quantification is done by GC-ECD.

Results and discussions

Table A 6: Recovery results from the confirmatory method validation of high water content matrix (cucumber) using the confirmatory method. Standards were prepared in solvent.

Matrix	Fortification level (mg/kg)	No of samples per fortifica-tion level	Mean recovery	RSD (%)	Comments
High water content	0.05	7	96	12	Published in the official method, 5 labs
High water content	0.1	7	91	10	Published in the official method, 5 labs
High water content	0.5	7	87	7	Published in the official method, 5 labs
High water content	0.01	5	76	3.1	Data from CRL datapool, 1 lab
High water content	0.05	5	94	7.3	Data from CRL datapool, 1 lab
High water	0.01	4	70	1.8	Data from CRL

Matrix	Fortification level (mg/kg)	No of samples per fortifica-tion level	Mean recovery	RSD (%)	Comments
content					datapool, 1 lab
High water content	0.05	4	83	6.4	Data from CRL datapool, 1 lab

Table A 7: **Recovery results from the confirmatory method validation of acidic matrix (kiwi) using the confirmatory method. Standards were prepared in solvent.**

Matrix	Fortification level (mg/kg)	No of samples per fortifica-tion level	Mean recovery	RSD (%)	Comments
Acidic matrix	0.05	6	92	15	Published in the official method, 5 labs
High water content	0.1	6	88	12	Published in the official method, 5 labs
High water content	0.5	6	73	13	Published in the official method, 5 labs
High water content	0.01	5	84	5.4	Data from CRL datapool, 1 lab
High water content	0.05	5	83	5.1	Data from CRL datapool, 1 lab

Table A 8: **Recovery results from the confirmatory method validation of dry matrix (wheat flour) using the confirmatory method. Standards were prepared in solvent.**

Matrix	Fortification level (mg/kg)	No of samples per fortifica-tion level	Mean recovery	RSD (%)	Comments
Dry matrix	0.05	6	86	14	Published in the official method, 5 labs
Dry matrix	0.1	6	74	14	Published in the official method, 5 labs
Dry matrix	0.5	6	84	15	Published in the official method, 5 labs
Dry matrix	0.01	5	86	4.5	Data from CRL datapool, 1 lab
Dry matrix	0.05	5	95	6.4	Data from CRL datapool, 1 lab

Table A 9: Recovery results from the confirmatory method validation of fatty matrix (hazelnut) using the confirmatory method. Standards were prepared in solvent.

Matrix	Fortification level (mg/kg)	No of samples per fortifica-tion level	Mean recovery	RSD (%)	Comments
Fatty matrix	0.05	5	78	18	Published in the official method, 5 labs
Fatty matrix	0.1	5	77	14	Published in the official method, 5 labs
Fatty matrix	0.5	4	79	18	Published in the official method, 5 labs
Fatty matrix	0.01	5	89	4.1	Data from CRL datapool, 1 lab
Fatty matrix	0.05	5	98	2.3	Data from CRL datapool, 1 lab

Table A 10: Characteristics for the confirmatory method used for the quantitation of propyzamide residues in dry matrix, high water content matrix, acidic matrix and fatty matrix.

	Propyzamide	
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 no datamatrix effects is presented (yes/no)	No	
Interference >30% of LOQ in blank sample is absent (yes/no)	Yes	

Conclusion

The multi-residue method L 00.00-34 (DFG S19) is validated for the quantification of propyzamide in dry, acidic, high water content, high sugar content and fatty plant commodities using MS/MS detection with a. limit of quantification of 0.01 mg/kg. The applicability of the method is proven by proficiency tests in 4-6 labs.

Comments of zRMS:	Acceptable.

A 1.1.1.3 Analytical method 2

Reference: OECD KII A, 4.3

Report: Anonymous (2013): Untersuchung von Lebensmitteln - Multimethode zur Bestimmung von Pflanzenschutzmittelrückständen in pflanzlichen Ölen mittels LC-MS(/MS) (QuOil) - nach §64 LFGB, ASB2013-7593 (not yet published)

Guideline(s): No

Deviations: Not applicable

GLP: Not applicable

Acceptability: Yes

Materials and methods

Fatty commodities (olive oil) are analyzed according to the multiresidue method QuOil. The sample material is extracted by shaking with acetonitrile. After phase separation by centrifugation (and optional freezing-out of fat components), an aliquot of the organic phase is cleaned up by dispersive solid phase extraction employing primary secondary amine sorbent (PSA) and C18. Following centrifugation, an aliquot of the extract is stabilized with formic acid/acetonitrile (5/95, v/v). Final quantification is done by LC-MS/MS using a C18 column, electrospray ionization in positive mode and monitoring the MS/MS transition(s) m/z 256→173. Quantification is performed using an internal standard, which is added to the extract after the initial addition of acetonitrile.

Results and discussions

Table A 11: Recovery results from method validation of propyzamide in wheat grain using the analytical method. Standards were prepared in blank matrix extract.

Matrix	Fortification level (mg/kg)	No of samples per fortifica-tion level	Mean recovery	RSD (%)	Comments
Olive oil	0.01	23	90	7.3	4 labs
Olive oil	0.1	24	91	7.8	4 labs

Table A 12: Characteristics for the analytical method used for the quantitation of propyzamide residues in olive oil.

	Propyzamide	
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	yes	

(duplicated points) or 5 levels (single points)? (yes/ no)		
Assessment of matrix effects is presented (yes/no)	no	
Interference >30% of LOQ in blank sample is absent (yes/no)	yes	

Conclusion

The multi-residue method QuOil is validated for the quantification of propyzamide in fatty plant commodities using MS/MS detection. The validated limit of quantification is 0.01 mg/kg. The applicability of the method is proven by proficiency tests in 4 labs.
Note: The multi-residue method QuOil only exists currently as a draft only, but is about to be published as a European standard method.

Comments of zRMS:	Acceptable.

A 1.1.2 Description of Methods for the Analysis of Water

A 1.1.2.1 Analytical method 1

Reference: OECD; KIIA 4.5

Report: Fast multi residue screening of 300 pesticides in drinking water; Greulich K., Alder, L.; 2006; study BfR-IX-2005, open, ASB2011-8450

Guideline(s): No

Deviations: Not applicable

GLP: No

Acceptability: Acceptable

Materials and methods

The study validates are a multi-residue method for the quantification of pesticides in drinking water. The sample is analysed after addition of methanol by direct injection in a LC-MS/MS system using an Aqua C18 column. Quantification is performed for propyzamide by monitoring of two transitions (m/z 256→190, m/z 256→173) after electrospray ionization in positive mode.

Results and discussions

Table A 13: Recovery results from method validation of propyzamide using the analytical method. Standards were prepared in matrix (drinking water)

Matrix	**Fortification level (mg/kg)**	**No of samples per fortifica-tion level**	**Mean recovery**	**RSD (%)**	**Comments**
Drinking water	0.1	4	115	3	m/z 256→190

Drinking water	1	5	103	5	m/z 256→190
Drinking water	0.1	4	105	4	m/z 256→173
Drinking water	1	5	104	5	m/z 256→173

Table A 14: Characteristics for the analytical method used for the quantitation of propyzamide residues in drinking water

	propyzamide, m/z 256→190	
Calibration function	y=478033x + 26239, in µg/L, R^2=0.9987	
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	0.03 – 5 ng/mL	
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.03 – 5 µg/L	
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 method is successfully validated for the quantification of propyzamide residues in drinking water for the m/z 256→190 transition. The limit of quantification is 0.1 µg/L.

Comments of zRMS:	Acceptable.

REGISTRATION REPORT
Part B

Section 3: Mammalian Toxicology
Detailed summary of the risk assessment

Product code: GF-2540

Active Substance: Aminopyralid 5.3 g/L

Propyzamide 500 g/L

Central Zone

Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Dow AgroSciences GmbH

Date: 08/05/2014

Table of Contents

3 MAMMALIAN TOXICOLOGY

3.1 Summary

Table 3.1-1: Information on GF-2540 *

Product name and code	GF-2540 (DOW-02540-H-0-SC)
Formulation type	Suspension concentrate
Active substances (incl. content)	Aminopyralid: 5.3 g/L Propyzamide: 500 g/L
Function	Herbicide
Product already evaluated as the 'representative formulation' during the Annex I inclusion	No
Product previously evaluated in an other MS according to Uniform Principles	No

* Information on the detailed composition of GF-2540 can be found in the confidential dRR Part C.

Justified proposals for classification and labelling

In accordance with Directives 67/548/EEC and 1999/45/EC and according to 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 Directives 67/548/EEC and 1999/45/EC	
Hazard symbol:	Xn
Indication of danger:	Harmful
Risk phrases:	R40
Safety phrases:	2-13-24-36-37-46
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use.
	'Contains 1.2-Benzisothiazol-3(2H)-one (CAS No. 2634-33-5). May produce an allergic reaction.'
C&L according to Regulation (EC) No 1272/2008	
Hazard class, category:	Carc. 2
Signal word:	Warning
Hazard statement:	H351
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]
	'Contains 1.2-Benzisothiazol-3(2H)-one (CAS No. 2634-33-5). May produce an allergic reaction.' [EUH208]

Table 3.1-3: Summary of risk assessment for operators, workers, bystanders and residents for GF-2540

	Result	**PPE / Risk mitigation measures**
Operators	Acceptable	- Avoid any unnecessary contact with the product. Misuse can lead to health damage. - The directive concerning requirements for personal protective gear in plant protection, "Personal protective gear for handling plant protection products" of the Federal Office of Consumer Protection and Food Safety must be observed. - Wear tight fitting eye protection when handling the undiluted product. - Wear standard protective gloves (plant protection) when handling the undiluted product. - Wear a protective suit against pesticides and sturdy shoes (e.g. rubber boots) when handling the undiluted product. - Wear a rubber apron when handling the undiluted product.
Workers	Acceptable	- Treated areas/crops may not be entered until the spray coating has dried.
Bystanders	Acceptable	None
Residents	Acceptable	None

No unacceptable risk for operators, workers, bystanders and residents was identified when product is used as intended.

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	10	11	12	13	14	15			
Use-	**Member states**	**Crop and/or situation (crop destination / purpose of crop)**	**F/G or I** [1)]	**Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)**	**Application**			**Application rate**			**PHI (days)**	**Remarks: safener/synergist per ha critical gap for operator, worker, bystander or resident exposure based on [*Exposure model*]**	**Acceptability of exposure assessment**			
					Method / Kind (incl. application technique)	**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**	**kg as/ha a) max. rate per appl. b) max. total rate per crop/season**	**Water L/ha min / max**			**Operator**	**Worker**	**Bystander**	**Residents**
1	Central Zone	Winter oilseed rape	F	Annual monocotyledonous weeds, annual dicotyledonous weeds	Spraying, FCTM [2)]	> BBCH 14; After emergence, late autumn to winter, November to February, after emergence of weeds	1 ; 1	a) 1.5 b) 1.5	a) aminopyralid: 0.00795 propyzamide: 0.75 b) aminopyralid: 0.00795 propyzamide: 0.75	200 – 300		German model				
												UK POEM				

[1)] F: field or outdoor application, G: greenhouse application, I: indoor application
[2)] FC: field crops, TM: tractor-mounted

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

3.2 Toxicological Information on Active Substances

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.

Table 3.2-1: Information on active substances

	Aminopyralid	**Propyzamide**
CAS-No.	150114-71-9	23950-58-5
Classification and proposed labelling		
With regard to toxicological enpoints (according to the criteria in Dir. 67/548/EEC)	Regulation (EC) No 1272/2008 (Notified) Xi - Irritant R41 - Risk of serious damage to eyes Proposal Germany: none additional	Regulation (EC) No 1272/2008 (Table 3.2): Xn - Harmful R40 - Limited evidence of a carcinogenic effect Proposal Germany: none additional
With regard to toxicological enpoints (according to the criteria in Reg. 1272/2008)	Regulation (EC) No 1272/2008 (Notified) Serious eye damage, cat. 1 H318 - Causes serious eye damage Proposal Germany: STOT SE 2 H371 - May cause damage to nervous system	Regulation (EC) No 1272/2008 (Table 3.1): Carcinogenicity, cat. 2 H351 - Suspected of causing cancer Proposal Germany: none additional
Agreed EU endpoints		
AOEL systemic	0.26 mg/kg bw/d	0.08 mg/kg bw/d (corrected for 80 % oral absorption
Reference	EFSA Conclusion on Pesticide Review (EFSA Journal 2013;11(9):3352	EC Review Report No 6502/VI/99 (2007)

3.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for GF-2540 is given in Table 3.3-1. Full summaries of studies on the product are presented in Appendix 2. MSDS on GF-2540 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 GF-2540

Type of test, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Dir. 67/548/EEC)	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD_{50} oral, rat (OECD 425)	> 5000 mg/kg bw	Yes	None	None	Durando, J., 2010a
LD_{50} dermal, rat (OECD 402)	> 5000 mg/kg bw	Yes	None	None	Durando, J., 2010b
LC_{50} inhalation, rat (OECD 403)	> 5.5 mg/L air	Yes	None	None	Krieger, S. M., 2010

Skin irritation, rabbit (OECD 404)	Non-irritant	Yes	None	None	Durando, J., 2009a
Eye irritation, rabbit (OECD 405)	Non-irritant	Yes	None	None	Durando, J., 2010c
Skin sensitisation, guinea pig (OECD 406, M&K)	Non-sensitising	Yes	None	None	Durando, J., 2009b
Supplementary studies for combinations of plant protection products	No data – not required				

Table 3.3-2: Additional toxicological information relevant for classification/labelling of GF-2540

	Substance (Concentration in product, % w/w)	**Classification of the substance (acc. to the criteria in Dir. 67/548/EEC and/or in Reg. 1272/2008)**	**Reference**	**Classification of product (acc. to the criteria in Dir. 67/548/EEC, in Dir. 1999/45/EC and/or in Reg. 1272/2008)**
Toxicological properties of active substances (relevant for classification of product)	Propyzamide (43.9 % (w/w))	R40 (≥ 1 %) H351 (≥ 1 %)	Reg. (EC) No 1272/2008	R40 H351
Toxicological properties of non-active substances (relevant for classification of product)	1.2-Benzisothiazol-3(2H)-one (CAS-No. 2634-33-5, 0.0176 % (w/w))	R43 (≥ 0.05 %); 'Contains 1.2-Benzisothiazol-3(2H)-one. May produce an allergic reaction.' (≥ 0.005 %) H317 (≥ 0.05 %); EUH208 (≥ 0.005 %)	Reg. (EC) No 1272/2008	'Contains 1.2-Benzisothiazol-3(2H)-one. May produce an allergic reaction.' EUH208
Further toxicological information	No data – not required			

3.4 Dermal Absorption

A summary of the dermal absorption endpoints for the active substances in GF-2540 are presented in Table 3.4-1.

Table 3.4-1: Dermal absorption endpoints for active substances in GF-2540

	Aminopyralid		**Propyzamid**	
	Value	**Reference**	**Value**	**Reference**
Concentrate	75 %	Default (EFSA Journal, 2012, 10(4):2665)	0.65 %	Whittingham, A.; 2005
Dilution	75 %	Default (EFSA Journal, 2012, 10(4):2665)	12.37 %	Whittingham, A.; 2005

3.4.1 Justification for proposed values - Aminopyralid

No data on dermal absorption for aminopyralid in an exclusively water-based suspension concentrate like GF-2540 is available. Justification for default values according to Guidance on Dermal Absorption (EFSA Journal 2012; 10(4):2665) are presented in Table 3.4-2.

Table 3.4-2: Default dermal absorption endpoints for aminopyralid

	Value	Justification for value	Acceptability of justification
Concentrate	75 %	GF-2540 containing 5.3 g/L of active substance (≤ 50 g/L)	The applicant used dermal absorption values derived from a study on a water-in-oil emulsion containing 3.5 % aminopyralid (Burgsteden, J.A., 2006, ASB2008-2670; this study was peer reviewed on EU-level). This is considered not applicable to an exclusively water-based suspension concentrate like GF-2540. Therefore default values were used.
Dilution	75 %	in use dilution containing 0.00795 g/L of active substance (≤ 50 g/L)	

3.4.2 Justification for proposed values - Propyzamide

Proposed endpoint for propyzamide is based on a dermal absorption study on a formulation similar to GF-2540. The study is summarized in Table 3.4-3. A detailed summary of this study is provided in Appendix 2 of this report.

Table 3.4-3: Summary of dermal absorption study for propyzamide

Test	Value		Formulation in study	Reference	Acceptability of study	Justification for representativity of study formulation for current product	Acceptability of justification
Human skin *in vitro*	Concentrate	0.65 %	Kerb Flo (GF-1197, i.e. SC-formulation containing 400 g/L propyzamide)	Whitting-ham, A.; 2005	Yes	Yes	Yes
	Dilution	12.37 % (Dilution 1:133)					

3.5 Exposure Assessment of Plant Protection Product

Table 3.5-1: Product information and toxicological reference values used for exposure assessment

Product name and code	GF-2540 (DOW-02540-H-0-SC)
Formulation type	Suspension concentrate
Category	Herbicide
Container sizes, short description	PET bottles 0.25, 0.5, 1, 2, 3 and 5 L; up to 2 L size 45 mm screw cap, 3 and 5 L size 63 mm screw cap

Active substances (incl. content)	**Aminopyralid** 5.3 g/L	**Propyzamide** 500 g/L
AOEL systemic	0.26 mg/kg bw/d	0.08 mg/kg bw/d
Inhalative absorption	100 %	100 %
Oral absorption	100 %	80 %
Dermal absorption	75 % for concentrate and dilution (for details, please, see above)	Concentrate: 0.65 % Dilution: 12.37 % (Dilution: 1:133) (for details, please, see above)

.

3.5.1 Selection of critical use and justification

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

3.5.2 Operator exposure

3.5.2.1 Estimation of operator exposure

A summary of the exposure models used for estimation of operator exposure towards the active substances during application of GF-2540 according to the critical use is presented in Table 3.5-2. Although authorization of GF-2540 is intended to apply for Germany only up to now exposure calculations are also carried out according to the UK POEM in order to make possible later mutual recognition procedures within the central zone.
Outcome of the estimation is presented in Table 3.5-3. Detailed calculations are in Appendix 3.

Table 3.5-2: Exposure models for intended uses

Critical use	Oilseed rape (max. 1.5 L product/ha)
Model	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]
Critical use	Oilseed rape (max. 1.5 L product/ha)
Model	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 3.5-3: Estimated operator exposure

		Aminopyralid		**Propyzamide**	
Model data	**Level of PPE**	**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:		0.00795 kg a.s./ha		0.75 kg a.s./ha	

German Model (Geometric mean) Body weight: 70 kg	no PPE [1)]	0.007567	2.9	0.057760	72.2
	+ Gloves mixing/loading	0.003520	1.4	0.054451	68.1
UK POEM Application volume: 200 L/ha Container: 5 L, 63 mm screw cap Body weight: 60 kg	no PPE [2)]	0.0306	11.8	0.3331	416.4
	+ Gloves mixing/loading and application	0.0037	1.4	0.0540	67.5

1) no PPE: Operator wearing T-shirt and shorts
2) no PPE: Operator wearing long sleeved shirt, long trousers ("permeable") but no gloves

3.5.2.2 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, a study to provide measurements of operator exposure was not necessary and was therefore not performed.

3.5.3 Worker exposure

3.5.3.1 Estimation of worker exposure

Table 3.5-4 shows the exposure model used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with GF-2540 according to the critical use. Outcome of the estimation is presented in Table 3.5-5. Detailed calculations are in Appendix 3.

Table 3.5-4: Exposure models for intended uses

Critical use	Oilseed rape (max. 1 x 1.5 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 3.5-5: Estimated worker exposure

		Aminopyralid		**Propyzamide**	
Model data	**Level of PPE**	**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 0.00795 kg a.s./ha		1 x 0.75 kg a.s./ha	
2 hours/day [1)], TC: 1500 cm^2/person/h [2)] Body weight: 60 kg	no PPE [3)]	0.000298	0.11	0.004639	5.8
	with PPE [4)]	0.000015	0.01	0.000232	0.3

1) 2 h/day for professional applications for maintenance, inspection or irrigation activities etc.
2) US-EPA policy paper [EPA, Science Advisory Council for Exposure; 2000; Agricultural Default Transfer Coefficients, Policy # 003.1, May 7 1998 revised 7 August 2000].
3) no PPE: Worker wearing long sleeved shirt, long trousers ("permeable") but no gloves
4) with PPE: see 'Instructions for use'

3.5.3.2 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.

3.5.4 Bystander and resident exposure

3.5.4.1 Estimation of bystander and resident exposure

Table 3.5-6 shows the exposure model used for estimation of bystander and resident exposure to aminopyralid and propyzamide. Outcome of the estimation is presented in Table 3.5-7. Detailed calculations are in Appendix 3.

Table 3.5-6: Exposure models for intended uses

Critical use	Oilseed rape (max. 1 x 1.5 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]

Table 3.5-7: Estimated bystander and resident exposure

	Aminopyralid		Propyzamide	
Model data	**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	1 x 0.00795 kg a.s./ha		1 x 0.75 kg a.s./ha	
Bystanders (adult) Drift rate: 2.77 % (1 m) Body weight: 60 kg	0.000275	0.11	0.004287	5.36
Bystanders (children) Drift rate: 2.77 % (1 m) Body weight: 16.15 kg	0.000215	0.08	0.003349	4.19
Residents (adult) Drift rate: 2.77 % (1 m) Body weight: 60 kg	0.000027	0.01	0.000589	0.74
Residents (children) Drift rate: 2.77 % (1 m) Body weight: 16.15 kg	0.000030	0.01	0.001186	1.48

3.5.4.2 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 aminopyralid and propyzamide 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.

3.5.5 Statement on combined exposure

The product is a mixture of two active substances.

The combined toxicological effect of these active substances has not been investigated, since no harmonized evaluation concept is available on EU-level.

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 *
KIIIA1 7.1.1	[redacted]	2010a	GF-2540: Acute oral up and down procedure in rats28372 ! 090334GLP: Yes Published: NoBVL-2355247, BVL-2355612, ASB2012-14193	Yes	DOW	Y
KIIIA1 7.1.2	[redacted]	2010b	GF-2540: Acute dermal toxicity in rats 28373 ! 090335 GLP: Yes Published: No BVL-2355252, ASB2012-14194	Yes	DOW	Y
KIIIA1 7.1.3	[redacted]	2010	Gf-2540: Acute liquid aerosol inhalation toxicity 091135 GLP: Yes Published: No BVL-2355301, ASB2012-14195	Yes	DOW	Y
KIIIA1 7.1.4	[redacted]	2009a	GF-2540: Primary skin irritation in rabbits 28375 ! 090336 GLP: Yes Published: No BVL-2355303, ASB2012-14196	Yes	DOW	Y
KIIIA1 7.1.5	[redacted]	2010c	GF-2540: Primary eye irritation in rabbits 28374 ! 090337 GLP: Yes Published: No BVL-2355351, ASB2012-14197	Yes	DOW	Y
KIIIA1 7.1.6	[redacted]	2009b	GF-2540: Dermal sensitization study in guinea pigs (Magnusson-Kligman method) 28376 ! 090338 GLP: Yes Published: No BVL-2355353, ASB2012-14198	Yes	DOW	Y
KIIIA1 7.6.2	Burgsteden, J. A.	2006	In vitro percutaneous absorption of [14C]Aminopyralid formulated as GF-839 and field dilution through rat and human skin membranes using flow-through diffusion cells GHE-T-1253 ! V7028 GLP: Yes Published: No BVL-2355492, ASB2008-2670	N	DOW	N
KIIIA1 7.6.2	Whittingham, A.	2005	The in vitro percutaneous absorption of 14C propyzamide formulated as a suspension concentrate (GF-1197) and field dilution through rat and human skin GHE-T-1246 ! 2058/001 GLP: Yes Published: No BVL-2355491, TOX2006-2209	Yes	DOW	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 studies relied upon

A 2.1 Statement on bridging possibilities

The studies were performed using the product GF-2540. Therefore no bridging is necessary.

A 2.2 Acute oral toxicity

Comments of zRMS:	Acceptable; no deviations, according to recent guidelines; used for evaluation

Reference:	7.1.1
Report	GF-2540: Acute Oral Toxicity Up and Down Procedure in Rats, Durando, J., 2010, 28372 ! 090334, ASB2012-14193
Guidelines:	OECD 425 U.S. EPA OPPTS 870.1100
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Test material (Lot/Batch No.)	GF-2540 (C2241-38-B, TSN031383-0001)
Species	Rat, Fischer 344
No. of animals (group size)	5 females
Dose(s)	5000 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 treated with GF-2540

Dose (mg/kg bw)	Toxicological results [1)]	Duration of signs	Time of death	LD_{50} (mg/kg bw) (14 days)
		Female rats		
5000	2/4/5	days 1-4	day 3 and 4	> 5000

[1)] 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 treated with GF-2540

Mortality:	Yes, two animals died within four days of test substance administration.
Clinical signs:	Clinical signs noted in the decedents prior to death included hypoactivity, hunched posture and/or piloerection and reduced fecal volume. Following administration, two surviving rats exhibited piloerection. However, the animals recovered by day 1 and along with the other survivor appeared active and healthy for the remainder of the 14-day observation period.
Body weight:	All surviving animals gained body weight during the study.
Macroscopic	Gross necropsy of the decedents revealed red intestines. No gross abnormalities were noted

examination:	for any of the euthanized animals necropsied at the end of the 14-day observation period.

Conclusion

Under the experimental conditions, the oral LD_{50} of GF-2540 is higher than 5000 mg/kg bw in rats. Thus, no classification is required according to the classification criteria of Council Directive 67/548/EEC and subsequent regulations as well as according to Regulation (EC) No. 1272/2008.

A 2.3 Acute percutaneous (dermal) toxicity

Comments of zRMS:	Acceptable; no deviations, according to recent guidelines, used for evaluation

Reference: 7.1.2
Report: GF-2540: Acute Dermal Toxicity Study in Rats,
Durando, J., 2010,
28373 ! 090335, ASB2012-14194
Guidelines: OECD 402
Reg. (EC) 440/2008, B.3
U.S. EPA OPPTS 870.1200
JMAFF 12-Nouan-8147
Deviations: No
GLP: Yes
Acceptability: Yes

Materials and methods

Test material (Lot/Batch No.)	GF-2540 (C2241-38-B, TSN031383-0001)
Species	Rat, Fischer 344
No. of animals (group size)	5 males and 5 females
Dose	5000 mg/kg bw
Exposure	24 hours (dermal, semi-occlusive)
Vehicle/Dilution	None
Post exposure observation period	14 days
Remarks	24 h after administration of the test substance the test sites were cleansed with 3 % soap solution followed by tap water.

Results and discussions

Table A 3: Results of acute dermal toxicity study in rats treated with GF-2540

Dose (mg/kg bw)	Toxicological results [1)]	Duration of signs	Time of death	LD_{50} (mg/kg bw) (14 days)
Male rats				
5000	0/0/5	--	--	> 5000
Female rats				
5000	0/0/5	--	--	> 5000

[1)] 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 treated with GF-2540

Mortality:	No mortality occurred.
Clinical signs:	No clinical signs of toxicity were observed.
Body weight:	All animals gained body weight over the 14-day observation period.
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 GF-2540 is higher than 5000 mg/kg bw in rats. Thus, no classification is required according to the classification criteria of Council Directive 67/548/EEC and subsequent regulations as well as according to Regulation (EC) No. 1272/2008.

A 2.4 Acute inhalation toxicity

Comments of zRMS:	Acceptable; no deviations, according to recent guidelines; used for evaluation

Reference: 7.1.3
Report: GF-2540: Acute liquid aerosol inhalation toxicity study in F344/DuCrl rats,
Krieger, S. M, 2010,
091135, ASB2012-14195
Guidelines: OECD 403 (2009)
EEC, B.2 (1992)
U.S. EPA OPPTS 870.1300 (1998)
JMAFF Acute Inhalation Toxicity Study (2000)
Deviations: No
GLP: Yes
Acceptability: Yes

Materials and methods

Test material (Lot/Batch No.)	GF-2540 (C2241-38-B, TSN031383-0001)
Species	Rat, Fischer 344/DuCrl
No. of animals (group size)	5 males and 5 females
Concentration	5.5 mg/L air
Exposure	4 hours (nose only)
Vehicle/Dilution	None
Post exposure observation period	14 days
Remarks	None

Results and discussions

Table A 5: Concentrations and exposure conditions

Nominal conc. [mg/L air]	Actual conc. [mg/L air]	MMAD [1)] [µm]	GSD [2)] [µm]
22.7	5.50	3.69	1.84

1) MMAD = Mass Median Aerodynamic Diameter
2) GSD = Geometric Standard Deviation

Table A 6: Results of acute inhalation toxicity study in rats treated with GF-2540

Dose (mg/L air)	Toxicological results [1)]	Duration of signs	Time of death	LC_{50} (mg/L air) (14 days)
Male rats				
5.50	0/0/5	--	--	> 5.50
Female rats				
5.50	0/1/5	until day 2	--	> 5.50

[1)] Number of animals which died/number of animals with clinical signs/number of animals used

Table A 7: Summary of findings of acute inhalation toxicity study in rats treated with GF-2540

Mortality:	No mortality occurred.
Clinical signs:	There were no clinical effects noted during the four-hour exposure period. In-life observations noted post-exposure were limited to perineal soiling in one female rat. All rats appeared normal by test day 2.
Body weight:	Mean body weight losses of 3.3 % and 1.9 % were noted for male and female rats on test day 2, respectively. Pre-exposure mean body weight values were exceeded on test day 4.
Macroscopic examination:	The necropsies performed at the end of the study revealed no apparent findings.

Conclusion

Under the experimental conditions, the inhalation LC_{50} of GF-2540 is higher than 5.50 mg/L air in rats. Thus, no classification is required according to the classification criteria of Council Directive 67/548/EEC and subsequent regulations as well as according to Regulation (EC) No. 1272/2008.

A 2.5 Skin irritation

Comments of zRMS:	Acceptable; no deviations, according to recent guidelines, used for evaluation

Reference: 7.1.4
Report GF-2540: Primary Skin Irritation Study in Rabbits,
Durando, J., 2009,
28375 ! 090336, ASB2012-14196
Guidelines: OECD 404
Reg. (EC) 440/2008, B.4
U.S. EPA OPPTS 870.2500
JMAFF 12-Nouan-8147
Deviations: No
GLP: Yes
Acceptability: Yes

Materials and methods

Test material (Lot/Batch No.)	GF-2540 (C2241-38-B, TSN031383-0001)
Species	Rabbit, New Zealand White
No. of animals (group size)	3 females
Initial test using one animal	Not mentioned
Exposure	0.5 mL (4 hours, semi-occlusive)

Vehicle/Dilution	None
Post exposure observation period	10 days
Remarks	Test sites were cleansed with 3 % soap solution followed by tap water after 4 h of exposure.

Results and discussions

Table A 8: Skin irritation results for GF-2540

Animal No.		Scores after treatment [1)]				Mean scores (24-72 h)	Reversible [day]
		1 h	24 h	48 h	72 h		
1	Erythema Oedema	1 0	1 1	1 1	1 1	1.0 1.0	10
2	Erythema Oedema	2 1	2 1	1 0	1 0	1.3 0.3	10
3	Erythema Oedema	1 1	1 1	1 0	1 0	1.0 0.3	7

[1)] scores in the range of 0 to 4

Clinical signs:	All animals appeared active and healthy and gained body weight during the study. Apart from the skin irritation there were no other signs of gross toxicity, adverse health effects, or abnormal behaviour.

Conclusion

Under the experimental conditions, GF-2540 is not a skin irritant. Thus, no classification is required according to the classification criteria of Council Directive 67/548/EEC and subsequent regulations as well as according to Regulation (EC) No. 1272/2008.

A 2.6 Eye irritation

Comments of zRMS:	Acceptable; no deviations, according to recent guidelines; used for evaluation

Reference: 7.1.5
Report: GF-2540: Primary Eye Irritation Study in Rabbits,
Durando, J., 2010,
28374 ! 090337, ASB2012-14197
Guidelines: OECD 405
Reg. (EC) 440/2008, B.5
U.S. EPA OPPTS 870.2400
JMAFF 12-Nouan-8147
Deviations: No
GLP: Yes
Acceptability: Yes

Materials and methods

Test material (Lot/Batch No.)	GF-2540 (C2241-38-B, TSN031383-0001)
Species	Rabbit, New Zealand White
No. of animals (group size)	3 females

Initial test using one animal	Yes
Exposure	0.1 mL (single instillation in conjunctival sac)
Irrigation (time point)	No
Vehicle/Dilution	None
Post exposure observation period	14 days
Remarks	None

Results and discussions

Table A 9: Eye irritation results for GF-2540

Animal No.		**Scores after treatment [1)]**				**Mean scores (24-72 h)**	**Reversible [day]**
		1 h	**24 h**	**48 h**	**72 h**		
1	Corneal opacity Iritis Redness conjunctivae Chemosis conjunctivae	0 0 1 0	0 0 1 0	0 0 0 0	0 0 0 0	0.0 0.0 0.3 0.0	2
2	Corneal opacity Iritis Redness conjunctivae Chemosis conjunctivae	0 0 1 1	0 0 0 0	0 0 0 0	0 0 0 0	0.0 0.0 0.0 0.0	1
3	Corneal opacity Iritis Redness conjunctivae Chemosis conjunctivae	0 0 1 0	0 0 1 0	0 0 1 0	0 0 0 0	0.0 0.0 0.7 0.0	3

[1)] 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:	All animals appeared active and healthy and gained body weight during the study. Apart from the eye irritation noted and the loss of weight of one animal, there were no other signs of gross toxicity, adverse health effects or abnormal behaviour.

Conclusion

Under the experimental conditions, GF-2540 is not an eye irritant. Thus, no classification is required according to the classification criteria of Council Directive 67/548/EEC and subsequent regulations as well as according to Regulation (EC) No. 1272/2008

A 2.7 <u>Skin sensitisation</u>

Comments of zRMS:	Acceptable; no deviations, according to recent guidelines; used for evaluation

Reference:	7.1.6
Report	GF-2540: Dermal Sensitization Study in Guinea Pigs (Magnusson-Kligman Method), Durando, J., 2009 28376 ! 090338, ASB2012-14198
Guidelines:	OECD 406 Reg. (EC) 440/2008, B.6 U.S. EPA OPPTS 870.2600 JMAFF 12-Nouan-8147

Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Test material (Lot/Batch No.)	GF-2540 (C2241-38-B, TSN031383-0001)
Species	Guinea pig, Hartley albino
No. of animals (group size)	Test substance group: 20 guinea pigs Vehicle control goup: 10 guinea pigs
Range finding:	Yes
Exposure (concentrations)	Intradermal induction: 5 % (w/w) in distilled water Topical induction: undiluted test substance Challenge: undiluted test substance
Vehicle	Distilled water
Pretreatment prior to topical application	No
Reliability check	Historical positive control: Alpha-Hexylcinnamaldehyde (concentration for intradermal induction not given, 100 % for topical induction and 75 % (w/w) in mineral oil for challenge)
Remarks	Treated sites were cleansed with 3 % soap solution followed by tap water after topical induction and challenge exposure.

Results and discussions

Table A 10: Results of skin sensitisation study for GF-2540

	24 hours	48 hours
	After challenge	
GF-2540	0/20	0/48
Test Vehicle Control Group	0/10	0/10
Positive control	8/10	6/10
Control group for positive control	0/4	0/4

1) Number of animals with positive dermal response (scores of 1-3) /number of animals in dose group; scores of 0.5 are not considered a positive reaction

Clinical signs:	None reported

Conclusion

Under the experimental conditions, GF-2540 is not a skin sensitiser. Thus, no classification is required according to the classification criteria of Council Directive 67/548/EEC and subsequent regulations as well as according to Regulation (EC) No. 1272/2008.

A 2.8 Supplementary studies for combinations of plant protection products

There are no studies on combinations of plant protection products since no combinations are intended.

A 2.9 Data on co-formulants

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

A study summary of the dermal absorption study with Kerb Flo (GF-1197) TOX2006-2209 is presented here:

Introduction. The herbicide Propyzamide was examined for *in vitro* percutaneous absorption through rat and human skin. The compound was tested at two nominal concentrations: Suspension Concentrate Formulation (GF-1197), 400g.L^{-1} (high dose) and as a Spray Dilution, 3g.L^{-1} (low dose). The mean dose levels achieved were 4171 and 4236 µg/cm^2 for the human and rat skin GF-1197 (high dose) and 29.87 and 30.06 µg/cm^2 for the human and rat skin spray dilution (low dose) respectively. The exposure time was 6 hours, i.e.: a normal working day, and the post exposure time was 18 hours.

The method was conducted to comply with the following guidelines:

- Council Directive EEC/91/414
- OECD Guidelines for the Testing of Chemicals: Test Guideline 428 for Skin Absorption: *In Vitro* Method. April 2004
- OECD Guidance Document for the Conduct of Skin Absorption Studies (OECD Environmental Health and Safety Publication series on Testing and Assessment No 28, 2004)

Method. The test preparations were applied at 10µL/cm^2 to human and rat split-thickness skin membranes. The membranes were mounted into flow through diffusion cells. Receptor fluid, sodium chloride (0.9% w/v) containing sodium azide (0.01% w/v) and polyoxyethylene 20-olyl ether (6% w/v), was pumped underneath at a rate of *ca.* 1.5mL.h^{-1}.

Prior to application, the integrity of the skin membranes was evaluated by measuring the electrical resistance (ER). The integrity of the skin samples was deemed acceptable if the ER across each membrane was $\geq$ 12.8 kΩ (20 kΩ/cm^2) for human skin membranes and $\geq$ 5 kΩ (7.8 kΩ/cm^2) for rat skin membranes.

The solubility of [^{14}C]-Propyzamide in the receptor fluid was found to be 0.0633 mg/mL^{-1}, approximately 60-fold greater than the highest concentration seen in any receptor fluid sample. As such, it can be assumed that the solubility of [^{14}C]-Propyzamide did not limit its absorption.

The skin surface temperature was maintained at *ca.* 32°C throughout the study.

Absorption was assessed by collecting receptor fluid in 2-hourly fractions from 0-24 hours post dosing. At 6 hours post dose, the exposure was terminated by washing and drying of the skin. At 24 hours post dosing, the skin was again washed and dried and the stratum corneum was then removed by successive tape stripping. All samples were analysed by liquid scintillation counting.

A summary of the results is provided below:

	Group			
	Human (High Dose) Mean (Standard Deviation)	Rat (High Dose) Mean (Standard Deviation)	Human (Low Dose) Mean (Standard Deviation)	Rat (Low Dose) Mean (Standard Deviation)
Concentration [mg/mL]	421.75	421.75	2.85	2.85
Dose [µg/cm²]	4171	4236	29.87	30.06
n	•5	6	6	°5
Initial absorption rate [µg/cm²/h]	0.295	0.436	0.064	0.114
Absorption rate at steady state [µg/cm²/h]	0.084	0.221	0.025	0.082
Results below expressed as percentage of applied dose				
Cell Wash (Donor)	0.24 (0.41)	0.10 (0.02)	1.20 (1.93)	1.27 (1.75)
Skin Swabs*	90.91 (4.97)	84.74 (7.75)	72.54 (13.67)	57.95 (7.53)
Tape Strips	0.31 (0.19)	0.78 (0.17)	17.41 (7.63)	28.24 (7.13)
Skin	0.56 (0.60)	1.59 (0.73)	9.21 (7.93)	9.80 (4.92)
Receptor fluid + receptor wash	0.09 (0.03)	0.24 (0.17)	3.16 (1.66)	7.22 (1.72)
Total recovery	92.12 (4.60)	87.45 (7.39)	103.53 (3.45)	104.49 (1.47)
Total absorption*	0.65 (0.62)	1.83 (0.62)	12.37 (8.99)	17.03 (5.34)

For both dose levels and skin types, the initial absorption of radioactivity during the initial 6 hour exposure time was higher than the absorption rate at steady state (typically between 10 and 24 hours post dose).

• = Results from one cell excluded due to failure of the membrane integrity test
° = Results from one cell excluded due to leakage of receptor fluid
* = Skin swabs taken at both 6 and 24 hours after administration and includes tape strips 1 and 2
** = Amount in receptor fluid, receptor compartment wash and the skin (excluding tape strips)

The absorption of radioactivity through rat skin was greater than that through human skin at both dose levels, being approximately 3-fold greater at steady state. At the high dose the absorption rates at steady state were 0.084 and 0.221 µg/cm^2/h with totals of 0.09 and 0.24% of dose penetrating into the receptor fluid for the human and rat skin respectively. At the low dose the absorption rates at steady state were 0.025 and 0.082 µg/cm^2/h with totals of 3.16 and 7.22% of dose penetrating into the receptor fluid for the human and rat skin respectively.

When the amount of test material in the skin is taken into account (excluding the amount recovered from the tape strips), the mean total absorption was 0.65% (high dose human skin), 1.83 % (high dose rat skin), 12.37% (low dose human skin) and 17.03% (low dose rat skin).

The stratum corneum is excluded because in the *in vivo* situation desquamation would remove the residue from the upper layers of the stratum corneum. Analysis of the distribution of the residue within the stratum corneum confirms that the majority of the residue is associated with the upper layers. The stratum corneum from the human skin acted as a better barrier with more residue retained in the surface layers in the human than the rat, particularly in the case of the spray dilution. Therefore the remaining stratum corneum residue would be excluded from the absorbed dose, particularly if the value is to be used for the calculation of a dermal exposure value to cover a single 24 hour period.

In conclusion, the mean total absorption of propyzamide from GF-1197 was 0.65 % (human skin) and 1.83 % (rat skin) and for a typical in use spray dilution, 12.37 % and 17.03 % for human and rat skin respectively.

A 2.11 Other/Special Studies

None, not necessary

Appendix 3 Exposure calculations

A 3.1 Operator exposure calculations

A 3.1.1 Calculations for aminopyralid

Table A 11: Input parameters considered for the estimation of operator exposure

Formulation type:	SC		**Application technique:**	Field Crop Tractor Mounted (FCTM)	
Application rate (AR):	0.00795	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	0.26	mg/kg bw/d	**Inhalation appl. (I_A):**	0.001	mg/person/kg a.s.

Table A 12: Estimation of operator exposure towards aminopyralid using the German model

Without PPE			**With PPE**		
Operators: Systemic dermal exposure after application in oilseed rape					
Dermal exposure during mixing/loading					
Hands			Hands		
$SDE_{OM(H)} = (D_{M(H)}$ x AR x A x DA) / BW			$SDE_{OM(H)} = (D_{M(H)}$ x AR x A x PPE [1] x DA) / BW		
(2.4 x 0.00795 x 20 x 75%) / 70			(2.4 x 0.00795 x 20 x 0.01 x 75%) / 70		
External dermal exposure	0.3816	mg/person	External dermal exposure	0.003816	mg/person
External dermal exposure	0.005451	mg/kg bw/d	External dermal exposure	0.000055	mg/kg bw/d
Systemic dermal exposure	**0.004089**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000041**	**mg/kg bw/d**
Dermal exposure during application					
Hands			Hands		
$SDE_{OA(H)} = (D_{A(H)}$ x AR x A x DA) / BW			$SDE_{OA(H)} = (D_{A(H)}$ x AR x A x PPE x DA) / BW		
(0.38 x 0.00795 x 20 x 75%) / 70			(0.38 x 0.00795 x 20 x 1 x 75%) / 70		
External dermal exposure	0.06042	mg/person	External dermal exposure	0.06042	mg/person
External dermal exposure	0.000863	mg/kg bw/d	External dermal exposure	0.000863	mg/kg bw/d
Systemic dermal exposure	**0.000647**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000647**	**mg/kg bw/d**
Body			Body		
$SDE_{OA(B)} = (D_{A(B)}$ x AR x A x DA) / BW			$SDE_{OA(B)} = (D_{A(B)}$ x AR x A x PPE x DA) / BW		
(1.6 x 0.00795 x 20 x 75%) / 70			(1.6 x 0.00795 x 20 x 1 x 75%) / 70		
External dermal exposure	0.2544	mg/person	External dermal exposure	0.2544	mg/person
External dermal exposure	0.003634	mg/kg bw/d	External dermal exposure	0.003634	mg/kg bw/d
Systemic dermal exposure	**0.002726**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.002726**	**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 0.00795 x 20 x 75%) / 70			(0.06 x 0.00795 x 20 x 1 x 75%) / 70		
External dermal exposure	0.00954	mg/person	External dermal exposure	0.00954	mg/person
External dermal exposure	0.000136	mg/kg bw/d	External dermal exposure	0.000136	mg/kg bw/d
Systemic dermal exposure	**0.000102**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000102**	**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	0.70596	mg/person	Total external dermal exposure	0.328176	mg/person
Total external dermal exposure	0.010085	mg/kg bw/d	Total external dermal exposure	0.004688	mg/kg bw/d
Total systemic dermal exposure	**0.007564**	**mg/kg bw/d**	**Total systemic dermal exposure**	**0.003516**	**mg/kg bw/d**
Operators: Systemic inhalation exposure after application in oilseed rape					
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 0.00795 x 20 x 100%) / 70			(0.0006 x 0.00795 x 20 x 1 x 100%) / 70		
External inhalation exposure	0.000095	mg/person	External inhalation exposure	0.000095	mg/person
External inhalation exposure	0.000001	mg/kg bw/d	External inhalation exposure	0.000001	mg/kg bw/d
Systemic inhalation exposure	**0.000001**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000001**	**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 0.00795 x 20 x 100%) / 70			(0.001 x 0.00795 x 20 x 1 x 100%) / 70		
External inhalation exposure	0.000159	mg/person	External inhalation exposure	0.000159	mg/person
External inhalation exposure	0.000002	mg/kg bw/d	External inhalation exposure	0.000002	mg/kg bw/d
Systemic inhalation exposure	**0.000002**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000002**	**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	0.000254	mg/person	Total external inhalation exposure	0.000254	mg/person
Total external inhalation exposure	0.000004	mg/kg bw/d	Total external inhalation exposure	0.000004	mg/kg bw/d
Total systemic inhalation exposure	**0.000004**	**mg/kg bw/d**	**Total systemic inhalation exposure**	**0.000004**	**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	0.529724	mg/person	Total systemic exposure	0.246386	mg/person
Total systemic exposure	**0.007567**	**mg/kg bw/d**	**Total systemic exposure**	**0.00352**	**mg/kg bw/d**
% of AOEL	**2.9**	%	**% of AOEL**	**1.4**	%

[1)] reduction factor for gloves is 0.01 (professional appl.)

Table A 13: Estimation of operator exposure towards aminopyralid using the UK-POEM

Without PPE

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)					
Active substance	**Aminopyralid**				
Product	GF-2540				
Formulation type	water-based				
Concentration of a.s.	5.3	mg/mL			
Dose	1.5	L preparation/ha	(0.008 kg a.s./ha)		
Application volume	200	L/ha			
Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles				
Container	5 litres 45 or 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	5	Litres			
Hand contamination/operation	0,01	mL			
Application dose	1.5	Litres product/ha			
Work rate	50	ha/day			
Number of operations	15	/day			
Hand contamination	0.15	mL/day			
Protective clothing	None				
Transmission to skin	100	%			
Dermal exposure to formulation	0.15	mL/day			
DERMAL EXPOSURE DURING SPRAY APPLICATION					
Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles				
Application volume	200	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	0.15	mL/day	41.55	mL/day
Concen. of a.s. product or spray	5.3	mg/mL	0.04	mg/mL
Dermal exposure to a.s.	0.795	mg/day	1.652	mg/day
Percent absorbed	75	%	75	%
Absorbed dose	0.596	mg/day	1.239	mg/day
INHALATION EXPOSURE DURING SPRAYING				
Inhalation exposure	0.01	mL/h		
Duration of exposure	6	h		
Concentration of a.s. in spray	0.04	mg/mL		
Inhalation exposure to a.s.	0.002	mg/day		
Percent absorbed	100	%		
Absorbed dose	0.002	mg/day		
PREDICTED EXPOSURE				
Total absorbed dose	1.837	mg/day		
Operator body weight	60	kg		
Operator exposure	0.031	mg/kg bw/day		
Amount of AOEL	**11.8**	**%**		

With PPE

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)					
Active substance	**Aminopyralid**				
Product	GF-2540				
Formulation type	water-based				
Concentration of a.s.	5.3	mg/mL			
Dose	1.5	L preparation/ha	(0.008 kg a.s./ha)		
Application volume	200	L/ha			
Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles				
Container	5 litres 45 or 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	5	Litres			
Hand contamination/operation	0,01	mL			
Application dose	1.5	Litres product/ha			
Work rate	50	ha/day			
Number of operations	15	/day			
Hand contamination	0.15	mL/day			
Protective clothing	Gloves				
Transmission to skin	5	%			
Dermal exposure to formulation	0.008	mL/day			
DERMAL EXPOSURE DURING SPRAY APPLICATION					
Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles				
Application volume	200	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	0.008	mL/day	6.45	mL/day
Concen. of a.s. product or spray	5.3	mg/mL	0.04	mg/mL
Dermal exposure to a.s.	0.04	mg/day	0.256	mg/day
Percent absorbed	75	%	75	%
Absorbed dose	0.03	mg/day	0.192	mg/day
INHALATION EXPOSURE DURING SPRAYING				
Inhalation exposure	0.01	mL/h		
Duration of exposure	6	h		
Concentration of a.s. in spray	0.04	mg/mL		
Inhalation exposure to a.s.	0.002	mg/day		
Percent absorbed	100	%		
Absorbed dose	0.002	mg/day		
PREDICTED EXPOSURE				
Total absorbed dose	0.224	mg/day		
Operator body weight	60	kg		
Operator exposure	0.004	mg/kg bw/day		
Amount of AOEL	**1.4**	**%**		

A 3.1.2 Calculations for propyzamide

Table A 14: Input parameters considered for the estimation of operator exposure

Formulation type:	SC		**Application technique:**	Field Crop Tractor Mounted (FCTM)	
Application rate (AR):	0.75	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):	0.65	% (concentr.)	**Dermal hands appl. ($D_{A(H)}$):**	0.38	mg/person/kg a.s.
	12.37	% (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	0.08	mg/kg bw/d	**Inhalation appl. (I_A):**	0.001	mg/person/kg a.s.

Table A 15: Estimation of operator exposure towards propyzamide using the German model

Without PPE			**With PPE**		
Operators: Systemic dermal exposure after application in oilseed rape					
<u>Dermal exposure during mixing/loading</u>					
Hands			Hands		
$SDE_{OM(H)} = (D_{M(H)}$ x AR x A x DA) / BW			$SDE_{OM(H)} = (D_{M(H)}$ x AR x A x PPE [1] x DA) / BW		
(2.4 x 0.75 x 20 x 0.65%) / 70			(2.4 x 0.75 x 20 x 0.01 x 0.65%) / 70		
External dermal exposure	36	mg/person	External dermal exposure	0.36	mg/person
External dermal exposure	0.514286	mg/kg bw/d	External dermal exposure	0.005143	mg/kg bw/d
Systemic dermal exposure	**0.003343**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000033**	**mg/kg bw/d**
<u>Dermal exposure during application</u>					
Hands			Hands		
$SDE_{OA(H)} = (D_{A(H)}$ x AR x A x DA) / BW			$SDE_{OA(H)} = (D_{A(H)}$ x AR x A x PPE x DA) / BW		
(0.38 x 0.75 x 20 x 12.37%) / 70			(0.38 x 0.75 x 20 x 1 x 12.37%) / 70		
External dermal exposure	5.7	mg/person	External dermal exposure	5.7	mg/person
External dermal exposure	0.081429	mg/kg bw/d	External dermal exposure	0.081429	mg/kg bw/d
Systemic dermal exposure	**0.010073**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.010073**	**mg/kg bw/d**
Body			Body		
$SDE_{OA(B)} = (D_{A(B)}$ x AR x A x DA) / BW			$SDE_{OA(B)} = (D_{A(B)}$ x AR x A x PPE x DA) / BW		
(1.6 x 0.75 x 20 x 12.37%) / 70			(1.6 x 0.75 x 20 x 1 x 12.37%) / 70		
External dermal exposure	24	mg/person	External dermal exposure	24	mg/person
External dermal exposure	0.342857	mg/kg bw/d	External dermal exposure	0.342857	mg/kg bw/d
Systemic dermal exposure	**0.042411**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.042411**	**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 0.75 x 20 x 12.37%) / 70			(0.06 x 0.75 x 20 x 1 x 12.37%) / 70		
External dermal exposure	0.9	mg/person	External dermal exposure	0.9	mg/person
External dermal exposure	0.012857	mg/kg bw/d	External dermal exposure	0.012857	mg/kg bw/d
Systemic dermal exposure	**0.00159**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.00159**	**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	66.6	mg/person	Total external dermal exposure	30.96	mg/person
Total external dermal exposure	0.951429	mg/kg bw/d	Total external dermal exposure	0.442286	mg/kg bw/d
Total systemic dermal exposure	**0.057417**	**mg/kg bw/d**	**Total systemic dermal exposure**	**0.054108**	**mg/kg bw/d**
Operators: Systemic inhalation exposure after application in oilseed rape					
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 0.75 x 20 x 100%) / 70			(0.0006 x 0.75 x 20 x 1 x 100%) / 70		
External inhalation exposure	0.009	mg/person	External inhalation exposure	0.009	mg/person
External inhalation exposure	0.000129	mg/kg bw/d	External inhalation exposure	0.000129	mg/kg bw/d
Systemic inhalation exposure	**0.000129**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000129**	**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 0.75 x 20 x 100%) / 70			(0.001 x 0.75 x 20 x 1 x 100%) / 70		
External inhalation exposure	0.015	mg/person	External inhalation exposure	0.015	mg/person
External inhalation exposure	0.000214	mg/kg bw/d	External inhalation exposure	0.000214	mg/kg bw/d
Systemic inhalation exposure	**0.000214**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000214**	**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	0.024	mg/person	Total external inhalation exposure	0.024	mg/person
Total external inhalation exposure	0.000343	mg/kg bw/d	Total external inhalation exposure	0.000343	mg/kg bw/d
Total systemic inhalation exposure	**0.000343**	**mg/kg bw/d**	**Total systemic inhalation exposure**	**0.000343**	**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	4.04322	mg/person	Total systemic exposure	3.81156	mg/person
Total systemic exposure	**0.05776**	**mg/kg bw/d**	**Total systemic exposure**	**0.054451**	**mg/kg bw/d**
% of AOEL	**72.2**	%	**% of AOEL**	**68.1**	%

[1)] reduction factor for gloves is 0.01 (professional appl.)

Table A 16: Estimation of operator exposure towards propyzamide using the UK-POEM

Without PPE

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)			
Active substance	**Propyzamide**		
Product	GF-2540		
Formulation type	water-based		
Concentration of a.s.	500	mg/mL	
Dose	1.5	L preparation/ha	(0.75 kg a.s./ha)
Application volume	200	L/ha	
Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles		
Container	5 litres 45 or 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	0.65	%	
Dermal absorption from spray	12.37	%	
EXPOSURE DURING MIXING AND LOADING			
Container size	5	Litres	
Hand contamination/operation	0,01	mL	
Application dose	1.5	Litres product/ha	
Work rate	50	ha/day	
Number of operations	15	/day	

Hand contamination	0.15	mL/day			
Protective clothing	None				
Transmission to skin	100	%			
Dermal exposure to formulation	0.15	mL/day			
DERMAL EXPOSURE DURING SPRAY APPLICATION					
Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles				
Application volume	200	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	0.15	mL/day		41.55	mL/day
Concen. of a.s. product or spray	500	mg/mL		3.75	mg/mL
Dermal exposure to a.s.	75	mg/day		155.813	mg/day
Percent absorbed	0.65	%		12.37	%
Absorbed dose	0.488	mg/day		19.274	mg/day
INHALATION EXPOSURE DURING SPRAYING					
Inhalation exposure	0.01	mL/h			
Duration of exposure	6	h			
Concentration of a.s. in spray	3.75	mg/mL			
Inhalation exposure to a.s.	0.225	mg/day			
Percent absorbed	100	%			
Absorbed dose	0.225	mg/day			
PREDICTED EXPOSURE					
Total absorbed dose	19.987	mg/day			
Operator body weight	60	kg			
Operator exposure	0.333	mg/kg bw/day			
Amount of AOEL	**416.4**	**%**			

With PPE

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)			
Active substance	**Propyzamide**		
Product	GF-2540		
Formulation type	water-based		
Concentration of a.s.	500	mg/mL	
Dose	1.5	L preparation/ha	(0.75 kg a.s./ha)
Application volume	200	L/ha	
Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles		
Container	5 litres 45 or 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	0.65	%	
Dermal absorption from spray	12.37	%	
EXPOSURE DURING MIXING AND LOADING			
Container size	5	Litres	
Hand contamination/operation	0,01	mL	
Application dose	1.5	Litres product/ha	
Work rate	50	ha/day	
Number of operations	15	/day	

Hand contamination	0.15	mL/day			
Protective clothing	Gloves				
Transmission to skin	5	%			
Dermal exposure to formulation	0.008	mL/day			
DERMAL EXPOSURE DURING SPRAY APPLICATION					
Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles				
Application volume	200	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	0.008	mL/day		6.45	mL/day
Concen. of a.s. product or spray	500	mg/mL		3.75	mg/mL
Dermal exposure to a.s.	3.75	mg/day		24.188	mg/day
Percent absorbed	0.65	%		12.37	%
Absorbed dose	0.024	mg/day		2.992	mg/day
INHALATION EXPOSURE DURING SPRAYING					
Inhalation exposure	0.01	mL/h			
Duration of exposure	6	h			
Concentration of a.s. in spray	3.75	mg/mL			
Inhalation exposure to a.s.	0.225	mg/day			
Percent absorbed	100	%			
Absorbed dose	0.225	mg/day			
PREDICTED EXPOSURE					
Total absorbed dose	3.241	mg/day			
Operator body weight	60	kg			
Operator exposure	0.054	mg/kg bw/day			
Amount of AOEL	**67.5**	**%**			

A 3.2 Worker exposure calculations

A 3.2.1 Calculations for aminopyralid

Table A 17: Input parameters considered for the estimation of worker exposure

Intended use:	Oilseed rape		**Dislodgeable foliar residues (DFR):**	1	µg/cm²/kg a.s.
Application rate (AR):	0.00795	kg a.s./ha	**Transfer coefficient (TC):**	1500	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	0.26	mg/kg bw/d			

Table A 18: Estimation of worker exposure towards aminopyralid using the German re-entry model

Without PPE [1)]			**With PPE [2)]**		
Worker (re-entry): Systemic dermal exposure after application in oilseed rape					
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 1500 x 2 x 0.00795 x 1 x 75%) / 60			(1 x 1500 x 2 x 0.00795 x 1 x 5% x 75%) / 60		
External dermal exposure	0.02385	mg/person	External dermal exposure	0.001193	mg/person
External dermal exposure	0.000398	mg/kg bw/d	External dermal exposure	0.00002	mg/kg bw/d
Total systemic exposure	0.017888	mg/person	Total systemic exposure	0.000894	mg/person

Total systemic exposure	**0.000298**	**mg/kg bw/d**	**Total systemic exposure**	**0.000015**	**mg/kg bw/d**
% of AOEL	**0.11**	**%**	**% of AOEL**	**0.01**	**%**

1) acceptable without PPE
2) acceptable only with PPE: see instructions for use

A 3.2.2 Calculations for propyzamide

Table A 19: Input parameters considered for the estimation of worker exposure

Intended use:	Oilseed rape		**Dislodgeable foliar residues (DFR):**	1	µg/cm²/kg a.s.
Application rate (AR):	0.75	kg a.s./ha	**Transfer coefficient (TC):**	1500	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):	12.37	% ('worst case')			
AOEL	0.08	mg/kg bw/d			

Table A 20: Estimation of worker exposure towards propyzamide using the German re-entry model

Without PPE 1)			**With PPE 2)**		
Worker (re-entry): Systemic dermal exposure after application in oilseed rape					
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 1500 x 2 x 0.75 x 1 x 12.37%) / 60			(1 x 1500 x 2 x 0.75 x 1 x 5% x 12.37%) / 60		
External dermal exposure	2.25	mg/person	External dermal exposure	0.1125	mg/person
External dermal exposure	0.0375	mg/kg bw/d	External dermal exposure	0.001875	mg/kg bw/d
Total systemic exposure	0.278325	mg/person	Total systemic exposure	0.013916	mg/person
Total systemic exposure	**0.004639**	**mg/kg bw/d**	**Total systemic exposure**	**0.000232**	**mg/kg bw/d**
% of AOEL	**5.8**	**%**	**% of AOEL**	**0.3**	**%**

1) acceptable without PPE
2) acceptable only with PPE: see instructions for use

A 3.3 <u>Bystander and resident exposure calculations</u>

A 3.3.1 Calculations for aminopyralid

Table A 21: Input parameters considered for the estimation of bystander exposure

Intended use:	Oilseed rape		**Drift (D):**	2.77	% (FC, 1 m)
Application rate (AR):	0.00795	kg a.s./ha	**Exposed body surface area (BSA):**	1	m² (adults)
	0.795	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:	0.26	mg/kg bw/d	**Exposure duration (T):**	5	min

Table A 22: Estimation of bystander exposure towards aminopyralid

Adults			**Children**		
Bystander: Systemic dermal exposure during/after application in oilseed rape (via spray drift)					
SDE_B = (AR x D x BSA x DA) / BW			SDE_B = (AR x D x BSA x DA) / BW		
(0.795 x 2.77% x 1 x 75%) / 60			(0.795 x 2.77% x 0.21 x 75%) / 16.15		
External dermal exposure	0.022022	mg/person	External dermal exposure	0.004625	mg/person
External dermal exposure	0.000367	mg/kg bw/d	External dermal exposure	0.000286	mg/kg bw/d
Systemic dermal exposure	**0.000275**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000215**	**mg/kg bw/d**
Bystander: Systemic inhalation exposure during/after application in oilseed rape (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 0.00795 x 20 x 5 x 100%) / 60			(0.000575 / 360 x 0.00795 x 20 x 5 x 100%) / 16.15		
External inhalation exposure	0.000002	mg/person	External inhalation exposure	0.000001	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	0.016518	mg/person	Total systemic exposure	0.00347	mg/person
Total systemic exposure	**0.000275**	**mg/kg bw/d**	**Total systemic exposure**	**0.000215**	**mg/kg bw/d**
% of AOEL	**0.11**	**%**	**% of AOEL**	**0.08**	**%**

Table A 23: Input parameters considered for the estimation of resident exposure

Intended use:	Oilseed rape		**Drift (D):**	2.77	% (FC, 1 m)
Application rate (AR):	0.00795	kg a.s./ha	**Transfer coefficient (TC):**	7300	cm^2/h (adults)
	0.0000795	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:	0.26	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 24: Estimation of resident exposure towards aminopyralid

Adults			**Children**		
Residents: Systemic dermal exposure after application in oilseed rape (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		
(0.0000795 x 1 x 2.77% x 5% x 7300 x 2 x 75%) / 60			(0.0000795 x 1 x 2.77% x 5% x 2600 x 2 x 75%) / 16.15		
External dermal exposure	0.001608	mg/person	External dermal exposure	0.000573	mg/person
External dermal exposure	0.000027	mg/kg bw/d	External dermal exposure	0.000035	mg/kg bw/d
Systemic dermal exposure	**0.00002**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000027**	**mg/kg bw/d**
Residents: Systemic inhalation exposure after application in oilseed rape (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		
			(0.0000795 x 1 x % x 5% x 50% x 20 x 20 x 2 x 100%) / 16.15		
			External oral exposure	0.000044	mg/person
			External oral exposure	0.000003	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		
			(0.0000795 x 1 x % x 20% x 25 x 100%) / 16.15		
			External oral exposure	0.000011	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	0.001206	mg/person	Total systemic exposure	0.000484	mg/person
Total systemic exposure	**0.00002**	**mg/kg bw/d**	**Total systemic exposure**	**0.00003**	**mg/kg bw/d**

% of AOEL	**0.01**	%	**% of AOEL**	**0.01**	%

A 3.3.2 Calculations for propyzamide

Table A 25: Input parameters considered for the estimation of bystander exposure

Intended use:	Oilseed rape		**Drift (D):**	2.77	% (FC, 1 m)
Application rate (AR):	0.75	kg a.s./ha	**Exposed body surface area (BSA):**	1	m² (adults)
	75	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):	12.37	% ('worst case')	**Area Treated (A):**	20	ha/d (based on FCTM)
Inhalation absorption (IA):	100	%			
AOEL:	0.08	mg/kg bw/d	**Exposure duration (T):**	5	min

Table A 26: Estimation of bystander exposure towards propyzamide

Adults			**Children**		
Bystander: Systemic dermal exposure during/after application in oilseed rape (via spray drift)					
SDE_B = (AR x D x BSA x DA) / BW			SDE_B = (AR x D x BSA x DA) / BW		
(75 x 2.77% x 1 x 12.37%) / 60			(75 x 2.77% x 0.21 x 12.37%) / 16.15		
External dermal exposure	2.0775	mg/person	External dermal exposure	0.436275	mg/person
External dermal exposure	0.034625	mg/kg bw/d	External dermal exposure	0.027014	mg/kg bw/d
Systemic dermal exposure	**0.004283**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.003342**	**mg/kg bw/d**
Bystander: Systemic inhalation exposure during/after application in oilseed rape (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 0.75 x 20 x 5 x 100%) / 60			(0.000575 / 360 x 0.75 x 20 x 5 x 100%) / 16.15		
External inhalation exposure	0.000208	mg/person	External inhalation exposure	0.00012	mg/person
External inhalation exposure	0.000003	mg/kg bw/d	External inhalation exposure	0.000007	mg/kg bw/d
Systemic inhalation exposure	**0.000003**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000007**	**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	0.257195	mg/person	Total systemic exposure	0.054087	mg/person
Total systemic exposure	**0.004287**	**mg/kg bw/d**	**Total systemic exposure**	**0.003349**	**mg/kg bw/d**
% of AOEL	**5.36**	**%**	**% of AOEL**	**4.19**	**%**

Table A 27: Input parameters considered for the estimation of resident exposure

Intended use:	Oilseed rape		**Drift (D):**	2.77	% (FC, 1 m)
Application rate (AR):	0.75	kg a.s./ha	**Transfer coefficient (TC):**	7300	cm^2/h (adults)
	0.0075	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):**	0.001	mg/m^3
Dermal absorption (DA):	12.37	% ('worst case')	**Inhalation Rate (IR):**	16.57	m^3/d (adults)
Inhalation absorption (IA):	100	%		8.31	m^3/d (children)
Oral absorption (OA):	80	%	**Saliva Extraction Factor (SE):**	50	%
AOEL:	0.08	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 28: Estimation of resident exposure towards propyzamide

Adults	**Children**
Residents: Systemic dermal exposure after application in oilseed rape (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

(0.0075 x 1 x 2.77% x 5% x 7300 x 2 x 12.37%) / 60			(0.0075 x 1 x 2.77% x 5% x 2600 x 2 x 12.37%) / 16.15		
External dermal exposure	0.151658	mg/person	External dermal exposure	0.054015	mg/person
External dermal exposure	0.002528	mg/kg bw/d	External dermal exposure	0.003345	mg/kg bw/d
Systemic dermal exposure	**0.000313**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000414**	**mg/kg bw/d**
Residents: Systemic inhalation exposure after application in oilseed rape (via vapour)					
$SIE_R = (AC_V \times IR \times IA) / BW$			$SIE_R = (AC_V \times IR \times IA) / BW$		
(0.001 x 16.57 x 100%) / 60			(0.001 x 8.31 x 100%) / 16.15		
External inhalation exposure	0.01657	mg/person	External inhalation exposure	0.00831	mg/person
External inhalation exposure	0.000276	mg/kg bw/d	External inhalation exposure	0.000515	mg/kg bw/d
Systemic inhalation exposure	**0.000276**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000515**	**mg/kg bw/d**
			Residents: Systemic oral exposure (hand-to-mouth transfer)		
			$SOE_{R(H)} = (AR \times NA \times D \times TTR \times SE \times SA \times Freq \times H \times OA) / BW$		
			(0.0075 x 1 x % x 5% x 50% x 20 x 20 x 2 x 80%) / 16.15		
			External oral exposure	0.004155	mg/person
			External oral exposure	0.000257	mg/kg bw/d
			Systemic oral exposure	**0.000206**	**mg/kg bw/d**
			Residents: Systemic oral exposure (object-to-mouth transfer)		
			$SOE_{R(O)} = (AR \times NA \times D \times DFR \times IgR \times OA) / BW$		
			(0.0075 x 1 x % x 20% x 25 x 80%) / 16.15		
			External oral exposure	0.001039	mg/person
			External oral exposure	0.000064	mg/kg bw/d
			Systemic oral exposure	**0.000051**	**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	0.03533	mg/person	Total systemic exposure	0.019147	mg/person
Total systemic exposure	**0.000589**	**mg/kg bw/d**	**Total systemic exposure**	**0.001186**	**mg/kg bw/d**
% of AOEL	**0.74**	%	**% of AOEL**	**1.48**	%

A 3.4 Combined exposure calculations for aminopyralid and propyzamide

Due to the lack of an accepted scientific method no combined exposure calculations have been carried out so far.

REGISTRATION REPORT
Part B

Section 4: Metabolism and Residues

Detailed summary of the risk assessment

Product code: GF-2540

Active Substances: Aminopyralid 5.3 g/L, Propyzamide 500 g/L

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Dow AgroSciences GmbH

Date: 08/05/2014

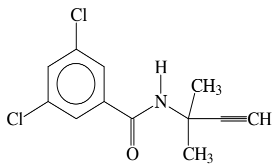
Table of Contents

4 METABOLISM AND RESIDUES DATA

4.1 Evaluation of the active substances

4.1.1 Propyzamide

Table 4.1-1: Identity of the active substance

Structural formula	
Common Name	Propyzamide
CAS number	23950-58-5

4.1.1.1 Storage stability

A brief summary of the storage stability data on propyzamide is given in the following table. Data, which has been previously evaluated at EU level is described in detail in the Reasoned opinion of EFSA on the review of the existing MRLs for propyzamide according to Article 12 of Regulation (EC) No 396/2005 (ASB2012-8952).

Table 4.1-2: Stability of residues (Annex IIA, point 6.1)

Stability of propyzamide	Storage stability of propyzamide was investigated in milk, alfalfa hay, apples, grapes, lettuce and peaches (RIP2000-747). Residues of propyzamide were stable at –20 °C during a storage period of 36 months. Storage stability (-20°C) of propyzamide in seeds of rape and soya (whole material!) was demonstrated for at least 18 and 24 months, respectively. In treated homogenized soya seed samples however, residues dropped below 70% of mean recovery as early as after 3 months at -20°C (ASB2012-14214). No study was available on dry commodities.

4.1.1.2 Metabolism in plants and plant residue definitions

The primary metabolism of propyzamide in plants was investigated in the framework of Directive 91/414/EEC (DAR, ASB2010-10283). A brief summary of the results is given in the following table.

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	Lettuce (leafy vegetables, RIP2006-1957), alfalfa (legume vegetables, RIP2006-1958) and rape seed (oilseeds, see DAR, ASB2010-10283), [^{14}C-phenyl] label The metabolism studies in alfalfa and lettuce indicate that the parent compound is rapidly degraded, but is still the major compound of the residue (50–84% TRR in alfalfa, 43–96% TRR in lettuce). In the study with oilseed rape, parent propyzamide was the main component of the TRR in the seeds and in forage. Metabolites RH-26702 and RH-24644 were also identified, but their amount did not exceed 10% TRR. The highest residue levels were found in roots of rape, where parent amounted to 13.9% TRR while metabolite RH-24644 was the major compound amounting to 45% TRR.
Rotational crops	Lettuce (leafy vegetables), carrots (root and tuber vegetables) and wheat (cereals), [^{14}C-phenyl] label, application of 4.48 kg as/ha onto bare soil, PBIs 30, 180 and 365 days (RIP2000-761, RIP2000-782) In rotational crops most components exceeding 10% TRR were sugar conjugates and parent propyzamide, the latter at slightly lower levels. This could be explained by slow degradation of propyzamide in soil, where it is partially transformed to one of its main soil metabolites RH-24644, which subsequently degrades to secondary metabolites, in this case mannose conjugate (RH-25337) and glucose conjugate (RH-26702).
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)	No study available
Residue pattern in raw and processed commodities similar? (yes/no)	Not applicable
Plant residue definition for monitoring	Propyzamide
Plant residue definition for risk assessment	Propyzamide
Conversion factor(s) (monitoring to risk assessment)	None

4.1.1.3 Metabolism in livestock and animal residue definitions

The nature of propyzamide residues in commodities of animal origin was investigated in the framework of Directive 91/414/EEC (DAR, ASB2010-10283). A brief summary of the results is given in the following table.

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 (RIP2006-1972,RIP2006-1970) were dosed with daily 50 mg/kg of ^{14}C-phenyl labeled propyzamide via their feed over four consecutive days Laying hens (RIP2000-749, RIP2006-1971) were dosed with daily 50 mg/kg of ^{14}C-phenyl labeled propyzamide via their feed over ten consecutive days In both species propyzamide was rapidly eliminated, mainly via urine and faeces. The highest residue concentrations in tissues were found in fat, liver and kidney. In milk, eggs, fat and muscle the residue mainly consisted of parent compound whereas propyzamide has been extensively metabolized in liver and kidney, indicated by the low levels of parent leading to at least 13 different metabolites, most of them containing the 3,5-dichlorobenzoyl group.
Time needed to reach a plateau concentration in milk and eggs	Eggs: 7 days Milk: 3-4 days (see DAR, ASB2010-10283)
Animal residue definition for monitoring	Sum of propyzamide and all metabolites containing the 3,5-dichlorobenzoic acid moiety, expressed as propyzamide
Animal residue definition for risk assessment	Sum of propyzamide and all metabolites containing the 3,5-dichlorobenzoic acid moiety, expressed as propyzamide
Conversion factor(s) (monitoring to risk assessment)	None
Metabolism in rat and ruminant similar (yes/no)	No
Fat soluble residue: (yes/no)	Yes

4.1.1.4 Residues in rotational crops

A brief summary of the field rotational crop studies on propyzamide is given in the following table.

Table 4.1-5: Residues in rotational crops (Annex IIA, point 6.6.3)

Field studies	Following applications of 1.5 kg as/ha to lettuce, rotational crops celery, carrots, kohlrabi, dwarf beans and lettuce were planted as follow-up crops (RIP2000-783, RIP2000-785, RIP2000-789). At harvest, quantifiable residues were neither seen in any of the edible commodities nor in leaves of carrots. Nonetheless, with a view to the results of the metabolism study in rotational crops, EFSA is recommending to consider the need for appropriate plant back intervals for crop failing events in order to avoid residues in rotational crops with short vegetation periods (ASB2012-8952).

4.1.1.5 Residues in livestock

Based on the outcome of the peer review of existing EU MRLs (ASB2012-8952) an actual calculation of the dietary burden of all relevant uses authorized in the EU is provided in Table 4.1-6.

Table 4.1-6: Calculation of the dietary burden (based on all relevant uses authorized 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 max. feed (DM) 120 g	**Dairy cattle** 550 kg bw daily max. feed (DM) 20 kg	**Beef cattle** 350 kg bw daily max. feed (DM) 15 kg	**Pig** 75 kg bw daily max. feed (DM) 3 kg		**Chicken**	**Dairy cattle**	**Beef cattle**	**Pig**
alfalfa	20	--	--	--	15	0.01[a)]	0.000	0.000	0.000	0.008
fruit pomace	23	--	--	30	--	0.03[b)]	0.000	0.000	0.033	0.000
alfalfa hay	20	--	70	--	15	0.01[a)]	0.000	0.033	0.000	0.000
pulses	86	30	--	10	25	0.01[c)]	0.003	0.000	0.001	0.003
sugar beet roots	20	20	30	60	60	0.05[d)]	0.050	0.075	0.150	0.150
oilseeds	86	10	--	--	--	0.01[e)]	0.001	0.000	0.000	0.000
Intake (mg/kg dry weight feed)							0.053	0.108	0.184	0.160
Intake (mg/kg bw/d)							0.003	0.004	0.008	0.006
Intake (mg/animal/d)							0.007	2.159	2.757	0.481

[a)] HR, based on the following cGAP: 1 x 760 g as/ha, PHI: 150 d, PF_{hay} = 4 (ASB2012-8952)
[b] HR, based on the following cGAP: 1 x 2500 g as/ha, PHI: >180 d, PF_{pomce} = 2.5 (ASB2012-8952)
[c)] HR, based on the following cGAP: 1 x 750 g as/ha, PHI: <180 d (ASB2012-8952)
[d)] HR, based on the following cGAP: 1 x 2000 g as/ha, PHI: 100 d, SEU (ASB2012-8952), no data were provided for the sugar beet tops and leaves (data gap identified for SEU GAP in (ASB2012-8952)
[e)] HR, based on the following cGAP: 1 x 840 g as/ha, PHI >150 d, SEU (ASB2012-8952)

Table 4.1-7: Conditions of requirement of livestock feeding studies

	Ruminant:	**Poultry:**	**Pig:**
Expected intakes by livestock ≥0.1 mg/kg diet (dry weight basis) (yes/no – If yes, specify the level)	yes 0.108 (dairy); 0.184 (beef)	no	yes 0.160
Potential for accumulation (yes/no):	no (RIP2000-751)	no	no (RIP2000-751)
Metabolism studies indicate potential level of residues ≥0.01 mg/kg in edible tissues (yes/no)	no	no	no

A brief summary of the available livestock feeding studies is given in the following table. They have been evaluated in the DAR (ASB2010-10283) to which it is referred for more details. Notably a further cow study involving higher feeding levels was also available but not further considered with a view to the expected maximum dietary intake of propyzamide residues by livestock.

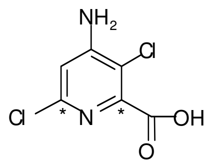
Table 4.1-8: Results of livestock feeding studies (Annex IIA, point 6.4)

	Ruminant:	**Poultry:**	**Pig:**
Feeding levels (mg/kg feed dry matter) Feeding levels (mg/kg bw/day)	dairy cows (RIP2000-751) 1.8; 3.5; 7.5 0.077; 0.15; 0.32	laying hens (RIP2000-754) 0.22, 0.51, 1.82	see ruminants
Relevant dosing levels in feeding study:	1.8	--	1.8
	Expected residue levels in animal matrices (mg/kg):		
Muscle	<0.01	<0.01	<0.01
Liver	<0.01	<0.01	<0.01

	Ruminant:	Poultry:	Pig:
Kidney	<0.01	<0.01	<0.01
Fat	<0.01	<0.01	<0.01
Milk	<0.01	–	–
Eggs	–	<0.01	–

4.1.2 Aminopyralid

Table 4.1-9: Identity of the active substance

Structural formula	
Common Name	Aminopyralid
CAS number	150114-71-9

4.1.2.1 Storage stability

A brief summary of the storage stability data on aminopyralid is given in the following table. Data, which has been previously evaluated at EU level is described in detail in the DAR (ASB2012-7176).

Table 4.1-10: Stability of residues (Annex IIA, point 6.1)

Stability of aminopyralid	Residues of aminopyralid were found to be stable at ≤ -20°C for up to ca. 16 months in matrices with high water content (forage and grass) and up to ca. 15 months in dry matrices (wheat grain and straw) (RIP2004-983, ASB2012-9128). No storage stability data have been provided for high oil content commodities like oilseed rape.

4.1.2.2 Metabolism in plants and plant residue definitions

The primary metabolism of aminopyralid in grass and wheat and the metabolism in rotational crops were evaluated by the United Kingdom in the DAR (ASB2012-7176). In addition, a metabolism study on oilseed rape was evaluated by EFSA in the framework of an MRL application (ASB2012-13388). A summary of the primary metabolism of aminopyralid in plants is given in the following table.

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	post-emergence applications, 2- and 6-^{14}C-pyridine label - grass (RIP2004-984): 1x 360 g as/ha - spring wheat (RIP2004-985): 1x 40 or 80 g as/ha, BBCH 26-28 - oilseed rape (ASB2010-7659): 1x 15 g as/ha, BBCH 51 The major component in grass, wheat and rape seed metabolism studies was parent aminopyralid and conjugates, which were released as parent aminopyralid upon hydrolytic extraction conditions.
Rotational crops	Confined study (RIP2004-998): 2- and 6-^{14}C-pyridine label, application of 0.1 kg as/ha to bare soil, PBI 90 and 120 days, rotational crops lettuce (leafy vegetables), turnip (root and tuber vegetables) and sorghum (cereals). Residues were low in all matrices. Aminopyralid was the major component of the residue. Although there were no specific data on levels of aminopyralid taken up at 30 days, the expectation is that residues would be similarly low as for longer PBIs, based on the soil residue profile.
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 applicant makes reference to hydrolysis of aminopyralid in aqueous solution at pH 5, 7 and 9 at 20ºC over a period of 31 days and at 50ºC over a period of 5 days (CHE2004-924). Aminopyralid was found to be stable under these conditions.
Residue pattern in raw and processed commodities similar? (yes/no)	yes
Plant residue definition for monitoring	aminopyralid (according to Reg. (EC) No 459/2010) proposal: sum of aminopyralid and its conjugates, expressed as aminopyralid (proposed by RMS (ASB2012-7176) and EFSA (ASB2012-13388) pending a full revision of the MRLs under Article 12 of Regulation (EC) No 396/2005).
Plant residue definition for risk assessment	sum of aminopyralid and its conjugates, expressed as aminopyralid (proposed by RMS (ASB2012-7176) and EFSA (ASB2012-13388)).
Conversion factor(s) (monitoring to risk assessment)	none

4.1.2.3 *Metabolism in livestock and animal residue definitions*

The metabolism of aminopyralid in ruminants and poultry was evaluated by the United Kingdom in the DAR (ASB2012-7176). A brief summary of the metabolism of aminopyralid in livestock is given in the following table.

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 (RIP2004-986): The radio-labelled substance was administered at 15 mg/kg feed over 6 consecutive days. Aminopyralid was readily excreted via urine and faeces (95.5% TRR); radioactive residues were <0.01 mg as-eq/kg in all tissues except kidney (0.07 mg/kg). The major part of the residue in kidney was identified being parent aminopyralid. Laying hens (RIP2004-987): The radio-labelled substance was administered at 11.6 mg/kg feed over 7 consecutive days. Only 0.01 % of the total administered dose was found in collected tissue or egg samples. The radioactive residues were <0.01 mg as-eq/kg in all tissues and were not identified due to low levels.
Time needed to reach a plateau concentration in milk and eggs	milk: 1-2 days Eggs: not possible to conclude if a plateau was reached as the residue levels appear to still be increasing at day 7, but on a very low absolute level (< 0.01 mg/kg).
Animal residue definition for monitoring	aminopyralid (according to Reg. (EC) No 459/2010)
Animal residue definition for risk assessment	aminopyralid (proposed by RMS, ASB2012-7176) proposal: sum of aminopyralid and its conjugates, expressed as aminopyralid (proposed by EFSA (ASB2012-13388)
Conversion factor(s) (monitoring to risk assessment)	none
Metabolism in rat and ruminant similar (yes/no)	yes
Fat soluble residue: (yes/no)	No / log Pow = 2.87 (pH)

4.1.2.4 Residues in rotational crops

No studies were available on residues in rotational crops. With a view to the low amount of substance applied, no relevant transfer into following crops is anticipated.

Table 4.1-13: Residues in rotational crops (Annex IIA, point 6.6.3)

Field studies	No field trials data for rotational crops were available; metabolism data indicated that significant residues are not to be expected in rotational crops.

4.1.2.5 Residues in livestock

An actual calculation of the dietary burden, based on those input data which have recently been used by EFSA in the framework of an application to establish an MRL in rapeseed (ASB2012-13388) is provided in Table 4.1-14.

Table 4.1-14: Calculation of the dietary burden based on relevant uses in EU (ASB2012-13388)

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 max feed (DM) 120 g	Dairy cattle 550 kg bw daily max feed (DM) 20 kg	Beef cattle 350 kg bw daily max feed (DM) 15 kg	Pig 75 kg bw daily max feed (DM) 3 kg		Chicken	Dairy cattle	Beef cattle	Pig
grass	20	--	100	100	--	2.97 [a)]	0.000	14.850	14.850	0.000
cereals grain	86	70	--	--	80	0.1 [b)]	0.081	0.000	0.000	0.093
oilseed meal	86	10	--	--	20	0.02 [c)]	0.001	0.000	0.000	0.002
Intake (mg/kg dry weight feed)							0.084	14.850	14.850	0.098
Intake (mg/kg bw/d)							0.005	0.540	0.636	0.004
Intake (mg/animal/d)							0.010	297.00	222.75	0.293

[a] HR, derived from cGAP of 1 x 0.06 kg as/ha, PHI: 7 d
[b] MRL (Reg. (EC) No 459/2010)
[c] STMR, derived from cGAP of 1 x 750 g as/ha, PHI F; default PF 2 assuming fat content 50 % in rape seed (ASB2012-13388)

Table 4.1-15: Conditions of requirement of livestock feeding studies

	Ruminant:	Poultry:	Pig:
Expected intakes by livestock ≥0.1 mg/kg diet (dry weight basis) (yes/no – If yes, specify the level)	Yes: 14.85	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)	yes	no	no

A brief summary of the available livestock feeding study is given in the following table. It becomes apparent from the dietary burden estimate that dietary burden of ruminants is driven by the use on grass, whereas adding of rape seed (meal) to the total livestock exposure is insignificant.

Table 4.1-16: Results of livestock feeding studies (Annex IIA, point 6.4)

	Ruminant:	Poultry:	Pig:
Feeding levels (mg/kg feed dry matter) Feeding levels (mg/kg bw/day)	RIP2004-997 32.8; 64.5; 181.5; 644.7 1.2; 2.35; 6.6	Not applicable	See ruminant
Relevant dosing levels in feeding study:	32.8	Not applicable	32.8
	Expected residue levels in animal matrices (mg/kg):		
Muscle	< 0.01	< 0.01	< 0.01
Liver	< 0.01	< 0.01	< 0.01
Kidney	0.102	< 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 critical GAP used for consumer intake and risk assessment is presented in Table 4.2-1.

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**	**kg as/ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**Water L/ha** **min / max**		
1	DE	winter rape	F	annual monocotyledonous weeds, annual dicotyledonous weeds	spraying	from BBCH 14, after emergence, late autumn to winter, November to February, after emergence of weeds	a) 1 b) 1	a) 1.5 b) 1.5	a) 0.75 (propyzamide) 0.0080 (aminopyralid) b) 0.75 (propyzamide) 0.0080 (aminopyralid)	200 / 300	F	6.3 g/L aminopyralid-K

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 rape

4.2.2.1 Residues in primary crops

The following table summarizes the results of the supervised residue trials selected for the assessment of propyzamide in oilseed rape.

Table 4.2-2: Overview of the selected supervised residue trials for propyzamide in winter oilseed rape

Commodity	Region [(a)]	Outdoor/ Indoor	Individual trial results (mg/kg)		STMR (mg/kg) [(b)]	HR (mg/kg) [(c)]	Median CF [(d)]
			Enforcement (aminopyralid)	Risk assessment (aminopyralid)			
seed	NEU	Outdoor	<0.01 (4)	<0.01 (4)	0.01	0.01	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.

The results of the supervised residue trials are average values from trials with two formulations tested in parallel (SC, WG) at 700 g as/ha each. In addition, two trials were available (one for each formulation) involving treatments of 1400 g as/ha. Also in these two overdosed trials, the residues in the seed were <LOQ (i.e. <0.01 mg/kg).
Samples of whole seed were frozen within 12 hours of threshing and stored for no longer than 18 months prior to analysis, a period for which storage stability was demonstrated.
It is noted that no field residue trials were available addressing both the intended use in terms of application rate and were residues of propyzamide have been reported for green forage.
With no such data available, potential contributions of rape forage could not be considered in the dietary burden estimate of livestock. For precautionary reasons a labeling of the product is therefore proposed by BfR, not to feed green forage to livestock in order to prevent from residues in commodities of animal origin which might be in excess of established legal limits.

The following table summarizes the results of the supervised residue trials selected for the assessment of aminopyralid in oilseed rape.

Table 4.2-3: Overview of the selected supervised residue trials for aminopyralid in winter oilseed rape

Commodity	Region [(a)]	Outdoor/ Indoor	Individual trial results (mg/kg)		STMR (mg/kg) [(b)]	HR (mg/kg) [(c)]	Median CF [(d)]
			Enforcement (aminopyralid)	Risk assessment (aminopyralid)			
seed	NEU	Outdoor	<0.01 (4)	<0.01 (4)	0.01	0.01	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.

The results of the supervised residue trials are suffering from the fact that no storage stability study was available on aminopyralid residues in oily matrices. It is noted however, that this data gap has also been addressed in the framework of an application for modification of the existing MRL for aminopyralid in rape seed (ASB2012-13388), but considered a minor deficiency, pending a re-evaluation of the data on rape seed residues under Article 12 of Regulation (EC) No 396/2005.
No samples of green forage were taken in the filed residue trials. As no such data were available, potential contributions of rape forage could not be considered in the dietary burden estimate of livestock.

For precautionary reasons a labeling of the product is therefore proposed by BfR, not to feed green forage to livestock in order to prevent from residues in commodities of animal origin which might be in excess of established legal limits.

4.2.2.2 Distribution of the residue in peel/pulp

The issue is not relevant for rapeseed.

4.2.2.3 Residues in processed commodities

The effect of industrial and/or household processing was not investigated during the peer review of propyzamide on grounds of exposure representing less than 10% of the ADI. It is also not considered relevant for the commodity under consideration due to low residues seen in the RAC at harvest.

Specific studies to assess the magnitude of aminopyralid residues during the processing of rape seed are not necessary as the residues in the RAC do not exceed the trigger value of 0.1 mg/kg and the TMDI accounts for less than 10 % of the ADI. Considering further the log $P_{o/w}$ of -1.76 to -2.96 for pH 5 to 9, it is not expected that aminopyralid residues accumulate in oil produced from treated rape seed.

4.2.2.4 Proposed pre-harvest intervals, withholding periods

With a view to the application early in the growing season, it is deemed appropriate not to establish a specific pre-harvest interval.

4.3 Consumer intake and risk assessment

4.3.1 Propyzamide

The consumer intake and risk assessment is based on the appropriate input values given in Table 4.3-1 and the toxicological reference values stated in Table 4.3-2. For the detailed calculation results it is referred to Appendix 3.

Table 4.3-1: Residue input values for the consumer risk assessment (propyzamide)

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	**Comment**	**Input value (mg/kg)**	**Comment**
oilseed rape	0.01	STMR	no acute risk assessment required as no ARfD was set for propyzamide	
other commodities as set out in Regulation (EU) No 600/2010	various	MRL as set out in Reg. (EC) No 149/2008		

Table 4.3-2: Consumer risk assessment for propyzamide (Annex IIA, point 6.9, Annex IIIA, point 8.8)

ADI	0.02 mg/kg bw
TMDI (% ADI) according to EFSA PRIMo	38% (based on diet of UK toddlers, 14.5 kg)
NTMDI (% ADI) according to NVS II	7% (based on diet of 2-4 years old DE children)
IEDI (EFSA PRIMo) (% ADI)	Not necessary
NEDI (NVS II) (% ADI)	Not necessary
Factors included in IEDI and NEDI	None
ARfD	Not allocated
IESTI (EFSA PRIMo) (% ARfD)	not appropriate

NESTI (NVS II) (% ARfD)	not appropriate
Factors included in IESTI and NESTI	none

4.3.2 Aminopyralid

The consumer intake and risk assessment is based on the appropriate input values given in Table 4.3-3 and the toxicological reference values stated in Table 4.4-4. For the detailed calculation results it is referred to Appendix 3.

Table 4.3-3: Residue input values for the consumer risk assessment (aminopyralid)

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
oilseed rape	0.01	STMR	0.01	STMR
other commodities as set out in Regulation (EU) No 600/2010	various	MRL as set out in Reg. (EC) No 459/2010	Not assessed	

Table 4.3-4: Consumer risk assessment for aminopyralid (Annex IIA, point 6.9, Annex IIIA, point 8.8)

ADI	0.26 mg/kg bw/d
TMDI (% ADI) according to EFSA PRIMo	0.5 % (based on DK children)
NTMDI (% ADI) according to German NVS II	0.5 % (based on 2-4 years old DE children)
IEDI (% ADI) according to EFSA PRIMo	not required
NEDI (% ADI) according to German NVS II	not required
Factors included in IEDI and NEDI	none
ARfD	0.26 mg/kg bw
IESTI (% ARfD) according to EFSA PRIMo	<0.1 % (based on 2-4 years old DE children)
NESTI (% ARfD) according to German NVS II	<0.1 % (based on 2-4 years old DE children)
Factors included in IESTI and NESTI	none

4.4 Proposed maximum residue levels (MRLs)

No new MRLs are required.

4.5 Conclusion

The data available is considered sufficient for risk assessment. It can be assumed that the MRLs currently set out for rapeseed in EU residue legislation at 0.05 mg/kg for propyzamide (Reg. (EC) No 149/2008) and at 0.01* mg/kg for aminopyralid (Reg. (EC) No 459/2010) will not be exceeded consequent to the use of the product, provided it has been applied in compliance with the notified instructions of use.

The chronic and the short-term intake of both propyzamide and aminopyralid residues in rapeseed is unlikely to pose a public health risk.

As far as consumer health protection is concerned, BfR/Germany agrees with the authorization of the intended use. For precautionary reasons a labeling of the product is proposed, not to feed green forage to livestock.

Appendix 1 Reference list

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	2012	Reasoned opinion on the review of the existing maximum residue levels (MRLs) for Propyzamide according to Article 12 of Regulation (EC) No 396/2005 EFSA Journal 2012;10(4):2690 ! EFSA-Q-2008-615 ASB2012-8952			Add
	EFSA	2012	Reasoned opinion on the modification of the existing MRL for Aminopyralid in rape seed EFSA Journal 2012;10(9):2894 ! EFSA-Q-2012-00022 ASB2012-13388			Add
	Sweden	1998	Propyzamide: (Monograph) Vol. 1-3 ASB2010-10283			Add
	United Kingdom	2012	Aminopyralid: (Draft Assessment Report) Volume 1-3 ASB2012-7176			Add
OECD KIIA 6.1.1	Lindsay, D. A.	2004	Frozen storage stability of XDE-750 in range land and pasture grass and hay and wheat grain and wheat straw - 030004 ! 998010-5001-4 ! 137871 BVL-1692144, BVL-1954910, RIP2004-983, ASB2012-9128			Add
OECD KIIA 6.1.1	Smith, S.	1998	Three year pronoamide storage stability study in milk, alfalfa, apples, grapes, lettuce and peaches 34-98-172 ! ER 53.2 BVL-1680800, BVL-1994089, BVL-2004362, RIP2000-747			Add
OECD KIIA 6.1.1	Wais, A.	2003	Propyzamide: Storage stability in oil seed rape (rac seeds) and soya (rac seeds) 770253 BVL-2355520, ASB2012-14214			Y
OECD: KIIA 6.2.1	Graper, L. K.; Smith, K. P.; Hilla, S.	2003	A nature of the residue study with 14C-labelled XDE-750 applied to spring wheat 020022 ! 98010-5051-2 ! 136893 BVL-1692141, BVL-1954911, RIP2004-985			Add
OECD: KIIA 6.2.1	Magnussen, J. D.; Balcer, J. L.	2004	14C XDE-750 grass nature of residue study 137840! 998010-5051-1 ! 010071 BVL-1692138, BVL-1954912, RIP2004-984			Add
OECD: KIIA 6.2.1	Nelson, S. S.	1987	Metabolism of 14C-Pronamide in lettuce 31C-88-02 BVL-1682369, BVL-1998914, BVL-2004381, RIP2006-1957			Add
OECD: KIIA 6.2.1	Reibach, P. H.	1988	Metabolism of 14C-Pronamide by alfalfa under field conditions 31C-88-03 BVL-1682364, BVL-1998911, BVL-2004378, RIP2006-1958			Add

Annex point/ reference No	**Author(s)**	**Year**	**Title Report-No. Authority registration No**	**Data protection claimed**	**Owner**	**How considered in dRR ***
OECD: KIIA 6.2.1	Linder, S. J., Balcer, J. L.	2007	A nature of residue study with 14 C labelled Aminopyralid applied to oilseed rape 060011 BVL-2355596, ASB2010-7659			Y
OECD: KIIA 6.2.2	[redacted]	1988	Metabolism of 14C-Pronamide in Laying Hens. #RHD 94/00064 ! 34C-88-44 (siehe WTOX 74) BVL-1682367, BVL-1998913, BVL-2004380, RIP2006-1971			Add
OECD: KIIA 6.2.2	[redacted]	2004	14C XDE-750 poultry nature or residue study. 998010-5050-1 ! 030009 ! 137867 ! DN0009589 BVL-1692139, BVL-1954913, RIP2004-987			Add
OECD: KIIA 6.2.2	[redacted]	1992	Addendum to the Metabolism of 14C-Pronamide in laying Hens 34-92-94 ! ER 40.6 BVL-1680790, BVL-1994098, BVL-2004363, RIP2000-749			Add
OECD: KIIA 6.2.3	[redacted]	1991	Pronamide metabolism in goats: Residue analysis of goat liver #RHD 94/00065 ! 34-91-63 (siehe WTOX 72) BVL-1682375, BVL-1998915, BVL-2004382, RIP2006-1970			Add
OECD: KIIA 6.2.3	[redacted]	1987	Metabolism of 14C-Pronamide in Lactating Goats. #RHD 94/00062 ! 31C-88-01 (siehe WTOX 72) BVL-1682366, BVL-1998912, BVL-2004379, RIP2006-1972			Add
OECD: KIIA 6.2.3	[redacted]	2003	The distribution and metabolism of [14C]- XDE-750 in the lactating goat 998010-5049-1 ! 010079 ! 138360 BVL-1692154, BVL-1954914, RIP2004-986			Add
OECD: KIIA 6.3	Murray, A.	1995	Kerb (Propyzamide) oilseed rape 1993 residue studies with Kerb 50W (500g ai/kg Propyzamide WP Formulation) and Kerb Flo (400g ai/l Propyzamide SC Formulation) ER 70.6 ! R70.6 BVL-1680792, BVL-1994100, BVL-2004365, RIP2000-750			Add
OECD KIIA 6.3	Devine, H. C.	2006	Residues of Clopyralid, Picloram and Aminopyralid in oil seed rape at intervals and at harvest following a single application of GF-1634, Germany, Poland and Hungary - 2005 GHE-P-11273 ! N238 ! CEMS-2698 BVL-2355600, ASB2010-7658			Y
OECD KIIA 6.3	Devine, H. C.	2007	Residues of Clopyralid, Picloram and Aminopyralid in oil seed rape at intervals and at harvest following a single application of GF-1633 or GF-871, Northern Europe, 2006 GHE-P-11493 ! CEMS-2965 BVL-2355601, ASB2010-7661			N
OECD KIIA 6.3	Morriss, A. W. J.; Devine, H. C.	2010	Residues of Picloram, Clopyralid and Aminopyralid in oil seed rape at intervals and at harvest following a single application of GF-1633, Northern and Southern Europe – 2009 CEMR-4348 ! GHE-P-12499 BVL-2355603, ASB2012-14215			Y

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
OECD KIIA 6.3	Pronier, I.	2011	Residues of Picloram, Clopyralid and Aminopyralid in oilseed rape at harvest following a single application of GF-1633. Southern Zone – 2010 GHE-P-12563 ! 14SRX10R01 BVL-2355606, ASB2012-14216			N
OECD KIIA 6.3	Pronier, I.	2011	Residues of Aminopyralid and Metazachlor in oilseed rape at harvest following a single application of GF-2545. Northern and Southern Zone – 2010 GHE-P-12564 ! 14SRX10R02 BVL-2355610, ASB2012-14217			Y
OECD: KIIA 6.4.2	[redacted]	1969	A study to determine residue levels in milk, tissues and excreta from cows fed field-aged residues of Kerb 23-11 ! 13.4 BVL-1680788, BVL-1994186, BVL-2004376, RIP2000-751			Add
OECD: KIIA 6.4.2	[redacted]	1970	A study to determine residue levels in eggs, tissues and excreta from laying hens fed field aged residues of Kerb an alfalfa hay 23-23 ! 46.1 ! 2984 BVL-1680787, BVL-1994176, BVL-2004375, RIP2000-754			Add
OECD: KIIA 6.4.2	[redacted]	2004	Magnitude of XDE-750 residues in bovine tissues and milk from a 28-Day feeding study 998010-5014-1 ! 030061 ! 138266 BVL-1692145, BVL-1954924, RIP2004-997			Add
OECD KIIA 2.9.1/6.5.1	Cook, W. L.	2003	Hydrolysis of XDE-750 at pH 5, 7, u. 9. 110561 ! 020067 CHE2004-924			Add
OECD: KIIA 6.6.2	Magnussen, J. D.	2004	A confined rotational crop study with 14C XDE-750 998010-5048-1 ! 030008 ! 138233 BVL-1692140, BVL-1954926, RIP2004-998			Add
OECD: KIIA 6.6.2	Nelson, S.	1990	Pronamide confined rotational crop study R67.1 ! 34-90-11 BVL-1680793, BVL-1994112, BVL-2004368, RIP2000-782			Add
OECD: KIIA 6.6.3	Smith, S.	1998	Field Rotation Crop Study of Kerb Herbicide in California- Bare Ground, Rotated with Small Grains, Root Crops and Leafy Vegetables 53.1 ! 34-98-146 BVL-1680791, BVL-1994111, BVL-2004367, RIP2000-761			Add
OECD: KIIA 6.6.3	Specht, W.	1981	Residues in rotation crops (peas, turinps, carrots and celery) following application to lettuce in Germany 1980 R63.20 BVL-1680797, BVL-1994130, BVL-2004371, RIP2000-783			Add
OECD: KIIA 6.6.3	Specht, W.	1981	Results of residue tests in rotation crops (celery, carrots) in Germany R63.21 BVL-1680796, BVL-1994131, BVL-2004372, RIP2000-785			Add
OECD: KIIA 6.6.3	Specht, W.	1981	Residues in rotation crops (lettuce, turnips and kidney beans) following application to lettuce 1981 R63.22 BVL-1680798, BVL-1994129, BVL-2004370, RIP2000-789			Add

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
OECD: MIIIA1 Sec 4	Applicant	2012	Aminopyralid + Propyzamid / GF-2540:Residues in or on treated products, food and feed - Tier 2, IIIA-8 - Draft Registration Report - Part B- Core assessment MIII / Sec. 4 BVL-2344028, BVL-2344029, ASB2012-14209			Y

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 Nature of residues

No further study on nature of residues submitted/needed.

A 2.2.2 Magnitude of residues in winter rape

Reference:	OECD KIIA 6.3
Report	Morriss, A. W. J.; Devine, H. C. (2010) Residues of Picloram, Clopyralid and Aminopyralid in oil seed rape at intervals and at harvest following a single application of GF-1633, Northern and Southern Europe – 2009; CEMR-4348; GHE-P-12499; ASB2012-14215
Guideline(s):	96/68/EC; 91/414/EEC, 1996; 7029/VI/95 Rec.5, 1997
Deviations:	no
GLP:	yes

Table A 2: Residues of aminopyralid in winter rape

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)	: 40 g/L
Formulation	(e.g. WP)	: Soluble concentrate (SL)
Commercial product	(name)	: GF-1633
Applicant		: Dow AgroSciences GmbH

Active ingredient	: aminopyralid
Crop / crop group	: Winter Rape
Crop Code	: BRSNW
Submission date	: 2012-10-24
Indoors / Outdoors	: Outdoors (European North)
Other a.i. in formulation (content and common name)	: 240 g/L clopyralid, 80 g/L picloram
Residues calculated as	: aminopyralid

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment kg a.i./ha	Water l/ha	kg a.i./hl	Dates of treatments	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
	(a)	(b)				(c)		(a)		(d)	(e)
PTR 10001439-5938-1, CEMR-4348, GHE-P-12499, CEMS-4348A France (FR) 56610 Arradon 2010-10-19	oilseed rape / Coklico	1) 2008-09-08 2) 2009-05 - 2009-05 3)	0.012	207	0.0058	2009-03-13	BBCH 51	rest of plant seed(s)	0.010 <0.010	110 110	sample storage time not validated, analytical method: Dow AgroSciences GRM 07.07 (HPLC-MS/MS), LOQ: 0.01 mg/kg (rest of plant, seed), max. sample storage time: 144 d (seed, rest of plant) ASB2012-14215

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

Comments of zRMS:	Acceptable.

Table A 3: Residues of aminopyralid in winter rape

Reference: OECD KIIA 6.3

Report: Pronier, I. (2011) Residues of Aminopyralid and Metazachlor in oilseed rape at harvest following a single application of GF-2545. Northern and Southern Zone – 2010; GHE-P-12564; 14SRX10R02; ASB2012-14217

Guideline(s): Commission Directive 96/681EC; 91/414/EEC, 7029NII95 rev.5

Deviations: no

GLP: yes

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Active ingredient : aminopyralid
Crop / crop group : Winter Rape
Crop Code : BRSNW

Submission date : 2012-10-24

Content of a.i. (g/kg or g/l) : 5.3 g/L
Formulation (e.g. WP) : Soluble concentrate (SL)
Commercial product (name) : GF-2545
Applicant : Dow AgroSciences GmbH

Indoors / Outdoors : Outdoors (European North)
Other a.i. in formulation (content and common name) : 500 g/L metazachlor, 13.3 g/L picloram
Residues calculated as : aminopyralid

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments	Growth stage at last treatment	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)
GHE-P-12564, 14SRX10R02, SRFR10-003-14HR France (North) 58190 Tanay 2011-02-28	oilseed rape / Aviator	1) 2009-08-22 2) 3) 2010-07-13	0.012	292.3	0.0041	2010-03-24	BBCH 32-33	rest of plant seed(s)	<0.010 <0.010	111 111	analytical method: GRM 07.07 (HPLC-MS/MS) LOQ: 0.01 mg/kg (rest of plant, seed), max. sample storage time 5 months ASB2012-14217
GHE-P-12564, 14SRX10R02, SRUK10-008-14HR United Kingdom Stowbridge, Norfolk 2011-02-28	oilseed rape / Excalibur	1) 2009-08-30 2) 3) 2010-07-20	0.012	317.8	0.0038	2010-03-27	BBCH 32-34	rest of plant seed(s)	<0.010 <0.010	115 115	analytical method: GRM 07.07 (HPLC-MS/MS) LOQ: 0.01 mg/kg (rest of plant, seed), max. sample storage time 5 months ASB2012-14217

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments	Growth stage at last treatment	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)
GHE-P-12564, 14SRX10R02, SRAT10-002-14HR Germany Pocking 2011-02-28	oilseed rape / Visby	1) 2009-08-20 2) 2010-05-01 - 2010-05-14 3) 2010-07-20	0.012	301.3	0.004	2010-04-02	BBCH 32	rest of plant seed(s)	0.010 <0.010	103 103	analytical method: GRM 07.07 (HPLC-MS/MS) LOQ: 0.01 mg/kg (rest of plant, seeds), max. sample storage time in months: 5 ASB2012-14217

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

Comments of zRMS:	Acceptable.

Table A 3: Residues of propyzamide in winter rape

Reference: OECD KIIA 6.3

Report: Murray, A. (1995) Kerb (Propyzamide) oilseed rape 1993 residue studies with Kerb 50W (500g ai/kg Propyzamide WP Formulation) and Kerb Flo (400g ai/l Propyzamide SC Formulation), R&H report No R70.6; RIP2000-750

Guideline(s): not specified

Deviations: no

GLP: yes

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Active ingredient : propyzamide
Crop / crop group : winter oilseed rape
Crop Code : BRSNW

Submission date : 17.02.2000

Content of a.i. (g/kg or g/l) : 500 g/kg / 400 g/L
Formulation (e.g. WP) : WP / SC
Commercial product (name) : KERB(R)50W / KERB Flo(R)
Applicant : Rohm and Haas Deutschland GmbH

Indoors / Outdoors : Outdoors (European North)
Other a.i. in formulation (content and common name) :
Residues calculated as : propyzamide

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 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	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
	(a)	(b)				(c)		(a)		(d)	(e)
R70.6; AK/2024/RH/1 GB-Spondon, Derbyshire 30.06.1995	oilseed rape / Apache	1) 16.09.1992 2) – 3) 22.07.1993	0.70	200	0.35	01.02.1993	BBCH 14-16	whole plant seed whole plant seed	70 <0.01 68.3 <0.01	0 171 0 171	formulations: KERB(R)50W / KERB Flo(R analytical method based on DFG 350 (GC/ECD) LOQ 0.01 mg/kg seed samples were frozen within 12 hrs of threshing max. sample storage: 18 months RIP2000-750
R70.6; AK/2024/RH/2 GB- Osgathorpe, Leicestershire 30.06.1995	oilseed rape / Bristol	1) 28.08.1992 2) – 3) 26.07.1993	0.70	200	0.35	02.02.1993	BBCH 14-16	whole plant seed whole plant seed	30 <0.01 32.3 <0.01	0 175 0 175	formulations: KERB(R)50W / KERB Flo(R analytical method based on DFG 350 (GC/ECD) LOQ 0.01 mg/kg seed samples were frozen within 12 hrs of threshing max. sample storage: 18 months RIP2000-750

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 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	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
	(a)	(b)				(c)		(a)		(d)	(e)
R70.6; AK/2024/RH/3 GB- Sedgebrook, Lincolnshire 25.01.2000	oilseed rape / Bristol	1) 24.09.1992 2) – 3) 27.07.1993	0.70	200	0.35	01.02.1993	BBCH 16-18	whole plant seed whole plant seed	35 <0.01 39.05 <0.01	0 166 0 166	formulations: KERB$^{(R)}$50W / KERB Flo$^{(R}$ analytical method based on DFG 350 (GC/ECD) LOQ 0.01 mg/kg seed samples were frozen within 12 hrs of threshing max. sample storage: 18 months RIP2000-750
R70.6; AK/2024/RH/4 GB- Sudbury, Staffordshire 30.06.1995	oilseed rape / Idol	1) 18.09.1992 2) – 3) 07.08.1993	0.70	200	0.35	01.02.1993	BBCH 14-17	whole plant seed whole plant seed	61 <0.01 56.02 <0.01	0 185 0 185	formulations: KERB$^{(R)}$50W / KERB Flo$^{(R}$ analytical method based on DFG 350 (GC/ECD) LOQ 0.01 mg/kg seed samples were frozen within 12 hrs of threshing max. sample storage: 18 months RIP2000-750
R70.6 AK/2024/RH/2 GB-Osgathorpe, Leicestershire 30.06.1995	oilseed rape / Bristol	1) 28.08.1992 2) – 3) 26.07.1993	1.4	200	0.70	02.02.1993	BBCH 14-16	whole plant seed	79 <0.01	0 175	formulation: KERB$^{(R)}$50W analytical method based on DFG 350 (GC/ECD) LOQ 0.01 mg/kg seed samples were frozen within 12 hrs of threshing max. sample storage: 18 months RIP2000-750
R70.6 AK/2024/RH/4 GB-Sudbury, Staffordshire 25.01.2000	oilseed rape / Idol	1) 18.09.1992 2) – 3) 07.08.1993	1.4	200	0.70	01.02.1993	BBCH 14-17	whole plant seed	108.41 <0.01	0 185	formulation: KERB Flo$^{(R}$ analytical method based on DFG 350 (GC/ECD) LOQ 0.01 mg/kg seed samples were frozen within 12 hrs of threshing max. sample storage: 18 months RIP2000-750

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

Comments of zRMS:	Acceptable.

A 2.3 Residues in processed commodities

No further study on residues in processed commodities submitted/needed.

A 2.4 Residues in rotational crops

No further study on residues in rotational crops submitted/needed.

A 2.5 Residues in livestock

No further study on residues in livestock submitted/needed.

A 2.6 Other studies/information

None

Appendix 3 Pesticide Residue Intake Model (PRIMo)

Propyzamide (F) (R)

Status of the active substance:		Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0,02	ARfD (mg/kg bw):	nn
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

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 38

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)
38,0	UK Toddler	34,3	Sugar beet (root)	1,0	Milk and cream,	0,7	Oilseeds	
19,3	UK Infant	15,1	Sugar beet (root)	1,9	Milk and cream,	0,6	FRUIT (FRESH OR FROZEN)	
7,9	UK Adult	6,0	Sugar beet (root)	0,6	Lettuce	0,3	Oilseeds	
7,8	WHO Cluster diet B	1,8	Lettuce	1,2	CEREALS	1,0	Sugar beet (root)	
7,6	UK vegetarian	5,7	Sugar beet (root)	0,7	Lettuce	0,3	FRUIT (FRESH OR FROZEN)	
6,8	NL child	1,5	FRUIT (FRESH OR FROZEN)	1,5	Milk and cream,	1,0	Scarole (broad-leaf endive)	
5,5	FR toddler	2,0	Milk and cream,	1,2	FRUIT (FRESH OR FROZEN)	0,8	Root and tuber vegetables	
5,4	DE child	2,3	FRUIT (FRESH OR FROZEN)	0,7	Milk and cream,	0,6	CEREALS	
5,1	ES child	2,1	Lettuce	0,6	Milk and cream,	0,6	FRUIT (FRESH OR FROZEN)	
4,8	WHO regional European diet	1,9	Lettuce	0,5	Root and tuber vegetables	0,4	CEREALS	
4,4	WHO cluster diet E	0,6	CEREALS	0,6	FRUIT (FRESH OR FROZEN)	0,5	Root and tuber vegetables	
4,4	ES adult	2,7	Lettuce	0,4	FRUIT (FRESH OR FROZEN)	0,3	CEREALS	
4,2	FR infant	1,5	FRUIT (FRESH OR FROZEN)	1,3	Milk and cream,	0,7	Root and tuber vegetables	
4,1	WHO Cluster diet F	1,5	Lettuce	0,5	CEREALS	0,4	Root and tuber vegetables	
4,1	IT adult	1,9	Lettuce	0,8	Other lettuce and other salad plants	0,5	CEREALS	
4,0	IE adult	1,1	FRUIT (FRESH OR FROZEN)	0,7	CEREALS	0,4	Lettuce	
3,8	IT kids/toddler	1,5	Lettuce	0,8	CEREALS	0,6	Other lettuce and other salad	
3,7	DK child	1,0	CEREALS	0,7	Lettuce	0,6	Milk and cream,	
3,4	FR all population	1,0	Other lettuce and other salad plants	0,6	FRUIT (FRESH OR FROZEN)	0,5	Lettuce	
3,2	NL general	0,6	Lettuce	0,6	Scarole (broad-leaf endive)	0,5	FRUIT (FRESH OR FROZEN)	
3,2	WHO cluster diet D	0,8	CEREALS	0,4	Root and tuber vegetables	0,3	Herbs	
2,9	SE general population 90th percentile	0,6	Milk and cream,	0,6	FRUIT (FRESH OR FROZEN)	0,6	Root and tuber vegetables	
1,9	PT General population	0,6	FRUIT (FRESH OR FROZEN)	0,5	CEREALS	0,3	Brassica vegetables	
1,8	LT adult	0,3	Root and tuber vegetables	0,3	Lettuce	0,3	CEREALS	
1,5	FI adult	0,4	Lettuce	0,3	Milk and cream,	0,3	FRUIT (FRESH OR FROZEN)	
1,3	DK adult	0,3	FRUIT (FRESH OR FROZEN)	0,3	CEREALS	0,3	Milk and cream,	
1,1	PL general population	0,4	Root and tuber vegetables	0,3	FRUIT (FRESH OR FROZEN)	0,1	Fruiting vegetables	

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Propyzamide (F) (R) is unlikely to present a public health concern.

Aminopyralid

Status of the active substance:		Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0,26	ARfD (mg/kg bw):	0,26
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

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

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)
0,5	DK child	0,2	Wheat	0,2	Rye	0,1	Milk and cream,	
0,5	NL child	0,2	Milk and cream,	0,2	Wheat	0,1	FRUIT (FRESH OR FROZEN)	
0,5	FR toddler	0,3	Milk and cream,	0,1	Wheat	0,1	VEGETABLES	
0,5	UK Infant	0,3	Milk and cream,	0,1	Wheat	0,0	SUGAR PLANTS	
0,5	WHO Cluster diet B	0,3	Wheat	0,1	VEGETABLES	0,0	FRUIT (FRESH OR FROZEN)	
0,5	UK Toddler	0,2	Milk and cream,	0,2	Wheat	0,1	SUGAR PLANTS	
0,4	DE child	0,2	Wheat	0,1	Milk and cream,	0,1	FRUIT (FRESH OR FROZEN)	
0,4	WHO cluster diet D	0,3	Wheat	0,0	Milk and cream,	0,0	VEGETABLES	
0,4	FR infant	0,2	Milk and cream,	0,1	VEGETABLES	0,1	FRUIT (FRESH OR FROZEN)	
0,3	ES child	0,2	Wheat	0,1	Milk and cream,	0,0	FRUIT (FRESH OR FROZEN)	
0,3	WHO cluster diet E	0,2	Wheat	0,0	VEGETABLES	0,0	Barley	
0,3	SE general population 90th percentile	0,1	Wheat	0,1	Milk and cream,	0,0	VEGETABLES	
0,3	IT kids/toddler	0,3	Wheat	0,0	VEGETABLES	0,0	FRUIT (FRESH OR FROZEN)	
0,3	WHO Cluster diet F	0,1	Wheat	0,0	Milk and cream,	0,0	Rye	
0,3	IE adult	0,1	Wheat	0,0	Barley	0,0	FRUIT (FRESH OR FROZEN)	
0,2	WHO regional European diet	0,1	Wheat	0,0	Milk and cream,	0,0	VEGETABLES	
0,2	PT General population	0,2	Wheat	0,0	FRUIT (FRESH OR FROZEN)	0,0	VEGETABLES	
0,2	NL general	0,1	Wheat	0,1	Milk and cream,	0,0	VEGETABLES	
0,2	ES adult	0,1	Wheat	0,0	Milk and cream,	0,0	Barley	
0,2	FR all population	0,1	Wheat	0,0	FRUIT (FRESH OR FROZEN)	0,0	Milk and cream,	
0,2	IT adult	0,2	Wheat	0,0	VEGETABLES	0,0	FRUIT (FRESH OR FROZEN)	
0,2	DK adult	0,1	Wheat	0,0	Milk and cream,	0,0	Rye	
0,2	UK vegetarian	0,1	Wheat	0,0	Milk and cream,	0,0	SUGAR PLANTS	
0,2	LT adult	0,0	Rye	0,0	Wheat	0,0	Milk and cream,	
0,1	UK Adult	0,1	Wheat	0,0	Milk and cream,	0,0	SUGAR PLANTS	
0,1	FI adult	0,0	Milk and cream,	0,0	Wheat	0,0	Rye	
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 Aminopyralid is unlikely to present a public health concern.

REGISTRATION REPORT
Part B

Section 5 Environmental Fate

Detailed summary of the risk assessment

Product code: GF-2540

Active Substance(s): Propyzamide 500 g/L
Aminopyralid 5.3 g/L

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Dow AgroSciences

Date: 08/05/2014

Table of Contents

Sec 5 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 GF-2540 containing the active substances propyzamide and aminopyralide.in its intended uses in oil seed rape according to Appendix 3.

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 GF-2540

Code	GF-2540	
plant protection product	-	
applicant	DOW AgroSciences	
date of application	20.08.2012	
Formulation type (WP, EC, SC, …; density)	SC	
active substance	propyzamide	aminopyralid
Concentration of as (g ai/L)	500	5.3

5.2 Proposed use pattern

The critical GAPs used for exposure assessment is presented in Table 5.2-1. A list of all intended uses within the zone is given in Appendix 3.

Table 5.2-1: Critical use pattern of GF-2540

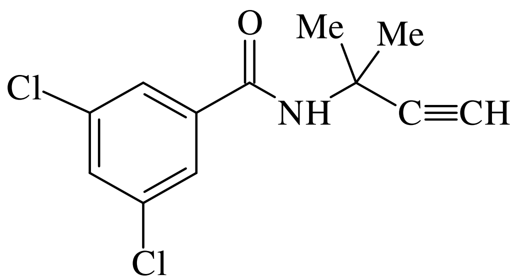
No.	Crop/growth stage	Application method / Drift scenario	Number of applications, Minimum application interval, interception, application time (season)	Application rate, cumulative (g as/ha)	Soil effective application rate (g as/ha)
001	Winter Oilseed Rape / BBCH 13-29	spraying / agriculture	1 x, late autumn to winter, november to february 40 %	propyzamide: 1 x 750 aminopyralid: 1 x 8	propyzamide: 1 x 450 aminopyralid: 1 x 4.8

5.3 Information on the active substances

5.3.1 Propyzamide

5.3.1.1 Identity, further information of propyzamide

Table 5.3-1: Identity, further information on propyzamide

Active substance (ISO common name)	propyzamide
IUPAC	3,5-dichloro-N-(1,1-dimethylprop-2-ynyl)benzamide
Function (e.g. fungicide)	herbicide
Status under Reg. (EC) No 1107/2009	Approved
Date of approval	01/04/2004
Conditions of approval	Only uses as herbicide may be authorised. Member States: - must pay particular attention to the protection of operators and must ensure that conditions of authorisation include risk mitigation measures, where appropriate - must pay particular attention to the protection of birds and wild mammals in particular if the substance is applied during the breeding season. Conditions of authorisation should include risk mitigation measures, where appropriate
Confirmatory data	-
RMS	Sweden
Minimum purity of the active substance as manufactured (g/kg)	920
Molecular formula	$C_{12}H_{11}Cl_2NO$
Molecular mass	256.13
Structural formula	

5.3.1.2 Physical and chemical properties of propyzamide

Physical and chemical properties of propyzamide as agreed at EU level (see Review Report 6502/VI/99-final) and considered relevant for the exposure assessment are listed in Table 5.3-6.

Table 5.3-2: EU agreed physical chemical properties of propyzamide relevant for exposure assessment

	Value	**Reference**
Vapour pressure (at 20 °C) (Pa)	2.67×10^{-5}	Review Report 6502/VI/99-final, 9 October 2007
Henry's law constant (Pa × m³ × mol⁻¹)	7.60×10^{-4}	Review Report 6502/VI/99-final, 9 October 2007

Solubility in water (at 25 °C in mg/L)	9.0 (pH 7) RH-24644: 0.34 mg L^{-1} in pure water	Review Report 6502/VI/99-final, 9 October 2007
Partition co-efficient (at 25 °), log P_{OW}	3.0	Review Report 6502/VI/99-final, 9 October 2007
Dissociation constant, pKa	According to the chemical structure propyzamide is not expected to dissociate in water	Review Report 6502/VI/99-final, 9 October 2007
Hydrolytic degradation	Stabile at pH 5, 7 and 9	Review Report 6502/VI/99-final, 9 October 2007
Photolytic degradation	41 d	Review Report 6502/VI/99-final, 9 October 2007
Quantum yield of direct phototransformation in water > 290 nm	$\Phi = 0.0159$	Review Report 6502/VI/99-final, 9 October 2007
Photochemical oxidative degradation in air (calculation according to Atkinson)	$DT_{50} = 0.8$ d	Calculated with AOP 1.92 (1.5×10^6 radicals/cm³, 12 h day)
Direct Phototransformation	$DT_{50} = 52.3$ y (Maximum for application period november to february)	Calculated with ABIWAS 2.0 (Central Europe (55°N) regarding radiation data, calculation is based on UV/VIS Spectrum and quantum yield, adsorption of the water body is not considered)

5.3.1.3 Metabolites of propyzamide

Environmental occurring metabolites of propyzamide requiring further assessment according to the results of the assessment of propyzamide for EU approval are summarized in Table 5.3-3.

No new study on the fate and behaviour of propyzamide or GF-2540 has been performed. Hence no potentially new metabolites need to be considered.

The risk assessment for these metabolites has not been performed for EU approval (see Review Report 6502/VI/99-final, 9 October 2007). Therefore risk and exposure assessment are performed for these metabolites in this core assesment.

The leaching potential into groundwater of the soil metabolites RH-24644 and RH-24580 will be assessed for the application of the plant protection product and its intended uses.

Table 5.3-3: Metabolites of propyzamide 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 formula**	**occurrence in compartments (Max. at day/**	**Status of Relevance (Review Report 6502/VI/99-final, 9 October 2007)**

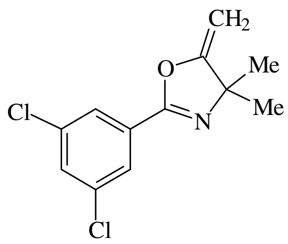
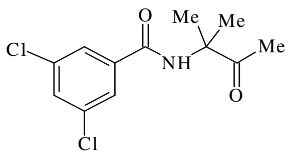
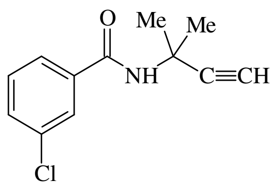
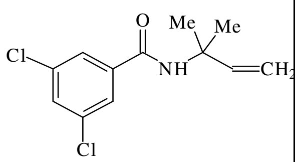
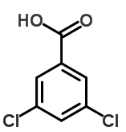
RH-24644 (2-(3,5-dichloro-phenyl)-4,4-dimethyl-5-methylene-oxazoline)		Soil: Max. 31.9 % at day 21	Aquatic organism: Water: not assessed Sediment: not assessed Terrestrial organism: not assessed Groundwater: not assessed
RH-24580 (N-(1,1-dimethyl-acetonyl)-3,5-dichlorobenzamide)		Soil: Max. 24.0 % at day 45	Aquatic organism: Water: not assessed Sediment: not assessed Terrestrial organism: not assessed Groundwater: not assessed
UK 1		Water: Max. 5.4 % at day 105 (end of study) W/S$_{total\ system}$: Max. 9.9 at day105 (end of study)	Aquatic organism: Water: not assessed Sediment: not assessed Terrestrial organism: not assessed Groundwater: not assessed
RH-24655 (UK 2) (3,5-dichloro-N-(1,1-dimethylpropenyl)benzamide)		Water: Max. 6.5 % at day 105 (end of study) Sediment: Max. 20.5 % at day 105 (end of study) W/S$_{total\ system}$: Max. 27.0 at day105 (end of study)	Aquatic organism: Water: not assessed Sediment: not assessed Terrestrial organism: not assessed Groundwater: not assessed

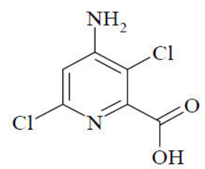
Table 5.3-4: Further metabolites of propyzamide

Metabolite	**Structural formula/ Molecular formula**	**occurrence in compartments/ Max. at day**
RH-20839 , (3,5-dichlorobenzoic acid)		Soil (anaerobic): Max. 6.2 % at day 123 (end of study)
RH-26059 (beta-(3,5-dichlorophenyl)-beta-me-butyric acid)		Direct photolysis in water: Max. 15.0 % at day 41

5.3.2 Aminopyralid

5.3.2.1 Identity, further information of aminopyralid

Table 5.3-5: Identity, further information on aminopyralid

Active substance (ISO common name)	aminopyralid
IUPAC	4-amino-3,6-dichloropyridine-2-carboxylic acid
Function (e.g. fungicide)	herbicide
Status under Reg. (EC) No 1107/2009	Pending
Date of approval	-
Conditions of approval	-
Confirmatory data	-
RMS	UK
Minimum purity of the active substance as manufactured (g/kg)	920
Molecular formula	$C_6H_4Cl_2N_2O_2$
Molecular mass	207.026
Structural formula	

5.3.2.2 Physical and chemical properties of aminopyralid

Physical and chemical properties of aminopyralid as proposed by RMS UK (see updated DAR, 03/2012) are listed in Table 5.3-6.

Table 5.3-6: EU agreed physical chemical properties of aminopyralid relevant for exposure assessment

	Value	**Reference**
Vapour pressure (Pa)	9.25×10^{-9} (20°C) 2.59×10^{-8} (25°C)	Updated DAR, Vol3, B8 (03/2012)
Henry's law constant (Pa × m³ × mol⁻¹)	Unbuffered: 5.18×10^{-10} At pH 7: 9.61×10^{-12}	Updated DAR, Vol3, B8 (03/2012)
Solubility in water (at 20 °C in mg/L)	205000 (pH 7)	Updated DAR, Vol3, B8 (03/2012)
Partition co-efficient (at 25 °), log P_{OW}	pH 5: -1.76 (19°C) pH 7: -2.87 (19°C) pH 9: -2.96 (19°C)	Updated DAR, Vol3, B8 (03/2012)
Dissociation constant, pKa	2.56	Updated DAR, Vol3, B8 (03/2012)
Hydrolytic degradation	Stable to hydrolysis at pH 5, 7 and 9	Updated DAR, Vol3, B8 (03/2012)
Photolytic degradation	DT_{50} =61 d	Updated DAR, Vol3, B8

		(03/2012)
Quantum yield of direct phototransformation in water > 290 nm	$\Phi = 2.4 \times 10^{-4}$	Updated DAR, Vol3, B8 (03/2012)
Photochemical oxidative degradation in air (calculation according to Atkinson)	DT_{50} =6.4 d (AOP version: 1.91, 1.5×10^6 radicals/cm³, 12 h day)	-
Direct Phototransformation	Month / DT_{50} November 298 December 626 January 344 February 139	Calculated by ABIWAS 2.0 for Central Europe (55°N) regarding radiation data. Calculation is based on UV/VIS Spectrum and quantum yield. Adsorption of the water body is not considered.

5.3.2.3 Metabolites of aminopyralid

There are no major metabolites of aminopyralid.

5.4 Summary on input parameter for environmental exposure assessment

5.4.1 Rate of degradation in soil

5.4.1.1 Laboratory studies

Propyzamide

No new studies have been submitted regarding route and rate of degradation in soil of propyzamide and its metabolites RH-24644 and RH-24580. The environmental exposure assessment is based on the EU agreed DT_{50} values from the laboratory as summarized in Table 5.4-1 to Table 5.4-3.

Table 5.4-1: Summary of aerobic degradation rates for propyzamide - laboratory studies

Soil type	pH	T (°C)	Moisture	DT_{50} (d)	DT_{90} (d)	DT_{50} (d) 20 °C pF2/ 10 kPa	Fit	Method of calculation	Reference
Sandy loam	6.5	20	40%	19.6	65.0	16.5	9.8	SFO	Völkl (2001)
Loamy sand	5.7	20	40%	42.4	140.7	42.4	2.8	SFO	Völkl (2001)
Silty clay loam	6.6	20	40%	18.2	60.5	14.3	5.2	SFO	Völkl (2001)
Sandy loam	7.7	26	75%	190*	k.A.	197.3	0.91	SFO	Olson and Laurence (1990)
Aggregated DT_{50} (n=4)	**Coefficient of variation (%)**					129			
	Geometric mean (d)					37.5			
	90. percentile					150.8			

* Only the data ponts of the first 3 months have been considered for the DT_{50} calculation

Table 5.4-2: Summary of aerobic degradation rates for propyzamide metabolite RH-24644 - laboratory studies

Soil type	pH	T (°C)	Moisture	DT_{50} (d)	DT_{90} (d)	DT_{50} (d) 20 °C pF2/ 10 kPa	Fit	Method of calculation	Reference
Sandy loam	6.5	20	40%	36.8	122.2	30.9	3.5	SFO	Völkl (2001)
Loamy sand	5.7	20	40%	37.9	125.8	37.9	4.2	SFO	Völkl (2001)
Silty clay loam	6.6	20	40%	25.8	85.7	16.5	4.5	SFO	Völkl (2001)
Aggregated DT_{50} (n=4)	**Coefficient of variation (%)**					38			
	Geometric mean (d)					26.8			
	90th percentile (d)					36.5			

Table 5.4-3: Summary of aerobic degradation rates for propyzamide metabolite RH-24580- laboratory studies

Soil type	pH	T (°C)	Moisture	DT_{50} (d)	DT_{90} (d)	DT_{50} (d) 20 °C pF2/ 10 kPa	Fit	Method of calculation	Reference
Sandy loam	6.6	20	40	16.7	55.5	14.5	n.a.	SFO	Völkl (2000)
Loam	7.2	20	40	12.1	40.3	12.1	n.a.	SFO	Völkl (2000)
Silt loam	5.8	20	40	12.4	41.2	11.0	n.a.	SFO	Völkl (2000)
Aggregated DT_{50} (n=4)	**Coefficient of variation (%)**					14			
	Geometric mean (d)					12.5			
	90th percentile (d)					14.0			

n.a. not available

Aminopyralid

Aminopyralid is a new active substance which is undergoing review for Annex I inclusion, with UK Chemicals Regulation Directorate (CRD) serving as the rapporteur. The Draft Assessment Report (DAR) on aminopyralid was issued by the United Kingdom in August 2006, an updated version was distributed for commenting in march 2012. Where appropriate this document refers to the conclusions of the DAR (03/2012) for aminopyralid.

The route and rate of degradation in soil of aminopyralid is evaluated in the EU approval procedure. No additional studies have been performed.

Table 5.4-4: Summary of aerobic degradation rates for aminopyralid - laboratory studies

Soil type	pH, $CaCl_2$	T (°C)	Moisture (% MWHC)	DT_{50} (d)	DT_{90} (d)	DT_{50} (d) 20 °C pF2/ 10 kPa	Fit (chi^2)	Method of calculation	Reference
Thessaloniki, Clay Loam	7.7	20	40	26.2	86.9	26.2	10.8	SFO	Yoder and Smith (2003)
Cuckney, Sand	5.6	20	40	144.7	480.8	144.7	1.3	SFO	Yoder and

									Smith (2003)
Charentilly, Clay Loam	5.8	20	40	28.4	94.4	28.0	7.2	SFO	Yoder and Smith (2003)
Parabraun Erde, Sandy loam	7.7	20	40	84.9	282.0	84.9	1.1	SFO	Yoder and Smith (2003)
Aggregated DT_{50} (n=4)	**Coefficient of variation (%)**					79			
	Geometric mean (d)					54.8			

5.4.1.2 Field studies

Propyzamide

The field dissipation rates of propyzamide were evaluated during EU assessment. No additional studies have been performed. The DT_{50} values are summarized in Table 5.4-6.

Table 5.4-5: Field degradation studies of propyzamide

soil / location	**pH**	**depth (cm)**	**DT_{50} (d)**	**DT_{90} (d)**	**Fit, Kinetic, Parame-ters**	**DT_{50} (d) 20 °C, pF2**	**Fit, Kinetic**	**Reference**
UK, Sandy loam	n.a.	n.a.	44	n.a.	n.a.	n.a.	n.a.	DAR, Vol3, B7
UK, Sandy loam	n.a.	n.a.	57	n.a.	n.a.	n.a.	n.a.	DAR, Vol3, B7
NL, Humic sand	n.a.	n.a.	33-75	60-70	n.a.	n.a.	n.a.	DAR, Vol3, B7
NL, Humic clay	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	DAR, Vol3, B7
NL, Sandy loam	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	DAR, Vol3, B7
NL, Humic sandy clay loam	n.a.	n.a.	260	n.a.	n.a.	n.a.	n.a.	DAR, Vol3, B7
USA, CA, Sandy loam	n.a.	n.a.	5-56	53-185	n.a.	n.a.	n.a.	DAR, Vol3, B7
USA, WI, Loam	n.a.	n.a.	55	184	n.a.	n.a.	n.a.	DAR, Vol3, B7

n.a. not available

An evaluation of the field dissipation trials according to the ctgb criteria has not been conducted. Thus the DT_{50} values cannot be used for PEC modeling.

Aminopyralid

Aminopyralid is a new active substance which is undergoing review for Annex I inclusion, with UK Chemicals Regulation Directorate (CRD) serving as the rapporteur. The Draft Assessment Report (DAR) on aminopyralid was issued by the United Kingdom in August 2006, an updated version was distributed for commenting in march 2012. Where appropriate this document refers to the conclusions of the DAR (03/2012) for aminopyralid.

The field dissipation rates of aminopyralid are evaluated in the EU approval procedure. No new studies have been submitted. However, two new studies (Knowles, 2011a+b) on the soil dissipation of aminopyralid under field conditions have been submitted in the context of a national PPP authorization procedure and are considered as necessary for the evaluation. A detailed evaluation of these studies is presented in Appendix 2. The DT_{50} values of the new studies together with the DT_{50} values from the EU assessment are summarized in Table 5.4-6.

Table 5.4-6: Field degradation studies of aminopyralid

soil / location	pH	depth (cm)	DT_{50} (d)	DT_{90} (d)	DT_{50} (d) 20 °C, pF2	Fit (Chi^2)	Method of calculation	Reference
France, Due La Fontaine, S10-01811-02, Sandy clay loam, 2010	7.8	0-30	n.a.	n.a.	13.8 (slow phase)	10.2	HS	Knowles (2011a+b)
Melbourne, UK, Clay loam, 2002	6.6	0-20	34.9	116.1	21.0	10.0	SFO	Knowles (2010) und Unsworth (2003)
Dollern, D, Sandy loam, 2002	6.2	0-20	n.a.	n.a.	--[1]	--	--	Knowles (2010) und Unsworth (2003)
Chalons le Verger, Southern France, Sandy loam, 2002	7.5	0-20	14.6	48.6	7.19[2]	9.07	SFO	Knowles (2010) und Unsworth (2003)
Sorgues, Northern France, Clay, 2002	8.0	0-20	27.7	92.1	13.7[2]	18.6	SFO	Knowles (2010) und Unsworth (2003)
Germany, CEMS-3991A, Silty clay loam, 2008	6.4	0-50	22.0	73.0	34.1[3] 17.2[4] 21.1[5]	32.3 8.34 15.4	SFO	Knowles (2010) und Kennedy (2009)
Southern France, CEMS-3991B, Clay loam, 2008	6.2	0-50	15.4	51.0	11.3	16.6	SFO	Knowles (2010) und Kennedy (2009)

[1] trial was omitted by the notifier due to the detection of residues in the deepest layer analysed (10-20 cm horizon)
[2] calculated assuming a pseudo layer for the 20-30cm horizon containing the same residues as the 10-20cm horizon (the lowest analysed horizon). This was intended to represent a worst case situation and address the fact that residues were found in the lowest analysed horizon. In the updated DAR (03(2012), RMS UK accepts this approach. However, as discussions in the EU evaluation process are still ongoing, zRMS Germany decided to exclude the DT_{50} values obtained from these two trials until the EU evaluation resulted in a final decision on this issue.
[3] calculation using all data points
[4] calculation excluding the first four data points (T = 0, 0.3, 0.7 and 2 d)
[4] calculation excluding the three data points (T = 0, 0.3 and 0.7 d)

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 are summarized in Table 5.4-7.

Table 5.4-7: Field degradation studies of aminopyralid fulfilling ctgb criteria (applicable for PEC_{GW})

soil / location	pH	depth (cm)	DT_{50} (d)	DT_{90} (d)	DT_{50} (d) 20 °C, pF2	Fit (Chi^2)	Method of calculation	Reference

France, Due La Fontaine, S10-01811-02, Sandy clay loam, 2010	7.8	0-30	n.a.	n.a.	13.8 (slow phase)	10.2	HS	Knowles (2011a+b)
Melbourne, UK, Clay loam, 2002	6.6	0-20	34.9	116.1	21.0	10.0	SFO	Knowles (2010) und Unsworth (2003)
Germany, CEMS-3991A, Silty clay loam, 2008	6.4	0-50	22.0	73.0	17.2	8.34	SFO	Knowles (2010) und Kennedy (2009)
Southern France, CEMS-3991B, Clay loam, 2008	6.2	0-50	15.4	51.0	11.3	16.6	SFO	Knowles (2010) und Kennedy (2009)
Geometric Mean						**15.4**		

The DT_{50} values of aminopyralid do not show any pH dependence.

5.4.2 Adsorption/desorption

Propyzamide

No new studies have been submitted regarding adsorption/desorption in soil of propyzamide and its metabolites RH-24644 and RH-24580. The exposure modeling is based on the EU K_{foc} values as summarized in Table 5.4-11

Table 5.4-8: K_f, K_{foc} and 1/n (Freundlich exponent) values for propyzamide

Soil Type	OC (%)	pH (-)	K_f (mL g^{-1})	K_{foc} (mL g^{-1})	1/n (-)	Reference
Lawrenceville, Silty clay loam	0.93	6.4	5.2	548	1.07	Vincent (1987)
Keetin, Loam	1.39	7.2	10.1	714	1.00	
Pasquotank, Sandy loam	1.39	4.9	8.1	570	1.01	
Hagerstown, Clay	0.70	7.5	4.9	688	1.10	
Arithmetic mean				642	1.045	

Table 5.4-9: K_f, K_{foc} and 1/n (Freundlich exponent) values for propyzamide metabolite RH-24644.

Soil Type	OC (%)	pH (-)	K_f (mL g^{-1})	K_{foc} (mL g^{-1})	1/n (-)	Reference
Lawrenceville, Silty clay loam	0.58	5.8	9.91	1680	0.917	Vincent (1987)
Keetin, Loam	1.39	7.2	33.2	2350	0.922	
Pasquotank, Sandy loam	1.39	4.9	55.1	3910	0.859	

Hagerstown, Clay	0.70	7.5	9.50	1350	0.907	
Arithmetic mean				2355	0.901	

Table 5.4-10: K_f, K_{foc} and 1/n (Freundlich exponent) values for propyzamide metabolite RH-24580.

Soil Type	OC (%)	pH (-)	K_f (mL g^{-1})	K_{foc} (mL g^{-1})	1/n (-)	Reference
Lawrenceville, Silty clay loam	0.58	5.8	1.00	170	0.836	Vincent (1987)
Keetin, Loam	1.39	7.2	2.97	210	0.805	
Pasquotank, Sandy loam	1.39	4.9	2.36	167	0.866	
Hagerstown, Clay	0.70	7.5	0.788	112	0.892	
Arithmetic mean				167	0.850	

Aminopyralid

The adsorption of aminopyralid is evaluated in the EU approval procedure. No additional studies have been performed.

Table 5.4-11: K_f, K_{foc} and 1/n (Freundlich exponent) values for aminopyralid

Soil Type	OC (%)	pH, $CaCl_2$ (-)	K_f (mL g^{-1})	K_{foc} (mL g^{-1})	1/n (-)	Reference
Thessaloniki (Europe), Silty Clay Loam	1.0	7.8	0.039	3.91	0.860	Rutherford (2002), updated DAR (03/2012)
Faringdon (Europe), Clay	3.2	7.5	0.079	2.45	0.919	Rutherford (2002), updated DAR (03/2012)
Ryerson (US), Silty Clay	3.9	7.8	0.232	5.94	0.887	Rutherford (2002), updated DAR (03/2012)
Cuckney (Europe), Sand	1.6	6.6	0.063	3.92	0.888	Rutherford (2002), updated DAR (03/2012)
Charentilly (Europe), Clay Loam	1.0	6.1	0.043	4.35	0.824	Rutherford (2002), updated DAR (03/2012)
Dowling (US), Clay	1.5	6.9	0.043	2.85	0.793	Rutherford (2002), updated DAR (03/2012)
Barnes (US), Clay Loam[1]	*3.6*	*4.8*	*0.625*	*17.36*	*0.903*	Rutherford (2002), updated DAR (03/2012)
Norfolk (US), Loamy Sand[1]	*0.6*	*4.5*	*0.147*	*24.46*	*0.881*	Rutherford (2002), updated DAR (03/2012)
Altlußheim, Germany, M696, Loam	1.7	7.5	0.203	11.92	0.950	Laughlin (2006), updated DAR (03/2012)
Barrow on Trent, UK, M697, Sandy Loam	4.6	6.3	0.184	4.01	0.870	Laughlin (2006), updated DAR (03/2012)

Hertfordshire, UK, M698, Clay Loam	2.2	7.6	0.193	8.77	0.960	Laughlin (2006), updated DAR (03/2012)
Römenberg, Germany, M699, Sandy Loam	0.7	7.4	0.099	14.18	0.920	Laughlin (2006), updated DAR (03/2012)
Languedoc, France, M700, Loam	3.2	7.6	0.255	7.96	0.980	Laughlin (2006), updated DAR (03/2012)
Empingham, UK, M701, Clay Loam	2.1	7.5	0.249	11.86	0.940	Laughlin (2006), updated DAR (03/2012)
Arithmetic mean, excluding acidic soils[1] (n = 12)				6.84	0.899	
Median, excluding acidic soils[1] (n = 12)				5.14	0.855[2]	
Arithmetic mean, acidic soils[1] (n = 2)				20.91	0.892	

[1] acidic soils (italic)
[2] the 1/n accompanying the median K_{foc} has been derived as the arithmetic mean of the 1/n values from the two soils (Ryserson and Charentilly) used to derive the median K_{foc}

5.4.3 Rate of degradation in water and sediment

Propyzamide

No new water/sediment study has been submitted. The exposure modeling is based on the results of the water/sediment study of propyzamide (Müller-Kallert, 1994) reviewed in the DAR.

The DT_{50} values of the water/sediment study are summarized in Table 5.4-12.

Table 5.4-12: Degradation in water/sediment of propyzamide

Water/ sediment system	pH wat.	pH sed.	T (°C)	$DegT_{50}$ / $DegT_{90}$ whole system	Kinetic, Fit	$DissT_{50}$/ $DegT_{50}$ wat.	Kinetic, Fit	$DissT_{50}$/ $DegT_{50}$ sed.	Kinetic, Fit	Reference
I (river)	7.2	7.7	20	118/391	n.a., 0.99	18/199	n.a., 0.98	n.a.	n.a.	Müller-Kallert, 1994
II (pond)	7.1	6.8	20	69/229	n.a., 0.99	24/127	n.a., 0.96	n.a.	n.a.	
Geometric mean				**90/299**		**21/159**				

n.a. - not available

Aminopyralid

No new water/sediment study has been submitted. The exposure modeling is based on the results of the water/sediment study of Yoder and Smith (2003) reviewed in the DAR.

The DT_{50} values of the water/sediment study are summarized in

Table 5.4-13.

Table 5.4-13: Degradation in water/sediment of aminopyralid

Water/ sediment system	pH water	pH sed.	whole system			water			sediment			Reference
			DT_{50}	DT_{90}	Kinetic, Fit (r^2)	DT_{50}	DT_{90}	Kinetic, Fit (r^2)	DT_{50}	DT_{90}	Kin., Fit	
Haut	5.9	6.1	809.5	2689	0.605	101.9	338	0.704	n.a.	n.a.	n.a.	Yoder and

Langudoc, France												Smith (2003) , updated DAR (03/2012)
Alto Garda, Italia	8.2	7.9	434.8	1444	0.671	211.4	702	0.626	n.a.	n.a.	n.a.	Yoder and Smith (2003) , updated DAR (03/2012)
North Dakota, USA	7.9	8.1	988.6	3284	0.647	398.9	1325	0.558	n.a.	n.a.	n.a.	Yoder and Smith (2003) , updated DAR (03/2012)
Geometric mean			**703.4**			**204.8**						

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: Input parameters related to application for PEC_{Soil} calculations

Plant protection product	GF-2540
Use No.	001
Crop	Winter oilseed rape
Application rate	1.5 L ha^{-1}
Number of application/interval	1x
Crop interception	40 %

Due to the fast degradation of propyzamide in soil (DT_{90} < 365 d, FSO, laboratory data) the accumulation potential of propyzamide does not need to be considered.

Due to the fast degradation of aminopyralid in soil (DT_{90} < 365 d, SFO, field data) the accumulation potential of aminopyralid does not need to be considered.

Table 5.5-2: Results of PEC_{soil} calculation for application of GF-2540 inwinter oil seed rape (soil bulk density 1.5 g/cm^{-3}, soil depth 5 cm) according to use No. 001.

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)
Active substance propyzamid	450.0	0.600	-	-	-	-

Metabolite RH-24644[1]	143.5	0.191	-	-	-	-
Metabolite RH-24580[2]	115.5	0.154	-	-	-	-
Active substance aminopyralid	4.8	0.006	-	-	-	-
Preparation GF-2540	1025.1[3]	1.367	-	-	-	-

[1] correction factor based on molecular weight: 0.999, max. 31.9 %
[2] correction factor based on molecular weight: 1.070, max. 24.0 %
[3] relative density of preparation GF-2540: 1.139 g L^{-1}

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.

Propyzamide

The relevant input parameters used for PEC calculations for propyzamide and its metabolites are summarized in the tables below.

Table 5.6-1: Input parameters of propyzamide for $PEC_{sw/sed}$ calculations

Parameter	**Endpoint used for $PEC_{sw/sed}$ calculation**	**Values in accordance to EU endpoint in LoEP**	**Remarks**
Active substance propyzamide			
Molecular weight (g/mol)	256.13	yes	-
Water solubility (mg/L)	9.0	yes	-
K_{oc}	642	no	Arithmetic mean (see Table 5.4-8)
DT_{50},soil (d)	37.5	no	Geomean (1st order, pF2,20°C) Laboratory data (see Table 5.4-1)
DT_{50},water (d)	90.0	yes	Geomean of whole system (1st order, 20°C) (see Table 5.4-12)
DT_{50},sed (d)	1000	-	Default value
DT_{50},whole system (d)	90.0	yes	Geomean of whole system (1st order, 20°C) (see Table 5.4-12)

Table 5.6-2: Input parameters of propyzamide metabolites RH 24644 and RH 24580 for $PEC_{sw/sed}$ calculations

Parameter	Endpoint used for $PEC_{sw/sed}$ calculation	Values in accordance to EU endpoint in LoEP	Remarks
Metabolite RH 24644			
Molecular weight (g/mol)	256	yes	-
Water solubility (mg/L)	0.34	-	Value of active substance
K_{oc}	2355	no	Arithmetic mean (see Table 5.4-9)
DT_{50},soil (d)	26.8	-	Geomean (1st order, pF2,20°C) Laboratory data (see Table 5.4-2)
DT_{50},water (d)	1000	-	Default value
DT_{50},sed (d)	1000	-	Default value
DT_{50},whole system (d)	1000	-	Default value
Metabolite RH 24580			
Molecular weight (g/mol)	274	yes	-
Water solubility (mg/L)	9.0	-	Value of active substance
K_{oc}	167	no	Arithmetic mean (see Table 5.4-10)
DT_{50},soil (d)	12.5	-	Geomean (1st order, pF2,20°C) Laboratory data (see Table 5.4-3)
DT_{50},water (d)	1000	-	Default value
DT_{50},sed (d)	1000	-	Default value
DT_{50},whole system (d)	1000	-	Default value

Table 5.6-3: Input parameters related to application for $PEC_{sw/sed}$ calculations

Plant protection product	GF-2540
Use No.	001
Crop	Winter oilseed rape
Application rate	750 g ai ha^{-1}
Interception	Minimal crop cover
Number of application/interval	1x

Results of FOCUS SW calculations for the worst-case application scenario of GF-2540 are summarized in the tables below.

Table 5.6-4: Maximum FOCUS Step 1 and Step 2 PEC_{sw} and PEC_{sed} of propyzamide and its metabolites RH 24644 and RH 24580 for the application of GF-2540 in winter oilseed rape according to use No 001.

Active substance	FOCUS Step 1	PECsw (µg/L)	PECsed (µg/L)
		141.60	864.76

propyzamide	**FOCUS Step 2**	**PECsw (µg/L)**	**PECsed (µg/L)**
	North Europe, oct.-feb.	41.82	264.12
	South Europe, oct.-feb.	34.31	215.96
Metabolite RH 24644	**FOCUS Step 1**	**PECsw (µg/L)**	**PECsed (µg/L)**
		19.32	453.42
	FOCUS Step 2	**PECsw (µg/L)**	**PECsed (µg/L)**
	North Europe, oct.-feb.	5.23	123.00
	South Europe, oct.-feb.	4.19	98.47
Metabolite RH 24580	**FOCUS Step 1**	**PECsw (µg/L)**	**PECsed (µg/L)**
		52.57	87.67
	FOCUS Step 2	**PECsw (µg/L)**	**PECsed (µg/L)**
	North Europe, oct.-feb.	12.68	21.15
	South Europe, oct.-feb.	10.16	16.94

Two metabolites (UK1 and RH 24655 [UK2]) were formed in the sediment/water study (Müller-Kallert, 1994) that reached maxima > 5 % AR at the end of the study. For these metabolites, no studies on the degradation or adsorption behaviour are available. As a worst-case assumption for the PECsw and PECsed calculations, it is assumed that all of the metabolites (UK1: 9.9 % and RH 24655: 27.0 %) is present in the water phase or the sediment, respectively. The PECsw and PECsed values for these metabolites were calculated by taking the initial (maximum) PECsw/PECsed values (FOCUS Step 2) for the active substance and correcting for the maximum percentage of metabolite formed and the difference in molecular weights (256 for propyzamide, for 221 UK1 and 258 for RH 24655).

$$\text{Initial } PEC_{SW,metab}\ (\mu g/L) = PEC_{initial,\ parent} * \frac{\text{max \% met}}{100} * \frac{\text{m.wt. metab}}{\text{m.wt. parent}}$$

Table 5.6-5: Maximum PECsw values for the metabolites UK1 and RH-24655 (UK2) of propyzamide for the application of GF-2540 in winter oilseed rape according to use No 001.

Metabolite	**PECsw (µg/L)**	**PECsed (µg/L)**
Metabolite UK1	3.57	22.57
Metabolite RH 24655 (UK2)	11.38	71.87

Aminopyralid

The relevant input parameters used for PEC calculations for aminopyralid are summarized in the tables below.

Table 5.6-6: Input parameters of aminopyralid for $PEC_{sw/sed}$ calculations

Parameter	**Endpoint used for $PEC_{sw/sed}$ calculation**	**Values in accordance to EU endpoint updated DAR (03/2012)**	**Remarks**
Active substance aminopyralid			

Molecular weight (g/mol)	207.026	yes	See Table 5.3-5
Water solubility (mg/L)	205000	yes	See Table 5.3-6
K_{oc}	5.14	yes	Median (see Table 5.4-11)
DT_{50},soil (d)	15.4	no	Geomean (1st order, pF2,20°C) field data (see Table 5.4-7)
DT_{50},water (d)	1000	yes	Default value
DT_{50},sed (d)	1000	yes	Default value
DT_{50},whole system (d)	1000	yes	Default value

Table 5.6-7: Input parameters related to application for $PEC_{sw/sed}$ calculations

Plant protection product	GF-2540
Use No.	001
Crop	oilseed rape, winter
Application rate	8 g ai ha^{-1}
Interception	Minimal crop cover
Number of application/interval	1x
Crop interception	40 %

Results of FOCUS SW calculations for the worst-case application scenario of GF-2540 are summarized in the tables below.

Table 5.6-8: Maximum FOCUS Step 1 and Step 2 PEC_{sw} and PEC_{sed} of aminopyralid for the application of GF-2540 in winter oilseed rape according to use No 001.

Active substance aminopyralid	**FOCUS Step 1**	**PECsw (µg/L)**	**PECsed (µg/L)**
		2.72	0.14
	FOCUS Step 2	**PECsw (µg/L)**	**PECsed (µg/L)**
	North Europe, oct.-feb.	0.74	0.04
	South Europe, oct.-feb.	0.60	0.03

5.7 Risk assessment ground water (KIIIA1 9.6)

5.7.1 Predicted environmental concentration in groundwater (PEC_{GW}) calculation for active substance and its metabolites RH 24655 and RH 24580 (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.

The PEC of propyzamide and its metabolites RH 24655 and RH 24580 in ground water have been assessed with standard FOCUS scenarios to obtain outputs from FOCUSPELMO 5.5.3.

Table 5.7-1: Input parameters related to application for PEC_{GW} modelling

plant protection product	GF-2540
use No.	001
application rate (kg ha^{-1})	propyzamide: 750 aminopyralid: 8
crop (crop rotation)	Winter oilseed rape
relative application date	BBCH 13 (Hamburg scenario: september 5th): 3 days after 1st emergence in the year BBCH 23 (Hamburg scenario: november 20th): 80 days after 1st emergence in the year
mode of application	every year and every 3rd year
interception (%)	40 % (application in september) 80% (application in november)
soil moisture	100 % FC
Q10-factor	2.58
moisture exponent	0.7
simulation period (years)	26

Propyzamide

Table 5.7-2: Input parameters related to active substance propyzamide for PEC_{GW} modelling

Parent	Parameter	Remarks/Reference
molecular weight (g/mol)	256	-
DT_{50} in soil (d)	37.5	Geomean (1st order, pF2,20°C) Laboratory data (see Table 5.4-1)
K_{foc}	642	Arithmetic mean (see Table 5.4-8)
1/n	1.045	Arithmetic mean (see Table 5.4-8)
plant uptake factor	0	-

Table 5.7-3: Input parameters related to metabolites of propyzamide for PEC_{GW} modelling

Metabolite	Parameter	Remarks/Reference
Metabolite RH-24644		
molecular mass	256	-
Formation fraction	1	worst case
DT_{50} in soil (d)	26.8	Geomean (1st order, pF2,20°C) Laboratory data (see Table 5.4-2)
K_{foc}	2355	Arithmetic mean (see Table 5.4-9)

1/n	0.901	Arithmetic mean (see Table 5.4-9)
plant uptake factor	0	-
Metabolite RH 24580		
molecular mass	274	-
Formation fraction	1	worst case
DT_{50} in soil (d)	12.5	Geomean (1st order, pF2,20°C) Laboratory data (see Table 5.4-3)
K_{foc}	167	Arithmetic mean (see Table 5.4-10)
1/n	0.85	Arithmetic mean (see Table 5.4-10)
plant uptake factor	0	-

Table 5.7-4: PEC$_{GW}$ at 1 m soil depth for propyzamide and its metabolites RH-24644 and RH 24580 for the application of GF-2540 in winter oilseed rape (based on geom. mean for DT_{50} value and arithm. mean for K_{foc}).

Crop/use No./app. date/ soil relevant app. rate	**Szenario**	**80th Percentile PEC$_{GW}$ at 1 m Soil Depth (µg L^{-1}) groundwater model: FOCUSPELMO 5.5.3**					
		propyzamide		**metabolite RH-24644**		**metabolite RH 24580**	
		appl. every year	**appl. every 3rd year**	**appl. every year**	**appl. every 3rd year**	**appl. every year**	**appl. every 3rd year**
Winter oilseed rape / 001 / app. date: september 5th / soil relevant app. rate: 450 g ai ha^{-1}	**Châteaudun**	<0.001	<0.001	<0.001	<0.001	<0.001	0.001
	Hamburg	0.010	0.004	0.001	<0.001	0.002	<0.001
	Kremsmünster	0.008	0.003	<0.001	<0.001	0.001	<0.001
	Okehampton	0.015	0.006	0.001	<0.001	0.003	<0.001
	Piacenza	0.006	0.002	0.001	<0.001	0.001	0.001
	Porto	0.011	0.003	<0.001	<0.001	0.002	<0.001
Winter oilseed rape / 001 / app. date: November 1st / soil relevant app. rate: 150 g ai ha^{-1}	**Châteaudun**	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Hamburg	0.004	0.002	<0.001	<0.001	0.001	<0.001
	Kremsmünster	0.003	0.001	<0.001	<0.001	0.001	<0.001
	Okehampton	0.008	0.003	<0.001	<0.001	0.001	0.001
	Piacenza	0.002	0.001	<0.001	<0.001	<0.001	<0.001
	Porto	0.004	0.002	<0.001	<0.001	0.001	<0.001

According to the PEC$_{GW}$ modelling with FOCUSPELMO 5.5.3 a groundwater contamination of the active substance propyzamide and its soil metabolites RH 24644 and RH 24580 at a concentration of ≥

0.1 µg/L is not expected for the FOCUS groundwater scenarios Châteaudun, Hamburg, Kremsmünster, Okehampton, Piacenza and Porto.

Aminopyralid

Table 5.7-5: Input parameters related to active substance for PEC_{GW} modelling

Parent	Aminopyralid	Remarks/Reference
molecular weight (g/mol)	207.026	See Table 5.3-5
DT_{50} in soil (d)	15.4	Geomean (1st order, pF2,20°C) field data (see Table 5.4-7)
K_{foc}	5.14	Median (excluding acidic soils) (see Table 5.4-11)
1/n	0.855	Arithmetic mean of the 1/n values from the two soils (Ryserson and Charentilly) used to derive the median K_{foc} (see Table 5.4-11)
plant uptake factor	0	default

Table 5.7-6: PEC_{GW} at 1 m soil depth for aminopyralid and its metabolites for the application of GF -2540 in winter oilseed rape.

Crop/ use No./app. date/ soil relevant app. rate	Szenario	80th Percentile PEC_{GW} at 1 m Soil Depth (µg L^{-1}) groundwater model: FOCUSPELMO 5.5.3	
		application every year	**application every 3rd year**
Winter oilseed rape / 001 / app. date: september 5th / soil relevant app. rate: 4.8 g ai ha^{-1}	**Châteaudun**	0.031	0.015
	Hamburg	**0.196**	0.063
	Kremsmünster	0.092	0.034
	Okehampton	0.087	0.036
	Piacenza	**0.222**	0.072
	Porto	**0.100**	0.033
Winter oilseed rape / 001 / app. date: November 1st / soil relevant app. rate: 1.6 g ai ha^{-1}	**Châteaudun**	0.010	0.003
	Hamburg	0.093	0.032
	Kremsmünster	0.038	0.015
	Okehampton	0.073	0.023
	Piacenza	0.027	0.010
	Porto	0.079	0.026

According to the PEC_{GW} modelling with FOCUSPELMO 5.5.3 groundwater contaminations of the active substance aminopyralid exceeding concentrations ≥ 0.1 µg/L are not expected for the FOCUS groundwater scenarios Châteaudun, Kremsmünster and Okehampton. However, for annual application in the FOCUS groundwater scenarios Hamburg, Piacenza and Porto aminopyralid can reach groundwater at concentrations of ≥ 0.1 µg/L.

5.7.2 Summary of risk assessment for ground water

Results of modelling with FOCUSPELMO 5.5.3 show that the active substance propyzamide and its soil metabolites RH 24644 and RH 24580 are not expected to penetrate into groundwater at concentrations of ≥ 0.1 µg/L in the intended uses in winter oilseed rape.

Active substance aminopyralid exceeds the groundwater concentration of 0.1 µg/L in 3 out of 6 FOCUS groundwater scenarios in the intended uses in winter oilseed rape assuming annual applications. Modelling groundwater entries of aminopyralid following applications every 3rd year results in PEC_{GW} <0.1 µg/L in all scenarios.

5.8 Potential of active substance for aerial transport

The vapour pressure at 20 °C of the active substance propyzamide is between 10^{-5} and 10^{-4} Pa/> 10^{-4} Pa. Hence the active substance is regarded as semivolatile (volatilisation only from plant surfaces). Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance propyzamide due to volatilization with subsequent deposition should be considered e.g. using the program EVA 2.1.

The vapour pressure at 20 °C of the active substance aminopyralid is < 10^{-5} Pa. Hence the active substance is regarded as non-volatile. Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance aminopyralid 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 7.3.1	Knowles, S.	2011	Soil dissipation study with one spring application of GF-1601 containing aminopyralid at one site on bare soil in Europe in 2010-2011 GHE-P-12692	yes	DOW Agro-Sciences	4
OECD: KIIA 7.3.1	Knowles, S.	2011	Calculation of field kinetics for Aminopyralid from an additional field dissipation study using FOCUS kinetics methodology GHE-P-12693	yes	DOW Agro-Sciences	4

*

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

Report only studies, which have not previously been evaluated within a peer reviewed process at EU level (Annex I inclusion of active substance).

Present the authority's evaluation of the study below each individual study.

KIIA 7 Fate and Behaviour in the Environment – Active Substance aminopyralid

KIIA 7.3.1 Knowles, 2011a

Reference:	KIIA 7.3.1
Author:	Knowles, S.
Report:	Soil dissipation study with one spring application of GF-1601 containing aminopyralid at one site on bare soil in Europe in 2010-2011 GHE-P-12692
Date:	29.09.2011
Guideline(s):	Yes SETAC-Europe guideline, Procedures for Assessing the Environmental Fate and Ecotoxicology of Pesticides, Part 1, Section 3.1 (1995).
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

The objective of this study was to determine aminopyralid residue levels and dissipation rate in soil at time intervals after application of GF-1601 (an SL-formulation containing 39.7 g/L a!T1inopyralid nominal). The application was done at one site in France in 2010. For this purpose GF-1601 was applied at the field site to bare soil on 26 May 2010 in France on the treated plot using a calibrated boom sprayer. The nominal application rate was 60 g a.s./ha with a nominal water volume of 300 L ha^{-1}.

France site (S10-01811-02): Samples for microbial biomass and soil characterization were taken before application. An untreated control sample was taken 0 days before application from the treated plot. After application on 26 May 2010 soil samples were taken immediately after application, 6 hours after application and at 1,3, 7, 15,29,43,61,91, 120,152,182 and 238 days after application. To verify the spray application, deposition trays with sieved soil from outside the plot were taken. After collection the samples were stored deep frozen.

Results and discussions

The recovery of aminopyralid in soil was tested by fortification of untreated soil samples from the current study with the reference item prior to extraction. The limit of quantification (LOQ) was defined as the lowest fortification level with mean recoveries ranging from 70 % to 110 % at a relative standard deviation (RSO) of ≤ 20 % with residues in the control samples not exceeding 30 % of the proposed LOQ. These criteria were fulfilled for the 0.001 mg/kg fortification level. The limit of detection (LOD) was defined as 30 % of the limit of quantification (i.e. 0.0003 mg kg^{-1}).

The temperature and moisture normalization and the kinetic evaluation of the field data was conducted in a separate study (Knowles, 2011b).

Comments of zRMS

Acceptable.

KIIA 7.3.1 Knowles, 2011b

Reference:	KIIA 7.3.1
Author:	Knowles, S.
Report:	Calculation of field kinetics for Aminopyralid from an additional field dissipation study using FOCUS kinetics methodology GHE-P-12693
Date:	31.10.2011
Guideline(s):	Yes FOCUS, 2006. Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration. Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference Sanco/10058/2005 version 2.0, 434pp.
Deviations:	No
GLP:	Non-GLP study
Acceptability:	Yes

<u>*Materials and methods*</u>

Data from a new field study in France has been assessed using methods outlined by the final report of the Work Group on Degradation Kinetics of FOCUS. Time-course data were normalised with an adjusted day length approach for temperature at 20°C (Q 10=2.58) and soil moisture at field capacity, and then the decline of aminopyralid was analysed with the KinGUI kinetic analysis tool.

Field study

A new field dissipation study (2010) from Northern France (3) has been reported (study code S10-01811-02). Soil residues were determined for all data points until a ND was reached in the lowest horizon. In most samples aminopyralid was not found in horizons below 10 cm so the majority of the mass was in the 0-1 Ocm horizon. In one horizon very minor residues < 1 % initial) were found. Overall the trial was considered valid for field DT50 degradation calculation.

Normalisation of Field Study Results

In order to use a $DT_{50(field)}$ in modelling, it must be demonstrated that the decline is due to degradation and not to dissipation. For aminopyralid this is justified as follows: Firstly, its low vapour pressure (9.25 x 10-9 Pa, 20°C) indicates minimal potential loss to air, and this was confirmed by a BBA wind tunnel study (5) where volatilisation of aminopyralid from soil was 2.6% of applied after 24 hours and from plant surfaces was 2.6% of applied after 24 hours. Secondly, previous dissipation trials (6, 7) sampled residues in the 0-30 cm with 10cm horizons, with analysis showing that aminopyralid was confined to the 0-10 cm layer in the majority of samples through 6 months after treatment, with most residues below the LOD at 10-20 cm depth. Finally, a laboratory soil surface photolysis study (S) showed the rate of degradation on soil surfaces to be slow compared to the rate of microbial degradation. Therefore, since none of these dissipative processes are likely to significantly contribute to the decline of aminopyralid under field conditions, it is considered that the $DT_{50(field)}$ is due to microbial degradation, and as such is suitable for model input.

The normalization procedure used is the "day-length adjustment" procedure from Hardy, with additional details taken from the FOCUS Degradation Kinetics Workgroup report. The normalisation is done by reducing or increasing day lengths depending on soil temperature and moisture by means of correction factors identical to those used in the regulatory leaching models. In the field dissipation study report, the soil moisture and temperature was taken from daily field measurements for the 2010 French site.

Evaluation of field kinetics

Evaluations of the field concentration versus time values (normalised to standard conditions and parent basis) were performed with the freeware KinGUI software package (v. 1.1).

The fitting of kinetic models to the field data was carried out following the recommendations of the FOCUS Kinetic Work Group Guidance Document (2). The methodology specified in this report takes a stepwise approach to estimation of kinetic parameters, essentially beginning with the simplest kinetic representation and progressing to more complex formulations as the data indicates.

Results and discussions

In all cases, the normalised day duration of the studies is shorter than the actual number of days, because of a combination of temperatures below 20°C and soil moistures below field capacity (pF2).

The soil residues from each timepoint are shown in Table A 2 with a summary of the kinetic analysis in Table A 3.

When all timepoints are included, some biphasic behavior could be postulated from the slow phase from the HS model (rate constant k2) giving the best overall fit and lowest Chi^2 value (field DT_{50} = 13.8 days).

By considering just the timepoints after 10mm rainfall, the SFO and HS (k2) give essentially the same result (field DT_{50} = 12.8 days).

Table A 2: Soil residues from field dissipation trial, Due La Fontaine, France, S10-01811-02

Due La Fontaine, France, S10-01811-02, 2010	DAA	0-10 cm	10-20 cm	20-30 cm	0-30 cm
	0	29.0	0.0	0.0	29.0
	0	28.0	0.0	0.0	28.0
	0	36.0	0.0	0.0	36.0
	0.3	18.0	0.0	0.0	18.0
	0.3	21.0	0.0	0.0	21.0
	0.3	21.0	0.0	0.0	21.0
	1	18.0	0.0	0.0	18.0
	1	25.0	0.0	0.0	25.0
	1	11.0	0.0	0.0	11.0
	3	11.0	0.0	0.0	11.0
	3	15.0	0.0	0.0	15.0
	3	16.0	0.0	0.0	16.3
	7	16.0	0.0	0.0	16.0
	7	16.0	0.3	0.0	16.0
	7	13.0	0.0	0.0	13.0
	14	12.0	0.0	0.0	12.0
	14	13.0	0.0	0.0	13.0
	14	15.0	0.0	0.0	15.0
	28	7.0	0.0	0.0	7.0
	28	6.0	0.0	0.0	6.0
	28	9.0	0.0	0.0	9.0
	45	1.0	0.0	0.0	1.0
	45	0.0	0.0	0.0	0.0
	45	7.0	0.0	0.0	7.0
	60	6.0	0.0	0.0	6.0
	60	5.0	0.0	0.0	5.0
	60	4.0	0.0	0.0	4.0
	90	2.0	0.0	0.0	2.0
	90	5.0	0.0	0.0	5.0
	90	6.0	0.0	0.0	6.0

	120	4.0	0.0	0.0	4.0
	120	2.0	0.0	0.0	2.0
	120	2.0	0.0	0.0	2.0
	150	0.5	0.0	0.0	0.5
	150	2.0	0.0	0.0	2.0
	150	1.0	0.0	0.0	1.0
	180	0.6	0.0	0.0	0.6
	180	0.5	0.0	0.0	0.5
	180	0.7	0.0	0.0	0.7

Table A 3: Summary of degradation rates of aminopyralid, KINGUI statistics (trial Due La Fontaine, France, S10-01811-02, 2010)

Kinetic parameters			**Regression parameters**		**Degradation rates (d^{-1})**		
Rate constant, k (d^{-1})	**Confidence limits**	**Prob>t**	**$Chi^2Err\%$**	**R^2**	**DT_{50}**	**DT_{90}**	**Model used**
All data points							
0.0869	0.0528 to 0.121	4.3E-6	27.4	0.789	7.98	26.5	SFO
α = 0.345 β = 0.140	0.2450 to 0.445 -0.0095 to 0.289	1.6E-8 0.0328	18.3	0.871	0.901	110.0	FOMC
k1 = 1.5910 **k2 = 0.0501**	**1.07 to 2.11** **0.0331 to 0.0671**	**2.0E-7** **4.1E-7**	**10.2**	**0.916**	**13.8 (k2)**	**45.8 (k2)**	**HS, k2 slow phase**
After 10 mm rainfall							
0.0543	0.0395 to 0.0692	3.3E-8	18.7	0.857	12.8	42.4	SFO
α = 1.47 β = 13.01	-0.04 to 2.98	0.0280	15.6	0.880	7.82	49.1	FOMC
k1 = 0.0916 k2 = 0.0543	- 0.0388 to 0.0698	- 1.1E-7	21.0	0.857	12.8 (k2)	42.5 (k2)	HS, k2 slow phase

Conclusion

Normalised data were generated from a new field dissipation study in France (2010) using a Q10 value = 2.58. If all timepoints are included, the best-fit DT_{50} is 13.8 days.

If timepoints before 10 mm of rainfall are excluded, the resulting DT50 is 12.8 days. The field DT_{50} appropriate for input into PEC modeling (France 2010) of aminopyralid is 13.8 days.

Comments of zRMS

Acceptable.

Appendix 3 Table of Intended Uses justification and GAP tables

GAP rev. BVL, date: 2012-10-05

PPP (product name/code)	**GF-2540**	**Formulation type:**	**SC**
active substance 1	**Propyzamide**	**Conc. of as 1:**	**500 g/L**
active substance 2	**Aminopyralid**	**Conc. of as 2:**	**5.3 g/L**
Applicant:	**DOW AgroSciences GmbH**	**professional use**	**X**
Zone(s):	**central/EU**	**non professional use**	

Verified by MS: Y

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 as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
001	DE	Winter oilseed Rape	F	Annual mono- and dicot weeds (post emergence of weeds)	Spraying	> BBCH 14 Late autumn to winter, November to February	a) 1 b) 1	a) 1.5 b) 1.5	a) 750 g/ha Propyzamide 7.95 g/ha Aminopyralid b) 750 g/ha Propyzamide 7.95 g/ha Aminopyralid	20 0 - 300		

REGISTRATION REPORT
Part B

Section 5 Environmental Fate
Detailed summary of the risk assessment

Product code:	**GF-2540**
Active Substance(s):	**Propyzamide 500 g/L**
	Aminopyralid 5.3 g/L

Central Zone

Zonal Rapporteur Member State: Germany

NATIONAL ADDENDUM – Germany

Applicant:	**DOW AgroSciences**
Date:	**08/05/2014**

Table of Contents

Sec 5 FATE AND BEHAVIOUR IN THE ENVIRONMENT (KIIIA 9)

The exposure assessment of the plant protection product GF-2540 in its intended uses in winter oilseed rape is documented in detail in the core assessment of the plant protection product GF-2540 dated from 10/2013 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 GF-2540 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 GF-2540

Code	GF-2540	
plant protection product	-	
applicant	DOW AgroSciences	
date of application	20.08.2012	
Formulation type (WP, EC, SC, …; density)	SC	
active substances (as)	propyzamide	aminopyralid
Concentration of as	500	5.3

Data pool/task force	-
letter of access/cross reference	-
existing authorisations in DE	-

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 use in Germany (use No. 001) is covered by the core assessment performed by zRMS Germany.

Table 5.2-1: Classification of intended uses in Germany for GF-2540

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)

001	Winter Oilseed Rape / BBCH 13-29	spraying / agriculture	1 x, late autumn to winter, november to february 40 %	propyzamide: 1 x 750 aminopyralid: 1 x 8	propyzamide: 1 x 450 aminopyralid: 1 x 4.8

* 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.

5.3 Information on the active substances

5.3.1 Propyzamide

Please refer to the core assessment (10/2013), part B, section 5, point 5.3.1.

5.3.2 Aminopyralid

Please refer to the core assessment (10/2013), part B, section 5, point 5.3.2.

5.4 Summary on input parameters for environmental exposure assessment

5.4.1 Rate of degradation in soil

Propyzamide

In case of propyzamide additional PECgw calculations for national authorization are performed. These are based on degradation parameters derived according to the recommendations in Holdt *et al.* (2011) which were realized in the Excel-tool Input Decision 3.3.

Table 5.4-1: Summary of aerobic degradation rates for propyzamide - laboratory studies

Soil type	**pH**	**T (°C)**	**Moisture**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20 °C pF2/ 10 kPa**	**Fit**	**Method of calculation**	**Reference**
Sandy loam	6.5	20	40%	19.6	65.0	16.5	9.8	SFO	Völkl (2001)
Loamy sand	5.7	20	40%	42.4	140.7	42.4	2.8	SFO	Völkl (2001)
Silty clay loam	6.6	20	40%	18.2	60.5	14.3	5.2	SFO	Völkl (2001)
Sandy loam	7.7	26	75%	190*	k.A.	197.3*	0.91	SFO	Olson and Laurence (1990)
Aggregated DT_{50} (n=4)	**Coefficient of variation (%)**					129	According to Input Decision 3.3		
	90th percentile (d)					150.8			
	10th percentile (d)					15.0			

For laboratory degradation rates of propyzamide metabolites RH-24644 and RH-24580 please refer to the core assessment (10/2013), part B, section 5, point 5.4.1.1.

Aminopyralid

Please refer to the core assessment (10/2013), part B, section 5, point 5.4.1.

5.4.2 Adsorption/desorption

Propyzamide

Please refer to the core assessment (10/2013), part B, section 5, point 5.4.2.

Aminopyralid

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 5.4-2: K_f, K_{foc} and 1/n (Freundlich exponent) values for aminopyralid

Soil Type	OC (%)	pH, $CaCl_2$ (-)	K_f (mL g^{-1})	K_{foc} (mL g^{-1})	1/n (-)	Reference
Thessaloniki (Europe), Silty Clay Loam	1.0	7.8	0.039	3.91	0.860	Rutherford (2002), updated DAR (03/2012)
Faringdon (Europe), Clay	3.2	7.5	0.079	2.45	0.919	Rutherford (2002), updated DAR (03/2012)
Ryerson (US), Silty Clay	3.9	7.8	0.232	5.94	0.887	Rutherford (2002), updated DAR (03/2012)
Cuckney (Europe), Sand	1.6	6.6	0.063	3.92	0.888	Rutherford (2002), updated DAR (03/2012)
Charentilly (Europe), Clay Loam	1.0	6.1	0.043	4.35	0.824	Rutherford (2002), updated DAR (03/2012)
Dowling (US), Clay	1.5	6.9	0.043	2.85	0.793	Rutherford (2002), updated DAR (03/2012)
Barnes (US), Clay Loam	3.6	4.8	0.625	17.36	0.903	Rutherford (2002), updated DAR (03/2012)
Norfolk (US), Loamy Sand	0.6	4.5	0.147	24.46	0.881	Rutherford (2002), updated DAR (03/2012)
Altlußheim, Germany, M696, Loam	1.7	7.5	0.203	11.92	0.950	Laughlin (2006), updated DAR (03/2012)
Barrow on Trent, UK, M697, Sandy Loam	4.6	6.3	0.184	4.01	0.870	Laughlin (2006), updated DAR (03/2012)
Hertfordshire, UK, M698, Clay Loam	2.2	7.6	0.193	8.77	0.960	Laughlin (2006), updated DAR (03/2012)
Römenberg, Germany, M699, Sandy Loam	0.7	7.4	0.099	14.18	0.920	Laughlin (2006), updated DAR (03/2012)
Languedoc, France, M700, Loam	3.2	7.6	0.255	7.96	0.980	Laughlin (2006), updated DAR (03/2012)

Empingham, UK, M701, Clay Loam	2.1	7.5	0.249	11.86	0.940	Laughlin (2006), updated DAR (03/2012)
Arithmetic mean all soils (n = 14)				**9.0**	**0.898**	

Table 5.4-3: Statistic values according to INPUT DECISION 3.2 for aminopyralid for PEC_{GW} modelling

Does the active substance dissociate ?	yes, pKs = 2.56	-
correlation K_{foc} and pH	Kendall-τ: -0.317 p-value: 0.136	not significant
correlation K_f and pH	Kendall-τ: 0.102 p-value: 0.658	Not significant
correlation K_f and oc	Kendall-τ: 0.425 p-value: 0.021	positively significant (p-value < significance level)
coefficient of variation K_{foc}	72	not relevant
coefficient of variation Kf	83	not relevant
Correlation K_f and other soil parameters (clay, CEC)	-	not relevant
K_{foc}/ PEC_{GW}	9.0	arithmetic mean all soils (n = 14)
1/n PECgw	0.989	arithmetic mean all soils (n = 14)

5.4.3 Rate of degradation in water/sediment

Propyzamide

Please refer to the core assessment (10/2013), part B, section 5, point 5.4.3.

Accumulation of active substance and relevant metabolites in the sediment

active substance	propyzamide
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) $f_{accu} = e^{-kt}/(1 - e^{-kt})$	0.13 based on $DT_{50,\ whole\ system}$ = 118 (maximum, see core assessment, part B, section 5, chapter 5.4.3), t = 356 d

Aminopyralid

Please refer to the core assessment (10/2013), part B, section 5, point 5.4.3.

Accumulation of active substance and relevant metabolites in the sediment

active substance	aminopyralid
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) **$f_{accu} = e^{-kt}/(1 - e^{-kt})$**	3.43 based on $DT_{50,\text{ whole system}}$ = 988.6 (maximum, see core assessment, part B, section 5, chapter 5.4.3), t = 356 d

5.5 Estimation of concentrations in soil (KIIIA1 9.4)

Results of PECsoil calculation for GF-2540 according to EU assessment considering 5 cm soil depth are given in the core assessment 10/2013, 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 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.

Due to the fast degradation of propyzamide in soil (DT90 < 365 d, FSO, laboratory data) the accumulation potential of propyzamide does not need to be considered.

Due to the fast degradation of aminopyralid in soil (DT90 < 365 d, SFO, field data) the accumulation potential of aminopyralid does not need to be considered.

Additional $PEC_{soil,act}$ was calculated for the formulation GF-2540 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 active substance propyzamide and its metabolites RH-24644 and RH 24580, for active substance aminopyralid and for the formulation GF-2540 are summarized in Table 5.5-1.

Table 5.5-1: Results of PEC_{soil} calculation for the intended use in winter oilseed rape used for German risk assessment

plant protection product:		GF-2540				
Use No.		001				
Crop		Winter oilseed rape				
Application rate		1.5 L ha^{-1}				
Number of application/interval		1x				
Crop interception		40 %				
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)**
Active substance propyzamid	450.0	1.0	3.000	-	-	-
Metabolite RH-24644[1]	143.5	1.0	0.957	-	-	-
Metabolite RH-24580[2]	115.5	2.5	0.308	-	-	-

Active substance aminopyralid	4.8	2.5	0.013	-	-	-
Preparation GF-2540	1025.1[3]	1	6.834	-	-	-

[1] correction factor based on molecular weight: 0.999, max. 31.9 %
[2] correction factor based on molecular weight: 1.070, max. 24.0 %
[3] relative density of preparation GF-2540: 1.139 g L^{-1}

5.6 Estimation of concentrations in surface water and sediment (KIIIA1 9.7)

Results of PECsw calculations of propyzamide and Aminopyralid for the intended for uses of GF-2540 in winter oilseed rape using FOCUS Surface Water are given in the core assessment (10/2013), 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 models EVA 2.1. Surface water exposure via surface run-off and drainage is estimated using the model EXPOSIT 3.01.

The German surface water exposure assessment is outlined in the following chapters.

5.6.1 PEC_{SW} after exposure by spraydrift and deposition following volatilisation

Propyzamide

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 propyzamide is between 10^{-5} and 10^{-4} Pa/> 10^{-4} Pa. Hence the active substance is regarded as semivolatile (volatilisation only from plant surfaces). Therefore exposure of surface water by the active substance propyzamide due to deposition following volatilization needs to be considered.

The calculation of PECsw after exposure via spray drift and volatilization with subsequent deposition is performed using the model EVA 2.1. For a single application, the exposure assessment via spray drift is based on the application rate in conjunction with the 90[th] percentile of the drift values. For multiple applications, lower percentiles of the drift values for each application are applied, resulting in an overall 90[th] percentile of drift probabilities. Only one volatilization event following the last use of pesticide is generally considered.

The endpoints used for modelling surface water exposure via spray drift and volatilization with subsequent deposition with EVA 2.1 are summarized in Table 5.6-5.

Table 5.6-1 Endpoints of propyzamide used for the PEC_{SW} calculations with EVA 2.1

Parameter	Active substance propyzamide	Reference
vapour pressure at 20 °C (Pa)	2.67 x 10^{-5}	See core assessment, section 5, point 5.3.1.2
Solubility in water (mg/L)	9.0	See core assessment, section 5, point 5.3.1.2
DT_{50} hydrolysis/photolysis (d)	1000 (default)	

The calculated PECsw values after exposure via spray drift and volatilization with subsequent deposition for the active substance propyzamide for the intended use in winter oilseed rape are summarized in Table 5.6-6.

Table 5.6-2 PEC_{SW} for the active substance propyzamide after exposure via spray drift and volatilization with subsequent deposition modelled with EVA 2.1

active substance		propyzamide					
use pattern/gap:		001					
application rate		750 g ai ha^{-1}					
$DissT_{50}$ (SFO) in water		24 d					
scenario/percentile:		Agriculture / 90. percentile					
distance (m)	PECsw via drift		PECsw via volatilisation		PECsw (via drift and volatilisation) (µg/L) depending on application technique (drift reduction)			
	(%)	(µg/L)	(%)	(µg/L)	common	90% red.	75% red.	50% red.
0	100.00	250.00	-	-	250.000	25.00	62.50	125.00
1	2.770	6.925	0.266	0.089	7.014	0.78	1.82	3.55
5	0.570	1.425	0.214	0.071	1.496	0.21	0.43	0.78
10	0.290	0.725	0.163	0.054	0.779	0.13	0.24	0.42
15	0.200	0.500	0.124	0.041	0.541	0.09	0.17	0.29
20	0.150	0.375	0.095	0.032	0.407	0.07	0.13	0.22

Two metabolites (UK1 and RH 24655 [UK2]) were formed in the sediment/water study (Müller-Kallert, 1994) that reached maxima > 5 % AR at the end of the study. For these metabolites, no studies on the degradation or adsorption behaviour are available. As a worst-case assumption for the PECsw and PECsed calculations, it is assumed that all of the metabolites (UK1: 9.9 % and RH 24655: 27.0 %) is present in the water phase or the sediment, respectively. The PECsw and PECsed values for these metabolites were calculated by taking the initial (maximum) PECsw values (EVA 2.1) for the active substance and correcting for the maximum percentage of metabolite formed and the difference in molecular weights (256 for propyzamide, for 221 UK1 and 258 for RH 24655).

$$\text{Initial } PEC_{SW,metab}\ (\mu g/L) = PEC_{initial,\ parent} * \frac{\text{max \% met}}{100} * \frac{\text{m.wt. metab}}{\text{m.wt. parent}}$$

Results of the calculations are presented in Table 5.6-3 and Table 5.6-4.

Table 5.6-3 PEC_{SW} for the active substance propyzamide metabolite UK1 after exposure via spray drift and volatilization with subsequent deposition

metabolite		UK1						
use pattern/gap:		001						
distance (m)	PECsw via drift		PECsw via volatilisation		PECsw (via drift and volatilisation) (µg/L) depending on application technique (drift reduction)			
	(%)	(µg/L)	(%)	(µg/L)	common	90% red.	75% red.	50% red.
0	100	21.366	-	-	21.366	-	-	-
1	2.77	0.592	0.266	0.008	0.592	0.059	0.148	0.296
5	0.57	0.122	0.214	0.006	0.122	0.012	0.030	0.061
10	0.29	0.062	0.163	0.005	0.062	0.006	0.015	0.031
15	0.2	0.043	0.124	0.004	0.043	0.004	0.011	0.021
20	0.15	0.032	0.095	0.003	0.032	0.003	0.008	0.016

Table 5.6-4 PEC$_{SW}$ for the active substance propyzamide metabolite RH 24655 (UK2) after exposure via spray drift and volatilization with subsequent deposition

metabolite		RH 24655 (UK2)					
use pattern/gap:		001					
distance (m)	PECsw via drift		PECsw via volatilisation		PECsw (via drift and volatilisation) (µg/L) depending on application technique (drift reduction)			
	(%)	(µg/L)	(%)	(µg/L)	common	90% red.	75% red.	50% red.
0	100	68.027	-	-	68.027	-	-	-
1	2.77	1.884	0.266	0.024	1.884	0.188	0.471	0.942
5	0.57	0.388	0.214	0.019	0.388	0.039	0.097	0.194
10	0.29	0.197	0.163	0.015	0.197	0.020	0.049	0.099
15	0.2	0.136	0.124	0.011	0.136	0.014	0.034	0.068
20	0.15	0.102	0.095	0.009	0.102	0.010	0.026	0.051

Aminopyralid

The vapour pressure at 20 °C of the active substance aminopyralid is < 10 5 Pa. Hence the active substance is regarded as non-volatile. Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance aminopyralid due to volatilization with subsequent deposition does not need to be considered.

The calculation of PECsw after exposure via spray drift is performed using the model DRIFTOX 4.0. 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 surface water exposure via spray drift and volatilization with subsequent deposition with DRIFTOX 4.0 are summarized in Table 5.6-5.

Table 5.6-5 Endpoints of propyzamide used for the PEC$_{SW}$ calculations with DRIFTOX 4.0

Parameter	Active substance aminopyralid	Reference
vapour pressure at 20 °C (Pa)	9.25 x10^{-9}	See core assessment, section 5, point 5.3.2.2
Solubility in water (mg/L)	205	See core assessment, section 5, point 5.3.2.2
DT$_{50}$ hydrolysis/photolysis (d)	1000 (default)	

The calculated PECsw values after exposure via spray drift for the active substance aminopyralid for the intended use in 001are summarized in Table 5.6-6.

Table 5.6-6 PEC$_{SW}$ for the active substance aminopyralid after exposure via spray drift and volatilization with subsequent deposition modelled with DRIFTOX 4.0

active substance	aminopyralid
use pattern/gap:	001
application rate	8 g ai ha^{-1}
DissT$_{50}$ (SFO) in water	918.7

scenario/percentile:	agriculture / 90. percentile							
distance (m)	PECsw via drift		PECsw via volatilisation		PECsw (via drift and volatilisation) (µg/L) depending on application technique (drift reduction)			
	(%)	(µg/L)	(%)	(µg/L)	common	90% red.	75% red.	50% red.
0	100.00	2.65	-	-	2.65	-	-	-
1	2.77	0.0734	-	-	0.0734	0.0073	0.0184	0.0367
5	0.57	0.0151	-	-	0.0151	0.0015	0.0038	0.0076
10	0.29	0.0077	-	-	0.0077	0.0008	0.0019	0.0038
15	0.20	0.0053	-	-	0.0053	0.0005	0.0013	0.0027
20	0.15	0.0040	-	-	0.0040	0.0004	0.0010	0.0020

5.6.2 PEC_{SW} after exposure by surface run-off and drainage

Propyzamide

The concentration of the active substance propyzamide and its metabolites in adjacent ditch due to surface runoff and drainage is calculated using the model EXPOSIT 3.01.

The parameters for propyzamide and its metabolites RH 24644 and RH 24580 used for modelling surface water exposure via run-off and drainage in an adjacent ditch with EXPOSIT 3.01 are summarized in Table 5.6-7 and Table 5.6-8.

Table 5.6-7 Input parameters for propyzamide used for PEC_{SW} calculations with EXPOSIT 3.01

Parameter	propyzamide	Reference
$K_{foc, Runoff}$	642	arithm. mean (see core assessment, section 5, chapter 5.4.2)
$K_{foc, mobility class}$	642	arithm. mean (see core assessment, section 5, chapter 5.4.2)
DT_{50} soil (d)	150.8	90. percentile (laboratory studies, see Table 5.4-1)
Solubility in water (mg/L)	9.0	see core assessment, section 5, point 5.3.1.2
Reduction by bank filtration (only relevant for PECgw see 5.7.2)	100 %	-

Table 5.6-8 Input parameters for propyzamide metabolites RH 24644 and RH 24580 used for PEC_{SW} calculations with EXPOSIT 3.01

Parameter	metabolite RH-24644	Reference
Metabolite RH 24644		
$K_{foc, Runoff}$	2355	arithm. mean (see core assessment, section 5, chapter 5.4.2)
$K_{foc, mobility class}$	2355	arithm. mean (see core assessment, section 5, chapter 5.4.2)
DT_{50} soil (d)	36.5	90. percentile (laboratory studies, see core assessment, section 5, chapter 5.4.1.1)
Solubility in water (mg/L)	0.34	see core assessment, section 5, chapter

		5.3.1.2
Maximum formation (%)	31.9	See core assessment, section 5, chapter 5.3.1.3
Molecular correction factor	0.999	-
Reduction by bank filtration (only relevant for PECgw see 5.7.2)	100 %	-
metabolite RH-24580		
$K_{foc,\ Runoff}$	167	arithm. mean (see core assessment, section 5, chapter 5.4.2)
$K_{foc,\ mobility\ class}$	167	arithm. mean (see core assessment, section 5, chapter 5.4.2)
DT_{50} soil (d)	14.0	90. percentile (laboratory studies, see Table 5.4-11.1)
Solubility in water (mg/L)	9.0	see core assessment, section 5, chapter 5.3.1.2
Maximum formation (%)	24	See core assessment, section 5, chapter 5.3.1.3
Molecular correction factor	1.07	-
Reduction by bank filtration (only relevant for PECgw see 5.7.2)	90 %	-

The calculated PEC_{SW} in an adjacent ditch due to surface run-off and drainage for the active substance propyzamide and its metabolites RH 24644 and RH 24580 for the intended use in winter oilseedrape are summarized inTable 5.6-9 to Table 5.6-11.

Table 5.6-9 PEC_{SW} of propyzamide in an adjacent ditch due to surface run-off and drainage

Active substance: propyzamide **Use pattern/GAP:** 001 **Application rate:** 750 g ai ha^{-1}		
Exposure by surface runoff		
vegetated buffer strip (m)	**PECsw in adjacent ditch ($PEC_{ini\ Runoff}$) (µg/L)**	**PECsw in adjacent ditch ($PEC_{ini\ Gesamtaustrag}$) (µg/L)**
0	3.14	3.48
5	2.72	3.02
10	2.33	2.59
20	1.63	1.81
Exposure by drainage		
time of application	**PECsw in adjacent ditch (µg/L)**	
autuum/winter/early spring	0.21	
Spring/summer	0.07	

Table 5.6-10 PEC_{SW} of propyzamide metabolite RH 24644 in an adjacent ditch due to surface run-off and drainage

metabolite:	RH 24644
Use pattern/GAP:	001

Exposure by surface runoff		
vegetated buffer strip (m)	**PECsw in adjacent ditch ($PEC_{ini\ Runoff}$) (µg/L)**	**PECsw in adjacent ditch ($PEC_{ini\ Gesamtaustrag}$) (µg/L)**
0	0.46	0.97
5	0.40	0.84
10	0.34	0.72
20	0.24	0.50
Exposure by drainage		
time of application	**PECsw in adjacent ditch (µg/L)**	
autuum/winter/early spring	0.07	
Spring/summer	0.02	

Table 5.6-11 PEC_{SW} of propyzamide metabolite RH 24580 in an adjacent ditch due to surface run-off and drainage

metabolite: RH 24580 **Use pattern/GAP:** 001		
Exposure by surface runoff		
vegetated buffer strip (m)	**PECsw in adjacent ditch ($PEC_{ini\ Runoff}$) (µg/L)**	**PECsw in adjacent ditch ($PEC_{ini\ Gesamtaustrag}$) (µg/L)**
0	1.10	1.11
5	0.95	0.96
10	0.82	0.82
20	0.57	0.58
Exposure by drainage		
time of application	**PECsw in adjacent ditch (µg/L)**	
autuum/winter/early spring	1.11	
Spring/summer	0.36	

Two metabolites (UK1 and RH 24655 [UK2]) were formed in the sediment/water study (Müller-Kallert, 1994) that reached maxima > 5 % AR at the end of the study. For these metabolites, no studies on the degradation or adsorption behaviour are available. As a worst-case assumption for the PECsw and PECsed calculations, it is assumed that all of the metabolites (UK1: 9.9 % and RH 24655: 27.0 %) is present in the water phase or the sediment, respectively. The PECsw and PECsed values for these metabolites were calculated by taking the initial (maximum) PECsw values (Exposit 3.01) for the active substance and correcting for the maximum percentage of metabolite formed and the difference in molecular weights (256 for propyzamide, for 221 UK1 and 258 for RH 24655).

$$\text{Initial } PEC_{SW,metab}\ (\mu g/L) = PEC_{initial,\ parent} * \frac{\text{max \% met}}{100} * \frac{\text{m.wt. metab}}{\text{m.wt. parent}}$$

Results of the calculations are presented in Table 5.6-12 and Table 5.6-13.

Table 5.6-12 PEC_{SW} of propyzamide metabolite UK1 in an adjacent ditch due to surface run-off and drainage

Metabolite: UK1		
Use pattern/GAP: 001		
Exposure by surface runoff		
vegetated buffer strip (m)	**PECsw in adjacent ditch ($PEC_{ini\ Runoff}$) (µg/L)**	**PECsw in adjacent ditch ($PEC_{ini\ Gesamtaustrag}$) (µg/L)**
0	0.27	0.30
5	0.23	0.26
10	0.20	0.22
20	0.14	0.15
Exposure by drainage		
time of application	**PECsw in adjacent ditch (µg/L)**	
autuum/winter/early spring	0.02	
Spring/summer	0.01	

Table 5.6-13 PEC_{SW} of propyzamide metabolite RH 24655 (UK2) in an adjacent ditch due to surface run-off and drainage

Metabolite: RH 24655 (UK2)		
Use pattern/GAP: 001		
Exposure by surface runoff		
vegetated buffer strip (m)	**PECsw in adjacent ditch ($PEC_{ini\ Runoff}$) (µg/L)**	**PECsw in adjacent ditch ($PEC_{ini\ Gesamtaustrag}$) (µg/L)**
0	0.85	0.95
5	0.74	0.82
10	0.63	0.70
20	0.44	0.49
Exposure by drainage		
time of application	**PECsw in adjacent ditch (µg/L)**	
autuum/winter/early spring	0.06	
Spring/summer	0.02	

Aminopyralid

The concentration of the active substance Aminopyralid in adjacent ditch due to surface runoff and drainage is calculated using the model EXPOSIT 3.01.

The parameters for aminopyralid used for modelling surface water exposure via run-off and drainage in an adjacent ditch with EXPOSIT 3.01 are summarized in Table 5.6-14.

Table 5.6-14 Input parameters for aminopyralid used for PEC_{SW} calculations with EXPOSIT 3.01

Parameter	aminopyralid	Reference
$K_{foc,\ Runoff}$	9	arithm. mean (see core assessment,

		section 5, chapter 5.4.2)
$K_{foc, mobility class}$	9	arithm. mean (see core assessment, section 5, chapter 5.4.2)
DT_{50} soil (d)	34.9	Maximum (non-normalized field studies, see core assessment point 5.4.1.2)
Solubility in water (mg/L)	205000	see core assessment, section 5, point 5.3.2.2)
Reduction by bank filtration (only relevant for PECgw see 5.7.2)	3	-

The calculated PEC_{SW} in an adjacent ditch due to surface run-off and drainage for the active substance aminopyralid for the intended use in winter oilseed rape are summarized in Table 5.6-15.

Table 5.6-15 PEC_{SW} of aminopyralid in an adjacent ditch due to surface run-off and drainage

Active substance: aminopyralid **Use pattern/GAP:** 001 **Application rate:** 8 ga ai ha^{-1}		
Exposure by surface runoff		
vegetated buffer strip (m)	**PECsw in adjacent ditch ($PEC_{ini\ Runoff}$) (µg/L)**	**PECsw in adjacent ditch ($PEC_{ini\ Gesamtaustrag}$) (µg/L)**
0	0.02	0.02
5	0.02	0.02
10	0.01	0.01
20	0.01	0.01
Exposure by drainage		
time of application	**PECsw in adjacent ditch (µg/L)**	
autuum/winter/early spring	0.04	
Spring/summer	0.01	

5.7 Risk assessment for groundwater (KIIIA1 9.6)

Results of PECgw calculation of aminopyralid for the intended uses of GF-2540 in winter oilseed rape according to EU assessment using FOCUSPELMO 5.5.3 are given in the core assessment (10/2013), 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 3.1 and subsequent simulations are performed for the groundwater scenarios "Hamburg" or with the scenarios "Hamburg" and "Kremsmünster" of FOCUS PELMO 4.4.3.

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 3.01.

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 of GF-2540 in winter oilseed rape according to Table 5.2-1.

Table 5.7-1 Input parameters related to application for PEC_{GW} modelling with FOCUS PELMO 5.5.3

plant protection product	GF-2540
use No.	001
application rate (kg ha^{-1})	propyzamide: 750 aminopyralid: 8
crop (crop rotation)	Winter oilseed rape
relative application date	BBCH 23- Hamburg scenario: november 20^{th}
mode of application	every 3^{rd} year
interception (%)	80% (application in november)
soil moisture	100 % FC
Q10-factor	2.58
moisture exponent	0.7
plant uptake	0
simulation period (years)	26

Propyzamide

The endpoints used for groundwater modelling for active substance propyzamide and its metabolites RH 24655 and RH 24580 according to INPUT DECISION 3.1 are summarized in Table 5.7-2.

Table 5.7-2 Input parameters related to active substance propyzamide for PEC_{GW} modelling

Parent	parameter	Remarks/Reference to core assessment, part B, section 5
molecular weight (g/mol)	256	-
DT_{50} in soil (d)	1	worst case
K_{foc}	150.8 15.0	90th percentile (1st order, pF2,20°C) 10th percentile (1st order, pF2,20°C) Laboratory data (see Table 5.4-1)

1/n	642	Arithmetic mean (see core assessment point 5.4.2)
plant uptake factor	1.045	Arithmetic mean (see core assessment point 5.4.2)

Table 5.7-3: Input parameters related to metabolites of propyzamide for PECGW modelling

Metabolite	Parameter	Remarks/Reference to core assessment, part B, section 5
Metabolite RH-24644		
molecular mass	256	-
Formation fraction	1	worst case
DT_{50} in soil (d)	26.8	Geomean (1st order, pF2,20°C) Laboratory data (see core assessment point 5.4.1.1)
K_{foc}	2355	Arithmetic mean (see core assessment point 5.4.2)
1/n	0.901	Arithmetic mean (see core assessment point 5.4.2)
plant uptake factor	0	-
Metabolite RH 24580		
molecular mass	274	-
Formation fraction	1	worst case
DT_{50} in soil (d)	12.5	Geomean (1st order, pF2,20°C) Laboratory data (see core assessment point 5.4.1.1)
K_{foc}	167	Arithmetic mean (see core assessment point 5.4.2)
1/n	0.85	Arithmetic mean (see core assessment point 5.4.2)
plant uptake factor	0	-

The results of the groundwater simulation are presented in Table 5.7-4.

Table 5.7-4 PEC_{GW} at 1 m soil depth of active substance propyzamide and its metabolites RH 24655 and RH 24580 considered relevant for German exposure assessment

Use No.	Szenario	DT_{50} propyzamide	80th Percentile PEC_{GW} at 1 m Soil Depth (µg L^{-1}) modeled by FOCUS PELMO 4.4.3		
			active substance propyzamide	**metabolite RH24655**	**Metabolite RH 24580**
001	Hamburg	90th percentile	**0.345**	0.010	0.017
		10th percentile	< 0.001	< 0.001	< 0.001

According to the results of the groundwater simulation with FOCUS-PELMO 5.5.3, a groundwater contamination of the active substance propyzamide in concentrations ≥ 0.1 µg/L is expected for the intended use in winter oilseed rape.

For the metabolites RH 24655 and RH 24580 of propyzamide a groundwater concentration ≥ 0.1 µg/L can be excluded for the application in winter oilseed rape according to the results of the groundwater simulation with FOCUS-PELMO 5.5.3.

In addition to the PECgw modelling experimental data from lysimeter studies are used to assess the leaching behaviour of the active substance propyzamide.

Aminopyralid

The endpoints used for groundwater modelling for active substance aminopyralid according to INPUT DECISION 3.1 are summarized in Table 5.7-5.

Table 5.7-5 Input parameters related to active substance aminopyralid for PEC_{GW} modelling

Parent	parameter	Remarks/Reference to core assessment, part B, section 5
molecular weight (g/mol)		
DT_{50} in soil (d)	15.4	Geometric mean (field studies) (see core assessment point 5.4.1.2)
K_{foc}	9.0	Arithmetic mean (see Table 5.4-2)
1/n	0.898	Arithmetic mean (see Table 5.4-2)
plant uptake factor	0	-

The results of the groundwater simulation are presented in Table 5.7-4.

Table 5.7-6 PEC_{GW} at 1 m soil depth of active substance aminopyralid considered relevant for German exposure assessment

Use No.	Szenario	Application date	80th Percentile PEC_{GW} at 1 m Soil Depth (µg L^{-1}) modeled by FOCUS PELMO 4.4.3 active substance aminopyralid
001	Hamburg	September 3rd	0.023

According to the results of the groundwater simulation with FOCUS-PELMO 5.5.3, a groundwater contamination of the active substance aminopyralid in concentrations ≥ 0.1 µg/L is not expected for the intended use in winter oilseed rape.

5.7.1.2 Experimental data to the leaching behaviour of the active aubstance propyzamide

In case of the active substance propyzamide exposure assessment is based additionally on results of a lysimeter study. The study by Morgenroth and Burgener (1997, Report No. RHD 97/10029) is described in detail in the Addendum to the Monograph (Feb. 2003).

The experimental data on the leaching behaviour of the active substance propyzamide show that the active substance propyzamide and its metabolites RH-24644 and RH-24580 are not expected to penetrate into groundwater at concentrations of ≥ 0.1µg/L assuming applications in winter (january).

Groundwater entries of the unknown metabolites U1, U3, U4, U5, U6 and U7 ≥ 0.1µg/L cannot be excluded:

Maximum of the mean annual concentrations

Metabolite U1: 0.24 µg/L (Lys.18)
Metabolite U3: 0.24 µg/L (Lys.17)
Metabolite U4: 0.42 µg/L (Lys.17)
Metabolite U5: 0.77 µg/L (Lys.17)
Metabolite U6: 0.40 µg/L (Lys.18)
Metabolite U7: 0.20 µg/L (Lys.18)

The metabolites U1-U7 can only be characterized (not identified). Therefore their biological activity in relation to the parent compound according to the Guidance Document SANCO/221/2000 cannot be estimated. A specific herbicidal action seems unlikely as these compounds are highly polar degradation products of a herbicidal active ingredient.

5.7.1.3 Summary on risk assessment for groundwater after direct leaching

Propyzamide

According to the results of the groundwater simulation with FOCUS-PELMO 5.5.3, a groundwater contamination of the active substance propyzamide in concentrations ≥ 0.1 µg/L is expected for the intended use in winter oilseed rape. For the metabolites RH 24655 and RH 24580 of propyzamide a groundwater concentration ≥ 0.1 µg/L can be excluded for the application in winter oilseed rape according to the results of the groundwater simulation with FOCUS-PELMO 5.5.3.

In addition to the PECgw modelling data from lysimeter studies are used to assess the leaching behaviour of the active substance propyzamide. The experimental data show that the active substance propyzamide and its metabolites RH-24644 and RH-24580 are not expected to penetrate into groundwater at concentrations of ≥ 0.1µg/L assuming applications in winter (january).

Aminopyralid

Results of modelling with FOCUSPELMO 5.5.3 show that the active substance aminopyralid is not expected to penetrate into groundwater at concentrations of ≥ 0.1µg/L in the intended uses in winter oilseed rape.

Consequences for authorization:

none

5.7.2 Ground water contamination by bank filtration due to surface water exposure via run-off and drainage

Propyzamide

The input parameters for propyzamide used for modelling surface water exposure via run-off and drainage in an adjacent ditch with subsequent bank filtration into the groundwater with EXPOSIT 3.01 are summarized in Table 5.7-12.

Table 5.7-7 Input parameters for propyzamide used for PEC_{GW} calculations with EXPOSIT 3.01

Parameter	propyzamide	Reference
$K_{foc, Runoff}$	642	arithm. mean (see core assessment, section 5, chapter 5.4.2)
$K_{foc, mobility\ class}$	642	arithm. mean (see core assessment, section 5, chapter 5.4.2)
DT_{50} soil (d)	150.8	90. percentile (laboratory studies, see Table 5.4-1)
Solubility in water (mg/L)	9.0	see core assessment, section 5, point 5.3.1.2
Mobility class	1	-
Reduction by bank filtration	100 %	-

The calculated PECgw for propyzamide after surface run-off and drainage with subsequent bank filtration are summarized in Table 5.7-13.

Table 5.7-8 PEC_{gw} for propyzamide after surface run-off and drainage with subsequent bank filtration (modelled with EXPOSIT 3.01)

Active substance		propyzamide			
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)**
001	750 g ai ha^{-1} 40 % interception	0	< 0.001	autumn/winter/ early spring	< 0.001
		5	< 0.001		
		10	< 0.001	spring/summer	< 0.001
		20	< 0.001		
required labelling		none			

According modelling with EXPOSIT 3.01, groundwater contamination at concentrations ≥ 0.1 µg/L by the active substance propyzamide due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

Metabolites

The soil metabolites RH 24644 and RH 24580 of active substance propyzamide (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 inTable 5.7-9, the results are given in Table 5.7-10 and Table 5.7-11.

Table 5.7-9: Input parameter for soil metabolites RH 24644 and RH 24580 of active substance propyzamide for EXPOSIT 3.01

Metabolite	Parameter
Metabolite RH 24644	

Molecular weight (g/mol)	256
Correction factor molecular weight	0.999
Maximum occurrence in soil (%)	31.9
$K_{foc, Runoff}$	2355
$K_{foc, mobility\ class}$	2355
DT_{50} soil (d)[1)]	36.5
Solubility in water (mg/L)	0.34
Mobility class	1
Reduction by bank filtration	100 %
Metabolite RH 24580	
Molecular weight (g/mol)	274
Correction factor molecular weight	1.07
Maximum occurrence in soil (%)	24.0
$K_{foc, Runoff}$	167
$K_{foc, mobility\ class}$	167
DT_{50} soil (d)[1)]	14.0
Solubility in water (mg/L)	9.0
Mobility class	3
Reduction by bank filtration	90 %

[1)] 90th percentile, only relevant for mobility class

Table 5.7-10: PEC_{gw} for soil metabolites RH 24644 of active substance propyzamide after surface run-off and drainage with subsequent bank filtration (modelled with EXPOSIT 3.01)

Metabolite		**RH 24644**			
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)**
001	143.5 g ha^{-1}	0	< 0.001	autumn/winter/ early spring	< 0.001
		5	< 0.001		
		10	< 0.001	spring/summer	< 0.001
		20	< 0.001		
required labelling		none			

Table 5.7-11: PEC_{gw} for soil metabolites RH 24580 of active substance propyzamide after surface run-off and drainage with subsequent bank filtration (modelled with EXPOSIT 3.01)

Metabolite	**RH 24580**

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)
001	115.5 ga ha^{-1}	0	0.009	autumn/winter/ early spring	0.009
		5	0.008		
		10	0.007	spring/summer	0.003
		20	0.005		
required labelling		none			

According to modelling with EXPOSIT 3.01, groundwater contamination at concentrations ≥ 0.1 µg/L by the soil metabolites RH 24644 and RH 24580 of propyzamide due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

Aminopyralid

The input parameters for aminopyralid used for modelling surface water exposure via run-off and drainage in an adjacent ditch with subsequent bank filtration into the groundwater with EXPOSIT 3.01 are summarized in Table 5.7-12.

Table 5.7-12 Input parameters for aminopyralid used for PEC_{GW} calculations with EXPOSIT 3.01

Parameter	aminopyralid	Reference
$K_{foc, Runoff}$	9	arithm. mean (see core assessment, section 5, chapter 5.4.2)
$K_{foc, mobility class}$	9	arithm. mean (see core assessment, section 5, chapter 5.4.2)
DT_{50} soil (d)	34.9	Maximum (non-normalized field studies, see core assessment point 5.4.1.2)
Solubility in water (mg/L)	205000	see core assessment, section 5, point 5.3.2.2)
Mobility class	3	-
Reduction by bank filtration	90 %	-

The calculated PECgw for aminopyralid after surface run-off and drainage with subsequent bank filtration are summarized in Table 5.7-13.

Table 5.7-13 PEC_{gw} for aminopyralid after surface run-off and drainage with subsequent bank filtration (modelled with EXPOSIT 3.01)

Active substance		aminopyralid	
Use No.	application rate	PECgw due to	
		run-off	drainage

	interception	**vegetated buffer strip (m)**	**bank filtrate (µg/L)**	**Time of application**	**bank filtrate (µg/L)**
		0	< 0.001	autumn/winter/ early spring	< 0.001
		5	< 0.001		
		10	< 0.001	spring/summer	< 0.001
		20	< 0.001		
required labelling		none			

According modelling with EXPOSIT 3.01, groundwater contamination at concentrations ≥ 0.1 µg/L by the active substance aminopyralid due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

Consequences for authorization:

The authorization of the plant protection product GF-2540 is linked with following labeling:

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

none

Appendix 3 GAP-Table of intended uses for Germany

GAP rev. BVL, date: 2012-10-05

PPP (product name/code)	**GF-2540**	**Formulation type:**	**SC**
active substance 1	**Propyzamid**	**Conc. of as 1:**	**500 g/L**
active substance 2	**Aminopyralid**	**Conc. of as 2:**	**5.3 g/L**
Applicant:	**DOW AgroSciences GmbH**	**professional use**	**X**
Zone(s):	**central/EU**	**non professional use**	

Verified by MS: Y

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 as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
001	DE	Winter oilseed Rape	F	Annual mono- and dicot weeds (post emergence of weeds)	Spraying	> BBCH 14 Late autumn to winter, November to February	a) 1 b) 1	a) 1.5 b) 1.5	a) 750 g/ha Propyzamid 7.95 g/ha Aminopyralid b) 750 g/ha Propyzamid 7.95 g/ha Aminopyralid	20 0 - 300		

REGISTRATION REPORT
Part B

Section 6 Ecotoxicological Studies
Detailed summary of the risk assessment

Product code: **GF-2540**
Active Substance: **Propyzamide 500 g/L**
Aminopyralid 5.3 g/L

Central Zone
Zonal Rapporteur Member State: Germany (DE)

CORE ASSESSMENT

Applicant: **Dow AgroSciences**
Date: **08/05/2014**

Table of content

Sec 6 ECOTOXICOLOGICAL STUDIES

This document reviews the ecotoxicological studies for the product GF-2540 containing the active substances Propyzamide and aminopyralid of which propyzamide is currently approved and aminopyralid is currently evaluated for approval under Reg. (EC) No 1107/2009 (repealing Directive 91/414/EEC) and fulfill the criteria according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2.

GF-2540 was not the representative formulation considered in the EU review process as part of the approval of the aminopyralid and propyzamide.

A full risk assessment according Commission Regulation (EU) No 546/2011 is provided.

Addenda are included containing country specific assessments for some annex points. In those cases this document should be read in conjunction with the relevant addenda.

Where appropriate, this document refers to the conclusions of the EFSA, especially when data on the active substance is relied upon in the risk assessment of the formulation. Each section will begin with a table providing the EU endpoints used in this evaluation.

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

Appendix 2 of this document reports the detailed evaluation of studies relied upon.

Appendix 3 of this document is the table of intended uses for GF-2540.

Information on the detailed composition of GF-2540 can be found in the confidential dossier of this submission (Registration Report - Part C).

6.1 Proposed use pattern and considered metabolites

Introduction

Section 6 of the submission summarises the ecotoxicological effects of the formulation GF-2540 containing the active substances aminopyralid and propyzamide and evaluates the potential risk to various representatives of terrestrial, aquatic and soil organisms. Full details or the proposed use patterns that will be assessed are shown in Appendix 3 of this document and summarized below. Moreover, an overview of the metabolites of aminopyralid and propyzamide that will be addressed in the risk assessment is given below.

6.1.1 Proposed use pattern

The critical GAP used for exposure assessment are presented in Table 6.1-1 that reports also a classification of intended uses for GF-2540 (see also Section 5). A list of all intended uses within the zone is given in Appendix 3.

Table 6.1-1: Critical use pattern of GF-2540

No.	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)
001	Winter Oilseed Rape / BBCH 13-29	spraying / agriculture	1 x, late autumn to winter, november to february 40 %	propyzamide: 1 x 750 aminopyralid: 1 x 8	propyzamide: 1 x 450 aminopyralid: 1 x 4.8

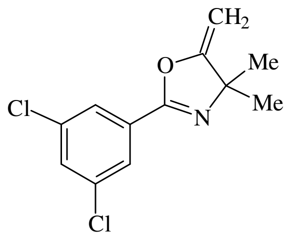
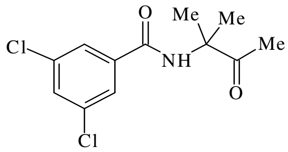
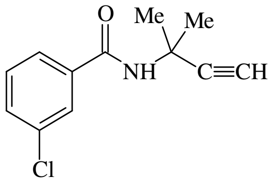
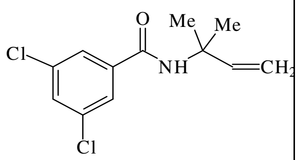
6.1.2 Consideration of metabolites

For propyzamide the occurrence and risk from potentially ecotoxicologically relevant metabolites have been considered in the EU review of the active substance. In the EU review of aminopyralid, no major metabolites of the active substance have been identified.

Further information is provided and in Part B, Section 5. Environmental occurring metabolites of propyzamide requiring further assessment according to the results of the assessment of propyzamide for EU approval are summarized in Table 6.1-2.

Table 6.1-2: Metabolites of propyzamide 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 formula	occurrence in compartments (Max. at day/	Status of Relevance (Review Report 6502/VI/99-final, 9 October 2007)

RH-24644 (2-(3,5-dichloro-phenyl)-4,4-dimethyl-5-methylene-oxazoline)		Soil: Max. 31.9 % at day 21	Aquatic organism: Water: not assessed Sediment: not assessed Terrestrial organism: not assessed Groundwater: not assessed
RH-24580 (N-(1,1-dimethyl-acetonyl)-3,5-dichlorobenzamide)		Soil: Max. 24.0 % at day 45	Aquatic organism: Water: not assessed Sediment: not assessed Terrestrial organism: not assessed Groundwater: not assessed
UK 1		Water: Max. 5.4 % at day 105 (end of study) W/S$_{total\ system}$: Max. 9.9 at day105 (end of study)	Aquatic organism: Water: not assessed Sediment: not assessed Terrestrial organism: not assessed Groundwater: not assessed
RH-24655 (UK 2) (3,5-dichloro-N-(1,1-dimethylpropenyl)benzamide)		Water: Max. 6.5 % at day 105 (end of study) Sediment: Max. 20.5 % at day 105 (end of study) W/S$_{total\ system}$: Max. 27.0 at day105 (end of study)	Aquatic organism: Water: not assessed Sediment: not assessed Terrestrial organism: not assessed Groundwater: not assessed

6.2 Effects on Birds

6.2.1 Overview and summary

Avian acute oral and long-term reproduction studies have been carried out with propyzamide and aminopyralid. Full details of avian toxicity studies are provided in the respective EU DAR as well as in Appendix 2 of this document (new studies).

Effects on birds of GF-2540 were not evaluated as part of the EU review of either propyzamide or aminopyralid. However, the provision of further data on the formulation GF-2540 is not considered essential as the available data on propyzamide and aminopyralid are deemed to be sufficient to assess the risk of birds exposed to GF-2540

The risk assessment for effects on birds and other terrestrial vertebrates is carried out according to the European Food Safety Authority Guidance Document on Risk Assessment for Birds and Mammals (EFSA Journal 2009; 7(12): 1438).

6.2.1.1 Toxicity

The studies with the relevant acute and long-term endpoints which are used in the risk assessment procedure are listed in the following table.

Table 6.2-1: Toxicity of propyzamide / aminopyralid to birds with reference to agreed endpoints

Species	Substance	Exposition Duration System	Results Toxicity	Reference Author Date	ICS-No.
Coturnix japonica	Propyzamide (WP containing 75 % as.)	Acute	LD50 > 6600 mg a.s./kg bw1)	[redacted] 27.06.1969 Report No.HRC 2839/69/265	32107
Colinus virginianus	Propyzamide (Kerb technical)	Long-term	NOAEL = 58.5 mg a.s./kg bw/d 1)	[redacted] 20.10.2000 Project No. 129-175	43952
Colinus virginianus	Aminopyralid	Acute	LD50 >2250 mg a.s./kg bw2) **	[redacted] 09.08.2001 379-106	50740
Colinus virginianus	Aminopyralid	Long-term	NOEL = 190.23 mg a.s./kg bw/d 2) **	[redacted] 25.02.2003b 011271, 110973	50773

1) EU list of endpoints (SANCO/6502/VI/99)

2) DAR aminopyralid - Volume 1, Level 2, Appendix 3 – List of endpoints, updated March 2012

**Reports are summarised in DAR aminopyralid, Annex B.9 : Ecotoxicology - updated March 2012

As indicated above, acute and long-term studies with the formulated product has not been conducted. Consequently, the toxicity of GF-2540 has been assessed considering data generated on the individual active substances and assuming dose additivity of the single active substances in the formulation (see 'Mixture toxicity' chapter below).
Concerning acute oral toxicity and bird reproduction, the endpoints refered to in the respective EU lists of endpoints for propyzamide and aminopyralid were used in the risk assessment.

6.2.1.2 Exposure

GF-2540 is a herbicide formulation containing aminopyralid and propyzamide as active substances. The product is formulated as a suspension concentrate. It will be used against Annual mono- and dicot weeds (post emergence of weeds) in Winter Oilseed Rape.

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)

$$\mathrm{DDD} = \sum_i \frac{\mathrm{PD}_i \times \mathrm{FIR}_{total}}{\mathrm{bw}} \times \mathrm{RUD} \times \mathrm{AR} \times \mathrm{PT}$$
$$= \sum_i \frac{\mathrm{FIR}_i}{\mathrm{bw}} \times \mathrm{RUD} \times \mathrm{AR} \times \mathrm{PT}$$

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 potential 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 toxicty

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 of GF-2540 is not an assessment of the formulation toxicity as such, but an assessment of 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 LD50 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(aminopyralid) = 5.3 g aminopyralid/1.139 kg / (5.3 g aminopyralid /1.139 kg + 500 g propyzamide /1.139 kg)

X(propyzamide) = 500 g propyzamide /1.139 kg / (5.3 g aminopyralid /1.139 kg +500 g propyzamide /1.139 kg)

LD_{50}(a.s. *i*) = acute toxicity value for active substance (*i*)

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*

6.2.1.3 Risk Assessment –overall conclusions

For risk assessment purposes, a risk envelope approach was used to cover highest risk for birds from intended use 001 (see also Table 6.1-1, page6).

The results of the acute and reproductive risk assessments are summarized in the following table.

Table 6.2-2: TER for birds

Compound	**Risk assessment level**	**Indicator species**	**Time scale**	**TER**	**TER trigger**
Aminopyralid	Screening	Small omnivorous bird (Oilseed rape)	Acute	>1771.1	10
	Screening	Small omnivorous bird (Oilseed rape)	Long-term	704.6	5
	Tier 1	Medium herbivorous/granivorous bird "pigeon"	Long-term	1988.7	5
Propyzamide	Screening	Small omnivorous bird (Oilseed rape)	Acute	>55.4	10
	Screening	Small omnivorous bird (Oilseed rape)	Long-term	**2.3**	5
	Tier 1	Medium herbivorous/granivorous bird "pigeon"	Long-term	6.5	5
TER mix	Screening	Small omnivorous bird (Oilseed rape)	Acute	>53.7	10
	Tier 1	Medium herbivorous/granivorous bird "pigeon"	Long-term	6.48	5
TER shown in bold are below the relevant trigger					

Based on the presumptions of the screening step/ Tier 1, the calculated TER values for the acute and long-term risk resulting from an exposure of birds to the active substances propyzamide and aminopyralid according to the GAP of the formulation GF-2540 achieve the acceptability criteria TER ≥ 10 and TER ≥ 5, respectively, 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.

Drinking water risk assessment

Drinking water assessment is not required as the ratio of effective treatment rate to toxicological endpoint does not exceed the trigger. Please refer to chapter 6.2.3.

Food chain behaviour

An assessment of the risk from secondary poisoning is required due to log P_{OW} values of propyzamide and propyzamide metabolite RH24-644 being above the trigger. Please refer to chapter 6.2.9.

6.2.2 Toxicity to exposure ratio for birds (K III A 10.2.1)

6.2.2.1 Acute toxicity to exposure ratio (TERA)

Screening step

In the screening step, the risk to indicator bird species from an exposure to GF-2540 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):

$$DDD_{\text{single application}} = \text{application rate [kg a.s./ha]} \times \text{shortcut value}^{1}$$

[1] see section 4.1 of EFSA/2009/1438

In case of multiple applications, the daily dietary dose for a single application is multiplied with an appropriate multiple application factor for 90th percentile residue data (MAF_{90}; see Table 7 of EFSA/2009/1438).A specific MAF_{90} may be calculated according to Appendix H of EFSA/2009/1438 for non-standard application intervals.

$$DDD_{\text{multiple application}} = DDD_{\text{single application}} \times MAF_{90}{}^{1}$$

Toxicity exposure ratio (acute):

$$TER_A = \frac{LD_{50}\ \text{(mg/kg bw/day)}}{\text{Acute DDD (mg/kg bw/day)}}$$

The resulting TER_A values are summarised in the following table,a long with the indicator species and the respective shortcut values .

Table 6.2-3: Acute screening risk assessment (TER_A) for birds. See text for details

Substance	Indicator species	Application rate (kg/ha)	Shortcut value, acute	MAF	DDD (mg/kg bw)	LD_{50} (mg/kg bw)	TER_A

Propyzamide	Small omnivorous bird	1 x 0.750	158.8	1	119.1	>6600 mg a.s./kg bw	>55.4
Aminopyralid	Small omnivorous bird	1 x 0.008	158.8	1	1.2704	>2250 mg a.s./kg bw	>1771.1
TER_{mix} (propyzamide + aminopyralid)	Small omnivorous bird	>53.7					
TERs shown in bold fall below the relevant trigger.							

Based on the highly conservative presumptions of the screening step, the calculated TER values for the acute risk resulting from an exposure of birds to the active substances aminopyralid and propyzamide according to the GAP of the formulation GF-2540 achieve the acceptability criteria TER ≥ 10, 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 risk for birds, no further refinement is necessary.

6.2.2.2 Short -term toxicity exposure ratio (TER_{ST})

There is no requirement for the calculation of TER_{ST} for birds under the EFSA birds and mammals guidance document (EFSA Journal 2009; 7(12): 1438) and, consequently, a risk assessment for short-term toxicity will not be conducted.

6.2.2.3 Long-term toxicity exposure ratio (TER_{LT})

Screening step

For the reproductive risk assessment, the calculation of the long-term toxicity exposure ratio (TER_{LT}) in principle follows the same procedure as for the acute risk assessment. However, the defined daily dose is obtained by multiplying the application rate with the mean short-cut values (based on mean RUD according to the new Guidance Document (EFSA, 2009)) as summarized in the following table.

Table 6.2-4: Avian generic focal species for the intended uses of GF-2540 and relevant shortcut values for long-term exposure

Crop	**Indicator species**	**Shortcut value (mean RUD)**
Oilseed rape	Small omnivorous bird	64.8

As stated in the guidance document, it is justified to apply a time-weighted average (TWA) factor of 0.53 based on a default observation interval of 21 days and a default DT_{50} of 10 days for the calculation of the DDD (daily dietary dose):

$$DDD_{single\ application} = \text{application rate [kg/ha]} \times \text{shortcut value} \times \text{TWA*}$$

* see section 4.3 of EFSA/2009/1438

Toxicity exposure ratio (Long-term):

$$TER_{LT} = \frac{NOEL(mg/kg\,bw/day)}{Long\text{-}term\,DDD(mg/kg\,bw/day)}$$

The relevant lowest NOEL for the reproduction exposure scenario is 190.23 mg a.s./kg bw/day for aminopyralid and 58.5 mg a.s./kg bw·day for propyzamide. Full details of the avian toxicity studies are provided in the respective EU DAR as well as in appendix 2 of this document (new studies). The relevant long-term endpoints are provided in the following table as well as calculated long-term toxicity exposure ratios (TER_{LT}) for birds exposed to aminopyralid and propyzamide following applications of GF-2540.

Table 6.2-5: Long-term screening risk assessment (TER_{LT}) for birds exposed to GF-2540 according to the intended uses

Substance	Indicator bird	Application rate (kg/ha)	Shortcut value (long-term)	f_{TWA}	MAF	DDD (mg/kg bw/day)	NOEL (mg/kg bw/day)	TER_{LT}
Propyzamide	Small omnivorous bird	1 x 0.750	64.8	0.53	1	25.76	58.5	2.3
Aminopyralid	Small omnivorous bird	1 x 0.008	64.8	0.53	1	0.27	190.23	704.6
TERs shown in bold fall below the relevant trigger.								

Based on the highly conservative presumptions of the screening step, the calculated TER values for the long-term risk resulting from an exposure of birds to the active substance propyzamide and according to the GAP of the formulation GF-2540 does not 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. The results of the assessment indicate an unacceptable risk for birds, further refinement is necessary.

Tier 1

For a general description of the followed approach in the Tier1 risk assessment step, please consult chapter 6.2.2.1 (acute toxicity).

For propyzamide the TER_A was below the trigger of 5 in the screening step for the intended uses in Winter Oilseed Rape. Based on an application rate of 1 x 750 g a.s./ha the risk was assessed for the following generic focal species:

Medium herbivorous/granivorous bird "pigeon", Large herbivorous bird "goose", Small omnivorous bird "lark".

The relevant short-cut values for these scenarios are summarized in the following table:

Table 6.2-6: Avian generic focal species for the intended uses of GF-2540 and relevant shortcut values for long-term risk assessment

Intended use	Crop Growth Stage	Generic Focal Species	Shortcut value (mean RUD)
001	Winter Oilseed Rape / BBCH 13-29	Medium herbivorous/granivorous bird "pigeon"	22.7
		Large herbivorous bird "goose"	15.9
		Small omnivorous bird "lark"	10.9

The outcome of the Tier 1 risk assessment step is presented in the following table:

Table 6.2-7: Reproductive bird risk assessment of GF-2540 uses in Winter Oilseed Rape / BBCH 13-29(Tier 1)

Substance	Generic Focal Species	Application Rate (kg a.s./ha)	MAF x twa	Short cut Value (Mean RUD)	DDD (mg a.s./kg bw/d)	NOEL (mg a.s./ kg bw/d)	TER
Propyzamide	Large herbivorous bird "goose"	0.750	0.53	15.9	6,281	58,5	9,3
Propyzamide	Small omnivorous bird "lark"	0.750	0.53	10.9	4,306	58,5	13,6
Propyzamide	Medium herbivorous/granivorous bird "pigeon"	0.750	0.53	22.7	8,968	58,5	6,5
Aminopyralid	Large herbivorous bird "goose"	0.008	0.53	15.9	0,067	190.23	2839,1
Aminopyralid	Small omnivorous bird "lark"	0.008	0.53	10.9	0,046	190.23	4141,5
Aminopyralid	Medium herbivorous/granivorous bird "pigeon"	0.008	0.53	22.7	0,096	190.23	1988,7
TER_{mix} (propyzamide + aminopyralid)	Medium herbivorous/granivorous bird "pigeon"	6,48					
TERs shown in bold fall below the relevant trigger.							

Based on refined Tier 1 assessment step, the calculated TER values for the long-term risk resulting from an exposure of birds to propyzamide and aminopyralid according to the GAP of the formulation GF-2540 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. The results of the assessment indicate an acceptable risk for birds due to the intended use of GF-2540 in Winter Oilseed Rape according to the label.

6.2.3 Drinking water exposure

In case of early post-emergence uses as intended for GF-2540, birds might be exposed via drinking water from puddles. According to the new Guidance Document (EFSA, 2009), no specific calculations of drinking water exposure and TER are necessary when the ratio of effective application rate (in g/ha) to the 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). This is due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by birds (for further details please refer to chapter 5.5. of the Guidance Document). The ratios do not exceed the value of 50 for aminopyralid (Koc = 5.14 L/kg) and 3000 for propyzamide (Koc = 642 L/kg), thus it is not necessary to conduct a drinking water risk assessment for birds.

6.2.4 Details on formulation type in proportion per item

6.2.4.1 Baits: Concentration of active substance in bait in mg/kg

GF-2540 is not formulated as bait. The formulation is intended for use as a foliar spray, and therefore this information is not required.

6.2.4.2 Pellets, granules, prills or treated seed

GF-2540 is not formulated as pellets, granules, prills or treated seeds. GF-2540 is intended for use as a foliar spray, and therefore this information is not required.

Amount of active substance in or on each item

Not applicable.

Proportion of active substance LD50 per 100 items and per gram of items

Not applicable.

Size and shape of pellet, granule or prill

Not applicable.

6.2.5 Acute toxicity of the formulation

Avian toxicity tests with the formulation were not performed and are not considered necessary.

Please refer to section 6.2.1.1 and 6.2.2 for an overview of the submitted data on the toxicity of aminopyralid / propyzamide to birds and the outcome of the risk assessment for birds.

6.2.6 Metabolites

Avian toxicity tests with metabolites of aminopyralid and propyzamide were not performed and are not considered necessary.

6.2.7 Supervised cage or field trials

The risk assessment above has demonstrated that the proposed uses of GF-2540 pose no unacceptable acute or long-term risks to birds, and therefore further studies are not considered necessary.

6.2.8 Acceptance of bait, granules or treated seeds (palatability testing)

GF-2540 is intended for use as a foliar spray, and therefore this information is not required.

6.2.9 Effects of secondary poisoning

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 aminopyralid /is 2,87 (pH=7) , this active substance is deemed to have a negligible potential to bioaccumulate in animal tissues and no formal risk assessment from secondary poisoning is therefore required. For the active substance propyzamide and its metabolite RH-24-644 the logKows of 3 and 5.5 resp. trigger an assessement. For the metabolite RH-24-644 no information concerning its long-term toxicity towards birds were available. But since the metabolite occurred in metabolism studies with hens, potential effects on birds are expected to be detected by tests with the active substance. However because the LogPow of RH-24-644 is higher compared to propyzamide, a separate assessment is performed. As an effect value the NOEL of propyzamide is used.

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 No 001 in Winter Oilseed Rape. with the maximal soil relevant amount of the formulation GF-2540.

Table 6.2-8: Assessement of the risk for earthworm eating birds from an exposure to propyzamide through secondary poisoning

parameter	**Propyzamide**	**comment**
PEC-soil (twa, 21 d) (mg/kg soil)	0,572	Application rate = 750 g/ha, Interception = 40 %, soil layer depth = 5 %, DT50 soil = 150,8d (90th percentile lab)
log Pow	3	Pow = 1000
Koc	642	
foc	0,02	default
BCF-worm	1,000	BCF-worm = (PEC-worm / PEC-soil) = (0.84 + 0.012 × Pow) / (foc × Koc)
PEC-worm	0,572	PEC-worm = PEC-soil × BCF-worm
Daily dietary dose (mg/kg bw/d)	0,601	DDD = PEC-worm × 1.05
NOEL (mg/kg bw/d)	58,5	*Colinus virginianus*, long-term
TER-lt	97,4	≥ 5, acceptable risk

Table 6.2-9: Assessement of the risk for earthworm eating birds from an exposure to propyzamide metabolite RH24-644 through secondary poisoning

parameter	Propyzamide metabolite RH24-644	comment
PEC-soil (twa, 21 d) (mg/kg soil)	0,158	Application rate = 239,25 g/ha (based on a formation rate of 31.9 % in soil (see Table 6.1-2)), Interception = 40 %, soil layer depth = 5 %, DT50 soil = 36.5d (90th percentile lab)
log Pow	--	not required
Koc	--	not required
foc	0,02	default
BAF-worm (exp.)[1)]	2,900	BAF-worm = (C-worm-ww / C-soil-dw)
PEC-worm	0,458	PEC-worm = PEC-soil × BAF-worm (exp.)
Daily dietary dose (mg/kg bw/d)	0,481	DDD = PEC-worm × 1.05
NOEL (mg/kg bw/d)	58,5	*Colinus virginianus*, long-term (propyzamide)
TER-lt	121,7	≥ 5, acceptable risk

[1)] EU list of endpoints (SANCO/6502/VI/99)

The risk assessment for fish eating birds according to the Guidance Document EFSA/2009/1438 is performed for a bird with 1000 g bw and a FIR (Food intake rate) of 4159 g (fresh weight) fish.

Table 6.2-10: Assessement of the risk for fish eating birds from an exposure from an exposure to Propyzamnide through secondary poisoning

parameter	Propyzamide	comment
PEC-sw (twa, 21 d) (mg/L)	0,032411	NOEC C. riparius / safety factor of 10, DT50 water = 150.8 (90th percentile lab)
BCF-fish	49	whole fish, 42 d
PEC-fish	1,588	PEC-fish = PEC-sw × BCF-fish
Daily dietary dose (mg/kg bw/d/d)	0,253	DDD = PEC-fish × 0.159
NOEL (mg/kg bw/d)	58,5	Colinus virginianus, long-term
TER-lt	231,7	≥ 5, acceptable risk

Based on the calculation of the risk arising from secondary poisoning , the calculated TER values for earthworm- and fish-eating birds exposed to the active substance propyzamide as well as for earthworm-eating mammals exposed through secondary poisoning to the propyzamide metabolite RH24-644according to the GAP of the formulation GF-2540 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, no further refinement is necessary.

Even though the logPOW of the propyzamide metabolite RH24-644 was above the relevant trigger of 3 (5.4), is has not been considered necessary in the EU review of propyzamide to determine the BCF of the metabolite in fish experimentally. However, based on FOCUS step 1 $PEC_{SW,}$ even assuming up to a 40x higher bioconcentration for this metabolite than for the parent compound, the calculated TER values for fish-eating mammals exposed through secondary poisoning to RH24-644 according to the GAP of the formulation GF-2540 do still 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 without further refinements. The RMS considers this margin of safety sufficient and the risk arising for fish-eating birds from secondary poisoning acceptable.

6.3 Effects on Terrestrial Vertebrates Other Than Birds

6.3.1 Overview and summary

The risk assessment for effects on mammals is carried out according to the European Food Safety Authority Guidance Document on Risk Assessment for Birds and Mammals (EFSA Journal 2009; 7(12): 1438).

6.3.1.1 Toxicity

Table 6.3-1: Toxicity of propyzamide and aminopyralid to mammals with reference to agreed endpoints

Species	Substance	Exposition Duration System	Results Toxicity	Reference Author Date Report No.	ICS-No.
Rat	propyzamide	Acute	LD50>2500 mg a.s./kg1)	LoEP	---
Rabbit	propyzamide	Long-term	NOAEL = 31.6 mg a.s./kg bw·day1)	LoEP	---
Rat	aminopyralid	Acute	LD50>5000 mg/kg bw 2)	[redacted] 30.08.2001 1953949 / TOX2004-1156 / 011115 ! DR-0293-9028-044**	---
Rabbit	aminopyralid	Long-term	NOEL = 26 mg a.s./kg bw/day (acid equivalent)2) **	[redacted] 05.03.2004 1954759 / 031142 145141	---
Rat	GF-2540	Acute	LD_{50}>5000 mg Prod./kg bw3)	[redacted] (2009) 090334	80212

1) EU list of endpoints (SANCO/6502/VI/99)

2) Aminopyralid - Volume 1, Level 2, Appendix 3 – List of endpoints June 2013

**Reports are summarised in DAR aminopyralid, Annex B.9 : Ecotoxicology and Addenda- updated July 2013

3) New study submitted by the applicant

6.3.1.2 Exposure

Exposure to standard generic indicator species was estimated according to the ‘EC Guidance Document on Risk Assessment for Birds and Mammals Council (EFSA/2009/1438). Please see chapter 6.2.1.2, page 8 for detailed information on the estimation of daily intake rates and the assessment of mixture toxicity.

6.3.1.3 Risk assessment –overall conclusions

The overall conclusion on the risk assessment for mammals and the calculated TER-values are shown in the following table.

Table 6.3-2: Minimum TER values for mammals after uses of GF-2540 in the intended uses

Substance	Risk assessment level	Indicator mammal	Time scale	TER	TER trigger
Propyzamide	Screening	Small herbivorous mammal (Oilseed rape)	Acute	>28.2	10
	Screening	Small herbivorous mammal (Oilseed rape)	Long-term	**1.7**	5
	Tier 1	Large herbivorous mammal "lagomorph"	Long-term	5.6	5
Aminopyralid	Screening	Small herbivorous mammal (Oilseed rape)	Acute	>5279.8	10
	Screening	Small herbivorous mammal (Oilseed rape)	Long-term	123.8	5
	Tier 1	Large herbivorous mammal "lagomorph"	Long-term	431.5	5
GF-2540	Screening	Small herbivorous mammal	Acute	>24.7	10
TER Mix	Screening	Small herbivorous mammal (Oilseed rape)	Acute	>28.1	10
	Tier 1	Large herbivorous mammal "lagomorph"	Long-term	5.5	10
TERs shown in bold fall below the relevant trigger.					

Based on the presumptions of the screening step/ Tier 1, the calculated TER values for the acute and long-term risk resulting from an exposure of mammals to the active propyzamide and aminopyralid according to the GAP of the formulation GF-2540 achieve the acceptability criteria TER ≥ 10 and TER ≥ 5, respectively, 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 mammals.

Drinking water risk assessment

Drinking water assessment is not required as the ratio of effective treatment rate to toxicological endpoint does not exceed the trigger. Please refer to chapter 6.2.3.

Food chain behaviour

An assessment of the risk from secondary poisoning is required due to log P_{OW} values of propyzamide and propyzamide metabolite RH24-644 being above the trigger. Please refer to chapter 6.2.9.

6.3.2 Toxicity exposure ratio

6.3.2.1 Acute toxicity exposure ratio (TER_A)

Screening step

In the screening step, indicator species are used. 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.

The indicator mammal species for the intended uses are listed in the following table.

Table 6.3-3: Indicator species for mammals according to intended use of GF-2540 and shortcut values. Shortcut values from section 4.1 of EFSA/2009/1438

Crop	Indicator species	Shortcut value (90th percentile RUD)
Oilseed rape	Small herbivorous mammal	118.4

For the estimation of Daily dietary doses (DDD) and the calculation of TER-values please refer to 6.2.2.1

Table 6.3-4: Acute screening risk assessment (TERA) for mammals. See text for details

Substance	Indicator species	Application rate (kg/ha)	Shortcut value, acute	MAF	DDD (mg/kg bw)	LD_{50} (mg/kg bw)	TER_A
Propyzamide	Small herbivorous mammal	0.750	118.4	1	88.8	>2500	>28.2
Aminopyralid	Small herbivorous mammal	0.008	118.4	1	0.947	>5000	>5279.8
GF-2540	Small herbivorous mammal	1.7085	118.4	1	202.3	>5000	>24.7
TER_{mix} (propyzamide + aminopyralid)	Small herbivorous mammal	>28.1					
TERs shown in bold fall below the relevant trigger.							

Based on the highly conservative presumptions of the screening step, the calculated TER values for the acute risk resulting from an exposure of mammals to the active substances aminopyralid and propyzamide according to the GAP of the formulation GF-2540 achieve the acceptability criteria TER ≥ 10, 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 risk for mammals due to the intended use of GF-2540 in Winter Oilseed Rape according to the label.

6.3.2.2 Short-term toxicity exposure ratio (TER_{ST})

There is no requirement for the calculation of TER_{ST} for mammals under the EFSA birds and mammals guidance document (EFSA Journal 2009; 7(12): 1438) and, consequently, a risk assessment for short-term toxicity has not been peformed.

6.3.2.3 Long-term toxicity exposure ratio (TER_{LT})

Screening step

For the reproductive risk assessment, the calculation of the long-term toxicity exposure ratio (TER_{LT}) follows in principle the same procedure as for the acute risk assessment.

The defined daily dietary dose is obtained by multiplying the application rate with the mean short-cut value (based on the mean RUD according to the new Guidance Document (EFSA, 2009)) as summarized in the following table.

Table 6.3-5: Mammal generic focal species for the intended uses of GF-2540 and relevant shortcut values for long-term exposure

Crop	Indicator species	Shortcut value (mean RUD)
Oilseed rape	Small herbivorous mammal	118.4

Please refer to section 6.2.2.3 for the equation employed in the estimation of the daily dietary doses and the calculation of TER-values.

The relevant lowest NOEL for the reproduction exposure scenario is = 26 mg a.s./kg bw/day for aminopyralid and 31.6 mg a.s./kg bw/day for propyzamide. Full details of the toxicity studies are provided in the respective EU DAR. The following table reports the calculated long-term toxicity exposure ratios (TER_{LT}) for mammals exposed to aminopyralid and propyzamide following applications of GF-2540.

Table 6.3-6: Long-term screening risk assessment (TER_{LT}) for mammals exposed to GF-2540 according to the intended uses

Substance	Indicator bird	Application rate (kg/ha)	Shortcut value (long-term)	f_{TWA}	MAF	DDD (mg/kg bw/day)	NOEL (mg/kg bw/day)	TER_{LT}
Propyzamide	Small herbivorous mammal	0.750	48.3	0.53	1	19.2	31.6	1.7
Aminopyralid	Small herbivorous mammal	0.008	48.3	0.53	1	0.2	26	123.8
TERs shown in bold fall below the relevant trigger.								

Based on the highly conservative presumptions of the screening step, the calculated TER values for the long-term risk resulting from an exposure of mammals to the active substance propyzamide according to the GAP of the formulation GF-2540 does not 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. The results of the assessment indicate an unacceptable risk for mammals due to the intended use of GF-2540 in <crop> according to the label, further refinement is necessary.

Tier 1 risk assessment

For the Tier 1 risk assessment, the defined daily doses and TER values were calculated for so-called generic focal species (see EFSA 1438/2009. Annex I). Please refer to section 6.2.2 for general consideration in the choice of generic focal species in risk assessment procedures.

The relevant short-cut values for scenarios evaluated are summarized in the following table.

Table 6.3-7: Mammal generic focal species for the inteded uses of GF-2540 and relevant shortcut values for long-term risk assessment

Intended use	Crop Growth Stage	Generic Focal Species	Shortcut value (mean RUD)
001	Winter Oilseed Rape / BBCH 13-29	Large herbivorous mammal "lagomorph"	14.3
		Small omnivorous mammal "mouse"	7.8
		Small insectivorous mammal "shrew"	4.2

The outcome of the Tier 1 risk assessment step is presented in the following table:

Table 6.3-8: Reproductive mammal risk assessment of GF-2540 uses in intended uses (Tier 1)

Substance	Generic Focal Species	Application Rate (kg a.s./ha)	MAF x twa	Short cut Value (Mean RUD)	PT value	DDD (mg a.s./kg bw/d)	NOEL (mg a.s./ kg bw/d)	TER
Propyzamide	Small insectivorous mammal "shrew"	0.75	0.53	4.2		1.659	31.6	19.0
Propyzamide	Small omnivorous mammal "mouse"	0.75	0.53	7.8		3.081	31.6	10.3
Propyzamide	Large herbivorous mammal "lagomorph"	0.75	0.53	14.3		5.649	31.6	5.6
Aminopyralid	Small insectivorous mammal "shrew"	0.008	0.53	4.2		0.018	26	1469.0
Aminopyralid	Small omnivorous mammal "mouse"	0.008	0.53	7.8		0.033	26	791.0
Aminopyralid	Large herbivorous mammal "lagomorph"	0.008	0.53	14.3		0.060	26	431.5
TERmix (propyzamide + aminopyralid)	Large herbivorous mammal "lagomorph"	5.5						
TERs shown in bold fall below the relevant trigger.								

Based on refined Tier 1 assessment step, the calculated TER values for the long-term risk resulting from an exposure of mammals to propyzamide and aminopyralid according to the GAP of the formulation GF-2540 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. The results of the assessment indicate an acceptable risk for mammals due to the intended use of GF-2540 in Winter Oilseed Rape according to the label.

6.3.3 Drinking water exposure

In case of early post-emergence uses as intended for GF-2540, mammals might be exposed via drinking water from puddles. According to the new Guidance Document (EFSA, 2009), no specific calculations of drinking water exposure and TER are necessary when the ratio of effective application rate (in g/ha) to the 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). This is due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by birds (for further details please refer to chapter 5.5. of the Guidance Document). The ratios do not exceed the value of 50 for aminopyralid (Koc = 5.14 L/kg) and 3000 for propyzamide (Koc = 642 L/kg), thus it is not necessary to conduct a drinking water risk assessment for mammals.

6.3.4 Details on formulation type in proportion per item

Please refer to section 6.2.4 for details on the formulation type of GF-2540.

6.3.4.1 Baits: Concentration of active substance in bait in mg/kg

Please refer to section 6.2.4.

6.3.4.2 Pellets, granules, prills or treated seed

Please refer to section 6.2.4.

Amount of active substance in or on each item

Please refer to section 6.2.4.

Proportion of active substance LD50 per 100 items and per gram of items

Please refer to section 6.2.4.

Size and shape of pellet, granule or prill

Please refer to section 6.2.4.

6.3.5 Acute toxicity of the formulation

Please refer to section 6.3.1 for an overview of the submitted data on the toxicity of aminopyralid / propyzamide / GF-2540 to mammals and the outcome of the risk assessment for mammals.

6.3.6 Metabolites

Mammal toxicity tests with metabolites of propyzamide were not performed, since it is possible to extrapolate from data obtained with the active substances.

6.3.7 Supervised cage or field trials

The risk assessment above has demonstrated that the proposed uses of GF-2540 pose no unacceptable acute or long-term risks to mamamls, and therefore further studies are not considered necessary.

6.3.8 Acceptance of bait, granules or treated seeds (palatability testing)

GF-2540 is intended for use as a foliar spray, and therefore this information is not required.

6.3.9 Effects of secondary poisoning

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 aminopyralid /is 2,87 (pH=7) , this active substance is deemed to have a negligible potential to bioaccumulate in animal tissues and no formal risk assessment from secondary poisoning is therefore required. For the active substance propyzamide and its metabolite RH-24-644 the logKows of 3 and 5.5 resp. trigger an assessement. For the metabolite RH-24-644 no information concerning its long-term toxicity towards mammal were available. But since the metabolite occurred in metabolism studies with rats and goats, potential effects on mammals are expected to be detected by tests with the active substance. However, because the LogPow of RH-24-644 is higher compared to propyzamide, a separate assessment is performed. As an effect value the NOEL of propyzamide is used.

The assessment of the risk to mammals exposed to GF-2540 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 No 001 in Winter Oilseed Rape with the maximal soil relevant amount of the formulation.

Table 6.3-9: Assessment of the risk for earthworm eating mammal from an exposure to propyzamide through secondary poisoning

parameter	Propyzamide	comment
PEC-soil (twa, 21 d) (mg/kg soil)	0,572	Application rate = 750 g/ha, Interception = 40 %, soil layer depth = 5 %, DT50 soil = 150,8d (90th percentile lab)
log Pow	3	Pow = 1000
Koc	642	0
foc	0,02	default
BCF-worm	1,000	BCF-worm = (PEC-worm / PEC-soil) = (0.84 + 0.012 × Pow) / (foc × Koc)
PEC-worm	0,572	PEC-worm = PEC-soil × BCF-worm
Daily dietary dose (mg/kg bw/d)	0,732	DDD = PEC-worm × 1.28
NOEL (mg/kg bw/d)	31,6	Rabbit, long-term
TER-lt	43,2	≥ 5, acceptable risk

Table 6.3-10: Assessment of the risk for earthworm eating mammal from an exposure to propyzamide metabolite RH24-644 through secondary poisoning

parameter	Propyzamide metabolite RH24-644	comment
PEC-soil (twa, 21 d) (mg/kg soil)	0,158	Application rate = 239,25 g/ha (based on a formation rate of 31.9 % in soil (see Table 6.1-2)), Interception = 40 %, soil layer depth = 5 %, DT50 soil = 36.5d (90th percentile lab)
log Pow	--	not required
Koc	--	not required
foc	0,02	default
BAF-worm (exp.)	2,900	BAF-worm = (C-worm-ww / C-soil-dw)
PEC-worm	0,458	PEC-worm = PEC-soil × BAF-worm (exp.)
Daily dietary dose (mg/kg bw/d)	0,586	DDD = PEC-worm × 1.28
NOEL (mg/kg bw/d)	31,6	Rabbit, long-term (propyzamide)
TER-lt	53,9	≥ 5, acceptable risk

The risk assessment for fish eating mammals according to the Guidance Document EFSA/2009/1438 is performed for a mammal with 3000 g bw and a food intake rate FIR =425 g fresh weight fish/ d.

Table 6.3-11: Assessement of the risk for fish eating mammal from an exposure to propyzamide through secondary poisoning

parameter	Propyzamide	comment
PEC-sw (twa, 21 d) (mg/L)	0,032411	NOEC C. riparius / safety factor of 10, DT50 water = 150.8 (90th percentile lab)
BCF-fish	49	whole fish, 42 d
PEC-fish	1,588	PEC-fish = PEC-sw × BCF-fish
Daily dietary dose (mg/kg bw/d/d)	0,226	DDD = PEC-fish × 0.142
NOEL (mg/kg bw/d)	31,6	Rabbit, long-term
TER-lt	140,1	≥ 5, acceptable risk

Based on the calculation of the risk arising from secondary poisoning , the calculated TER values for earthworm- and fish-eating mammals exposed through secondary poisoning to the active substance propyzamide as well as for earthworm-eating mammals exposed through secondary poisoning to the propyzamide metabolite RH24-644 according to the GAP of the formulation GF-2540 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 , no further refinement is necessary.

Even though the logPOW of the propyzamide metabolite RH24-644 was above the relevant trigger of 3 (5.4), is has not been considered necessary in the EU review of propyzamide to determine the BCF of the metabolite in fish experimentally. However, based on FOCUS step 1 $PEC_{SW,}$ even when assuming up to a 40x higher bioconcentration for this metabolite than for the parent compound, the calculated TER values for fish-eating mammals exposed through secondary poisoning to RH24-644 according to the GAP of the formulation GF-2540 do still 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 without further refinements. The RMS considers this margin of safety sufficient and the risk arising for fish-eating mammals from secondary poisoning acceptable.

6.4 Effects on Aquatic Organisms

6.4.1 Overview and summary

For propyzamide the EU agreed endpoints for aquatic organisms exposed to the active substance are reported in the respective EU list of endpoints (SANCO/6502/VI/99) . For aminopyralid endpoints are presented according to the LoEP provided by RMS in March 2012 (see table below).

The applicant provides further studies on the risk for aquatic organisms with the formulation GF-2540. Detailed study summaries for the studies performed with the formulated product GF-2540 are presented in Appendix 2.

6.4.1.1 Toxicity

The endpoints for aquatic organisms relevant for the risk assessment are indicated in the following table.

Table 6.4-1: Ecotoxicological endpoints for aquatic species exposed to propyzamide, aminopyralid and GF-2540 with indication to agreed endpoints

Species	Substance	Exposition Duration System	Results Toxicity	Reference Date author Report No.	ICS-No.
Acute toxicity to fish					
Oncorhynchus mykiss	**Propyzamide**	Acute	LC50 (96h) > 4.7 mg a.s./L[1)]	[redacted] 14.04.1993 Report Nr. 93-3-4687	28870
Oncorhynchus mykiss	**Aminopyralid**	Acute	LC50 (96h) >100 mg a.s./L (nominal)[2)**]	[redacted] 19.11.2001 011078	51910 50802
Cyprinodon variegatus	**Aminopyralid**	Acute	LC50 (96h) >100 mg a.s./L (mean measured) [2)**]	[redacted] 23.04.2002 12550.6191	50806
Lepomis macrochirus	**Aminopyralid**	Acute	LC50 (96h) >100 mg a.s./L (nominal) [2)**]	[redacted] 10.10.2003 12550.6162	51911 50803
Chronic toxicity to fish					
Oncorhynchus mykiss	**Propyzamide**	Chronic	NOEC (21d) = 0.61 mg a.s./L (mean measured) (= 0,938 mg/L nom.) *** (Deviating form the LOEP the endpoint was based on the mean measured concentration since the recovery of the test item was < 80 %)	[redacted] 23.08.1990 Project No.RCC 227338	28866

Cyprinodon variegatus	**Aminopyralid**	ELS study 28 d (flow through)	NOEC (complete hatch) = 0.1 mg a.s./L 2)**	[redacted] 25.02.2011 101582 ! 66015	80375
Oncorhynchus mykiss	**GF-2540**	Acute	96 hour LC50 >30.4 mg GF-2540/L (mean measured)	[redacted] 17.09.2010 101368 ! 65883	80801
Freshwater invertebrates					
Daphnia magna	**Propyzamide**	Acute	LC50(48h) >5.6 mg/L (nominal)1.)	26.09.1980 Project No.UCCES 11506-33-42	28868 2002
Daphnia magna	**Propyzamide**	Chronic	NOEC (21d Reproduction) = 0.6 mg/L(mean measured)1)	[redacted] 05.05.1995 RHD 98/10006 ! Ref.No. 46.10	38156
Daphnia magna	**Propyzamide metabolite RH-24,644**	Acute	EC50(48h)= 0.54 mg /L Immobility1)	Sutherland et al. 17.07.2000 Project No.129A-172	42766
Daphnia magna	**Propyzamide metabolit RH-24,580**	Acute	EC50(48h) > 4 mg/L Immobility1)	Sutherland et al. 13.06.2000 Project No.129A-167	42774
Daphnia magna	**Aminopyralid**	Acute	EC50(48h) > 100 mg a.s./L Immobility2)**	[redacted] 06.11.2001 011079	51912
Crassostrea virginica	**Aminopyralid**	Acute	EC50(96h) >89 mg a.s./L (mean measured) Shell growth 2)**	[redacted] 23.04.2002 12550.6189	50834
Daphnia magna	**Aminopyralid**	Chronic	NOEC (21d) = 100 mg a.s./L (nominal) 2)**	[redacted] 27.01.2003 021085	51933
Daphnia magna	**GF-2540**	Acute	EC50(48h) >34.5 mg Prod./L (mean measured) Immobility3.)	[redacted] 17.09.2010 101367 / 65882	80200
Sediment organism					
Chironomus riparius	**Propyzamide**	Chronic	NOEC (28d) = 0,34 mg/L (real)1)	Kolk, J. 23.11.1999 99GC-0110	42745
Chironomus riparius	**Propyzamide metabolite RH-24,655**	Chronic	NOEC (28d) = 0.082 mg/L (mean measured) 1)	Kolk, J. 15.12.2000 Springborn Study No. 1007.060.173	43953
Chironomus	**Aminopyralid**	Chronic	NOEC (28d) = 130	Putt, A.E.	50853

riparius			mg a.s./L (nominal) 2)**	02.05.2002 12550.6195	51941
Algae					
Selenastrum capricornutum	**Propyzamide**	Chronic	EC50(120h) = 0.83 mg/L1)	Hoberg, J.R. 19.12.1991 Report No.91-11-4005	40763
Selenastrum capricornutum	**Propyzamide metabolite RH-24,644**	Chronic	EbC50(72h)= 0.58 mg/L (Deviating from the LoEP, the EbC50 is used instead of the ErC50 since it is the most sensitive endpoint) ***	Sutherland et al. 13.06.2000 Project No.129A-173	42772
Selenastrum capricornutum	**Propyzamide metabolite RH-24,580**	Chronic	EbC50(72h) > 3.8 mg/L1)	Sutherland et al. 12.06.2000 Project No.129A-168	42773
Navicula pelliculosa	**Aminopyralid**	Chronic	EbC50(72h) = 18 mg a.s./L (mean measured) NOEC (growth rate) = 23 mg a.i./ha 2)**	Hoberg, J.R. 17.05.2002 12550.6198	51923 50844
Pseudokirchneriella subcapitata	**GF-2540A**	Chronic	EyC50(72h) = 2.7 mg Prod./L ErC50(72h) = 6.4 mg Prod./L NOEC = 0.63 mg Prod./L3)	Rebstock, M. 17.09.2010 101365 ! 65881	80201
Aquatic higher plants					
Lemna gibba	**Propyzamide**	Chronic	EC50=1.4 mg a.s./L NOEC = 0.082 mg a.s./L 1)	Rohm and Haas 20.04.1995 Reg.Doc. RHD 98/10008 (94RC-0191)	38160
Lemna gibba	**Aminopyralid**	Chronic	EC50 (14d) > 88 mg a.s./L (mean measured) NOEC (14d, growth rate) = 88mg a.s./L 2)**	Hoberg, J.R. 10.10.2003 12550.6160	51955 50885
Myriophyllum spicatum	**Aminopyralid**	Chronic	EC50(14d, fresh weight) = 188 µg/L (mean measured concentration) 2) ** NOEC (14d)= 63.9 µg/L	----	---
Lemna gibba	**GF-2540**	Chronic	EbC50 (7d, frond number) = 2 mg	Rebstock, M. 17.09.2010	80202

			Prod./L ErC50(7d) = 5.5 mg Prod./L[3)] NOEC = 0.31 mg Prod./L[3)]	101366 ! 65884	
Bioaccumulation fish					
Lepomis macrochirus	**Propyzamide**		BCF = 49 (whole fish, 42 d)[1)]	Forbis & Leak 1994 LoEP	

1) EU list of endpoints (SANCO/6502/VI/99)

***Reports are summarised in DAR propyzamide; Addendum 6, updated April 2013

2) Aminopyralid - Volume 1, Level 2, Appendix 3 – List of endpoints June 2013

**Reports are summarised in DAR aminopyralid, Annex B.9 : Ecotoxicology and Addenda- updated July 2013

3) New study submitted by the applicant

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; xxxx., 1948 and 1971).

Toxicity studies on acute and chronic effects of the active substances and GF-2540 to aquatic organisms are available. For a more detailed assessment of mixture toxicity, a surrogate LC_{50} or EC_{50} can be calculated. Hovewer, 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.

The following formula is used to derive a surrogate LC_{50} or EC_{50} for the mixture of active substances with known toxicity assuming concentration additivity:

$$LC_{50}(mix) = \left(\sum_i \frac{X(a.s._i)}{LC_{50}(a.s._i)} \right)^{-1}$$

where:

X(a.s. *i*) = fraction of active substance (i) in the mixture expressed as:

X(aminopyralid) = 5.3 g aminopyralid/1.139 kg / (5.3 g aminopyralid /1.139 kg + 500 g propyzamide /1.139 kg)

X(propyzamide) = 500 g propyzamide /1.139 kg / (5.3 g aminopyralid /1.139 kg +500 g propyzamide /1.139 kg)

LC_{50}(a.s. *i*) = acute toxicity value for active substance (*i*)

Because of the direct proportionality of the calculated TER to the LC_{50}, it is possible to calculate a TER(mix) with the following formula:

$$TER(mix) = \left(\sum_i \frac{1}{TER(a.s._i)} \right)^{-1}$$

where:

$TER_{(a.s.i)}$= calculated TER for the active substance *i*

6.4.1.2 Exposure

GF-2540 is a herbicide formulation containing aminopyralid and propyzamide as active substances. The product is formulated as a suspension concentrate. It will be used against Annual mono- and dicot weeds (post emergence of weeds) in Winter Oilseed Rape.

Aquatic organisms may be exposed to plant protection products as a result of emission from treated fields. When GF-2540 is applied according to good agricultural practice, the active ingredients can reach surface waters unintentionally by spraydrift during application, by run-off and drainage.

The predicted environmental concentrations in surface water (PEC_{SW}) have been calculated based on the application rates of 750 g propyzamide and 8 g aminopyralid / ha. For details on the FOCUS modeling, see dRR CA Part B, Section 5.7.

The relevant global maximum FOCUS Step 1 and 2 PEC_{SW} for risk assessments covering all proposed use patterns are summarized in the following table.

Table 6.4-2: Summary of highest global maximum FOCUS surface water PECsw and PECsed values for propyzamideand aminopyralid and their metabolites - Step 1 and 2

Plant protection product:	GF-2540		
Use No evaluated	001		
Crop	Winter Oilseed Rape		
Application method (-)	Spray		
Growth stage at first application (BBCH)	BBCH 13-29		
Application time	late autumn to winter, november to february		
Crop interception:	40 %		
Number of applications/interval	1		
Application rate:	1,5 L GF-2540/ha 75g propyzamide / ha 8g aminopyralid / ha		
Active substance propyzamide	FOCUS Step 1	PECsw (µg/L)	PECsed (µg/L)
		141.60	864.76
	FOCUS Step 2	PECsw (µg/L)	PECsed (µg/L)
	North Europe, oct.-feb.	41.82	264.12
	South Europe, oct.-feb.	34.31	215.96
Metabolite RH 24644	FOCUS Step 1	PECsw (µg/L)	PECsed (µg/L)
		19.32	453.42

	FOCUS Step 2	PECsw (µg/L)	PECsed (µg/L)
	North Europe, oct.-feb.	5.23	123.00
	South Europe, oct.-feb.	4.19	98.47
Metabolite RH 24580	FOCUS Step 1	PECsw (µg/L)	PECsed (µg/L)
		52.57	87.67
	FOCUS Step 2	PECsw (µg/L)	PECsed (µg/L)
	North Europe, oct.-feb.	12.68	21.15
	South Europe, oct.-feb.	10.16	16.94
	Focus step 2	PECsw (µg/L)	PECsed (µg/L)
Metabolite UK1		3.57	22.57
Metabolite RH 24655 (UK2)		11.38	71.87
Active substance propyzamide	FOCUS Step 1	PECsw (µg/L)	PECsed (µg/L)
		2.72	0.14
	FOCUS Step 2	PECsw (µg/L)	PECsed (µg/L)
	North Europe, oct.-feb.	0.74	0.04
	South Europe, oct.-feb.	0.60	0.03
Active substance aminopyralid	FOCUS Step 1	PECsw (µg/L)	PECsed (µg/L)
		2.72	0.14
	FOCUS Step 2	PECsw (µg/L)	PECsed (µg/L)
	North Europe, oct.-feb.	0.74	0.04
	South Europe, oct.-feb.	0.60	0.03

6.4.1.3 Risk assessment –overall conclusions

Based on the calculated concentrations of aminopyralid/propyzamide and their metabolites in surface water (PEC_{SW} FOCUS Step 1 and 2), the calculated TER values for the acute and long-term risk resulting from an exposure of aquatic organisms to propyzamide and the Propyzamide metabolites Uk1 and Uk2 (RH-24,655) according to the GAP of the formulation GF-2540 do not achieve the TER acceptability criteria, 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 unacceptable risk for aquatic organisms due to the intended use of GF-2540 in Winter Oilseed Rape according to the label.

According to the results of the TER-values calculations based on $FOCUS_{SW}$ Step 2 PEC values for the intended use No 001 in Winter Oilseed Rape, the implementation of management practices might be necessary to reduce the exposure of aquatic organisms to GF-2540. Refinement of Exposure calculations and management practices relevant for Germany are given in the respective Addendum.

TER values for the most sensitive aquatic organisms (lowest quotient of Endpoint/SF) based on PEC_{SW} FOCUS calculations are summarized in the following table.

Table 6.4-3: Aquatic TER values for propyzamide, aminopyralid and their metabolites after applications of GF-2540.

Test organism	EC_{50} NOE(AE)C (µg/L)	FOCUS Step	Scenario	Max. PEC_{SW} worst case (µg/L)	TER_{LT}	Trigger value
Propyzamide						
Chironomus riparius	340	2	North Europe	41.82	**8.1**	10
		2	South Europe	34.31	**9.9**	
Propyzamide metabolite RH-24,580						
Pseudokirchneriella subcapitata	>3800	2	North Europe	12.68	>300	100
		2	South Europe	10.16	>374	
Propyzamide metabolite RH-24,644						
Daphnia magna	540	2	North Europe	5,23	103,3	100
		2	South Europe	4,19	128,9	
Propyzamide metabolite RH-24,655						
Chironomus riparius	82	2	Worst-case	11.38	**7.2**	10
Propyzamide metabolite Uk 1						
NOEC Propyzamide *Chironomus riparius* /10	34	2	Worst-case	3.57	**9.5**	10
Aminopyralid						
NOEC *Cyprinodon variegatus*	100	2	North Europe	0.74	135.1	10
		2	South Europe	0.6	166.7	
TER-values in bold are below the relevant trigger						

6.4.2 Toxicity to Exposure ratio

The risk for aquatic organisms exposed to aminopyralid, propyzamide and their metabolites was assessed according to the intended uses.

As first step, the initial maximum PEC_{SW} values (Step 1 and 2) were compared to the relevant acute and long-term toxicity endpoints available for propyzamide and aminopyralid. Based on all studies on aquatic toxicity as well as the corresponding safety factors, the relevant endpoint for propyzamide is NOEC = 0.082 mg propyzamide metabolite RH-24-655 / L (*Chironomus riparius).* For aminopyralid, the relevant endpoint is NOEC = 0.1 mg aminopyralid/L (*Cyprinodon variegatus*). Risk assessment is predominantly driven by the the toxicity of the active substance propyzamide (resp. its metabolite RH-24-655).

In the table below, the TER values relative to the most sensitive endpoint of each organisms' group are given.

Tabelle 6.4-1: Aquatic organisms: PECsw for propyzamide and relevant ecotoxicological endpoints for each organism' group.

Scenario	PEC global max (µg/L)	Propyzamide						
		Fish acute	Fish prolonged	Invertebrates acute	Invertebrates prolonged	Algae	Aquatic higher plants	Sed. dweller prolonged
		O. mykiss	*O. mykiss*	*D.magna*	*D. magna*	*S.capricornutum*	*L. gibba*	*C. riparius*
		LC_{50} (µg/L) **>4700**	NOEC (µg/L) **>610**	EC_{50} (µg/L) **>5600**	NOEC (µg/L) **>600**	E_bC_{50} (µg/L) **830**	EC50(µg/L) **1400**	NOEC (µg/L) **340**
FOCUS Step 1								
	141,6	>33,2	>4,3	>39,5	>4,2	5,9	9,9	2,4
FOCUS Step 2								
North Europe	41,82	>112,4	>14,6	>133,9	>14,3	19,8	33,5	**8,1**
South Europe	34,31	>137	>17,8	>163,2	>17,5	24,2	40,8	**9,9**
TER criterion		100	10	100	10	10	10	10

Tabelle 6.4-2: Aquatic organisms: PECsw for propyzamide metabolites and relevant ecotoxicological endpoints for each organism' group.

Scenario	Propyzamide metabolite RH-24-644			Propyzamide metabolite RH-24-580			Propyzamide metabolite RH-24-655		Propyzamide metabolite Uk 1	
	PEC global max	Inv. acute	Algae	PEC global max	Inv. acute	Algae	PEC global max	Sed. dweller prolonged	PEC global max	Endpoint leading to lowest RAC for Propyzamide (=

	(µg/L)			**(µg/L)**			**(µg/L)**		**(µg/L)**	**NOEC *C. riparius)/10***
		D.magna	***P. subcapitata***		***D.magna***	***P. subcapitata***		***Chironomus riparius***		**NOEC (µg/L)**
		EC_{50} (µg/L)	**E_bC_{50} (µg/L)**		**EC_{50} (µg/L)**	**E_bC_{50} (µg/L)**		**NOEC (µg/L)**		
		>4000	**>3800**		**540**	**580**		**82**		**34**
FOCUS Step 1										
	52,57	>76,1	>72,3	19,32	28	30	---	---	---	---
FOCUS Step 2										
North Europe	12,68	>315,5	>299,7	5,23	103,3	110,9	11.38	**7.2**	3.57	**9.5**
South Europe	10,16	>393,7	>374	4,19	128,9	138,4				
TER criterion		100	10		100	10		10		10

Tabelle 6.4-3: Aquatic organisms: PECsw for aminopyralid and relevant ecotoxicological endpoints for each organism' group.

Scenario	**PEC global max (µg/L)**	**Fish acute**	**Fish prolonged**	**Invertebrates acute**	**Invertebrates acute**	**Invertebrates prolonged**	**Sed. dweller prolonged**	**Algae**	**Aquatic higher plants**
		Oncorhynchus mykiss	***Cyprinodon variegatus***	***Daphnia magna***	***Crassotrea virginica***	***Daphnia magna***	***Chironomus riparius***	***Navicula pelliculosa***	***Lemna gibba***
		LC_{50} (µg/L) >100000	**NOEC (µg/L) 100**	**EC_{50} (µg/L) >100000**	**EC50 (µg/L) >89000**	**NOEC (µg/L) 100000**	**NOEC (µg/L) 130000**	**E_bC_{50} (µg/L) 18000**	**EC50(µg/L) >88000**
FOCUS Step 1									

	2,72	>36764,7	36,8	>36764,7	>32720,6	36764,7	47794,1	6617,6	>32352,9
FOCUS Step 2									
North Europe	0,74	>135135,1	135,1	>135135,1	>120270,3	135135,1	175675,7	24324,3	>118918,9
South Europe	0,6	>166666,7	166,7	>166666,7	>148333,3	166666,7	216666,7	30000	>146666,7
TER criterion		100	10	100	100	10	10	10	10

Based on the calculated concentrations of aminopyralid/propyzamide and their metabolites in surface water (PEC_{SW} FOCUS Step 1 and 2), the calculated TER values for the acute and long-term risk resulting from an exposure of aquatic organisms to propyzamide and the Propyzamide metabolites Uk1 and Uk2 (RH-24,655) according to the GAP of the formulation GF-2540 do not achieve the TER acceptability criteria, 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 unacceptable risk for aquatic organisms due to the intended use of GF-2540 in Winter Oilseed Rape according to the label.

A comparison of endpoints derived from (acute) studies conducted with the formulation and the active substances do not indicate a higher toxicity of the preparation when assuming dose/concentration additivity of toxicity of the two active substances.

According to the results of the TER-values calculations based on $FOCUS_{SW}$ Step 2 PEC values for the intended use No 001 in Winter Oilseed Rape, the implementation of management practices might be necessary to reduce the exposure of aquatic organisms to GF-2540. Refinement of Exposure calculations and management practices relevant for Germany are given in the respective Addendum.

6.4.3 Acute toxicity and chronic toxicity of the formulation

Please refer to section 6.4.1.1 for a summary of the provided studies on the effects of GF-2540 on aquatic organisms. Section 6.4.2, page 34, gives the details of the risk assessment for aquatic organisms on the basis of all available data.

6.4.4 Metabolites of propyzamide

The metabolites RH-24644 and RH-24580 are formed in soil with 31.9 % and 24 %, respectively Contamination via run-off and drainage cannot be excluded. Ecotoxicological studies are available for both metabolites testing aquatic invertebrates (*Daphnia magna*) and algae (*Pseudokirchniella subcapitata*). The parent compound propyzamide has a herbicidal mode of action and there was no indication that fish tend to be more sensitive towards the active substance than aquatic invertebrates and algae. Hence, the risk of the propyzamide metabolites RH-24644 and RH-24580 towards aquatic organisms is considered to be sufficiently addressed by the submitted studies on the effects of the metabolites towards aquatic invertebrates and algae.

In a water/sediment study a third metabolite, RH-24655 (UK2), was identified in relatively high amounts in the sediment (20.5 %), but at lower concentrations in the water phase (6.5 %). A prolonged toxicity study with *Chironomus riparius* has been submitted by the applicant. In accordance with the DAR propyzamide, Addendum Rev6, updated February 2003, risk assessment is carried out on the sediment living chironomid *Chironomus riparius,* assuming main intake from the porewater (=calculated concentration in the water phase) to address the risk of this metabolite towards aquatic organisms.

Please refer to section 6.1.2, page 6 for the assessment of the metabolites of propyzamide that was performed during peer review of the active substance in view of its approval.

Please refer to section 6.4.1.1 for a summary of the provided studies on the effects of propyzamide metabolites on aquatic organisms. Section 6.4.2, page 34, gives the details of the risk assessment for aquatic organisms on the basis of all available data. Since no data are available for the metabolite Uk1 that is formed in the wate phase (5.4 %), a ten-fold higher toxicity for aquatic organisms than the parent substance propyzamide was assumed for risk assessment purposes. However, the identified risk is lower, based on a lower exposure.

As already discussed in section 6.4.1.3, the comparison of the outcome of the studies for propyzamide, the propyzamide metabolites RH-24-655, RH-24-644 and RH-24-580 and Amininopyralid shows that the risk for aquatic organisms resulting from an exposure to GF-2540 is driven by the toxicity of the metabolite RH-24,655.

6.4.5 Accumulation in aquatic non-target organisms

Since aminopyralid has a logPow of <3, bioaccumulation of the active substance under natural conditions is not expected to occur and a study is not necessary to determine bioaccumulation in aquatic non-target organisms.

Since propyzamide has a logPow of 3, a bioaccumulation study in fish was performed to determine bioaccumulation in aquatic non-target organisms (see Table 6.4-1). The BCF factor of 49 for propyzamide indicates a low risk for bioaccumulation. The depuration in fish was 96% elimination from the whole fish within 14 days of the depuration phase. Based on the results of tests with Propyzamid, the trigger < 100 (not readily biodegradable) (set in commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2.) is met.

Although the soil propyzamide metabolite RH24-644 (formed 31.9 % at day 21) has a logPow of 5 (above the trigger of 3), bioaccumulation in aquatic non-target organisms, in the course of the EU review of propyzamide, it was not considered necessary by MS to determine the bioconcentration in fish experimentally. Based on its DT_{50} of 36.5d (90th Perc.) and the high K_{OC} of this metabolite only low entries into surface waters are expected and the zRMS considers it sufficient that only bioaccumulation in Earthworms has been addressed experimentally and does not to require additional vertebrate studies to determine the BCF in fish experimentally.

6.5 Effects on Bees

The recommended use pattern for GF-2540 includes application in oilseed rape at a maximum application rate of up to 1.5 L/ha. This maximum single application rate is equivalent to 1709 g product/ha.

Bees may be exposed to GF-2540 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.

6.5.1 Hazard quotients for bees

Table 6.5.1-1 presents the hazard quotients for oral and contact exposure according to EPPO (2003) Environmental risk assessment scheme for plant protection products (Chapter 10: Honeybees (PP 3/10(2)). The HQs were calculated as follows:

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

Table 6.5.1-1 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
GF-2540	1709	oral	> 330.25 µg	< 6	50
		contact	> 300 µg	< 6	

Risk assessment
Due to the results of laboratory tests GF-2540 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 and exposure ob brood is considered negligible.

Overall conclusion:
It is concluded that GF-2540 will not adversely affect bees or bee colonies when used as recommended. Label NB6641 is applicable.

6.5.1.1 Oral exposure QHO

Please refer to table 6.5.1-1.

6.5.1.2 Contact exposure QHC

Please refer to table 6.5.1-1.

6.5.2 Acute toxicity of the formulation to bees

Table 6.5.2-1 presents the results of laboratory bee toxicity studies with the formulation.

Table 6.5.2-1: Results of laboratory bee toxicity studies

Test substance	Exposure route	LD_{50}	Reference
GF-2540	oral 48 h	> 330.25 µg product/bee	Kling, A. (2010); S09-00693-L1_BLEU
	contact 48 h	> 300 µg product/bee	

6.5.2.1 Oral

Please refer to table 6.5.2-1.

6.5.2.2 Contact

Please refer to table 6.5.2-1.

6.5.3 Effects on bees of residues on crops

Not required.

6.5.4 Cage tests

Not required

6.5.5 Field tests

Not required

6.5.6 Investigation into special effects

Not required

6.5.6.1 Larval toxicity

6.5.6.2 Long residual effects

6.5.6.3 Disorienting effects on bees

6.5.7 Tunnel tests

Not required

6.6 Effects on Arthropods Other Than Bees

6.6.1 Overview and summary

Effects on arthropods other than bees for GF-2540 were not evaluated as part of the EU review of propyzamide and aminopyralid. Data on GF-2540 have been submitted by the applicant and are evaluated here. They are considered adequate to assess the risk for non-target arthropods following the use of GF-2540 according to the intended uses.

6.6.1.1 Toxicity

The critical endpoints employed in the risk assessment for non-target arthropods are indicated in the table below.

Table 6.6-1: Toxicity of GF-2540 to non-target arthropods with reference to agreed endpoints

Species	Substance	Exposition Duration System	Results Toxicity	Reference Author Date Report No.	ICS-No.
Typhlodromus pyri	GF-2540	2 d Lab, glass plate	ER_{50} > 1700 mL Prod../ha (mortality), ER_{50} = 1437 mL Prod./ha (reproduction) 3)	Klug, T. 22.10.2009 S09-00694	80205
Aphidius rhopalosiphi	GF-2540	2 d Lab, glass plate	LR_{50} > >1700 mL Prod../ha 3)	Klug, T. 22.10.2009 S09-00695	80206
Typhlodromus pyri	GF-2540	2 d extend. lab	ER_{50}>3400 mL Prod../ha (mortality and reproduction) 3)	Höhn, P. 08.07.2010 S10-01125	80207
Chrysoperla carnea	GF-2540	2 d extend. lab	ER_{50}>1700 mL Prod../ha (mortality and reproduction) 3)	Höhn, P. 27.07.2010 S10-01126	80208

3) New study submitted by the applicant

6.6.1.2 Exposure

In field

Non-target arthropods living in the crop can be exposed to residues from GF-2540 by direct contact either as a result of overspray or through contact with residues on plants and soil or in food items.

GF-2540 is a herbicide formulation containing aminopyralid and propyzamide as active substances. The product is formulated as a suspension concentrate. It will be used against Annual mono- and dicot weeds (post emergence of weeds) in Winter Oilseed Rape.

The in-field exposure, given as predicted environmental rates, PER, for non-target arthropods resulting from the intended uses of GF-2540 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. Since GF-2540 will be applied in only one application scheme, the assessment is based on this application scheme (use No 001)

The maximum predicted environmental rate (PER) occurring in the field after application of GF-2540 at its application rate according to use No 001 is presented in the following table.

Table 6.6-2: In-field predicted environmental rates (PER) for GF-2540, intended use 001

Substance	**Application rate (L Product/ha)**	**in-field PER (L Product/ha)**
GF-2540	1.5	1.5

Off-field

Exposure of non-target arthropods living in non-target off-field areas to GF-2540 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:

$$Off-field\ PER = \frac{Maximum\, in-field\ PER\ x \left({drift\ percentile}/{100} \right)}{vegetation\, distribution\ factor\ (vdf)}$$

[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.

[2] BBA (Biologische Bundesanstalt für Land- und Forstwirtschaft) (2000): Abtrifteckwerte für Flächen- und Raumkulturen sowie für den gewerblichen Gemüse-, Zierpflanzen- und Beerenobstanbau. Bundesanzeiger 100, 26. Mai 2000, Köln, pp. 9879.

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 dilution factor of 10 is recommended by the Guidance Document, but has been questioned. The risk assessment procedure here considers a dilution factor of 5 more appropriated. For endpoint resulting from 3-dimensional studies, i.e. where spray treatment is applied onto whole plants, the dilution factor is not used.

The drift rate at 1 m distancein field crops is 2.77% of the application rate (90th percentile drift).

The 2d laboratory studies (on glass plates) on the effects of GF-2540 towards *T. pyri* / *A. rhopalosiphi* submitted by the applicant are used to assess the risk of the product towards no-target arthropods. For the results of these studies, a vegetation distribution factor has to be considered (study conducted in 2D environment).

The resulting PERoff-field values are shown in the following table.

Table 6.6-3: Off-field predicted environmental rates (PER) resulting from the intended uses of GF-2540

Study type	Max. rate (ml Prod./ha)	MAF	Maximum in-field PER (ml Prod./ha)	Drift rate (% appl. rate)	Vegetation distribution factor	Off-field PER (ml Prod./ha)
3-dimensional	1500	1	1500	2.77%	1	41.55
2-dimensional	1500	1	1500	2.77%	5	8.31

Reduction of the amount of drift reaching the off-field areas can be achieved by implementing a in-field buffer strip of a given width. The resulting drift values (according also to spray-drift predictions of Ganzelmeier & Rautmann (2000)[3]) are given in the table below.

[3] Ganzelmeier H., Rautmann D. (2000) Drift, drift-reducing sprayers and sprayer testing. Pesticide Application, Aspects of Applied Biology 57

Table 6.6-4: Maximum off-field PER (predicted environmental rates) of GF-2540 at increasing distances from the sprayed areas following intended uses

Maximum intended in-field rate	Maximum PERoff-field at 1m (2.77% drift)
(mL GF-2540/ha)	
1500	41.55

Risk assessment –overall conclusions

The outcome of the risk assessment for non-target arthropods exposed to GF-2540 is given in the table below.

Tier 1

Table 6.6-5: Maximum HQ and minimum TER values for arthropod species other than bees after uses of GF-2540 in Winter oilseed rape

Test substance	Species	Test type	Endpoint ER50 (ml Prod./ha)	Worst-case PER in-field (ml Prod./ha)	HQ In-field	PER off-field (1 m) (ml Prod./ha)	HQ Off-field	TER Off-field
GF-2540	*Aphidius rhopalosiphi*	Lab. 2D	1437	1500	1.04	8.31	0.06	173
	Typhlodromus pyri	Lab. 2D	> 1700	1500	0.88	8.31	0.05	205
HQ and TER values in bold are below the trigger								

Based on the calculated rates of GF-2540 in in-field and off-field areas, the calculated HQ and TER values describing the potential risk resulting from an exposure of non-target arthropods according to the GAP of the formulation GF-2540 achieve the acceptability criteria HQ ≤ 2 resp. TER ≥ 10 (Tier 1), 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 GF-2540 in winter oilseed rape according to the label. Management practices relevant for Germany are given in the respective Addendum.

6.6.2 Risk assessment for Arthropods other than Bees

6.6.2.1 In-field

Tier 1

The potential risk for non-target arthropods exposed in-field to GF-2540 was assessed by calculating the hazard quotient (HQ = exposure/toxicity) as the ratio of the predicted environmental rate (PER) and the lowest lethal rate (LR50) estimated in standard toxicity tests with non-target arthropods according to the formula:

$$\text{In field HQ} = \frac{\text{In - field PER}}{\text{LR}_{50}}$$

The resulting HQ in-field values for the standard species are presented in the following table.

Table 6.6-6: Tier 1 in-field HQ values for non-target arthropods other than bees and acceptability criteria for Tier 1 data

Species	**L/ER50** **(mL Product/ha)**	**PER** **(mL Product/ha)**	**HQ In-field**	**Trigger value**
Aphidius rhopalosiphi	1437	1500	1.04	2
Typhlodromus pyri	> 1700	1500	0.88	2
HQ values in bold are above the trigger				

The in-field HQ values for exposure to maximum residues for the representative species *Typhlodromus pyri* and *Aphidius rhopalosiphi* are lower than the trigger value of 2 (Candolfi et al, 2001).

The results indicate that GF-2540 poses low risk to non-target arthropods in-field following application according to the intended uses.

6.6.2.2 Off field

HQ approach

In order to assess the potential risk of GF-2540 to non-target arthropods in off-field areas, the predicted environmental rate in the Off-field (see chapter 6.6.1.2) is compared to the toxicity endpoints according to the following formula:

$$Off - field\ \ HQ = \frac{Off - field\ PER}{LR_{50}} \times correction\ factor$$

where:

Correction factor (also ‘safety factor’) = amounts to 10 in conjunction with Tier I data from tests on glass plates; amounts to 5 for Tier II data from extended laboratory tests/field tests. The factor accounts for extrapolation from testing few representative species to the species diversity expected in off-crop areas.

Tier 1

Calculated HQ off-field values are given in the following table.

Table 6.6-7: Calculated off-field HQs for non-target arthropods and acceptability criteria for Tier 1 data

Species	Test type	L/ER50 (mL product/ha)	PER in-field (mL product/ha)	Distance (m)	PER off-field	PER off-field x correction factor (mL product/ha)	HQ Off-field	HQ trigger
Aphidius rhopalosiphi	2 D glass plate	1437	1500	1	8.31	83.1	0.06	2
Typhlodromus pyri	2 D glass plate	> 1700		1	8.31	83.1	0.05	2

The off-field HQ values for *Typhlodromus pyri* and *Aphidius rhopalosiphi* are below the trigger value, indicating that GF-2540 does not pose an unacceptable risk to non-target arthropods in off-field areas.

TER approach

Additionally to the HQ-approach, the assessment of the risk to non-target arthropods due to an exposure to GF-2540 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 when the data were obtained in higher tier test (extended lab or field tests).

The resulting TER off-field values are given in the following table. Since the calculated TER values for *Aphidius rhopalosiphi* and *Typhlodromus pyri* were above the trigger of 10.

Table 6.6-8: Calculated TER values for non-target arthropods exposed to GF-2540 in off-field areas according to intended uses

Species	Test type	Correction factor	L/ER50 (mL product/ha)	PER in-field (mL product/ha)	Distance (m)	PERoff-field (mL product/ha)	TER
Aphidius rhopalosiphi	2 D glass plate	10	1437	1500	1	8.31	173
Typhlodromus pyri	2 D glass plate	10	> 1700		1	8.31	205
TER values in bold are below the trigger							

Based on the calculated rates of GF-2540 in off-field areas, the calculated TER values for the risk resulting from an exposure of non-target arthropods according to the GAP of the formulation GF-2540 achieve the acceptability criteria 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 GF-2540 in winter oilseed rape according to the label. Management practices relevant for Germany are given in the respective Addendum.

6.7 Effects on Earthworms, other Non-target Soil Organisms and Organic Matter Breakdown

6.7.1 Overview and summary

Earthworms, other soil non-target macro and mesofauna as well as soil organisms involved in the breakdown of dead organic matter will be exposed to propyzamide and aminopyralid whenever contamination of soil may occur as a result of the intended uses of GF-2540.

Effects on earthworms and other soil non-target organisms resulting from an exposure to <active substance> / GF-2540 were not evaluated as part of the EU review of <active substance>. All relevant study data for the assessment of the risk to earthworm and other soil non-target macro-and mesofauna from the inteded uses of GF-2540 are provided here. New data are listed in Appendix 1 and summarized in Appendix 2 (new studies).

6.7.1.1 Toxicity

Table 6.7-1: Ecotoxicological endpoints for terrestrial non-target soil fauna and organic matter breakdown following exposure to propyzamide, aminopyralid and GF-2540 with indication to agreed endpoints

Species	Substance	Exposition Duration System	Results Toxicity	Reference Author Date Report No.	ICS-No.
Eisenia fetida	Aminopyralid	Acute 14d, 10% peat	LC50 > 1000 mg/kg[2)**]	Ward, T. and Boeri, R. 03.12.2001 2219-DO	50890
Eisenia fetida	Aminopyralid	Long-term	NOEC = 3.2 mg/kg[2)**]	DAR Aminopyralid, March 2012	---
Eisenia fetida	Propyzamide	Acute 14d, 10% peat	LC50 > 346,3 mg/kg LC50 corr > 173,2 mg/kg [1) *]	Roberts, N. L., Hakin, B. 17.01.1986 R&H 55B/851266/2 ! Ref.No. 21.	28864
Eisenia fetida	Kerb 50 W (500g/kg Propyzamide)	Chronic 56 d, 10% peat		Nienstedt, K. M. 06.08.2001 1007.071.631	44169
Eisenia fetida	Propyzamide metabolite RH-	Acute 14d, 10% peat	LC50 corr =261 mg /kg	Rohm and Haas 18.04.2000	42750

	24,580		soil dw Mortality1) *	Rep-No.99RC-0244	
Eisenia fetida	Propyzamide metabolite RH-24,644	Acute 14d, 10% peat	LC50corr = 86.6 mg /kg soil dw1 Mortality1) *	Bryan et al. 14.07.2000 Rep-No.99RC-0261	42778
Eisenia fetida	Propyzamide metabolite RH-24,644	Chronic 56 d, 10% peat	NOECcorr = 5.5 mg /kg soil dw Reproduction 3)	Davies, N. 12.10.2004 040077 ! CEMS-2253	63609
Eisenia fetida	GF 2540	Acute 14d, 10% peat	LC50 corr > 500 mg Prod. /kg soil dw1 Mortality 3)	Stäbler, D. 21.01.2010 090216 ! S09-00689	80209
Eisenia fetida	GF 2540	Chronic 56 d, 10% peat	NOECcorr = 26.1 mg Prod./kg soil dw Reproduction 3)	Stäbler, D. 09.02.2010 090217 ! S09-00690	80210
Eisenia fetida	Propyzamide metabolite RH-24,644	Bioconcentration/Depuration study	Estimated BCF = 2.9 1)*	LoEp propyzamide	---

1) EU list of endpoints (SANCO/6502/VI/99)

*Reports are summarised in DAR propyzamide, Addendum Rev6, updated February 2003

2) Aminopyralid - Volume 1, Level 2, Appendix 3 – List of endpoints June 2013

**Reports are summarised in DAR aminopyralid, Annex B.9 : Ecotoxicology and Addenda- updated July 2013

3) New study submitted by the applicant

The log K_{ow} of propyzamide, RH 24644 and RH 24,580 are greater than the agreed trigger value of 2. Therefore, the endpoints for RH-24-644, RH-24-580 and the Product GF-2540 were corrected in order to account for the relatively high organic matter content of the artificial test soil compared to agricultural soils and a resulting lower bioavailability of the active substance to soil organisms.

6.7.1.2 Exposure

GF-2540 is a herbicide formulation containing aminopyralid and aopyzamide as active substances. The product is formulated as a suspension concentrate. It will be used against Annual mono- and dicot weeds (post emergence of weeds) in winter oilseed rape.

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 product GF-2540, the active substances propyzamide, aminopyralid and the major soil degradation products are presented in the table below. Calculations considered the application rate of 1.5 L formulation/ha and a minimum of 40% foliar interception for applications to winter oilseed rape at BBCH growth stage 13-29. PEC values for the soil metabolites were calculated considering the maximum percentage of their formation observed in either the aerobic or anaerobic soil degradation studies and correcting for molecular weight.

All calculations assumed an even distribution of the substances in the top 5 cm horizon with a soil bulk density of 1.5 g/mL. Due to the fast degradation of propyzamide in soil (DT_{90} < 365 d, FSO, laboratory data) the accumulation potential of propyzamide and aminopyralid does not need to be considered.

Table 6.7-2: Maximum predicted environmental concentrations in soil PECs[1)] for aminopyralid / propyzamide / GF-2540 and major soil degradation products of propyzamide following application in the intended use winter oilseed rape.

plant protection product:		GF-2540				
use:		001				
Number of applications/intervall		1.5 L ha^{-1}				
application rate:		1x				
crop interception:		40 %				
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)**
Active substance propyzamid	450.0	0.600	-	-	-	-
Metabolite RH-24644	143.5	0.191	-	-	-	-
Metabolite RH-24580	115.5	0.154	-	-	-	-
Active substance aminopyralid	4.8	0.006	-	-	-	-
Preparation GF-2540	1025.1	1.367	-	-	-	-

1) PEC_{act} = maximum annual soil concentration for a soil depth of 5 cm
PEC_{bkgd}= background concentration in soil considering a tillage depth of 20 cm (arable crop) or 5 cm (permanent crops)
PEC_{accu} = accumulated soil concentration

The propyzamide metabolites RH-24644 and RH-24580 were formed in concentrations >10 % total AR at day 21 (RH-24644) and day 45 (RH-24580) in soil. For details please see Section 5, Part 9.1 of this submission and Table 6.1-2, page 6.

6.7.1.3 Risk assessment –TER values and overall conclusions

The risk assessment results are summarized in the following table:

Table 6.7-3: Ecotoxicological endpoints, PECsoil values and Toxicity to Exposure ratios to assess the risk for earthworms and other soil macro- and mesofauna following application of GF-2540 according to the intended uses

Test substance	Intended use	Timescale	Endpoint (mg/kg dw soil)	PEC (mg/kg soil dw)	TER	TER trigger
Earthworms (*Eisenia fetida*)						
Active substance aminopyralid	750 g propyzamide ha^{-1} and 8 g aminopyralid ha^{-1} (1.5 L ha^{-1} GF-2540)	Acute	> 1000	0.006	>166666	10
		Long-term	3.2		533	5
Active substance propyzamide		Acute	> 173,2	0.600	>289	10
		Long-term	34		56.7	5
Propyzamide metabolite RH-24644		Acute	86.6	0.191	453	10
		Long-term	5.5		28.8	5
Propyzamide metabolite RH-24580		Acute	>261	0.154	>1695	10
Preparation GF-2540		Acute	> 500	1.367	>366	10
		Long-term	26.1		19.1	5
TER values in bold are below the trigger						

Based on the predicted concentrations of aminopyralid /propyzamide / propyzamide metabolites RH-24580 and RH-24644 / GF-2540 in soils, the TER values describing the acute and longterm risk for earthworms and other non-target soil organisms following exposure to according to the GAP of the formulation GF-2540 achieves 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 GF-2540 in winter oilseed rape according to the label.

6.7.2 Toxicity to Exposure Ratio

6.7.2.1 Acute risk

The potential acute risk for earthworms and other non-target soil macro- and mesofauna resulting from an exposure to GF-2540 / propyzamide / aminopyralid as well as the metabolite of propyzamide RH 24580 was assessed by comparing the maximum PECsoil 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 resulting TER_A values are shown in Table 6.7-3 above.

6.7.2.2 Chronic risk

The long term risk of the active substances aminopyralid, propyzamide, the propyzamide metabolite RH 24644 and the product GF-2540 for Earthworms has been addressed by long-term studies with *Eisenia fetida.* The potential chronic risk for earthworms was assessed by comparing the maximum PECsoil 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 resulting TER_{LT} values are shown in Table 6.7-3 above.

The long-term risk of the propyzamide metabolite RH 24580 for earthworms and other soil macro- and mesofauna does not need to be addressed, since its degradation in soil (DT90 < 100 d, Kinetic, laboratory/field data, Guidance Document on Terrestrial Ecotoxicology SANCO/10329/2002 rev2 final) is relatively fast.

According to the Guidance Document on Terrestrial Ecotoxicology, a test for assessing effects on other soil other soil macro- and mesofauna (Collembola reproduction test or test on gamasid mites) is required where:

- $DT_{90field}$ of of the active substance is between 100 and 365 days and
- standard HQ for arthropods (*Typhlodromus* and *Aphidius*) >2

For propyzamide and Aminopyralid the max DT_{90}s in the field are <365 but >100 (185 and 116.1 d resp.) and for the propyzamide metabolite RH 24644 the DT90 lab was <365 but >100 (125.8d max). No risk was identified for non-target arthropods, Earthworms and soil micro-organisms from the use of GF-2540. Hence, it is not considered necessary to provide studies on the effects of GF-2540 on other soil macro- and mesofauna.

According to the Guidance Document on Terrestrial Ecotoxicology, a test for assessing effects on organic matter breakdown (litterbag) is required where:

- DT_{90fiel}d of the active substance is > 365 days or
- $DT_{90field}$ of of the active substance is between 100 and 365 days and
- Effects on soil microflora > 25 % or TER_{LT} earthworm < 5
- or Collembola TER_{LT} < 5

For propyzamide and Aminopyralid the max DT_{90}s in the field are <365 but >100 (185 and 116.1 d resp.). Effects of both active substances on soil microflora were <25 % and TER_{LT} earthworm was > 5. Therefore no tests for assessing effects on organic matter breakdown are considered to be necessary.

For the propyzamide metabolite RH 24580 the DT90 lab was 55.5 (max), so no tests for assessing effects on organic matter breakdown are required. For the RH 24644 the DT90 lab was <365 but >100 (125.8d max) but the TER_{lt} for Earthworms was >5 and effects on soil microflora were <25 %. Hence, for this metabolite no tests for assessing effects on organic matter breakdown are considered to be necessary.

Submitted data are reported in Table 6.7-1.

6.7.3 Residue content of earthworms

The log Kow values of the Propyzamide metabolite RH-24,644 is > 3. Thus bioaccumulation in earthworms was assessen. In an earthworm bioconcentration / depuration study a BCF of 2.9 was estimated for Eisenia fetida.

6.8 Effects on Soil Microbial Activity

6.8.1 Overview and summary

Soil microorganisms will be exposed to plant protection products containing propyzamide, aminopyralid and their soil metabolites whenever contamination of soil may occur as a result of the intended uses of GF-2540.

Effects on soil microorganisms resulting from an exposure to propyzamide and aminopyralid were evaluated as part of the EU review of propyzamide and aminopyralid. However, effects resulting from an exposure to GF-2540 have not been evaluated. All relevant study data for the assessment of the risk to soil microorganisms from the intended uses of GF-2540 are provided here. New studies are listed in Appendix 1 and summarized in Appendix 2.

6.8.1.1 Toxicity

Table 6.8-1: Ecotoxicological endpoints for soil microbial activity following exposure to GF-2540 with indication to agreed endpoints

Process	Substance	Exposition Duration System	Results Toxicity	Reference Author Date Report No.	ICS-No.
N-tranformation	Propyzamide	28d, 2.5 and 25 kg ai/ha (equivalent to 3.3 and 33.3 mg/kg soil dw)	<25 % effects[1)]***	Greaves 01.12.1985 1994870 / BMF2000-16	---
C-transformation	Propyzamide	28d, 2.5 and 25 kg ai/ha (equivalent to 3.3 and 33.3 mg/kg soil dw)	<25 % effects[1)]***	Greaves 01.12.1985 1994870 / BMF2000-16	---
N-tranformation	Propyzamide metabolite RH 24644	28d, 1.1 and 5.5 mg/kg dry soil	<25 % effects[3)]	Rix, S. 01.11.2004 040076 ! CEMS-2257	80226
C-transformation	Propyzamide metabolite RH 24644	28d, 1.1 and 5.5 mg/kg dry soil	<25 % effects[3)]	Rix, S. 01.11.2004 040076 ! CEMS-2257	80227
N-tranformation	Aminopyralid	28d, 1.68 and 8.4 mg a.s./kg soil dw	<25 % effects[2)]**	McMurray, A. 20.06.2002	80663

				1955827 / BMF2004-48 / 101890 ! GHE-T-1180	
C-transformation	Aminopyralid	28d, 1.68 and 8.4 mg a.s./kg soil dw	<25 % effects[2)]**	McMurray, A. 20.06.2002 1955827 / BMF2004-48 / 101890 ! GHE-T-1180	80663
N-tranformation	GF-2540	56 d, medium silty sand, 13 mg/kg soil	<25 % effects[3)]	Stäbler, D. 18.01.2010 090218 ! S09-00691	80211
C-transformation	GF-2540	56 d, medium silty sand, 13 mg/kg soil	<25 % effects[3)]	Stäbler, D. 18.01.2010 090218 ! S09-00691	80211

1) EU list of endpoints (SANCO/6502/VI/99)

***Reports are summarised in DAR propyzamide, Addendum Rev6, updated February 2003

2) Aminopyralid - Volume 1, Level 2, Appendix 3 – List of endpoints June 2013

**Reports are summarised in DAR aminopyralid, Annex B.9 : Ecotoxicology and Addenda- updated July 2013

3) New study submitted by the applicant

6.8.1.2 Exposure

Please refer to section 6.7.1.2 above for the predicted environmental concentrations in soil (PECsoil) of Propyzamide, Aminopyralid, Propyzamide metabolite RH 24644 and GF-2540.

6.8.1.3 Risk assessment –overall conclusions

The Predicted Environmental Concentrations of the formulation GF-2540, the active substance(s) and the propyzamide metabolite RH 24644 are below the concentrations at which no unacceptable effects (< 25%) regarding the soil microbial activity were observed after 28 days of exposure.

The results of the comparison expressed as Margin of Safety (MoS) are presented in the following table.

Table 6.8-2: Summary of risk assessment for soil micro-organisms exposed to GF-2540/ aminopyralid, propyzamide, propyzamide metabolite RH 24644 and GF-2540

Substance	Test type	Maximum initial PEC (mg/kg soil dw)	Effects <25% (mg/kg soil dw)	MoS
Active substance aminopyralid	N transformation	0.006	8.4	323
	C transformation		8.4	323
Active substance propyzamide	N transformation	0.6	33.3	13,9
	C transformation		33.3	13,9
Propyzamide	N transformation	0.191	5.5	7,2

metabolite RH-24644	C transformation		5.5	7,2
Preparation GF-2540	N transformation	1.367	13	2,4
	C transformation		13	2,4

For the active ingredients in GF-2540, propyzamide, aminopyralid and the propyzamide metabolite RH-24644, the soil concentrations which caused no deviations greater than ±25% in the activity of the soil microorganisms are at least 10-times higher than the corresponding maximum PEC in soil. For GF-2540 the soil concentrations which caused no deviations greater than ±25% in the activity of the soil microorganisms are 4.8 times higher than the corresponding maximum PEC in soil. Hence, a low risk to soil microflora is concluded.

The metabolite Uk1 is formed in relevant amounts in soil (max 24% of AR on day45) and its toxicity towards soil microorganisms has not been assessed in the EU review of propyzamide. However, the toxicity of this metabolite is considered to be covered in the 56d study with the preparation GF-2540.

Based on the predicted concentrations in soils, the risk to soil microbial processes following exposure to GF-2540 according to the GAP of the formulation GF-2540 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.

6.9 Effects on Non-Target Plants

6.9.1 Overview and summary

Effects on non-target plants resulting from an exposure to GF-2540 were not evaluated as part of the EU review of aminopyralid/proyzamide. Therefore, all relevant study data for the assessment of the risk to non-target plants from the inteded uses of GF-2540 are provided here, listed in Appendix 1 and summarized Appendix 2 (new studies).

6.9.1.1 Toxicity

As the tests performed with the formulation GF-2540 represent the exposure of non-target plants in the field rather than the tests evaluated in the EU process for the active substances aminopyralid and propyzamide, only these studies are presented and considered here.

Table 6.9-1: Ecotoxicological endpoints for non-target plants following exposure to GF-2540 with indication to agreed endpoints

Species (most sensitive species marked in bold)	**Substance**	**Exposition Duration System**	**Results Toxicity**	**Reference Author Date Report No.**	**ICS-No.**

Vegetative vigour					
Tomato (*Lycopersicon esculentum*) Ryegrass (*Lolium perenne*), Oats (*Avena sativa*), Barley (*Hordeum vulgare*), Onion (*Allium cepa*), Oilseed rape (*Brassica napus*), Soybean (*Glycine max*), Cucumber (*Cucumis sativa*), Sugar beet (*Beta vulgaris*), Carrot (*Daucus carota*)	GF-2540	Vegetative vigour	ER_{50} = 210.95 mL prod./ha (*Lycopersicon esculentum*)	Rockliff, C. 19.06.2013 130508 ! STC/13/E760 3)	82739
Seedling emergence					
Tomato (*Lycopersicon esculentum*) Ryegrass (*Lolium perenne*), Oats (*Avena sativa*), Barley (*Hordeum vulgare*), Onion (*Allium cepa*), Oilseed rape (*Brassica napus*), Soybean (*Glycine max*), Field bean (*Vicia faba*), Cucumber (*Cucumis sativa*), Sugar beet (*Beta vulgaris*), Carrot (*Daucus carota*)	GF-2540	Seedling emergence	ER_{50} = 211.47 mL prod./ha (*Lycopersicon esculentum*)	Rockliff, C. 25.06.2013 130509 ! STC/13/E761 3)	82740

3) New study submitted by the applicant

The number of plants grown per pot ind seedling emergence and vegetative vigour studies significantly deviated from the requirements according to guideline OECD 227 for several species and it could not be checked whether the light intensity met the guideline requirements (please refer to IIIA1 10.8.1.2/ IIIA1 10.8.1.3).

Else the studies with the product are considered plausible, and suitable to be used in the risk assessment but to cover additional additional uncertainties regarding the light intensity in the study / possible overcrowding of pots an a TER acceptability criterion of 10 is used even though more than 6 plant species were tested.

The endpoint driving the risk assessment is the ER_{50} = 210.95 mL prod./ha from the vegetative vigour study.

6.9.1.2 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-field= Maximum in-field PER (including MAF) x %drift

For calculation of PER in-field, please refer to section 6.6.1.2, page 43.

The resulting maximum off-field predicted environmental rates (PER off-field) are summarized in the following table:

Table 6.9-2: Maximum off-field predicted environmental rates of GF-2540 following intended uses

Maximum intended in-field rate	Maximum PERoff-field at 1m (2.77% drift)	Maximum PERoff-field at 1m (0.57% drift)
(mL GF-2540/ha)		
1500	41.55	8.55

6.9.1.3 Risk assessment –TER values and overall conclusions

The risk assessment results are summarized in the following table:

Table 6.9-3: Summary of risk assessment for non-target terrestrial plants exposed to GF-2540 following intended uses

Endpoint	ER50 (mL product/ha)	PERin-field (mL product/ha)	Distance (m)	Exposure PERoff-field (mL product/ha)	TER
Vegetative vigour	210.95	1500	1	41.55	5.1
			5	8.55	24.7

Based on the predicted rates of GF-2540 in off-field areas, the TER values describing the risk for non-target plants following exposure to GF-2540 according to the GAP of the formulation GF-2540 do not achieve the acceptability criteria TER ≥ 10 according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. Mitigation measures will have to be implemented to reduce the exposure of non-target terrestrial plants to GF-2540 comparable to 5m m in-field buffer strip. Management practices relevant for Germany are given in the respective Addendum.

6.10 Other Non-Target Species (Flora and Fauna)

6.10.1 Overview and summary

6.10.1.1 Toxicity

6.10.1.2 Exposure

6.10.1.3 Risk assessment –overall conclusions

6.10.2 Toxicity to Exposure Ratio

6.11 Other/Special Studies

6.11.1 Laboratory studies

6.11.2 Field studies

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	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner	How considered in dRR Study-Status/ Use*
KIIIA1 10.2.2.1/01	[redacted]	2010	GF-2540: Acute Toxicity to the Rainbow Trout, Oncorhynchus mykiss, Determined Under Static-Renewal Test Conditions. [redacted]. September 17, 2010. unpublished report, Study Number 101368	Y	Dow AgroSciences	1
KIIIA1 10.2.2.2/01	Bergfield, A.	2010	GF-2540: Acute Toxicity to the Water Flea, *Daphnia magna*, Determined Under Static-Renewal Test Conditions. ABC Laboratories, Columbia, Missouri, ABC study number 65882. 7 September 2010 ,unpublished report, Study Number 101367	Y	Dow AgroSciences	1
KIIIA1 10.2.2.3/01	Rebstock, M	2010	GF-2540: Growth Inhibition Test with the Unicellular Green Alga, *Pseudokirchneriella subcapitata*. ABC Laboratories, Inc., 7200 E. ABC Lane, Columbia, Missouri 65202. ABC Study No. 65881. 17 September 2010. Dow AgroSciences unpublished report, Study Number 101365	Y	Dow AgroSciences	1

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner	How considered in dRR Study-Status/ Use*
KIIIA1 10.5.1/01	Klug, T	2009	GF-2540: Toxicity to the Aphid Parasitoid. *Aphidius rhopalosiphi* De Stefani Perez (Hymenoptera. Braconidae) in the Laboratory (Rate Response Test). eurofins-GAB GmbH. Eutinger Str. 24. D-75223 Niefern-Öschelbronn. Study Report Completion Date: 22 October 2009, Study Code S09-00695. Dow AgroSciences unpublished report. DAS Study ID: 090222	Y	Dow AgroSciences	1
KIIIA1 10.5.1/02	Klug, T	2009	Toxicity to the Predatory Mite, Typhlodromus pyri Scheuten (Acari, Phytoseiidae) in the Laboratory (Rate Response Test). eurofins-GAB GmbH, Eutinger Str. 24, D-75223 Niefern-Öschelbronn, Study Report Completion Date: 22 October 2009, Study Code S09-00694. Dow AgroSciences unpublished report, DAS Study ID: 090221	Y	Dow AgroSciences	1

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner	How considered in dRR Study-Status/ Use*
KIIIA1 10.5.2/01	Höhn, P	2010	GF-2540: Toxicity to the Predatory Mite, *Typhlodromus pyri* Scheuten (Acari, Phytoseiidae) Using an Extended Laboratory Test (Rate Response Test). eurofins-GAB GmbH, Eutinger Str. 24, D-75223 Niefern-Öschelbronn. Study Report Completion Date: 08 July 2010, Study Code S10-01125. Dow AgroSciences unpublished report, DAS Study ID: 101369	Y	Dow AgroSciences	1
KIIIA1 10.5.2/02	Höhn, P	2010	GF-2540: Toxicity to the Green Lacewing, *Chrysoperla carnea* Steph. (Neuroptera, Chrysopidae) under Extended Laboratory Conditions. Eurofins Agroscience Services GmbH, Eutinger Str. 24, D-75223 Niefern-Öschelbronn, Study Report Completion Date: 27 July 2010, Study Code S10-01126. Dow AgroSciences unpublished report, DAS Study ID: 101370	Y	Dow AgroSciences	1
KIIIA1 10.6.2/01	Stäbler, D	2010	GF-2540: Acute Toxicity of GF-2540 on Earthworms, *Eisenia fetida* Using an Artificial Soil Test. eurofins-GAB GmbH, Eutinger Str. 24, D-75223 Niefern-Öschelbronn, , Study Report Completion Date: 21 January 2010. Study Code S09-00689. DowAgroSciences, unpublished report, DAS Study No. 090216	Y	Dow AgroSciences	1

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner	How considered in dRR Study-Status/ Use*
KIIIA1 10.6.3/01	Stäbler, D	2010	GF-2540: Sublethal Toxicity of GF-2540 to the Earthworm *Eisenia fetida* in Artificial Soil. eurofins-GAB GmbH, Eutinger Str. 24, D-75223 Niefern-Öschelbronn, Study Report Completion Date: 09 February 2010, Study Code S09-00690. DowAgroSciences, unpublished report, DAS Study No. 090217	Y	Dow AgroSciences	1
KIIIA1 10.6.3/02	Davies, N	2004	RH-24644 metabolite: effects on the reproduction and growth in the earthworm *Eisenia fetida*. Dow AgroSciences unpublished report 040077, CEMS-2253, 12 October 2004	Y	Dow AgroSciences	1
KIIIA1 10.7.1/01	Stäbler, D	2010	GF-2540: Assessment of the Side Effects of GF-2540 on the Activity of the Soil Microflora. eurofins-GAB GmbH, Eutinger Str. 24, D-75223 Niefern-Öschelbronn, 18 January 2010. Study Code S09-00691. DowAgroSciences, unpublished report, DAS Study No. 090218	Y	Dow AgroSciences	1
KIIIA1 10.8.1.3/01	R Eley	2004	Evaluation of the Phytotoxicity of Kerb (propyzamide, 400 SC) Vegetative Vigour Test – Terrestrial Non Target Plants (Based on OECD Guideline 208 B) North Europe 2004. Unpublished report date 15-January 2005. Document number GHE-P- 11015	Y	Dow AgroSciences	3

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner	How considered in dRR Study-Status/ Use*
KIIIA1 10.8.1.2/02	R Eley	2006	Evaluation of the Phytotoxicity of aminopyralid (GF-1601 30 g as/l SL: GLP Vegetative Vigour Test Terrestrial Non Target Plants (Based on OECD Guideline 227) Europe 2006. 20 November 2006. Dow AgroSciences, unpublished report, No. GHE-P -11453	Y	Dow AgroSciences	3
KIIIA1 10.8.1.3/01	Rockliff	2005	Evaluation of the Phytotoxicity of Kerb Flo (propyzamide 400 SC) Seedling Emergence and Seedling Growth Test – Terrestrial Non Target Plants (Based on OECD Guideline 208 A) North Europe 2005. Unpublished report date December 2005. Document number GHE-P-11311	Y	Dow AgroSciences	3
KIIIA1 10.8.1.3/02	R Eley	2006.	Evaluation of the Phytotoxicity of aminopyralid (GF-1601, 30 g as/l, SL): GLP Seedling Emergence and Seedling Growth Test (Based on OECD Guideline 208) Europe 2006. Dow AgroSciences, unpublished report, No. GHE-P -11452, 27	Y	Dow AgroSciences	3

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner	How considered in dRR Study-Status/ Use*
KIIIA1 10.8.1.2/01	C. Rockliff	2013	GF-2540 (aminopyralid, 6 g ai/l, + propyzamide, 500 g a.i./l, SC) - GLP Vegetative Vigour Test - Terrestrial Non Target Plants (based on OECD Guideline 227) - Europe, 2013	Y	Dow AgroSciences	1
KIIIA1 10.8.1.3/01	C. Rockliff	2013	GF-2540 (aminopyralid, 6 g ai/l, + propyzamide, 500 g a.i./l, SC) - GLP Seedling Emergence and Seedling Growth Test - Terrestrial Non Target Plants (based on OECD Guideline 208) - Europe, 2013	Y	Dow AgroSciences	1
KIIIA1 10.8.2.1/01	Rebstock, M.	2010	GF-2540: Growth Inhibition Test with the Freshwater Aquatic Plant, Duckweed, ABC 65884. September 17, 2010. Dow AgroSciences unpublished report, Study Number 101366	Y	Dow AgroSciences	1
KIIIA1 7.1.1/01	[redacted]	2009	GF-2540: Acute Oral Toxicity Up and Down Procedure in Rats document No DR-0430-1331-003; 090334 80212	Y	Dow AgroSciences	1
KIIA 8.5.2/01	Kolk, J.,	1999	Kerb technical: Chronic toxicity test with midge larvae (Chironomus riparius) in a water/sediment system 99GC-0110 ICS No. 42745	Y	Dow AgroSciences	1
KIIA 8.9.2/01	Davies, N.	2004	RH-24644 Metabolite - Effects on reproduction and growth in the Earthworm Eisenia fetida 2361167 / ARW2006-156 / 040077 ! CEMS-2253	Y	Dow AgroSciences	1
KIIA 8.10/01	Rix, S.	2004	RH-24644 Metabolite - Determination of effects on soil microflora activity according to OECD Test Guidelines OECD 216 (2000) and OECD 217 (2000), Study Code 040076 ! CEMS-2257	Y	Dow AgroSciences	1

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner	How considered in dRR Study-Status/ Use*
KIIIA1 7.1.1/01	[redacted]	2009	GF-2540: Acute Oral Toxicity Up and Down Procedure in Rats document No DR-0430-1331-003; 090334 80212	Y	Dow AgroSciences	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

KIIA 8 Ecotoxicological Studies on the Active Substance

IIA 8.5.2 Effects on sediment dwelling organisms- chronic test. analytical data on concentrations in the test media

Reference:	KIIA 8.5.2/01
Report	Kolk, J., 1999 Kerb technical: Chronic toxicity test with midge larvae (*Chironomus riparius*) in a water/sediment system 99GC-0110 ICS No. 42745
Guideline(s):	Yes OECD Guideline 219, Draft, May 1998
Deviations:	No deviations that are expected to have influenced the outcome of the study
GLP:	Yes
Acceptability:	Yes
Original study evaluation by zRMS since no evaluation was submitted by the applicant	

Materials and methods

Propyzamid (Lot # RB04-92; 98.8% active ingridient) was tested. 2-3d old first instar larvae of Chironomus riparius (4 beakers per test concentration and control with 25 animals each) were exposed in a static test system for 28 days to initial nominal concentrations in the overlying medium (spiked water application) of 0.01, 0.02, 0.04, 0.08, 0.16 and 0.32 mg a.i./L of a water-sediment system. Dissolved oxygen concentrations ranged in the water phase from 5.1-8.8 mg O2/L, the water pH values ranged from 8.02 to 8.79 and the water temperature ranged from 20.1°C to 21.8°C.

Recoveries of propyzamide were measured three times during the study: 1 hour, 7 days and 28 days after application in the overlying water and the pore water of the sediment.

Results and discussions

Analytical Findings: Chemical analysis of overlying water and pore water over time reflect expected aquatic fate data with high recoveries of ≥100% for all test concentrations at the beginning of the exposure period in the overlying water (0.01, 0.023, 0.048, 0.088, 0.18, 0.34 mg/l.). Up to day 28, mean measured concentrations in the overlying water decreased (day 7: 0.005, 0.012, 0.025, 0.048, 0.1, 0.19 mg/l.; day 28: 0.004, 0.009, 0.017, 0.033, 0.068, 0.13 mg/l.).

Biological findings: Start of emergence was on day 11-12 for the control/solvent control and test concentrations. The validity criteria according to OECD Guideline 219, Draft, May 1998 were met.

Influence on emergence and development rate after 28 days (based on measured initial concentrations of the test item in the overlying water):

Concentration initial mean measured mg a.s./L	Mean Emergence rate (sum of midges emerged / sum of larvae introduced) ± sd (pooled sex)	Mean development Rate (1/d) ± sd (pooled sex)
Control	0.8 ± 0.09	0.069 ± 0.004
Solvent control	0.91 ± 0.09	0.073 ± 0.001
0.01	0.73 ± 0.1	0.072 ± 0.001
0.023	0.91 ± 0.09	0.074 ± 0.003
0.048	0.89 ± 0.05	0.073 ± 0.004
0.088	0.93 ± 0.1	0.071 ± 0.002
0.18	0.85 ± 0.04	0.07 ± 0.003
0.34	0.88 ± 0.06	0.071 ± 0.003

No statistically significant difference in the ratio of emerged male and female midges was observed between the control and the solvent control (t-test, p=ß.383). Therefore the results of the control and the solvent control were combined for further analysis. Since no statistically significant differences between dose groups were found, male and female results were pooled for further evaluation

Since no statistically significant differences in the development rate between the control and the solvent control was detected (t-test, p=0.102), the results of both were combined for further anaylsis. Subsequent analysis yielded no statistically significant differences in the development rate between dose groups (Anova, p=0.456). The resulting NOEC for this parameter based on initioal mean measured concentrations of propyzamide in the overlying water was 0.34 mg a.s./L.

Since no statistically significant differences in the numer of emerged midges between the control and the solvent control was detected (t-test, p=0.125), the results of both were combined for further anaylsis. Subsequent analysis yielded no statistically significant differences in the numer of emerged midges between dose groups (Anova, p=0.102). The resulting NOEC for this parameter based on initioal mean measured concentrations of propyzamide in the overlying water was 0.34 mg a.s./L.

Conclusion

Test conditions met all validity criteria, given by the mentioned guideline. Results are based on measured initial concentrations in mg a.s./L of the test item in the overlying water:

Endpoints	**NOEC [mg a.s./L]**
Emergence ratio (pooled sex)	0.34
Development rate (pooled sex)	0.34

Comments of zRMS [Commenting box]

Study Comments:	none

Agreed Endpoints:	NOEC (28 d) = 0.34 mg a.s./L (emergence and development)

KIIA 8.9.2 Effects on earthworms - Sublethal effects on earthworms

Reference:	KIIA 8.9.2/01
Report	Davies, N (2004) RH-24644 metabolite: effects on the reproduction and growth in the earthworm *Eisenia fetida.,* Dow AgroSciences unpublished report 040077, CEMS-2253, 12 October 2004 ICS No: 63609
Guideline(s):	OECD 222 (2004); ISO 11268-2 (1998)
Deviations:	No deviations that are expected to have influenced the outcome of the study
GLP:	Yes
Acceptability:	Yes
Original study evaluation revised by zRMS	No

Materials and methods

A 56-day reproduction study with Eisenia fetida based on test guideline ISO 11268-2 (1998) was carried out using a sample of RH-24644 metabolite (batch number TSN104666, purity 98.0%). Six nominal application rates of RH-24644 were tested; 0.35, 0.70, 1.38, 2.75, 5.50 and 11.0 mg RH-24644 metabolite/kg soil plus a water only control. Each treatment was replicated four times. The test item was incorporated into the test substrate. The adult worms were removed after 28 days and weighed, leaving the juveniles to develop in the treated soil for a further 28 days. The numbers of juveniles and cocoons present in each vessel were then counted. The treated groups were compared for numbers of juveniles, unhatched cocoons, and change in biomass and mortality of adult worms with the water only controls.

A separate reference study was carried out using the reference items, carbendazim (technical material) incorporated into the soil and Carbendazim Flowable applied to the surface of the soil (CEMS-2177, final report number CEMR-2177, issued 06 February 2004). The results were comparable to ISO 11268-2 (1998). Annex F of this guideline states that the reference item, when incorporated into the soil, should have a significant effect ($\alpha = 0.05$) at a concentration between 1 mg and 5 mg carbendazim/kg dry soil. A significant effect in the incorporated test in that study was seen at 1.8 mg carbendazim/kg dry soil for earthworm reproduction. Annex D of the guideline requires that the reference item, when applied by surface application, should have a significant effect ($\alpha = 0.05$) at an application rate equivalent of between 250 to 500 gai/ha. The significant effect in the surface applied test in that study was seen at 0.358 L Carbendazim Flowable/ha, nominally equivalent to 179 g carbendazim/ha, which was slightly below that stated in the guideline. However, as this was a formulated product, the toxicity of the product was dependent on the total mix of the product and not only the active ingredient. As such, the results were comparable

Results and discussion

The validity criteria required by test guideline ISO 11268-2 (1998) were met for this study. These were:- (1) the mortality rate of adult worms was less than 10% among the controls (0% mortality was actually seen in this study). (2) The coefficient of variance for juvenile numbers in the control replicates was less than 30% (the actual value in this study was 17%). (3) The numbers of juveniles present in all the controls were greater than 30 per container (the actual numbers found in this study ranged from 123 to 173 per container). The test item RH-24644 metabolite caused no statistically significant effects ($P \leq 0.05$) on adult mortality and growth or on juvenile and cocoon production in the earthworm *Eisenia fetida* at any of the rates tested, compared to the control. A summary of the results is given in the following table.

Table 1: Long term effects of RH-24644 metabolite on earthworms

Treatment mg RH-24644/kg soil	**Adult worms**		**Juveniles**	**Cocoons**
	%Mortality day 28	**Mean % weight change from day 0 to 28**	**Mean juveniles / worm surviving adult worm on day 56**	**Mean unhatched cocoons per surviving adult worm on day 56**
0 (control)	0	+49.1	14.9	0.1
0.35	2.5	+57.5	12.7	0.1
0.70	0	+55.0	17.3	0.1
1.38	0	+48.6	16.3	0.2
2.75	0	+58.9	15.2	0.1
5.50	0	+57.2	14.2	0.3
11.0	0	+44.3	10.9	0.2

Conclusions:

The no-observed-effect concentration (NOEC) was determined to be > 11.0 mg RH-24644 metabolite/kg soil for adult mortality, biomass change and juvenile production. Therefore the lowest-observed-effect concentration (LOEC) was > 11.0 mg RH-24644 metabolite/kg soil for adult mortality, biomass change and juvenile production.

As the logKow for RH-24644 is > 2.0 and the study was conducted in the artificial substrate of the earthworm laboratory test the corrected endpoints are equivalent to a NOECcorr of >5.5 mg a.s./kg soil.

Study Comments: KIIA 8.9.2/01	None
Agreed endpoint/s: KIIA 8.9.2/01	$NOEC_{corr}$ = 5.5 mg RH 24644 /kg soil dw

IIA 8.10. Effects on soil microbial activity

Reference:	KIIA 8.10/01

Report	Rix, S., 2004 RH-24644 Metabolite - Determination of effects on soil microflora activity according to OECD Test Guidelines OECD 216 (2000) and OECD 217 (2000), Study Code 040076 ! CEMS-2257 ICS No: 80226 / 80227
Guideline(s):	OECD 216 (2000) and OECD 217 (2000)
Deviations:	No deviations that are expected to have influenced the outcome of the study
GLP:	Appendix 3 Yes

Appendix 4 Acceptability:	Appendix 5 Yes
Original study evaluation revised by zRMS since no evaluation was submitted by the applicant	

Test material

Test item:	RH-24644 (propyzamide metabolite),
Purity	98%
Description:	Clear liquid
Test item No./Lot No.:	NB32156-83

Test system	
Organism:	Soil micro organisms
Study Type:	laboratory study with OECD guideline natural soil, assessed for: Nitrate formation Microbial respiration
GLP Status:	GLP-Laboratory certified by the Department of Health of the Government of the United Kingdom
Guidelines followed:	OECD 216 and 217 (2000)
Guideline deviations reported by Study Director:	None
Deviations to the Study Plan:	Stock solutions were prepared using 100g amounts of sand, not 50g of sand as stated in Study plan. No impact of this deviation on the study outcome is expected The soils were adjusted to 30% of the maximum water holding capacity for acclimation, not 45% as stated in the study plan. No impact of this deviation on the study outcome is expected as the soils were adjusted to 45% on day zero of the test, prior to dosing.
Duration of study:	28 days
Parameters measured:	Nitrogen transformation: analysis of nitrate, nitrite ion concentration and ammonium in extracted soil samples, soil water content pH Microbial respiration: soil respiration rates after addition of glucose soil water content pH
Observation intervals:	0, 7, 14 and 28 days after application
Test concentrations:	1.1 and 5.5 mg /kg soil dry weight (820 and 4120 g /ha)
Toxic reference item:	Dinoterb at 1 and 10 mg a.i./kg soil dry weight
Method of application:	Test item and toxic reference item dissolved in acetone, draed onto sand. mixed into the soil
Environmental conditions:	Conducted in the dark at 20 ± 2 °C; pH: 6.43-6.58
Soil properties:	Soil source: Natural soil, location "Club field", Waltham Place Estate, Church Hill, White Waltham, Berkshire, SL6 3JH, United Kingdom Moisture content of soil at start: 30 % of MWHC (maximum water holding capacity) Moisture content of soil at end: 44.8-45.2 % of MWHC Sand (%): 75

Organic Carbon(%): 1.5
Textural classification: Sandy loam (Uk system)

Methodology

Incorporation of the test item at two test concentrations into standard soil according to OECD 216 and 217 for determination of effects on nitrogen turnover (mineralisation) and carbon transformation (short-term substrate-induced respiration); Incubation of test vessels in the dark at 20 ± 2 °C; Sampling of soil at 0, 7, 14, and 28days after application; Determination of pH, dry mass, nitrogen turnover and short-term respiration; Comparison of the results with the untreated control; The test was terminated after 28 days for nitrogen turnover and after 28 days for short-term respiration, since by this time the differences between treated and untreated soils were below 25 %.

Tabel 1: Effects of RH-24644on the Nitrate formation rate

Interval sampling days	Control	RH-24644 1.1 mg/kg soil dry weight		RH-24644 5.5 mg/kg soil dry weight	
	[mg/kg/day [1]]	[mg/kg/day [1]]	[%[2]]	[mg/kg/day [1]]	[%[2]]
0-7	0.633	0.608	-4	0.723	+14.2
7-14	0.898	0.928	+3	0.87	-3.1
14-28	1.46	1.45	-0.8	1.5	+2.6
1: mean mg NO3-N/kg soil dry weight per day 2: deviation from control					

Table 2: Effects of RH-24644on the Respiration rate

Days after application	Control	RH-24644 1.1 mg/kg soil dry weight		RH-24644 5.5 mg/kg soil dry weight	
	[mg/kg/h [1]]	[mg/kg/h [1]]	[%[2]]	[mg/kg/h [1]]	[%[2]]
0	26.15	27.61	+5.6	30.07	+15
7	25.78	27.08	+5	27.6	+7.1
14	24.11	24.48	+3	25.43	+5.5
28	22.06	22.94	+4	25.61	+16
1: mean mg CO2/h/kg soil dry weight per day 2: deviation from control					

Conclusions:

Based on the results of this study and in accordance with OECD Guidelines 216 and 217, the test item had no adverse effect on soil respiration and on nitrogen turnover (< 25 % deviation between treatments and control) in a field soil tested up to 5.5 mg/kg soil dry weight at study termination after 28 days of exposure. The study fulfilled the validity criteria according to OECD 216/217.The range of the percentage of variation within the control samples for nitrate nitrogen concentrations was from +2.9% to +3.1%. The range of percentage of variation within the control samples for CO_2 concentrations was from -3.4% to +3.1%..

Study Comments: KIIA 8.10/01	None
Agreed endpoint/s: KIIA 8.10/01	< 25 % effects on microbial activity at 1.1 and 5.5 mg RH-24644/kg dry soil

KIIIA1 7 Toxicological Studies and Exposure Data and Information

KIIIA1 7.1.1 Acute oral toxicity

Reference:	KIIIA1 7.1.1/01
Report	[redacted], 2009 GF-2540: Acute Oral Toxicity Up and Down Procedure in Rats document No DR-0430-1331-003; 090334 80212
Guideline(s):	OECD 425
Deviations:	No deviations that are expected to have influenced the outcome of the study
GLP:	Yes
Acceptability:	Yes/
Original study evaluation revised by zRMS	No

Materials and methods

An initial limit dose of 5,000 mg/kg was administered to one healthy female rat by oral gavage.

Results and discussions

Due to the absence of mortality in this animal, two additional females received the same dose level, simultaneously. One of these animals died; therefore a fourth animal was dosed at 5,000 mg/kg. Due to mortality in this animal, a fifth animal was dosed at the same dose level. Since three of five animals survived, no additional animals were tested. Females were selected for the test because they are frequently more sensitive to the toxicity of test compounds than males. All animals were observed for mortality, signs of gross toxicity, and behavioral changes at least once daily for 14 days after dosing or until death occurred. Body weights were recorded prior to administration and again on Days 7 and 14 (termination) following dosing or after death.

Necropsies were performed on all animals. Two animals died within four days of test substance administration. Clinical signs noted in the decedents prior to death included hypoactivity, hunched posture and/or piloerection and reduced fecal volume. Following administration, two surviving rats exhibited piloerection. However, the animals recovered by Day 1 and along with the other survivor appeared active and healthy and gained body weight for the remainder of the 14-day observation period. Gross necropsy of the decedents revealed red intestines. No gross abnormalities were noted for any of the euthanized animals necropsied at the conclusion of the 14-day observation period.

Conclusion

Under the conditions of this study, the acute oral LD50 of GF-2540 was greater than 5,000 mg/kg of body weight in female rats.

Comments of zRMS [Commenting box]

Study Comments:	None
Agreed Endpoints:	Rat oral LD50 of GF-2540 >5000 mg/kg of body weight

KIIIA1 10 Ecotoxicological Studies on the Plant Protection Product

IIIA1 10.2.2.1 Effects on aquatic organisms - Fish acute toxicity LC50, freshwater, cold-water species

Reference:	KIIIA1 10.2.2.1/01
Report	[redacted], 2010 GF-2540: Acute Toxicity to the Rainbow Trout, *Oncorhynchus mykiss*, Determined Under Static-Renewal Test Conditions. Dow AgroSciences unpublished report, Study Number 101368 ICS No: 80801
Guideline(s):	OECD 203
Deviations:	No deviations that are expected to have influenced the outcome of the study
GLP:	Yes
Acceptability:	Yes
Original study evaluation revised by zRMS	Yes

Test material

Test item:	GF-2540
Purity:	0.58 wt.% aminopyralid potassium (0.49 wt.% aminopyralid a.e.), 43.6 wt.% propyzamide
Description:	Brown liquid
Lot No./Batch No. :	C2241-38-B

Test system	
Organism (Species):	Rainbow Trout (*Oncorhynchus mykiss*)
Study Type:	Acute
GLP Status:	GLP
Guidelines followed:	OECD guideline 203
Guideline deviations reported by Study Director:	None
Duration of study:	96 hours
Test conditions:	Static-renewal
Parameters measured:	Survival, sublethal effects
Observation intervals:	24 hours
Age range of fish at test initiation:	Juvenile
Weight range of fish at study initiation:	0.523 to 0.981 g blotted wet weight
Range of fish length at study initiation:	40 to 45 mm total length

Test concentrations:	Nominal: 0 (Control), 6.5, 13, 25, 50, and 100 mg/L Mean calculated: < MQL (control), 6.10, 11.4, 16.7, 19.8, and 30.4 mg GF-2540/L
Analytical confirmation of test concentrations:	0, 24, 72, and 96 hours
Reference substance:	propyzamide
No. of holding days before dosing:	39 days
Number of fish per dose group:	7
Number of fish per control group:	7
Feeding:	None
Environmental conditions:	Temperature: 14.6 to 15.5°C Photoperiod: 16 hour light:8 hour dark, 489 lux Dissolved Oxygen concentration: 7.9 to 10.7 mg/L Bioloading: 0.277 g/L pH: 7.5 to 8.7 Water alkalinity: 160 mg CaCO3/L Water hardness: 140 mg CaCO3/L Water conductivity: 331 µS

Methodology

A 96-hour static-renewal test was performed with test concentrations of 0 (control), 6.5, 13, 25, 50, and 100 mg GF-2540/L. Test fish were impartially assigned to treatment replicates by adding one fish per chamber until seven fish were present in each test chamber. There was one replicate per test treatment. Observations for mortality and sublethal responses were made at 24, 48, 72, and 96 hours. Temperature, pH, and dissolved oxygen concentration were measured in each test chamber on a daily basis. In addition, a continuous record of the temperature from the water bath was also maintained. Alkalinity, hardness, and conductivity were measured in a sample of the dilution water at test initiation.

Table 1 Effect of GF-2540 on mortality

Treatment (mg GF-2540/L)		No. of fish	Cumulative mortality				
Nominal	Mean Calculated		24-h	48-h	72-h	96-h	Total (%)
Negative control	<MQL	7	0	0	0	0	0
6.5	6.10	7	0	0	0	0	0
13	11.4	7	0	0	0	0	0
25	16.7	7	0	0	0	0	0
50	19.8	7	0	0	0	0	0
100	30.4	7	0	0	0	1	14
96 hour LC50		>30.4 mg GF-2540/L (measured)					
95% C.I.		Could not be calculated					
96 hour NOEC		11.4 mg GF-2540/L (measured)					

Table 2 Sub-lethal effects of GF-2540

Treatment (mg GF-2540/L)		**Observation period % affected (number of fish showing different sublethal signs of toxicity shown in brackets)**			
Nominal	**Mean Calculated**	**24-h**	**48-h**	**72-h**	**96-h**
Negative	<MQL	0	0	0	0

control					
6.5	6.10	0	0	0	0
13	11.4	0	0	29 (2 D)	43 (3 D)
25	16.7	57 (3 D, 1 D+B)	71 (4 D, 1 D+L, 1 D+S)	86 (5 D, 1 D+B)	86 (5 D, 1 D+B)
50	19.8	100 (7 D)	100 (7 D)	100 (7 D)	100 (7 D)
100	30.4	100 (6 D, 1 D+S)	100 (6 D, 1 D+S)	100 (5 D, 1 D+L, 1 D+S)	100 (5 D, 1 D+B)

D=Discoloured; B = on bottom of the test chamber; L = Lethargic; S = Surfacing

Conclusions

Based on mean calculated concentrations, the estimated 24-, 48-, 72-, and 96-hour LC50 was >30.4 mg GF-2540/L, the highest concentration tested. The slope of the 96-hour concentration response curve could not be calculated. The 96-hour NOEC was 6.1 mg GF-2540/L, based on the occurrence of sublethal effects above this test substance concentration.

Study Comments: IIIA 10.2.2.1/01	The 96-hour NOEC was 6.1 mg GF-2540/L, based on the occurrence of sublethal effects above this test substance concentration.
Agreed endpoint/s: IIIA 10.2.2.1	96 hour LC50 >30.4 mg GF-2540/L (measured)

IIIA1 10.2.2.2 Effects on aquatic organisms - Acute toxicity (24 & 48 h) for Daphnia preferably Daphnia magna

Reference	KIIIA1 10.2.2.2/01
Report	Bergfield, A., 2010 GF-2540: Acute Toxicity to the Water Flea, *Daphnia magna*, Determined Under Static-Renewal Test Conditions. ABC Laboratories, Columbia, Dow AgroSciences unpublished report, Study Number 101367 Missouri, ABC study number 65882. 7 September 2010.
Guidelines:	OECD 202
Deviations	No deviations that are expected to have influenced the outcome of the study
Acceptability	Yes
GLP	Yes
Original study evaluation revised by zRMS	No

Test material

Test item:	GF-2540
Purity:	0.58 wt.% aminopyralid potassium (0.49 wt.% aminopyralid a.e.), 43.6 wt.% propyzamide
Description:	Brown liquid

Lot No./Lot no. :	C2241-38-B
Test system	
Organism (*Species*):	Water flea (*Daphnia magna*)
Study Type:	Acute
GLP Status:	GLP
Guidelines followed:	OECD guideline 202
Guideline deviations reported by Study Director:	None
Duration of study:	48 hours
Test conditions:	Static-Renewal
Parameters measured:	Immobility
Observation intervals:	24 hours
Age range of water fleas at test initiation:	<24 hours
Test concentrations:	Nominal: 0 (control), 6.5, 13, 25, 50, and 100 mg GF-2540/L Mean Calculated: <MQL (Control), 5.75, 11.7, 19.1, 21.5, and 34.5 mg GF-2540/L
Analytical confirmation of test concentrations:	0, 24, and 48 hours
Reference substance:	propyzamide
Number of water fleas per dose group:	20
Number of water fleas per control group:	20
Feeding:	None
Environmental conditions:	Temperature: 20.3 to 21.8°C Photoperiod: 16 hour light:8 hour dark Dissolved Oxygen concentration: 7.8 to 9.4 mg/L pH: 7.8 to 8.6 Water alkalinity: 168 mg $CaCO_3$/L Water hardness: 166 mg $CaCO_3$/L Water conductivity: 336 µS

Methodology

A definitive test was performed at nominal concentrations of 0 (control), 6.5, 13, 25, 50, and 100 mg GF-2540/L. Five neonates (<24-hours old) were added to each of four test chambers per treatment at the start of the test. The daphnids were observed for immobility and sublethal effects at approximately 24 and 48 hours after test initiation. Total hardness, total alkalinity, and conductivity were measured in the dilution water at test initiation. Temperature, dissolved oxygen concentration, and pH were measured in all treatment replicates daily. A thermistor probe was located in a surrogate test chamber to continuously record temperature.

Table 1 Effect of GF-2540 on Immobility

Treatment (mg GF-2540/L)		No. of water fleas	Cumulative percent immobile	
Nominal	**Mean Calculated**		**24-h**	**48-h**
Negative control	<MQL	20	0	0
6.5	5.75	20	0	0
13	11.7	20	0	0
25	19.1	20	0	0
50	21.5	20	0	0

100	34.5	20	0	5
EC_{50}		>34.5 mg GF-2540/L		
95% C.I.		Could not be calculated		
NOEC		34.5 mg GF-2540/L		

Conclusions

Based on mean calculated concentrations, the 24 and 48-hour EC_{50} value was estimated to be >34.5 mg GF-2540/L, the highest concentration tested. The slope of the 48-hour concentration-response line was unable to be determined by Trimmed Spearman Karber analysis. No sublethal effects were noted during the definitive test. The 48-hour NOEC was 34.5 mg GF-2540/L, based on mean calculated concentrations and a lack of statistically significant immobility and sublethal effects at this and all lower test substance concentrations.

Study Comments: IIIA 10.2.2.2/01	None
Agreed endpoint/s: IIIA 10.2.2.2	*Daphnia magna* acute EC50(48h) >34.5 mg Prod./L (mean measured)

IIIA1 10.2.2.3 Effects on aquatic organisms - Effects on algal growth and growth rate

Reference	KIIIA1 10.2.2.3/01
Report	Rebstock, M. 2010 GF-2540: Growth Inhibition Test with the Unicellular Green Alga, *Pseudokirchneriella subcapitata*. Dow AgroSciences unpublished report, Study Number 101365. ABC Study No. 65881. 17 September 2010.
Guidelines:	OECD 201
Deviations	No deviations that are expected to have influenced the outcome of the study
Acceptability	Yes
GLP	Yes
Original study evaluation revised by zRMS	No

Test material

Test item:	GF-2540
Purity:	0.58 wt.% aminopyralid potassium (0.49 wt.% aminopyralid a.e.), 43.6 wt.% propyzamide
Description:	Brown liquid
Lot No./Batch No. :	C2241-38-B

Test system

Organism (*Species*):	Freshwater Green Algae, *Pseudokircheriella subcapitata*
Study Type:	laboratory study assessing algal growth static
GLP Status:	GLP
Guidelines followed:	OECD Guideline 201

Guideline deviations reported by Study Director:	None.
Duration of study:	72 hrs
Parameters measured:	Cell density, growth rate, yield
Environmental conditions:	Test solution pH (range): 7.5 to 8.5 Test solution temperature (range): 22.9 to 24.0°C Temperature (range): Within the 24 ± 2°C specified in the protocol. Photoperiod: Continuous light. Light intensity (range): 8,140 to 8,432 lux
Observation intervals:	0, 24, 48, 72 hours
Test concentrations:	Nominal: 0 (Control), 0.31, 0.63, 1.3, 2.5, 5.0, and 10 mg GF-2540/L Mean calculated concentrations: <MQL (control), 0.318, 0.567, 1.26, 2.38, 4.63, 9.72 mg GF-2540/L
Age of inoculum	4 days old
Acclimation period/conditions	The prepared cultures were maintained in a temperature-controlled environmental chamber under continuous light. Periodically, new cultures were cloned from an existing culture derived from the parent stock. All cultures were maintained under the same conditions as those used for testing.
Initial cell density	5 x 10^3 cells/mL
Growth medium	Name: AAP pH at test initiation: 7.5 (control solution) pH at test termination: 8.5 (control solution) Constant stirring?: Yes, all test solutions were swirled on an orbital shaker table at 100 rpm throughout the test.
Method of test item added to the test medium	A 0.010 mg GF-2540/mL primary standard was prepared 24 August 2010, by transferring 0.0100 g of GF-2540 to a 1000 mL glass volumetric flask, and bringing the flask to volume with test medium. This primary standard was used as the highest test substance treatment and the five lower test substance treatments, each at a volume of 500 mL, were prepared individually using appropriate volumes of the primary standard and test medium. The control consisted of test medium only.
No. of control replicates	6
No. of test concentration replicates	3
Analytical verification:	Method: measuring concentrations of propyzamide using GC-NCI-MSD. Samples taken: Test initiation and termination. Limit of Detection: Not determined. Limit of Quantitation: Reported as the minimum quantifiable limit (MQL) and was 0.0485 mg propyzamide/L or 0.111mg GF-2540/L. Recoveries from QC fortifications: (range) 82 to 109% of the nominal concentrations.

Methodology

The exposure flasks were 250-mL Erlenmeyer flasks with foam stoppers and labeled with study number, treatment, replicate, and grid position. The control was replicated six times and each test substance treatment was replicated three times. Each replicate contained 100 mL of the appropriate parent solution. An additional replicate of the 0.31 mg GF-2540/L nominal test substance treatment, containing 100 mL of the appropriate parent solution, was also prepared and used to evaluate the potential for incorporation of the test substance into the algal biomass (abiotic replicate). At test initiation, all biotic replicates were inoculated with 1.0 mL of an algal concentrate containing approximately 5.0 x 10^5 cells/mL, resulting in a final density of approximately 5.0 x 10^3 cells/mL for each flask. The replicates were inoculated with algae within 30 minutes after test solution preparation. At 24, 48, and 72 hours (±1 hour), cell density was measured in all replicates of the control, as well as replicates A, B, and C of each test substance treatment by direct microscopic counting with a hemacytometer. The abiotic replicate was not inoculated with algae.

Effects of GF-2540 on algal growth:

Hour	EC Type	EC Value [mg GF-2540/L]	95% Confidence Limits [mg GF-2540/L]	NOEC [mg GF-2540/L])
72	E_rC_{10}	3.2	3.1 to 3.4	
	E_rC_{20}	4.1	4.0 to 4.3	
	E_rC_{50}	6.4	6.2 to 6.5	Growth rate: 0.63
	E_yC_{10}	1.1	0.96 to 1.2	
	E_yC_{20}	1.5	1.4 to 1.6	
	E_yC_{50}	2.7	2.6 to 2.8	Yield: 0.63

Conclusions

The test acceptability criteria were met for this study. The number of algal cells in the control at test termination was 139 times the number initially inoculated to verify logarithmic phase growth and greater than the 16 fold increase required. The mean coefficient of variation for daily growth rates in the control replicates during the course of the test was 9%, less than the 35% acceptance limit for this parameter. The coefficient of variation of average specific growth rates during the whole test period in control replicates was 2%, less than the 7% acceptance limit for this parameter. The pH in the control increased 1.0 units based on reported values, less than the 1.5 units allowed during the study. This study satisfies the OECD guideline requirement for a growth inhibition test with *Pseudokirchneriella subcapitata*. EyC_{50}(72h) = 2.7 mg GF-2540/L; ErC_{50}(72h) = 6.4 mg GF-2540/L; NOEC = 0.63 mg GF-2540/L

Study Comments: IIIA 10.2.2.3/01	None
Agreed endpoint/s: IIIA 10.2.2.3	EyC_{50}(72h) = 2.7 mg GF-2540/L ErC_{50}(72h) = 6.4 mg GF-2540/L NOEC = 0.63 mg GF-2540/L

IIIA1 10.4 Effects on bees – Acute oral and contact toxicity (IIIA1 10.4.1)

Report:	**KIIIA1 10.4.1/01**
	Kling, A. (2010): Final Report Amendment 1 - GF-2540 - Acute Oral and Contact Toxicity to Honeybee *Apis mellifera* L. in the Laboratory –. Trial code: S09-00693-L1_BLEU.eurofins-GAB GmbH, Niefern-Öschelbronn, Germany
Document No:	090219 and 090220
Guidelines:	OECD 213 and 214
GLP	Yes

Materials and Methods

In a test under laboratory conditions GF-2540 was offered to worker honey bees (*Apis mellifera* L.) in oral and contact route. Treatments with the test substance, the reference item (dimethoate) and the control were carried out in 5 replicates containing 10 bees for the oral and contact test.

Test species: Worker honey bees *Apis mellifera carnica* L.

Test substance: active substances (a.s.) of GF-2540:
1. propyzamide 43.6% wt/wt
2. aminopyralid potassium 0.55% wt/wt

Control: oral: 50% (w/v) sucrose solution
contact: deionised water

Toxic standard: Perfekthion EC®; dimethoate: 400 g/L
oral: 0.08, 0.11, 0.14, 0.18 µg a.s./bee
contact: 0.10, 0.15, 0.23, 0.34 µg a.s./bee

Test Item: limit test:
oral (GF-2540 sucrose solution): 300 µg product/bee (actual: 330.25 µg product/bee)
contact (GF-2540 diluted in deionised water): 300 µg product/bee

Bees per dose: 10

Replicates: 5

Exposure: 48 h

Oral toxicity study:

In a limit test, five replicates of 10 bees were fed with a sugar/water solution containing GF-2540. The tested concentration was 300µg product/bee (actual: 330.25 µg product/bee). An untreated sugar/water solution was used as water control and dimethoate was used as toxic standard. The test was conducted at darkness and a temperature of 23.5 - 25.5°C and humidity between 48 and 58%. 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 limit test, five replicates of 10 bees were exposed to GF-2540, administered topically in a small droplet to the thorax of each bee. The tested concentration was 300µg product/bee. For the control deionised water was used. Dimethoate solved in deionised water was used as toxic standard. The test was conducted at darkness and a temperature of 23.5 - 25.5°C and humidity between 48 and 58%. Biological observations, including mortality and behavioural changes were recorded at 4, 24 and 48 hours after application. Results are based on nominal concentrations of the product per bee.

Findings
Oral toxicity study:
At the end of the oral toxicity test (48 hours after application), there was 4% mortality at 330.25 µg product/bee. No mortality was recorded in the control group. No sub-lethal effects were recorded in any test or control group. The 24-hour oral LD50 value for dimethoate was 0.13 µg a.s./bee (95% confidence limits: 0.12 - 0.139 µg a.s./bee).

Treatment	Target dose	Actual dose ingested	**Mortality**		**Corrected mortality [%]**
	(µg product/bee)		**24 h**	**48 h**	**48 h**
Control (sugar solution)	--	--	0.0	0.0	-
Test item: GF-2540	300	330.25	2.0	4.0	-
48 h LD_{50}		> 330.25 µg product/bee			

Contact toxicity study:
At the end of the contact toxicity test (48 hours after application), no mortality occurred. Furthermore, no mortality was recorded in any control group and no sub-lethal effects were recorded in any test or control groups.
The 24-hour contact LD_{50} value for dimethoate was 0.22 µg a.s./bee (95% confidence limits: 0.156 - 0.212 µg a.s./bee).

Treatment	Applied dose (µg product/bee)	**Mortality [%]**		**Corrected mortality [%]**
		24 h	**48 h**	**48 h**
Control (2 µL deionised water)	--	2.0	4.0	-
Test item: GF-2540	300	0.0	0.0	-4.2
48 h LD_{50}	> 300 µg product/bee			

Conclusions
The results can be considered as valid, as all validity criteria of the test were met: control mortality is 0% for both tests, LD_{50} (24 h) of the toxic standard in the oral test equals 0.13 µg a.s./bee, LD_{50} (24 h) of the toxic standard in the contact test equals 0.22 µg a.s./bee.
In the oral toxicity test of GF-2540, 4.0% mortality occurred over the whole 48-hour observation period. In the contact toxicity test no mortality occurred. No behavioural effects were observed.

The LD_{50} (48 h) was > 330.25 µg product/bee in the oral toxicity test and > 300 µg product/bee in the contact toxicity test.

Study Comments: IIIA 10.4.1	None
Agreed endpoint/s: IIIA 10.4.1	48 h LD_{50} > 300 µg product/bee

IIIA1 10.5.1 Effects on arthropods other than bees - Effects on sensitive species already tested, using artificial substrates/01

Reference	KIIIA1 10.5.1/01
Report	Klug, T., 2009 GF-2540: Toxicity to the Aphid Parasitoid. Aphidius rhopalosiphi De Stefani Perez (Hymenoptera. Braconidae) in the Laboratory (Rate Response Test). Study Code S09-00695. Dow AgroSciences unpublished report. DAS Study ID: 090222.
Guidelines:	IOBC (Mead-Briggs et al. 2000). ESCORT I Guidance Document (Barrett et al. 1994) and ESCORT II Guidance Document (Candolfi et al. 2001)
Deviations	No deviations that are expected to have influenced the outcome of the study
Acceptability	Yes
GLP	Yes
Original study evaluation revised by zRMS	No

Test material

Test item:	GF-2540
Purity:	1. propyzamide 43.6 % wt/wt 2. aminopyralid potassium 0.58 % wt/wt
Description:	liquid, light brown
Lot No./Batch No. :	C2241-38-B

Test system

Organism (*Species*):	Parasitic wasp (*Aphidius rhopalosiphi)*
Study Type:	Tier 1 laboratory study. glass plates for mortality and barley plants for fecundity
GLP Status:	GLP
Guidelines followed:	IOBC (MEAD-BRIGGS *et al.* 2000). ESCORT I Guidance Document (BARRETT *et al.* 1994) and ESCORT II Guidance Document (CANDOLFI *et al.* 2001)
Guideline deviations reported by Study Director:	None
Study design:	Assessments of mortality measured 48 hrs after treatment and parasitisation 14 days after treatment. 4 replicates. each consisting of 10 wasps in one arena per test concentration for mortality phase.
Test concentrations:	47, 212, 425, 850 and 1700 mL GF-2540/ha
Environmental conditions:	Temperature: 18.5 to 21.0 °C Relative Humidity: 61 to 86 % Photoperiod: long day conditions 16 hrs light / 8 hrs dark Light intensity: 800 lux - 1020 lux (exposure and 24 h

	parasitation), 7800 - 10000 lux (reproduction) Feeding: honey-agar-water solution
Reference substance:	Perfekthion (a.s. 400 g/L dimethoate)

Methodology

For assessment of the mortality of *Aphidius rhopalosiphi* adults wasps less than 48 hrs old were exposed for 48 hrs to an untreated control and to fresh dried residues of GF-2540 applied to glass plates at five nominal rates. A toxic reference and a water treated control were also included in the test. The study was performed with 4 replicates per treatment group. containing 10 wasps (5 females and 5 males) each. After the 48-hr exposure period. reproduction (parasitisation rate) was evaluated by transferring 17 surviving female wasps from treatments with a corrected mortality ≤ 50% to individual test units containing barley seedlings infested with aphids (*Rhopalosiphum padi*). Following a 24-hr parasitation period the wasps were discarded and the plants and aphids (parasitized) were held for an additional period of 11 days after which the number of parasitised aphids (aphid mummies) per surviving female wasp was determined.

Table 1: Effects of GF-2540 on the survival of *Aphidius rhopalosiphi*

Test concentrations (mL GF-2540/ha)	% mortality	Abbott corrected % mortality
Control	2.5	--
47	0.0	-2.6
212	10.0	7.7
425	0.0	-2.6
850	7.5	5.1
1700	10.0	7.7
Toxic Reference	100.0	100.0 *
(negative values indicate better survivorship compared to control) * statistically different from the control		

Table 2: Effects of GF-2540 on the parasitism rate of *Aphidius rhopalosiphi*

Test concentrations (mL GF-2540/ha)	Mean No. of mummies per female	% difference compared to control
Control	19.6	-
47	17.4	11.2
212	28.8	-46.9
425	22.6	-15.3
850	26.6	-35.7
1700	19.6	0.0
(negative values indicate better performance compared to control)		

Conclusions

GF-2540 caused no statistically significant effects on mortality or reproduction of *Aphidius rhopalosiphi* when compared to the control up to and including 1700 mL GF-2540/ha, the highest rate tested. It can be concluded that the 48-hour LR_{50} and ER_{50} for *A. rhopalosiphi* based on mortality, reproduction and nominal rates is > 1700 mL GF-2540/ha, the highest rate tested.

Study Comments: IIIA 10.5.1/01	None
Agreed endpoint/s: IIIA 10.5.1	LR_{50} > >1700 mL Prod../ha

IIIA1 10.5.1 Effects on arthropods other than bees - Effects on sensitive species already tested, using artificial substrates/02

Reference	KIIIA1 10.5.1/02
Report	Klug, T., 2009. Toxicity to the Predatory Mite, *Typhlodromus pyri* Scheuten (Acari, Phytoseiidae) in the Laboratory (Rate Response Test). Study Code S09-00694. Dow AgroSciences unpublished report, DAS Study ID: 090221..
Guidelines:	IOBC (Mead-Briggs et al. 2000). ESCORT I Guidance Document (Barrett et al. 1994) and ESCORT II Guidance Document (Candolfi et al. 2001)
Deviations	No deviations that are expected to have influenced the outcome of the study
Acceptability	Yes
GLP	Yes
Original study evaluation revised by zRMS	No

Test material

Test item:	GF-2540
Purity:	1. propyzamide 43.6 % wt/wt 2. aminopyralid potassium 0.58 % wt/wt
Description:	liquid, light brown
Lot No./Batch No. :	C2241-38-B

Test system

Organism (Species):	Predatory mite *Typhlodromus pyri*
Study Type:	Tier 1 laboratory study, glass plates for mortality and fecundity
GLP Status:	GLP
Guidelines followed:	IOBC (BLÜMEL *et al.*(2000), ESCORT I Guidance Document (BARRETT *et al.* 1994) and ESCORT II Guidance Document (CANDOLFI *et al.* 2001)
Guideline deviations reported by Study Director:	None
Study design:	Assessments of mortality measured 7 days after treatment and egg production 14 days after treatment. 4 replicates, each consisting of 20 mites in one arena per test concentration.
Test concentrations:	47, 212, 425, 850 and 1700 mL GF-2540/ha
Environmental conditions:	Temperature: 23.0 to 26.0 °C Relative Humidity: 69 to 88 % Photoperiod: long day conditions 16 hrs light / 8 hrs dark Feeding: pollen of bean and birch, three times a week
Reference substance:	Perfekthion (a.s. 400 g/L dimethoate)

Methodology

For assessment of the mortality of *Typhlodromus pyri* (protonymphs less than 24 hrs old) were exposed to dry residues of GF-2540 on glass plates. The study comprised five treatment rates, a water treated control and a toxic reference. The study was performed with 4 replicates per treatment, containing 20 protonymphs each. Direct treatment effects were assessed after 3 and 7 days. The fertility test was conducted with all test item groups and the control group. Reproduction assessments were carried out 9, 11, and 14 days after treatment by counting the number of females and eggs/juveniles present in each test unit and determining the cumulative number of eggs per female.

Table 1: Effects of GF-2540 on the survival of *Typhlodromus pyri*

Test concentrations (mL GF-2540/ha)	% mortality	Abbott corrected % mortality
Control	2.5	-
47.0	1.3	-1.2
212.0	5.0	2.6
425.0	6.3	3.9
850.0	11.3	9.0
1700.0	11.3	9.0
Toxic Reference	83.8	83.4
(negative values indicate better survivorship compared to control) * statistically different from the control		

Table 2: Effects of GF-2540 on the fecundity of *Typhlodromus pyri*

Test concentrations (mL GF-2540/ha)	Mean No. of eggs per female	% difference compared to control
Control	7.1	-
47.0	7.6	-7.0
212.0	6.6	7.0
425.0	6.0	15.5
850.0	5.0	29.6
1700.0	2.6	59.2
(negative values indicate better performance compared to control) * statistically different from the control		

Conclusions

GF-2540 caused no statistically significant effects on mortality of *Typhlodromus pyri* when compared to the control, up to and including 1700 mL GF-2540/ha, the highest rate tested. It can be concluded that the 7-day LR_{50} for *Typhlodromus pyri* is > 1700.0 mL GF-2540, the highest rate tested.

The reproduction assessed for the highest test item rate applied at 1700.0 mL GF-2540/ha was statistically significantly reduced compared to the control group. The 14-day ER_{50} based on reproduction results and nominal rates for *Typhlodromus pyri* was calculated to be 1437.0 mL GF-2540/ha. The lower and higher confidence limits were 959.7 mL and 1753.0 mL GF-2540/ha.

Study Comments: IIIA 10.5.1/02	None
Agreed endpoint/s: IIIA 10.5.1	ER_{50} (mortality) > 1700 mL GF-2540./ha ER_{50} (reproduction) = 1437 mL GF-2540/ha

IIIA1 10.5.2 Effects on arthropods other than bees - Effects on non-target terrestrial arthropods in extended laboratory tests/01

Reference	KIIIA1 10.5.2/01
Report	Höhn, P, 2010 GF-2540: Toxicity to the Predatory Mite, *Typhlodromus pyri* Scheuten (Acari, Phytoseiidae) Using an Extended Laboratory Test (Rate Response Test).. Study Code S10-01125. Dow AgroSciences unpublished report, DAS Study ID: 101369.
Guidelines:	ESCORT I Guidance Document (Barrett *et al.*, 1994), ESCORT II Guidance Document (Candolfi *et al.*, 2001), IOBC (Blümel *et al.*, 2000) modified according to IOBC (Overmeer, 1988 and Oomen, 1988))
Deviations	No deviations that are expected to have influenced the outcome of the study
Acceptability	Yes
GLP	Yes
Original study evaluation revised by zRMS	No

Test material

Test item:	GF-2540
Purity:	1. propyzamide 43.60 % w/w 2. aminopyralid potassium 0.58 % w/w
Description:	liquid, brown
Lot No./Batch No. :	C2241-38-B

Test system

Organism (*Species*):	Predatory mite *Typhlodromus pyri*
Study Type:	Tier 2 laboratory study, leaf discs for mortality and fecundity
GLP Status:	GLP
Guidelines followed:	ESCORT I Guidance Document (Barrett *et al.*, 1994), ESCORT II Guidance Document (Candolfi *et al.*, 2001), IOBC (Blümel *et al.*, 2000) modified according to IOBC (Overmeer, 1988 and Oomen, 1988)
Guideline deviations reported by Study Director:	None
Study design:	Assessments of mortality measured 7 days after treatment and egg production 14 days after treatment. 6 replicates, each consisting of 10 mites in one arena per test concentration.
Test concentrations:	94, 425, 850, 1700 and 3400 mL GF-2540/ha
Environmental conditions:	Temperature: 23.5 to 26.0 °C

	Relative Humidity: 65 to 87 % Photoperiod: long day conditions 16 hrs light / 8 hrs dark Feeding: pollen of bean and birch, three times a week
Reference substance:	Perfekthion (a.s. 414.8 g/L dimethoate)

Methodology

For assessment of the mortality of *Typhlodromus pyri* protonymphs (age: 24 h as maximum) were exposed to dry residues of GF-2540 on bean leaf discs. The study comprised five treatment rates, a water treated control and a toxic reference. The study was performed with 6 replicates per treatment, containing 10 protonymphs each. Direct treatment effects were assessed after 3 and 7 days. The fertility test was conducted with all test item groups and the control group. Reproduction assessments were carried out 10, 12, and 14 days after treatment by counting the number of females and eggs/juveniles present in each test unit and determining the cumulative number of eggs per female.

Table 1: Effects of GF-2540 on the survival of *Typhlodromus pyri*

Test concentrations (mL GF-2540/ha)	% mortality	Schneider-Orelli corrected % mortality
Control	3.3	-
94	5.0	1.8
425	28.3*	25.9
850	38.3*	36.2
1700	23.3*	20.7
3400	38.3*	36.2
Toxic Reference	100.0*	100.0
* statistically different from the control (Fisher's Exact Test, Bonferroni-Holms corrected, one tailed, p ≤ 0.05)		

Table 2: Effects of GF-2540 on the fecundity of *Typhlodromus pyri*

Test concentrations (mL GF-2540/ha)	Mean No. of eggs per female	% difference compared to control
Control	9.9	-
94	10.6	-7.1
425	10.2	-3.0
850	7.7	22.2
1700	8.1	18.2
3400	8.7	12.1
(negative values indicate better performance compared to control)		

Conclusions

GF-2540 caused statistically significant effects on mortality of *Typhlodromus pyri* from 425 mL GF-2540/ha when compared to the control. Therefore, the NOEC for mortality was determined to be 94 mg GF-2540/kg dry soil and the LOEC was determined to be 425 mg GF-2540/kg dry soil.

The LR50 was estimated to be greater than 3400 ml GF-2540/ha, the highest rate tested.

GF-2540 caused no statistically significant effects on reproduction of *Typhlodromus pyri* when compared to the control. Therefore the ER50 was estimated to be greater than 3400ml GF-2540/ha, the highest rate tested.

Study Comments: IIIA 10.5.2/01	None
Agreed endpoint/s: IIIA 10.5.2	ER_{50}>3400 mL GF-2540./ha (mortality and reproduction)

<u>IIIA1 10.5.2 Effects on arthropods other than bees - Effects on non-target terrestrial arthropods in extended laboratory tests/02</u>

Reference	KIIIA1 10.5.2/02
Report	Höhn, P., 2010 GF-2540: Toxicity to the Green Lacewing, Chrysoperla carnea Steph. (Neuroptera, Chrysopidae) under Extended Laboratory Conditions, Study Code S10-01126. Dow AgroSciences unpublished report, DAS Study ID: 101370.
Guidelines:	ESCORT I Guidance Document (Barrett et al., 1994), ESCORT II Guidance Document (Candolfi et al., 2001), IOBC (Blümel et al., 2000) modified according to IOBC (Overmeer, 1988 and Oomen, 1988)
Deviations	No deviations that are expected to have influenced the outcome of the study
Acceptability	Yes
GLP	Yes
Original study evaluation revised by zRMS	No

Test material

Test item:	GF-2540
Purity:	1. propyzamide 43.60 % w/w 2. aminopyralid potassium 0.58 % w/w
Description:	liquid, brown
Lot No./Batch No. :	C2241-38-B

Test system

Organism (*Species*):	Lacewing (*Chrysoperla carnea)*
Study Type:	Tier 2 extended laboratory study, leaf discs for mortality and fecundity
GLP Status:	GLP
Guidelines followed:	ESCORT I Guidance Document (BARRETT *et al*., 1994), ESCORT II Guidance Document (CANDOLFI *et al.,* 2001) and VOGT *et al.* (2000).

Guideline deviations reported by Study Director:	None
Study design:	Assessment of the survival of larvae and pupae, the number of eggs laid per female (fecundity) and the larval hatching rate (fertility). 30 replicates, consisting of 1 lacewing in each arena per test concentration for mortality phase.
Test concentrations:	94 and 1700 mL GF-2540/ha
Environmental conditions:	Temperature: 23.5 – 26.0 °C Relative Humidity: 74 - 82 % Photoperiod: long day conditions 16 hrs light / 8 hrs dark Feeding: during larval development: eggs of the grain moth *Sitotroga cerealella*, during reproduction phase: tap water and an artificial diet
Reference substance:	Perfekthion (a.s. 414.8 g/L dimethoate)

Methodology

For assessment of the mortality 2-3 day old larvae of *Chrysoperla carnea* were exposed to freshly applied dry residues of GF-2540 on detached apple leaves. After emergence of the adults, total mortality was calculated taking into account the number of dead larvae and not emerged adults. A toxic reference and a water treated control were also included in the test.

The number of eggs per female laid by the surviving organisms was assessed in a fertility test. For that, all emerged adults were collected and transferred into reproduction boxes. Egg counting was conducted twice a week for one week. The viability of these eggs was evaluated by measuring the hatching rate after six days. Assessments of the reproductive performance indicate possible adverse effects of the test substance on fecundity and fertility of the test organisms.

Table 4. Effects of GF-2540 on the survival of *Chrysoperla carnea*

Test concentrations (mL GF-2540/ha)	% mortality	SCHNEIDER-ORELLI corrected % mortality
Control	0.0	-
94	3.3	3.3
1700	6.7	6.7
Toxic Reference	73.3*	73.3
* statistically different from the control (Fisher's Exact Test, one-tailed, p ≤ 0.05)		

Table 2: Effects of GF-2540 on the fecundity and fertility of *Chrysoperla carnea*

Test concentrations (mL GF-2540/ha)	Mean No. of eggs per female per day (fecundity)	Mean % larval hatching rate (fertility)
Control	37.1	92.2
94	43.5	94.2
1700	31.8	91.0

Conclusions

With respect to the test results it can be concluded that GF-2540 applied to detached apple leaves caused no statistically significant effects on mortality of *Chrysoperla carnea* larvae up to and including an application rate of 1700 mL product/ha when compared to the control.

Reproduction assessments were carried out for all test item treatment groups. No adverse effects on reproduction rate were found at any of the test item treatment groups.

Study Comments: IIIA 10.5.2/02	None
Agreed endpoint/s: IIIA 10.5.2	ER_{50}>1700 mL Prod../ha (mortality and reproduction)

IIIA1 10.6.2 Effects on Earthworms and Other Soil Non-target Macro-organisms - Acute toxicity

Reference:	KIIIA1 10.6.2/01
Report	Stäbler, D (2010) GF-2540: Acute Toxicity of GF-2540 on Earthworms, Eisenia fetida Using an Artificial Soil Test Study Code S09-00689. DowAgroSciences, unpublished report, DAS Study No. 090216 ICS No: 80209
Guideline(s):	OECD 207 (1984); ISO 11268-1 (1993), EC-method C.8. (88/302/EEC) (1988)
Deviations:	No deviations that are expected to have influenced the outcome of the study
GLP:	Yes
Acceptability:	Yes
Original study evaluation revised by zRMS	No

Test material

Test item:	GF-2540
Active ingredient:	propyzamide; aminopyralid (a.e.)
Content of a.i. (analysed):	43.6 % w/w (500 g/L); 0.49 % w/w a.e. (5.6 g a.e./L)
Description:	liquid, light brown
Test item No./Lot No.:	C2241-38-B

Test system

Organism:	Earthworm (*Eisenia fetida*)
Source:	In-house culture
Study Type:	14 day acute earthworm study
GLP Status:	GLP-Laboratory certified by the 'Umweltministerium Baden-Württemberg'
Guidelines followed:	OECD 207 (1984); ISO 11268-1 (1993), EC-method C.8. (88/302/EEC) (1988)

Guideline deviations reported by Study Director:	None major
Study design: (No. of replicates, assessments made etc.)	Assessment of the survival, behaviour and weight change of worms. 4 replicates, consisting of 10 worms in each vessel per test concentration.
Test concentrations:	100; 178; 316; 562; 1000 mg GF-2540/kg sdw
Soil parameters:	Artificial soil according to OECD 207 pH of untreated control at initiation: 5.95 pH of untreated control at termination: 6.62 water content at initiation: 31.4 % - 33.5 % water content at termination: 28.2 % - 31.5 %
Environmental conditions:	Temperature: 17.5 – 20.0°C Light intensity: approx. 450 - 800 lux Photoperiod: continuous light
Toxic reference item:	2-Chloroacetamide; tested in the testing facility as a separate study (issued 29 April 2009, dates of work: 19 March 2009 – 3 April 2009)

Methodology

14-day exposure in treated artificial soil; five different test item concentrations were mixed into the soil; four replicates per test concentration and control with ten worms each; Assessment of worm mortality and body weight change after 14 days.

Table 1: Effects of test material on earthworm survival and biomass

Test concentrations (mg)	% mortality after 14 days	% bodyweight change after 14 days (%)
Control	0.0	-11.1
100	0.0	-15.7*
178	0.0	-19.2*
316	2.5	-17.4*
562	0.0	-19.2*
1000	0.0	-19.8*

* = statistically significantly different from the control (Dunnett's t-Test; left-sided, $p \leq 0.05$); within the biological variability fixed by the control validity criteria of ISO 11268-1 of 20 % for body weight loss and therefore can be considered as not affected in contrast to statistical findings.

Conclusions

The NOEC and the LOEC for mortality were determined to be 1000 and > 1000 mg/kg sdw, respectively. The LC_{50} based on nominal concentrations could not be determined and is assumed to be > 1000 mg/kg soil dry weight. The NOEC and the LOEC for body weight loss were determined to be below 100 and 100 mg/kg sdw, respectively. As the weight changes for all test item concentrations were below 20 %, which is the variability fixed by the control validity criteria of ISO 11268-1, this results in an overall NOAEC (= highest concentration with no adverse effects) of 1000 mg/kg sdw and an overall LOAEC (= lowest concentration with adverse effects) of > 1000 mg/kg sdw.

Study Comments: IIIA 10.6.2/01	none
Agreed endpoint/s: IIIA 10.6.2	LC50 > 1000 mg GF-2540/kg soil dw (LC50 corr >500mg GF-2540/kg soil dw)

IIIA1 10.6.3 Effects on Earthworms and Other Soil Non-target Macro-organisms - Sublethal effects

Reference:	KIIIA1 10.6.3/01
Report	Stäbler, D (2010) GF-2540: Sublethal Toxicity of GF-2540 to the Earthworm *Eisenia fetida* in Artificial Soil., Study Code S09-00690. DowAgroSciences, unpublished report, DAS Study No. 090217, ICS No: 80210
Guideline(s):	OECD 222 (2004); ISO 11268-2 (1998)
Deviations:	No deviations that are expected to have influenced the outcome of the study
GLP:	Yes
Acceptability:	Yes
Original study evaluation revised by zRMS	No

Test material

Test item:	GF-2540
Active ingredient:	propyzamide; aminopyralid (a.e.)
Content of a.i.:	43.6 % w/w (500 g/L); 0.49 % w/w a.e. (5.6 g a.e./L)
Description:	liquid, light brown
Test item No./Lot No.:	C2241-38-B

Test system

Organism:	Earthworm (*Eisenia fetida*)
Source:	In-house culture
Study Type:	56 day earthworm reproduction study
GLP Status:	GLP-Laboratory certified by the 'Umweltministerium Baden-Württemberg'
Guidelines followed:	OECD 222 (2004); ISO 11268-2 (1998)
Guideline deviations reported by Study Director:	None
Study design: (No. of replicates, assessments made etc.)	Assessment of the survival, behaviour and weight change of worms after 28 days exposure. Assessment of the number of offspring 56 days after treatment.
Test concentrations:	3.26; 6.52; 13.0; 26.1; 52.1 mg GF-2540/kg sdw
Soil parameters:	Artificial soil according to OECD 222 pH of untreated control at initiation: 5.83 pH of untreated control at termination: 6.58

	water content at initiation: 21.3 % - 22.8 % water content at termination: 22.4 % - 26.3 %
Environmental conditions:	Temperature: 18.0 – 22.0°C Light intensity: approx. 530 - 760 lux Photoperiod: long day conditions (16 h light/8 h darkness) Feeding: weekly up to the 28-day assessment with dried and finely ground cow manure
Toxic reference item:	Derosal flüssig (active ingredient: carbendazim)

Methodology

56-day exposure in treated artificial soil; five different test item concentrations were mixed into the soil; four replicates per test concentration with ten worms each (control: eight replicates); feeding with dried cow manure up to the 28-day assessment depending on feeding activity and re-moistening weekly up to the end of the study by re-weighing test units. Assessment of worm mortality and body weight change after 28 days, assessment of reproduction after 56 days.

Table 1: Effects of test material on earthworm survival, biomass and reproduction

Test concentrations (units)	% mortality after 28 days	% bodyweight change after 28 days	Mean No. of juveniles at day 56	% change in number of juveniles compared to control
Control	0.0	30.2	70.4	-
3.26	2.5	14.8*	101.0	+43.5
6.52	0.0	27.7	106.3	+51.0
13.0	0.0	15.4*	103.3	+46.7
26.1	0.0	27.4	120.8	+71.6
52.1	0.0	21.4	121.0	+71.9

* = statistically significantly different from the control (Dunnett's t-Test; two-tailed, $p \leq 0.05$)

Conclusions

The NOEC and LOEC for body weight change and for reproduction – corresponding to the overall NOEC and LOEC - was determined to be 52.1 and above 52.1 mg GF-2540/kg sdw, respectively. The EC_{50} for reproduction could not be calculated and was determined to be above 52.1 mg GF-2540/kg sdw, since the number of juveniles was higher at any of the test item treatment groups up to and including 52.1 mg/kg soil dry weight as compared with the control.

Study Comments: IIIA 10.6.3/01	None
Agreed endpoint/s: IIIA 10.5.2	NOEC = 52.1 mg GF-2540/kg soil dw (NOECcorr=26.1 mg GF-2540/kg soil dw)

IIIA1 10.7.1 Effects on soil microbial activity - Laboratory test to investigate impact on soil microbial activity

Reference:	KIIIA1 10.7.1/01
Report	Stäbler, D., 2010 GF-2540: Assessment of the Side Effects of GF-2540 on the Activity of the Soil Microflora Study Code S09-00691. DowAgroSciences, unpublished report, DAS Study No. 090218 Lit No: 80211
Guideline(s):	OECD 216 and 217 (2000)
Deviations:	No deviations that are expected to have influenced the outcome of the study
GLP:	Yes
Acceptability:	Yes
Original study evaluation revised by zRMS	No

Test material

Test item:	GF-2540
Active ingredient (a.i.):	propyzamide; aminopyralid (a.e.)
Content of a.i.:	43.6 % w/w (500 g/L); 0.49 % w/w a.e. (5.6 g a.e./L)
Description:	liquid, light brown
Test item No./Lot No.:	C2241-38-B

Test system

Organism:	Soil micro organisms
Study Type:	laboratory study with OECD guideline natural soil, assessed for: Nitrate formation Microbial respiration
GLP Status:	GLP-Laboratory certified by the ‘Umweltministerium Baden-Württemberg’
Guidelines followed:	OECD 216 and 217 (2000)
Guideline deviations reported by Study Director:	None
Deviations to the Study Plan:	Due to technical problems with the nitrogen analysing equipment the nitrite content of the samples could not be determined. Since the OECD 216 guideline requires only determination of the nitrate content, this deviation had no impact on the interpretation of the test item effects on soil nitrogen mineralization and on the compliance of the study with the test guideline.
Duration of study:	56 days
Parameters measured:	Nitrogen transformation: analysis of nitrate and ammonium in extracted soil samples, via ion sensitive electrode and Ionanalyser; limits of quantification: NO_3-N: 5.24 mg/kg soil dry weight (0 days) and 10.5 mg/kg soil dry weight (7 to 56 days) NH_4-N: 0.898 mg/kg soil dry weight soil water content pH

	Microbial respiration: soil respiration rates after addition of glucose soil water content pH
Observation intervals:	0, 7, 14, 28, 42 and 56 days after application
Test concentrations:	2.61 and 13.0 mg product/kg soil dry weight (1.133 and 5.667 mg a.i./kg sdw)
Toxic reference item:	Dinoterb at 13.3 mg a.i./kg soil dry weight
Method of test item application:	Incorporation into the soil
Environmental conditions:	Conducted in the dark at 20 ± 2 °C; pH: 6.50 to 7.11
Soil properties:	Soil source: Standard soil according to OECD 216 and 217 (LUFA Speyer) Moisture content of soil at start: 43.76 - 45.19 % of MWHC (maximum water holding capacity) Moisture content of soil at end: 44.49 - 50.60 % of MWHC Clay (%): 4.0 Silt (%): 29.8 Sand (%): 66.1 Organic Carbon(%): 1.22 Textural classification: medium silty sand (DIN 4220)

Methodology

Incorporation of the test item at two test concentrations into standard soil according to OECD 216 and 217 for determination of effects on nitrogen turnover (mineralisation) and carbon transformation (short-term substrate-induced respiration); Incubation of test vessels in the dark at 20 ± 2 °C; Sampling of soil at 0, 7, 14, 28, 42 and 56 days after application; Determination of pH, dry mass, nitrogen turnover and short-term respiration; Comparison of the results with the untreated control; The test was terminated after 56 days for nitrogen turnover and after 28 days for short-term respiration, since by this time the differences between treated and untreated soils were below 25 %.

Tabel 1: Effects of GF-2540 on the Nitrate formation rate

Interval sampling days	Control	GF-2540 2.61 mg/kg soil dry weight			GF-2540 13.0 mg/kg soil dry weight		
	[mg/kg/day [1]]	[mg/kg/day [1]]	[%[2]]	[sig[3]]	[mg/kg/day [1]]	[%[2]]	[sig[3]]
0-7	0.314	-0.400	-227	--	-0.414	-232	--
7-14	7.57	8.84	+16.8	--	8.26	+9.11	--
14-28	-0.264	-0.857	+225	--	0.0929	-135	--
28-42	1.78	1.77	-0.562	--	0.821	-53.9	--
42-56	-0.200	-0.200	0.00	--	-0.193	-3.50	--
[1]: mean mg NO_3-N/kg soil dry weight per day [2]: deviation from control [3]:statistical significance							

Table 2: Effects of GF-2540 on the Respiration rate

Days after application	Control	GF-2540 2.61 mg/kg soil dry weight			GF-2540 13.0 mg/kg soil dry weight		
	[mg/kg/h [1]]	[mg/kg/h [1]]	[%[2]]	[sig[3]]	[mg/kg/h [1]]	[%[2]]	[sig[3]]

Days after application	Control	GF-2540 2.61 mg/kg soil dry weight			GF-2540 13.0 mg/kg soil dry weight		
0	11.1	11.6	+4.50	--	11.2	+0.901	--
7	7.81	9.92	+27.0	--	10.4	+33.2	--
14	9.40	9.93	+5.64	--	9.92	+5.53	--
28	8.98	9.45	+5.23	--	9.18	+2.23	--
[1]: mean mg CO_2/h/kg soil dry weight per day [2]: deviation from control [3]:statistical significance							

Conclusions:

Based on the results of this study and in accordance with OECD Guidelines 216 and 217, the test item had no adverse effect on soil respiration and on nitrogen turnover (< 25 % deviation between treatments and control) in a field soil tested up to 13.0 mg/kg soil dry weight at study termination after 56 days of exposure. For the interval of the 42 day sampling to the 56 day sampling the deviation between soil treated with the test item and control was 0.0 % for the 2.61 mg/kg soil dry weight treatment and -3.50 % for the 13.0 mg/kg soil dry weight treatment. For short-term respiration the deviations between test item treated soil and control were +5.23 % at 2.61 mg/kg soil dry weight and +2.23 % at 13.0 mg/kg soil dry weight after 28 days.

Study Comments: IIIA 10.7.1/01	None
Agreed endpoint/s: IIIA 10.7.1	< 25 % effects on microbial activity at 2.61 and 13 mg GF-2540/kg dry soil

IIIA1 10.8.1.2 Effects on non-target terrestrial plants – vegetative vigour

Report:	KIIIA1 10.8.1.2/01 C. Rockliff, (2013)
Title:	GF-2540 (aminopyralid, 6 g ai/l, + propyzamide, 500 g a.i./l, SC) - GLP Vegetative Vigour Test - Terrestrial Non Target Plants (based on OECD Guideline 227) - Europe, 2013
Document No:	130508 ! STC/13/E760
Guidelines:	OECD 227
Deviations	No deviations that are expected to have influenced the outcome of the study
Acceptability	Acceptable with restrictions
GLP	Yes
Original study evaluation revised by zRMS	No

Materials and methods

The effects of GF-2540 (aminopyralid 6g a.i./L + propyzamide, 500g a.i./L, SC) on Ryegrass (Lolium perenne), Oats (Avena sativa), Barley (Hordeum vulgare), Onion (Allium cepa), Oilseed rape (Brassica napus), Soybean (Glycine max), Cucumber (Cucumis sativa), Sugar beet (Beta vulgaris), Tomato (Lycopersicon esculentum) and Carrot (Daucus carota) were assessed in a glasshouse study. In total 4 monocotyledon and 6 dicotyledon species from eight different plant families were tested.

The species evaluated represented members of the Gramineae, Liliaceae, Brassicaceae, Leguminoseae, Cucurbitaceae, , Chenopdiaceae, Umbelliferae and Solanaceae. The Batch Number of the sample of GF-2540 used in the study was E-3213-24-3. GF-2540 was applied at 23.44, 46.88, 93.75, 187.5, 375, 750, 1500 and 3000 mL prod./ha in a total volume of 200 L/ha. The concentration of the highest rate spray solution was analytically verified using a high performance liquid chromatography (HPLC) technique. The soil medium used was a sandy loam with an organic carbon matter of < 1.5 %.
Five replicate pots were used per treatment. Except cucumber 3 plants per pot 5 plants were grown per pot and for onion 10 plants per pot. Therefore the number of plants grown per pot significantly deviated from the requirements according to guideline OECD 227 (i.e. for sugar beet, tomato and soybean 5 instead of 1-2 plants -as recommended- were grown per pot). Watering pre- and post-application was via sub pot irrigation. Plants were raised and the study conducted under glasshouse conditions maintained within acceptable limits for growth of the test species. Temperature range 14.8-26.2 o C, humidity range 41% to 79 %. Lighting was ambient and a daily photoperiod of 16 hours was achieved by using supplementary lighting. There were no records of the light intensity during the test available that allowed to check whether the lighting intensity meets the guideline criteria of 350 µE/(m2*s) throughout the study. Nevertheless, the study is considered plausible. Plants were visually assessed for damage and number of plants was recorded 7, 14 and 21 days after application. At the end of the study foliar fresh weight was measured and the number of dead plants recorded.
Visual injury was rated on a scale from 1-100 whith 0 % = no visual injury, 1-39 % = slight visual injury, 40-69% = moderate visual injury, 70-99% = severe visual injury, 100 % = all plants dead and/or not emerged.

Results

ER_{50} (mL prod./ha) based on shoot fresh weight data, for all test species

Species	EC50 [mL prod../ha] based on foliar fresh weight reduction
Ryegrass	>3000
Oats	1041.77
Barley	491.70
Onion	>3000
Oilseed rape	>3000
Soybean	>3000
Cucumber	>3000
Sugar beet	2982.23
Tomato	313,94 **(210,95 based on % visual injury)**
Carrot	>3000

The most sensitive species were tomato and barley based. For tomato, the ER50 was re-calculated by the zRMS based on the endpoint visual injury, that was severe at the four highest treatment rates (on average 62-92%) with plants displaying a check in growth with thinner stems and leaves, curled leaves, distorted growing points. The most severely affected plants also drooped over.

Conclusions

The derived endpoint for the most sensitive species tomato to be used in the risk assessment is 210.9 mL prod./ha.

Study Comments: IIIA 10.7.1/01	For tomato, the ER_{50} was re-calculated by the zRMS based on the endpoint visual injury.
Agreed endpoint/s: IIIA 10.7.1	The derived endpoint for the most sensitive species tomato to be used in the risk assessment is 210.9 mL prod./ha.

<u>IIIA1 10.8.1.3Effects on non-target terrestrial plants – seedling emergence</u>

Report:	KIIIA1 10.8.1.3/01 C. Rockliff, (2013)
Title:	GF-2540 (aminopyralid, 6 g ai/l, + propyzamide, 500 g a.i./l, SC) - GLP Seedling Emergence and Seedling Growth Test - Terrestrial Non Target Plants (based on OECD Guideline 208) - Europe, 2013
Document No:	130509 ! STC/13/E761
Guidelines:	OECD 208
Deviations	No deviations that are expected to have influenced the outcome of the study
Acceptability	Acceptable with restrictions
GLP	Yes
Original study evaluation revised by zRMS	Yes

Materials and methods

The effects of GF-2540 (aminopyralid 6g a.i./L + propyzamide, 500g a.i./L, SC) on Ryegrass (Lolium perenne), Oats (Avena sativa), Barley (Hordeum vulgare), Onion (Allium cepa), Oilseed rape (Brassica napus), Field bean (Vicia faba), Soybean (Glycine max), Cucumber (Cucumis sativa), Sugar beet (Beta vulgaris), Tomato (Lycopersicon esculentum) and Carrot (Daucus carota) were assessed in a glasshouse study. In total 4 monocotyledon and 7 dicotyledon species from eight different plant families were tested. The species evaluated represented members of the Gramineae, Liliaceae, Brassicaceae, Leguminoseae, Cucurbitaceae, , Chenopdiaceae, Umbelliferae and Solanaceae. The Batch Number of the sample of GF-2540 used in the study was E-3213-24-3. GF-2540 was applied at 23.44, 46.88, 93.75, 187.5, 375, 750, 1500 and 3000 mL prod./ha in a total volume of 200 L/ha. The concentration of the highest rate spray solution was analytically verified using a high performance liquid chromatography (HPLC) technique. The soil medium used was a sandy loam with an organic carbon matter of < 1.5 %.
Five replicate pots were used per treatment. Except cucumber grown with 5 plants per pot, 10 plants were grown per pot. Therefore the number of plants grown per pot significantly deviated from the requirements according to guideline OECD 227 (i.e. for sugar beet, tomato, field bean and soybean 10 instead of 1-2 plants -as recommended- were grown per po, for cucumber 5 instead of 1-2 plants were grown per pot). Watering pre- and post-application was via sub pot irrigation. Plants were raised and the study conducted under glasshouse conditions maintained within acceptable limits for growth of the test species. Lighting was ambient and a daily photoperiod of 16 hours was achieved by using supplementary lighting. There were no records of the light intensity during the test available that allowed to check whether the lighting intensity meets the guideline criteria of 350 µE/(m2*s) throughout the study. Nevertheless, the study is considered plausible. Plants were visually assessed for damage and number of plants was recorded 7, 14

and 21 days after application. At the end of the study foliar fresh weight was measured and the number of dead plants recorded.
Visual injury was rated on a scale from 1-100 whith 0 % = no visual injury, 1-39 % = slight visual injury, 40-69% = moderate visual injury, 70-99% = severe visual injury, 100 % = all plants dead and/or not emerged.

Results

ER_{50} (mL prod./ha) based on shoot fresh weight data, for all test species

Species	EC50 [mL prod../ha] based on foliar fresh weight reduction
Ryegrass	356.3
Oats	2141.56
Barley	>3000
Onion	>3000
Oilseed rape	1986.35
Soybean	1521.21
Field bean	1395.61
Cucumber	1337.72
Sugar beet	569.41
Tomato	402.91 **(211.47based on % visual injury)**
Carrot	>3000

The most sensitive species were tomato and ryegrass. For tomato, the ER50 was re-calculated by the zRMS based on the endpoint visual injury, that was severe at the four highest treatment rates (on average 84-100%) with plants displaying a check in growth and/or stunting. the most severely stunted plants displayed cotyledon leaves tightly curled under. The larger affected plants displayed distortion of the newest leaves and growing points. The effects increased clearly dose-dependent

Conclusions

The derived endpoint for the most sensitive species tomato to be used in the risk assessment is 211.47 mL prod./ha.

Study Comments: IIIA 10.7.1/01	For tomato, the ER_{50} was re-calculated by the zRMS based on the endpoint visual injury.
Agreed endpoint/s: IIIA 10.7.1	The derived endpoint for the most sensitive species tomato to be used in the risk assessment is 211.47 mL prod./ha.

IIIA1 10.8.2.1 Effects on non-target plants - Effects on non-target aquatic plants - Aquatic plant growth – Lemna

Reference	KIIIA1 10.8.2.1/01
Report	Rebstock, M. 2010 GF-2540: Growth Inhibition Test with the Freshwater Aquatic Plant, Duckweed Dow AgroSciences unpublished report, Study Number 101366.
Guidelines:	OECD 221
Deviations	No deviations that are expected to have influenced the outcome of the study
Acceptability	Yes
GLP	Yes
Original study evaluation revised by zRMS	No

Test material

Test item:	GF-2540
Purity:	0.58 wt.% aminopyralid potassium (0.49 wt.% aminopyralid a.e.), 43.6 wt.% propyzamide
Description:	Brown liquid
Lot No./Batch No. :	C2241-38-B

Test system	
Organism (*Species*):	Freshwater aquatic plant, *Lemna gibba*
Study Type:	Static Renewal
GLP Status:	GLP
Guidelines followed:	OECD guideline 221
Guideline deviations reported by Study Director:	None
Duration of study:	7 days
Test conditions:	Static Renewal, renewals on days 3 and 5
Parameters measured:	Growth and Yield (Number of fronds and biomass as dry weight)
Observation intervals:	Days 3, 5, 7
Age of fronds at test initiation:	7 days
Number of fronds at test initiation:	12 per rep
Test concentrations:	Nominal: 0 (control), 0.31, 0.63, 1.3, 2.5, 5.0, and 10 mg GF-2540/L Mean measured: <MQL (control), 0.288, 0.604, 1.25, 2.30, 4.68, and 9.31 mg GF-2540/L
Analytical confirmation of test concentrations:	0, 3, 5, and 7 days
Reference substance:	propyzamide analytical reference standard
Number of fronds per dose group:	36
Number of fronds per control group:	36
Feeding:	N/A
Environmental conditions:	Temperature: 23.1 to 24.9ºC Photoperiod: 24 hour light Growth medium: 20X-AAP pH of fresh solutions: 7.5 to 7.7 as measured on days 0, 3, and 5 pH of spent solutions: 8.5 to 8.9 as measured on days 3, 5, and 7

Methodology

A 7-day static renewal test with the freshwater aquatic plant, *Lemna gibba* was performed with nominal test concentrations of : 0 (control), 0.31, 0.63, 1.3, 2.5, 5.0, and 10 mg GF-2540/L. Each test flask received three plants for a total of 12 fronds at test initiation. There were three replicates per test treatment, resulting in 36 fronds per test treatment. Frond observations and counts were made at 3, 5, and 7 days, with renewals at days 3 and 5. Temperature and pH were measured in all fresh parent solutions, on days 0, 3 and 5. On days 3, 5, and 7, temperature and pH were measured in replicate A of all treatment spent solutions. Biomass (dry weight) measurements of each control and test substance treatment replicate were performed on day 7 (test termination).

	Parameter Effect Concentration as mg GF-2540/L			
Endpoint	**Frond Yield (95% CL)**	**Frond Average Specific Growth Rate (95% CL)**	**Biomass Yield as Dry Weight (95% CL)**	**Biomass Average Specific Growth Rate as Dry Weight (95% CL)**
NOEC	0.31	0.31	2.5	2.5
LOEC	0.63	0.63	5.0	5.0
EC_{10}	0.32 (0.080 to 0.55)	0.38 (0.048 to 0.72)	<0.31 (Not Statistically Sound)	0.67 (0 to 1.7)
EC_{20}	0.62 (0.28 to 0.96)	1.0 (0.44 to 1.6)	0.72 (0 to 1.7)	2.7 (0.80 to 4.6)
EC_{50}	2.0 (1.4 to 2.5)	5.5 (4.1 to 6.9)	4.3 (1.8 to 6.8)	>10 (Not Statistically Sound)

Conclusions

The test acceptability criteria for control growth (i.e., frond doubling time < 2.5 days, greater than a seven-fold increase in the number of fronds, and minimum average specific growth rate of 0.275 day $^{-1}$) set by OECD 221 test guideline were met for this study. The doubling time for the control fronds was 1.8 days, corresponding to a 9-fold increase in the number of fronds, and the average specific growth rate was 0.315 day $^{-1}$. This study is classified as acceptable and satisfies the guideline requirement for a growth inhibition test with *Lemna gibba*. EbC_{50} (7d, frond number) = 2 mg GF-2540L; ErC_{50}(7d) = 5.5 mg GF-2540/L; NOEC = 0.31 mg GF-2540/L.

Study Comments: IIIA 10.2.2.2/01	None
Agreed endpoint/s: IIIA 10.2.2.2	EbC_{50} (7d, frond number) = 2 mg Prod./L ErC_{50}(7d) = 5.5 mg Prod./L NOEC = 0.31 mg Prod./L

Appendix 3 Table of Intended Uses justification and GAP tables

GAP rev. BVL, date: 2014-03-19

PPP (product name/code)	**GF-2540**	**Formulation type:**	**SC**
active substance 1	**Propyzamid**	**Conc. of as 1:**	**500 g/L**
active substance 2	**Aminopyralid**	**Conc. of as 2:**	**5.3 g/L**
Applicant:	**DOW AgroSciences GmbH**	**professional use**	**X**
Zone(s):	**central/EU**	**non professional use**	

Verified by MS: Y

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 as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
001	DE	Winter oil-seed Rape	F	annual monocotyledonous weeds (TTTMS), annual dicotyledonous weeds (TTTDS) (post emergence of weeds)	Spraying	BBCH >14 Late autumn to winter (November to February)	a) 1 b) 1	a) 1.5 b) 1.5	a) Propyzamid 750 g/ha Aminopyralid 7.95 g/ha b) Propyzamid 750 g/ha Aminopyralid 7.95 g/ha	20 0 - 300		

Remarks:

(1) Numeration of uses in accordance with the application/as verified by MS
(2) Member State(s) or zone for which use is applied for
(3) 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)
(4) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(5) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds, developmental stages
(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 of treatment(s) (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 applications possible under practical conditions of use for each single application and per year (permanent crops) or crop (annual crops) must be provided
Min. interval between applications (days) were relevant
(10) The application rate of the product a) max. rate per appl. and b) max. total rate per crop/season must be given in metric units (e.g. kg or L product / ha)
(11) The application rate of the active substance a) max. rate per appl. and b) max. total rate per crop/season must be given in metric units (e.g. g or kg / ha)
(12) The range (min/max) of water volume under practical conditions of use must be given (L/ha)
(13) PHI - minimum pre-harvest interval
(14) Remarks may include: Extent of use/economic importance/restrictions/minor use etc.

REGISTRATION REPORT
Part B

Section 6 Ecotoxicological Studies
Detailed summary of the risk assessment

Product code: GF-2540
Active Substance: Propyzamide 500 g/L
Aminopyralid 5.3 g/L

Central Zone
Zonal Rapporteur Member State: Germany (DE)

NATIONAL ADDENDUM

Applicant: Dow AgroSciences
Date: 08/05/2014

Table of content

Sec 6 ECOTOXICOLOGICAL STUDIES

Please refer to the core assessment part B section 6 for the central zone.

6.1 Proposed use pattern and considered metabolites

Introduction

Section 6 of the submission summarises the ecotoxicological effects of the formulation GF-2540 containing the active substances aminopyralid and propyzamide and evaluates the potential risk to various representatives of terrestrial, aquatic and soil organisms. Full details or the proposed use patterns that will be assessed are shown in Appendix 1 of this document and summarized below. For an overview of the metabolites of aminopyralid and propyzamide that are addressed in the risk assessment please refer to the core assessment.

6.1.1 Proposed use pattern

The critical GAP used for exposure assessment are presented in Table 6.1-1 that reports also a classification of intended uses for GF-2540 (see also Section 5). The intended use in Germany (use No. 001) is covered by the core assessment performed by zRMS Germany.

A list of all intended uses within the zone is given in Appendix 1.

Table 6.1-1: Critical use pattern of GF-2540

No.	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)
001	Winter Oilseed Rape / BBCH 13-29	spraying / agriculture	1 x, late autumn to winter, november to february 40 %	propyzamide: 1 x 750 aminopyralid: 1 x 8	propyzamide: 1 x 450 aminopyralid: 1 x 4.8

6.1.2 Consideration of metabolites

Please refer to the core assessment part B section 6 for the central zone.

6.2 Effects on Birds

Please refer to the core assessment part B section 6 for the central zone.

6.3 Effects on Terrestrial Vertebrates Other Than Birds

Please refer to the core assessment part B section 6 for the central zone.

6.4 Effects on Aquatic Organisms

6.4.1 Overview and summary

Please refer to the core assessment part B section 6 for the central zone.

6.4.1.1 Toxicity

Please refer to the core assessment part B section 6 for the central zone.

6.4.1.2 Exposure

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. The vapour pressures at 20 °C of the active substance propyzamide is < 10-5 Pa. Therefore, exposure of surface water by the active substance propyzamide due to deposition following volatilization was considered

Surface water exposure via spray drift and volatilization with subsequent deposition is estimated with the models EVA 2.1. Surface water exposure via surface run-off and drainage is estimated using the model EXPOSIT 3.0.

For details of the calculated PEC_{sw} values (i.a. input parameters for EXPOSIT and EVA) please refer to the national addendum part B, section 5.

6.4.1.3 Risk assessment –overall conclusions

Based on Based on all studies on aquatic toxicity no risk mitigation measurements are necessary.

6.4.2 Toxicity to Exposure ratio

The risk for aquatic organisms exposed to propyzamide, aminopyralid and their metabolites was assessed according to the intended uses.

PEC_{SW} values were compared to the relevant acute and long-term toxicity endpoints available for propyzamide, aminopyralid and their metabolites.

In the tables below, the TER values relative to the overall most sensitive endpoints (worst case)/SF are given for the entry pathway spray drift and volatilization/deposition as well as the entry pathway run-off and drainage.

6.4.2.1 TER: Entry pathway spray drift and volatilization/deposition

The calculation of PECsw after exposure via spray drift and volatilization with subsequent deposition is performed using the model EVA 2.1. For a single application, the exposure assessment via spray drift is based on the application rate in conjunction with the 90^{th} percentile of the drift values. For multiple applications, lower percentiles of the drift values for each application are applied, resulting in an overall 90^{th} percentile of drift probabilities. The vapour pressure of the active substance aminopyralid is < 10^{-5} Pa at 20 °C and the vapour pressure of the active substance propyzamide is > 10^{-5} Pa. Therefore, exposure of surface water due to deposition following volatilization was considered for the active substance propyzamide but not for the active substance aminopxralid . Only one volatilization event following the last use of pesticide is generally considered.

The endpoints used for modelling surface water exposure via spray drift and volatilization with subsequent deposition with EVA 2.1 are summarized in section 5 of the national addendum Table 5.6-5.

Tabelle 6.4-1: PECs, TER values and and safety factors entry pathway drift/volatilization

Species	Endpoint type	Endpoint [µg/L]	SF	Worst case, without drift reduction at 1m distance		
				PEC (µg/L)	TER	TER/ SF
Active substance propyzamide						
Chironomus riparius	NOEC	340	10	7.01	48	4.8
Propyzamide metabolite RH 24644						
Daphnia magna	EC50	>4000	100	not relevant	--	---
Propyzamide metabolite RH 24580						
Daphnia magna	EC50	540	100	not relevant	--	---
Propyzamide metabolite RH 24655						
Chironomus riparius	NOEC	82	10	1.884	45.3	4.53
Propyzamide metabolite Uk 1						
Endpoint leading to lowest RAC for Propyzamide (= NOEC C. riparius)/10	NOEC	34	10	0.592	57	5.7
Active substance aminopyralid						
Cyprinodon variegatus	NOEC	100	10	0.0734	1360	136
Product GF-2540						
Lemna gibba	EC50	2000	10	15.77	1270	127

Based on all studies on aquatic toxicity as well as the corresponding safety factors, the relevant endpoint driving the risk assessment is the NOEC for *Chironomus riparius* for the propyzamide metabolite RH 24655 (=82 µg/L). Risk assessment is driven by this endpoint; the ratio TER/corresponding safety factor is higher for all other scenarios.

As it can be seen in the table above all TER values achieve the acceptability criteria of TER ≥ 10 / TER ≥ 100 according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. Risk mitigation measures do not need to be applied. acceptability criteria for the intended use in winter oilseed rape without further risk mitigation. Also considering mixture toxicity of active substances and their metabolites did not indicate an unacceptable risk. This indicates that GF-2540

containing the active substances propyzamide and aminopyralid poses an acceptable risk to aquatic organisms due to an exposure via drift/volatilization at the proposed application rates.
Risk mitigation measures do not need to be applied.

6.4.2.2 TER: Entry pathway surface runoff and drainage

The concentration of the active substance propyzamide and its metabolites in adjacent ditch due to surface runoff and drainage was calculated using the model EXPOSIT 3.01. The parameters for propyzamide and its metabolites RH 24644 and RH 24580 used for modelling surface water exposure via run-off and drainage in an adjacent ditch with EXPOSIT 3.01 are summarized in section 5 of the national addendum, Table 5.6 7 and Table 5.6 8. In the tables below, the TER values relative to the overall most sensitive endpoints (worst case) for the exposure pathways run-off and drainage / SF are shown in the table below.

Tabelle 6.4-2: PECs, TER values and and TERs/safety factors entry pathway surface runoff / drainage

Species	Endpoint type	Endpoint [µg/L]	SF	Exposure in adjacent ditch			TER/SF		
				surface runoff	drainage		surface runoff	drainage	
				(PECini Gesamtaustrag) (µg/L), 0 m buffer strip	(PECini Gesamtaustrag) (µg/L), 0 m buffer strip		(PECini Gesamtaustrag) (µg/L), 0 m buffer strip	(PECini Gesamtaustrag) (µg/L), 0 m buffer strip	
					autuum/winter/early spring	Spring/summer		autuum/winter/early spring	Spring/summer
Active substance propyzamide									
Chironomus riparius	NOEC	340	10	3.48	0.21	0.07	**9.77**	161.9	485.7
Propyzamide metabolite RH 24644									
Daphnia magna	EC_{50}	>4000	100	0.97	0.07	0.02	41.24	571.43	2000
Propyzamide metabolite RH 24580									
Daphnia magna	EC_{50}	540	100	1.11	1.11	0.36	**4.86**	**4.86**	15
Propyzamide metabolite RH 24655									
Chironomus riparius	NOEC	82	10	0.95	0.06	0.02	**8.63**	136.67	410
Propyzamide metabolite Uk 1									
Endpoint leading to lowest RAC for Propyzamide (= NOEC *C. riparius*)/10	NOEC	34	10	0.30	0.02	0.01	11.3	170	340
Active substance aminopyralid									
Cyprinodon variegatus	NOEC	100	10	0.02	0.04	0.01	500	250	1000

Based on all studies on aquatic toxicity as well as the corresponding safety factors, the relevant endpoint driving the risk assessment is the EC_{50} *Daphnia magna* >4000 µg/L with the propyzamide metabolite RH 24580. Risk assessment is driven by these endpoints; the ratio TER/corresponding safety factor is higher for all other scenarios.

Tabelle 6.4-3: PECs, TER values and and TERs entry pathway surface runoff / drainage

Species	Endpoint type	Endpoint [µg/L]	SF	Exposure in adjacent ditch			TER		
				surface runoff	drainage		surface runoff	drainage	
				(PECini Gesamtaustrag) (µg/L), 0 m buffer strip	(PECini Gesamtaustrag) (µg/L), 0 m buffer strip		(PECini Gesamtaustrag) (µg/L), 0 m buffer strip	(PECini Gesamtaustrag) (µg/L), 0 m buffer strip	
					autuum/winter/early spring	Spring/summer		autuum/winter/early spring	Spring/summer
Active substance propyzamide									
Chironomus riparius	NOEC	340	10	3.48	0.21	0.07	97.7	1619	4857
Propyzamide metabolite RH 24644									
Daphnia magna	EC_{50}	>4000	100	0.97	0.07	0.02	>4124	>57143	>200000
Propyzamide metabolite RH 24580									
Daphnia magna	EC_{50}	540	100	1.11	1.11	0.36	486	486	1500
Propyzamide metabolite RH 24655									
Chironomus riparius	NOEC	82	10	0.95	0.06	0.02	86.3	1367	4100
Propyzamide metabolite Uk 1									
Endpoint leading to lowest RAC for Propyzamide (= NOEC *C. riparius)/10*	NOEC	34	10	0.30	0.02	0.01	113	1700	3400
Active substance aminopyralid									
Cyprinodon variegatus	NOEC	100	10	0.02	0.04	0.01	5000	2500	10000

As it can be seen in the table above the calculated TER values for the risk to aquatic organisms resulting from an exposure of surface water by the active substances aminopyralid, propyzamide and their metabolites due to run-off and drainage according to the use No 001 achieve the acceptability criteria of TER ≥ 100 or 10 respectively, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. Risk mitigation measures do not need to be applied.

6.4.3 Acute toxicity and chronic toxicity of the formulation

Please refer to the core assessment part B section 6 for the central zone.

6.4.4 Metabolites of Propyzamide and Aminopyralid

Please refer to the core assessment part B section 6 for the central zone.

6.4.5 Accumulation in aquatic non-target organisms

Please refer to the core assessment part B section 6 for the central zone

6.5 Effects on Bees

Please refer to the core assessment part B section 6 for the central zone.

6.6 Effects on Arthropods Other Than Bees

The Core risk assessment covers all intended uses in Germany and indicates a low risk to Arthropods other than bees off-field (please refer to the Core assessment, section 6.6, especially 6.6.1and 6.6.2.2)

Hence, no risk mitigation measures are required in Germany.

6.7 Effects on Earthworms, other Non-target Soil Organisms and Organic Matter Breakdown

6.7.1 Overview and summary

Please refer to the core assessment part B section 6 for the central zone.

6.7.1.1 Toxicity

Please refer to the core assessment part B section 6 for the central zone.

6.7.1.2 Exposure

GF-2540 is a herbicide formulation containing aminopyralid and aopyzamide as active substances. The product is formulated as a suspension concentrate. It will be used against Annual mono- and dicot weeds (post emergence of weeds) in winter oilseed rape.

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 product GF-2540, the active substances propyzamide, aminopyralid and the major soil degradation products are presented in the table below. Calculations considered the application rate of 1.5 L formulation/ha and a minimum of 40% foliar interception for applications to winter oilseed rape at BBCH growth stage 13-29. PEC values for the soil metabolites were calculated considering the maximum percentage of their formation observed in either the aerobic or anaerobic soil degradation studies and correcting for molecular weight.

All calculations assumed an even distribution of the substances in the top 2.5 cm horizon with a soil bulk density of 1.5 g/mL. Due to the fast degradation of propyzamide in soil (DT_{90} < 365 d, FSO, laboratory data) the accumulation potential of propyzamide and aminopyralid does not need to be considered.

Table 6.7-1: Maximum predicted environmental concentrations in soil PEC_S[1)] for aminopyralid / propyzamide / GF-2540 and major soil degradation products of propyzamide following application in the intended use winter oilseed rape.

plant protection product:	GF-2540
use:	001
Number of applications/intervall	1.5 L ha^{-1}
application rate:	1x

crop interception:		40 %				
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)**
Active substance propyzamid	450.0	1.2	-	-	-	-
Metabolite RH-24644	143.5	0.383	-	-	-	-
Metabolite RH-24580	115.5	0.308	-	-	-	-
Active substance aminopyralid	4.8	0.013	-	-	-	-
Preparation GF-2540	1025.1	6.834	-	-	-	-

1) PEC_{act} = maximum annual soil concentration for a soil depth of 2.5 cm

PEC_{bkgd}= background concentration in soil considering a tillage depth of 20 cm (arable crop) or 2.5 cm (permanent crops)

PEC_{accu} = accumulated soil concentration

The propyzamide metabolites RH-24644 and RH-24580 were formed in concentrations >10 % total AR at day 21 (RH-24644) and day 45 (RH-24580) in soil. For details please see Section 5, Part 9.1 of this submission and **Fehler! Verweisquelle konnte nicht gefunden werden.**, page **Fehler! Textmarke nicht definiert.**.

6.7.1.3 Risk assessment –TER values and overall conclusions

The risk assessment results are summarized in the following table:

Table 6.7-2: Ecotoxicological endpoints, PECsoil values and Toxicity to Exposure ratios to assess the risk for earthworms and other soil macro- and mesofauna following application of GF-2540 according to the intended uses

Test substance	**Intended use**	**Timescale**	**Endpoint (mg/kg dw soil)**	**PEC (mg/kg soil dw)**	**TER**	**TER trigger**
Earthworms (*Eisenia fetida*)						
Active substance aminopyralid	750 g propyzamide ha^{-1} and 8 g aminopyralid ha^{-1} (1.5 L ha^{-1} GF-2540)	Acute	> 1000	0.013	76923	10
		Long-term	3.2		246	5
Active substance propyzamide		Acute	> 173,2	1.200	>144	10
		Long-term	34		28.3	5
Propyzamide		Acute	86.6	0.383	226	10

metabolite RH-24644		Long-term	5.5		17.9	5
Propyzamide metabolite RH-24580		Acute	>261	0.308	>847	10
Preparation GF-2540		Acute	> 500	6.834	>73,2	10
		Long-term	26.1		**3.81**	5
TER values in bold are below the trigger						

Based on the predicted concentrations of aminopyralid /propyzamide / propyzamide metabolites RH-24580 and RH-24644 in soils, the TER values describing the acute and longterm risk for earthworms and other non-target soil organisms following exposure to according to the GAP of the formulation GF-2540 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.

Based on the predicted concentrations of GF-2540 in soils, the TER values describing the longterm risk for earthworms following exposure according to the GAP of the formulation GF-2540 do not 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 (TER = 3.81).

However, the NOEC for the product did not indicate a considerably higher chronic toxicity than expected by the active substances and the NOEC was the highest concentration tested. Additionally, the TER for of 3.8 for GF-2540 is based on the assumption that all ingredients of the formulation remain in the upper 1cm soil layer for 56d (which is only reasonable to assume for the active substance propyzamide). Thereforer, on a national level, the TER of 3.8 for GF-2540 is still considered to indicate an acceptable long-term risk for Earthworms following exposure according to the GAP of the formulation GF-2540.

Concluding, the results of the assessment indicate an acceptable risk for soil organisms due to the intended use of GF-2540 in winter oilseed rape according to the label.

6.7.2 Toxicity to Exposure Ratio

6.7.2.1 Acute risk

The potential acute risk for earthworms and other non-target soil macro- and mesofauna resulting from an exposure to GF-2540 / propyzamide / aminopyralid as well as the metabolite of propyzamide RH 24580 was assessed by comparing the maximum PECsoil 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 resulting TER_A values are shown in Table 6.7-2 above.

6.7.2.2 Chronic risk

The long term risk of the active substances aminopyralid, propyzamide, the propyzamide metabolite RH 24644 and the product GF-2540 for Earthworms has been addressed by long-term studies with *Eisenia fetida.* The potential chronic risk for earthworms was assessed by comparing the maximum PECsoil 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 resulting TER_{LT} values are shown in Table 6.7-2 above.

The long-term risk of the propyzamide metabolite RH 24580 for earthworms and other soil macro- and mesofauna does not need to be addressed, since its degradation in soil (DT90 < 100 d, Kinetic, laboratory/field data, Guidance Document on Terrestrial Ecotoxicology SANCO/10329/2002 rev2 final) is relatively fast.

According to the Guidance Document on Terrestrial Ecotoxicology, a test for assessing effects on other soil other soil macro- and mesofauna (Collembola reproduction test or test on gamasid mites) is required where:

- $DT_{90field}$ of of the active substance is between 100 and 365 days and
- standard HQ for arthropods (*Typhlodromus* and *Aphidius*) >2

For propyzamide and Aminopyralid the max DT_{90}s in the field are <365 but >100 (185 and 116.1 d resp.) and for the propyzamide metabolite RH 24644 the DT90 lab was <365 but >100 (125.8d max). No risk was identified for non-target arthropods, Earthworms and soil micro-organisms from the use of GF-2540. Hence, it is not considered necessary to provide studies on the effects of GF-2540 on other soil macro- and mesofauna.

According to the Guidance Document on Terrestrial Ecotoxicology, a test for assessing effects on organic matter breakdown (litterbag) is required where:

- DT_{90fiel}d of the active substance is > 365 days or
- $DT_{90field}$ of of the active substance is between 100 and 365 days and
- Effects on soil microflora > 25 % or TER_{LT} earthworm < 5
- or Collembola TER_{LT} < 5

For propyzamide and Aminopyralid the max DT_{90}s in the field are <365 but >100 (185 and 116.1 d resp.). Effects of both active substances on soil microflora were <25 % and TER_{LT} earthworm was > 5. Therefore no tests for assessing effects on organic matter breakdown are considered to be necessary.

For the propyzamide metabolite RH 24580 the DT90 lab was 55.5 (max), so no tests for assessing effects on organic matter breakdown are required. For the RH 24644 the DT90 lab was <365 but >100 (125.8d max) but the TER_{lt} for Earthworms was >5 and effects on soil microflora were <25 %. Hence, for this metabolite no tests for assessing effects on organic matter breakdown are considered to be necessary.

Submitted data are reported in **Fehler! Verweisquelle konnte nicht gefunden werden.**.

6.7.3 Residue content of earthworms

Please refer to the core assessment part B section 6 for the central zone.

6.8 Effects on Soil Microbial Activity

6.8.1 Overview and summary

Soil microorganisms will be exposed to plant protection products containing propyzamide, aminopyralid and their soil metabolites whenever contamination of soil may occur as a result of the intended uses of GF-2540.

6.8.1.1 Toxicity

Please refer to the core assessment part B section 6 for the central zone.

6.8.1.2 Exposure

Please refer to section 6.7.1.2 above for the predicted environmental concentrations in soil (PECsoil) of Propyzamide, Aminopyralid, Propyzamide metabolite RH 24644 and GF-2540.

6.8.1.3 Risk assessment –overall conclusions

The Predicted Environmental Concentrations of the formulation GF-2540, the active substance(s) and the propyzamide metabolite RH 24644 are below the concentrations at which no unacceptable effects (< 25%) regarding the soil microbial activity were observed after 28 days of exposure.

The results of the comparison expressed as Margin of Safety (MoS) are presented in the following table.

Table 6.8-1: Summary of risk assessment for soil micro-organisms exposed to GF-2540/ aminopyralid, propyzamide, propyzamide metabolite RH 24644 and GF-2540

Substance	Test type	Maximum initial PEC (mg/kg soil dw)	Effects <25% (mg/kg soil dw)	MoS
Active substance aminopyralid	N transformation	0.013	8.4	646
	C transformation		8.4	646
Active substance propyzamide	N transformation	1.200	33.3	27.8
	C transformation		33.3	27.8
Propyzamide metabolite RH-24644	N transformation	0.383	5.5	14.4
	C transformation		5.5	14.4
Preparation GF-2540	N transformation	6.834	13	2
	C transformation		13	2

For the active ingredients in GF-2540, propyzamide, aminopyralid and the propyzamide metabolite RH-24644, the soil concentrations which caused no deviations greater than ±25% in the activity of the soil microorganisms are at least 10-times higher than the corresponding maximum PEC in soil. For GF-2540 the soil concentrations which caused no deviations greater than ±25% in the activity of the soil microorganisms are 2 times higher than the corresponding maximum PEC in soil. Hence, a low risk to soil microflora is concluded.

The metabolite Uk1 is formed in relevant amounts in soil (max 24% of AR on day45) and its toxicity towards soil microorganisms has not been assessed in the EU review of propyzamide. However, the toxicity of this metabolite is considered to be covered in the 56d study with the preparation GF-2540.

Based on the predicted concentrations in soils, the risk to soil microbial processes following exposure to GF-2540 according to the GAP of the formulation GF-2540 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.

6.9 Effects on Non-Target Plants

6.9.1 Overview and summary

Please refer to the core assessment part B section 6 for the central zone.

6.9.1.1 Toxicity

Please refer to the core assessment part B section 6 for the central zone.

6.9.1.2 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-field= Maximum in-field PER (including MAF) x %drift

For calculation of PER in-field, please refer to section **Fehler! Verweisquelle konnte nicht gefunden werden.**, page **Fehler! Textmarke nicht definiert.**.

The resulting maximum off-field predicted environmental rates (PER off-field) are summarized in the following table:

Table 6.9-1: Maximum off-field predicted environmental rates of GF-2540 following intended uses

active substance/formulation	GF-2540
use pattern/gap:	00-001

application rate/number of applications / interval			1 x 1.5 L ha^{-1}					
MAF			**1**					
scenario/percentile:			Agriculture /90.					
distance (m)	PER via drift		PER via volatilisation		PER (via drift and volatilisation) (mL prod./ha) depending on application technique (drift reduction)			
	(%)	(mL prod./ha)	(%)	(g/ha)	no drift reduction	50% drift reduction	75% drift reduction	90% drift reduction
1	2.77	41.55	--	--	41.550	20.775	10.388	4.155
5	0.57	8.655	--	--	8.550	4.275	2.138	0.855

6.9.1.3 Risk assessment –TER values and overall conclusions

The risk assessment results are summarized in the following table:

Table 6.9-2: Summary of risk assessment for non-target terrestrial plants exposed to GF-2540

active substance/formulation			GF-2540					
use pattern/gap:			00-001					
application rate/number of applications / interval			1 x 1.5 L ha^{-1}					
MAF			**1**					
scenario/percentile:			Agriculture /90.					
distance (m)	PER via drift		PER via volatilisation		PER (via drift and volatilisation) (mL prod./ha) depending on application technique (drift reduction)			
	(%)	(mL prod./ha)	(%)	(g/ha)	no drift reduction	50% drift reduction	75% drift reduction	90% drift reduction
1	2.77	41.55	--	--	41.550	20.775	10.388	4.155
5	0.57	8.655	--	--	8.550	4.275	2.138	0.855
relevant toxiciy:		**ER50 = 210.95 g/ha (tomato)**						
relevant TER:		**10**						
Distance (m)					TER-values (calculated)			
1					**5.1**	10.2	20.3	50.8
5					24.7	49.3	98.7	246.7
required labelling:		**NT 101 (50% drift reduction)**						

For the intended use of GF-2540 risk mitigation corresponding to 50% (NT 101) drift reduction has to be applied to achieve an acceptable risk according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2.

6.10 Other Non-Target Species (Flora and Fauna)

6.10.1 Overview and summary

6.10.1.1 Toxicity

6.10.1.2 Exposure

6.10.1.3 Risk assessment –overall conclusions

6.10.2 Toxicity to Exposure Ratio

6.11 Other/Special Studies

6.11.1 Laboratory studies

6.11.2 Field studies

Appendix 1 GAP-Table of intended uses for Germany

GAP rev. BVL, date: 2012-10-05

PPP (product name/code)	**GF-2540**	**Formulation type:**	**SC**
active substance 1	**Propyzamid**	**Conc. of as 1:**	**500 g/L**
active substance 2	**Aminopyralid**	**Conc. of as 2:**	**5.3 g/L**
Applicant:	**DOW AgroSciences GmbH**	**professional use**	**X**
Zone(s):	**central/EU**	**non professional use**	

Verified by MS: Y

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 as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
001	DE	Winter oilseed Rape	F	Annual mono- and dicot weeds (post emergence of weeds)	Spraying	> BBCH 14 Late autumn to winter, November to February	a) 1 b) 1	a) 1.5 b) 1.5	a) 750 g/ha Propyzamid 7.95 g/ha Aminopyralid b) 750 g/ha Propyzamid 7.95 g/ha Aminopyralid	20 0 - 300		

~~DRAFT~~ REGISTRATION REPORT

Part B

Section 7: Efficacy Data and Information

Detailed Summary

Product Code: GF-2540

Reg. No.: 007726-00/00

Active Substances: propyzamide 500 g/L
aminopyralid 5.3 g/L

Central Zone

Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Dow AgroSciences

Date: 2012-08-22

Evaluator: Germany

Date: ~~08/05/2014~~06/08/2014

Table of Contents

IIIA1 6 Efficacy Data and Information on the Plant Protection Product

General information

Germany acts as the zonal Rapporteur Member State (zRMS) and belongs according to Regulation EC No 1107/2009 to the central registration zone (zone B). According to EPPO standard PP1/241 (Guidance on comparable climates) Germany is part of the maritime EPPO region.

No countries were defined as concerned Member States (cMS) in the central zone.

This document summarises the information related to the efficacy of the plant protection product GF-2540 containing the active substances propyzamide (500 g a.s./L) and aminopyralid (5.3 g a.s./L). Propyzamide is included in Annex I of the European directive 91/414 EEC. Aminopyralid has not yet been included in Annex I of the European directive 91/414 EEC. An application for inclusion was submitted in the UK in September 2004. Recently with the decision from August 2nd 2011 the Commission allowed Member States to extend provisional authorisations granted for the new active substance aminopyralid.

The product is intended to be used as a post-emergence herbicide for the control of annual monocotyledonous and dicotyledonous weeds in winter rape for use from the end of the vegetation period in the year of drilling of oil-seed rape until the start of the vegetation period in the year of oil-seed rape harvest. At application the plants should have reached the 4-leaf stage (BBCH 14).
The use recommendations for GF-2540 are basically identical in terms of propyzamide application rate, application time and application conditions with the registered uses of propyzamide in the propyzamide solo products of the KERB brands. The difference between KERB FLO and GF-2540 is just the addition of aminopyralid.

Recent registration situation/history of the PPP

Aminopyralid is approved for use in a number of European countries including the UK, Ireland and Germany in established grassland. It was first approved in the UK in 2006 for use in established grassland for the control of perennial weeds. Currently in Germany aminopyralid is registered as an ingredient in the herbicide SIMPLEX, a mixture of aminopyralid and fluroxypyr for use against broadleaved weeds in grassland.

Propyzamide is registered in several crops including oil-seed rape against grass weeds and STEME (*Stellaria media*). The proposed uses of GF-2540 fall within those approved for propyzamide as shown in table 6-1.

Table 6-1: Approved uses of propyzamide in oil-seed rape in countries of the maritime registration zone

Country	Name	Registration number	Max. registered use rate in oil-seed rape
France	KERB FLO	8400574	750 g a.s./ha
	KERB 80 WG	9900139	760 g a.s./ha
Netherlands	KERB FLO	13152	760 g a.s./ha

UK	KERB FLO	13716	840 g a.s./ha
Germany	KERB FLO	006220-00	750 g a.s./ha
	KERB 50 W	062002-00	750 g a.s./ha

Information on the active ingredients (Uptake and mode of action)

Propyzamide

Propyzamide belongs to the chemical group of benzamides. Mainly, propyzamide is taken up from the soil by plant roots and translocated into the plants. Plant uptake through the leaves is also possible to some extent. In this case only small parts of the substance are translocated within plants. Propyzamide inhibits cell division and photosynthesis. This results in inhibition of the formation of microtubuli and division of cell nucleus. Germination of seed will not be interrupted. After germination, seedlings become chlorotic and die as a consequence of interrupted photosynthesis. The effect of propyzamide depends on the growth stage of plants at the time of application and the microclimate at the location of treatment. For an optimum effect, wet weather is required. However, there is a dependency between application rate and the sensitivity of plants. Degradation studies in soils and plants showed three main metabolites: 2-(3,5-dichlorphenyl)-4,4-dimethyl-5-methylen-oxalin, N-(1,1-dimethyl-1-acetylmethyl)-3,5-dichlorbenzamide and N-(1,1-dimethyl-2-oxo-3-hydroxypropyl)-3,5-dichlorbenzamide. Partly, metabolites form conjugates of glucoside. Site of action (HRAC-group): K1.

Aminopyralid

Aminopyralid (4-Amino-3,6-Dichloropyridin-2-carboxylsäure) belongs to the chemical group of pyridine–carboxylic acids. Aminopyralid will mainly be absorbed through green leaves. Uptake through roots is of much less importance. Aminopyralid has systemic properties. Acropetal translocation of aminopyralid in xylem into young meristems and youngest leaves as well as basipetal transport in phloem into roots is possible. It has been shown that aminopyralid is accumulated in meristematic tissue and influences cell division, cell elongation and cell extension as well as RNA synthesis. Consequently, meristematic tissue dies off. The tissues of dicotyledonous plants are destroyed, while monocotyledonous plants are not affected. Typical symptoms of susceptible plants are deformation and curling of young leaves and stems followed by growth stop and necrosis. In the case of reduced plant metabolism, e.g. low temperature and drought stress, efficacy decreases. In plants, aminopyralid is transformed into N-glycoside and conjugates, or into non-extractable substances occurring naturally in plants. Causes of the selective effect of aminopyralid are still not fully understood. The main reason is probably based on different velocities of the formation of conjugates. Site of action (HRAC-group): O.

Information on crops and pests

The intended pest/crop can be classified in Germany according to its importance (occurrence, cultivation) as follows:

Table 6-2: Importance of intended pest/crop in Germany

Pest/Crop	EPPO	Country	Classification
Pest			
Monocotyledonous weeds	TTTMS	Germany	major

Dicotyledonous weeds	TTTDS	Germany	major
Crop			
Winter oil-seed rape	BRSNW	Germany	major

Information on the intended uses

Use No.	**007726-00/00-001**
Area of application	Agriculture (field crops)
Crop(s)/object(s)	winter oil-seed rape (BRSNW)
Crop stage(s) (BBCH)	from 14
Pest(s)/target(s)/aim(s)	annual monocotyledonous weeds (TTTMS), annual dicotyledonous weeds (TTTDS)
Area of use	Outdoors
Time of treatment	After emergence, late autumn to winter, November to February, after emergence of weeds
Max. number of treatments for the use	1
Max. number of treatments per crop or season	1
Application technique/ type of treatment	spraying
Dose rate(s) in amount of water to be used	1.5 L/ha in 200 to 300 L water/ha
Additional requirements (06.09.2013)	

IIIA1 6.1 Efficacy data

The trial results are from the maritime climatic zone as defined in EPPO standard PP1/241 from France, UK and Germany. All of the results presented here are considered relevant for judging efficacy and selectivity of GF-2540 in countries belonging to the maritime climatic zone as defined in the EPPO standard.
For discussion of efficacy observed in this document the EPPO codes for the weed species are used. The codes used are listed in table 6.1-1.

Table 6.1-1: Weed decoding list

Weed code	***Scientific name***	**Common name**
ALOMY	*Alopecurus myosuroides*	Blackgrass
APESV	*Apera spica-venti*	Windgrass
CAPBP	*Capsella bursa-pastoris*	Shepherd's purse
CENCY	*Centaurea cyanus*	Cornflower
CHEAL	*Chenopodium album*	Common lambsquarters
GALAP	*Galium aparine*	Catchweed bedstraw
GERRT	*Geranium rotundifolium*	Round-leaved cranesbill
HORVW	*Hordeum vulgare* (winter)	Winter Barley
LAMAM	*Lamium amplexicaule*	Henbit
LAMPU	*Lamium purpureum*	Purple deadnettle
LOLMU	*Lolium multiflorum*	Italian ryegrass
MATCH	*Matricaria chamomilla*	Wild chamomile
MATIN	*Matricaria inodora*	False chamomile

Weed code	***Scientific name***	**Common name**
MATSS	*Matricaria* sp.	Chamomile
MERAN	*Mercurialis annua*	Annual mercury
MYOAR	*Myosotis arvensis*	Field forget-me-not
PAPRH	*Papaver rhoeas*	Corn poppy
POAAN	*Poa annua*	Annual bluegrass
SENVU	*Senecio vulgaris*	Common groundsel
STEME	*Stellaria media*	Common chickweed
TRZAW	*Triticum aestivum* (winter)	Winter wheat
VERAR	*Veronica arvensis*	Corn speedwell
VERPE	*Veronica persica*	Bird's-eye speedwell
VIOAR	*Viola arvensis*	Field violet
APHAR	*Aphanes arvensis*	Break-stone
CERGL	*Cerastium glomeratum*	Mouse-ear chickweed
DESSO	*Descurainia sophia*	Flixweed
EHIVU	*Echium vulgare*	Blue thistle
GERDI	*Geranium dissectum*	Cut-leaved geranium
VERHE	*Veronica hederifolia*	Ivy-leaved speedwell
VEROF	*Veronica officinalis*	Common speedwell
SSYOF	*Sisymbrium officinale*	Hedge mustard

The standard products used in the trials were usually propyzamide solo products. Efficacy was only compared in a few trials to “BUTISAN TOP” applied at 2 l/ha. BUTISAN TOP is registered in Germany and contains 375 g a.s./ha metazachlor and 125 g/l quinmerac.

IIIA1 6.1.1 Preliminary range-finding tests

In order to fix the rate of aminopyralid in the formulation of GF-2540, in the year 2007 three GEP trials were performed with 3 rates of aminopyralid solo and in tank mix combination with propyzamide. All 3 trials were performed in France on oil-seed rape drilled between the end of August and the beginning of September 2007. The applications were performed in November 2007 with 200 to 250 l/ha spray volume at temperatures between 9 to 10.5 °C. The observations made were visual observations on weed control efficacy as well as selectivity observations.
Assessments were performed between approx. 15 and 90 days after treatment, for ALOMY up to 121 days. As the treatments were at the end of the vegetation period in the year of drilling, typically the last assessments made at the beginning of March at the beginning of the new vegetation period are the most relevant showing the weed control potential of the mixture.

It appears that contrary to the solo application of propyzamide (KERB FLO) at 750 g a.s./ha, the addition of aminopyralid in these trials increased the weed control spectrum for PAPRH. In addition, the performance of propyzamide solo for CERGL, GALAP and GERDI was increased in these trials. Although increasing the aminopyralid rate from 8 to 10 and 12 g a.s./ha increased the performance of aminopyralid solo applications, this rate response is not clearly visible when aminopyralid is combined with the target rate of 750 g a.s./ha propyzamide that is the registered propyzamide rate in the product KERB FLO and is required for the control of ALOMY, for example. Results on earlier assessments for aminopyralid as well as for propyzamide solo and in combinations show in these trials that full performance is not visible soon after application in early winter. The full potential of herbicidal activity is not assessable until the end of February onwards.

IIIA1 6.1.2 Minimum effective dose tests

The trial results presented for demonstration of dose rate effect are results from trials performed in oil-seed rape. The trials were performed in the maritime climatic area in France, in the UK and in Germany by GEP-accredited contract research organisations.

Field trials were carried out in Germany, UK and in the northern part of France over two years: 2009 and 2010. Trials allowed studying dose effects between three rates. Dose response was assessed in trials in which product application was performed after weed emergence. Three rates of GF-2540 – 0.75, 1.0 and 1.5 L/ha – were tested in 10 trials; three rates – 1.0, 1.5 and 1.7 L/ha – were studied in 11 trials. The northern part of France belongs to the maritime climate EPPO region. Therefore, trial results can be taken into account for the assessment in the central zone.

All trials were carried out by testing facilities or organisations officially recognised as competent to perform efficacy testing in accordance with the requirements of Directive 93/71/EEC, and with the principles of GEP. Trials were conducted across a wide range of sites representative of a wide range of agricultural, plant health and environmental conditions (including climatic conditions) likely to be encountered in practice in the area of proposed use. Trials were located in Germany (8), UK (8) and in the northern part of France (5). France is not part of the central registration zone (zone B) but belongs to the maritime climate EPPO region.

All trials were conducted in accordance with the relevant EPPO standards (PP 1/49, PP 1/135) and the CEB guideline (France). Application rates ranged from 0.75 to 1.7 L/ha in water volumes of 150 to 200 L/ha. The standard reference product was Kerb Flo (750 g propyzamide/ha).
Site details for rate response studies:

- Field size 10-30 square metres
- Layout: RCB
- Replicates: 3 (12 trials) - 4 (9 trials)

<u>Results</u>

The weed control levels achieved at the final assessment date with reduced rates and the target rate 758 g a.s./ha (1.5 L/ha) of GF-2540 are summarized in table 6.1.2-1, for reduced and increased rates (up to 1.7 L/ha) they are presented in table 6.1.2-2.

For the weed species that are controlled at levels above 70% with 758 g a.s./ha (1,5 L/ha) GF-2540, a reduction of the application rate resulted in an obvious reduction of the performance achieved except for APESV which was controlled at 100% level even at the lowest tested application rate of 0,75 L/ha. Also, for the control of voluntary cereal crops in oil-seed rape, only marginal efficacy reductions were noticed when the application rate was reduced.

Weed control for a reduced (1 L/ha) as well as for an increased (1.7 L/ha) application rate of GF-2540 is summarised in table 6.1.2-2. Here again it is obvious that reducing the application rate of GF-2540 from 758 g a.s./ha (1,5 L/ha) to only 1 L/ha, efficacy is lost for ALOMY, CENCY, LOLMU, MATSS, PAPRH, POAAON, and VERSS. On the other hand, the additional efficacy observed due to increasing the rate further above the planned target rate only has significant benefits for controlling LAMAM, MATSS, SENVU and VEROF. However, for these weeds the selected rate of 758 g a.s./ha (1.5 L/ha) has already resulted in control levels that are commercially satisfactory.
Looking at the individual results it appears that typically, full efficacy is achieved at the end of March to the beginning of April.

Dose response between 0.75, 1.0 and 1.5 L/ha

Table 6.1.2-1: Efficacy of GF-2540 - study of the dose response between 3 rates (0.75, 1.0 and 1.5 L/ha)

Weed species	**Trials**	**GF-2540**								
		0.75 L/ha (379 g a.s./ha)			**1.0 L/ha (505 g a.s./ha)**			**1.5 L/ha (758 g a.s./ha)**		
		mean	**min**	**max**	**mean**	**min**	**max**	**mean**	**min**	**max**
ALOMY	3	87	73	99	96	91	99	98	97	99
APESV	2	100	99	100	100	100	100	100	100	100
CAPBP	3	29	17	39	45	30	57	56	13	73
CENCY	1	58			74			90		
DESSO	1	0			5			5		
EHIVU	1	0			3			9		
GERRT	1	39			68			86		
HORVW	2	95	91	100	98	96	100	99	98	100
LAMAM	2	58	35	64	71	45	77	77	48	91
MATCH	1	66			87			95		
MATIN	5	76	66	95	92	84	99	99	98	100
MYOAR	1	6			8			15		
PAPRH	4	80	69	99	87	75	99	98	96	100
POAAN	1	79			88			100		
SENVU	1	51			49			51		
SSYOF	1	25			0			8		
STEME	2	76	71	81	88	81	96	97	96	99
TRZAW	2	94	88	99	98	96	100	100	100	100
TTLWI	1	98			99			99		
VERHE	2	69	68	70	78	77	78	92	91	92
VIOAR	6	51	5	81	63	5	88	73	8	97

Dose response between 1.0, 1.5 and 1.7 L/ha

Table 6.1.2-2: Efficacy of GF-2540 - study of the dose response between 3 rates (1.0, 1.5 and 1.7 L/ha)

Weed species	**Trials**	**GF-2540**								
		1.0 L/ha (505 g a.s./ha)			**1.5 L/ha (758 g a.s./ha)**			**1.7 L/ha (861 g a.s./ha)**		
		mean	**min**	**max**	**mean**	**min**	**max**	**mean**	**min**	**max**
ALOMY	2	91	85	100	96	92	100	96	92	100
CENCY	1	89			99			98		
EHIVU	1	3			9			9		
LAMAM	1	45			48			68		
LOLMU	1	67			95			97		
MATCH	3	90	83	97	94	90	98	97	96	99
MATIN	2	81	70	93	93	86	99	95	90	99
MYOAR	1	8			15			19		
PAPRH	5	89	75	100	97	95	100	98	96	100
POAAN	2	94	88	100	100	100	100	100	100	100
SENVU	3	81	49	100	82	51	100	87	65	100
STEME	4	90	67	100	90	67	100	95	82	100

Weed species	Trials	GF-2540								
		1.0 L/ha (505 g a.s./ha)			1.5 L/ha (758 g a.s./ha)			1.7 L/ha (861 g a.s./ha)		
		mean	min	max	mean	min	max	mean	min	max
VEROF	1	81			85			98		
VERPE	1	95			100			100		
VIOAR	3	52	5	100	54	8	97	57	10	92

Conclusions - Minimum effective dose
For the minimum effective dose determination in respect to the label claims regarding the control of annual dicotyledonous and monocotyledonous weeds, the applicant evaluated 21 trials in total from Germany, UK and France in 2009 and 2010. Dose response was evaluated from trials treated at post-emergence of weeds. The trials were conducted with the applied/normal and reduced dose rates (e.g. 50-67-100-113%) and according to GEP and EPPO standards. In most cases reduced dose rates resulted in minor control of the target weeds/organisms in comparison to the normal dose rate.
All trials showed a more or less clear dose response to the respective target organism. The minimum effective dose appears to be justified.

The evaluation was carried out in accordance with the Uniform Principles.

IIIA1 6.1.3 Efficacy tests

The trials presented were performed in Germany, UK and the maritime part of France by GEP-certified contractors.

A set of 38 trials are presented where 758 g a.s./ha (1.5 L/ha) of GF-2540 was tested for weed control efficacy in comparison to the standard product KERB FLO at a rate of 750 g a.s./ha propyzamide applied in winter between November and February in oil-seed rape.
In 13 of these trial sites, instead of GF-2540 the tank mix of 750 g a.s./ha propyzamide plus 8 g a.s./ha aminopyralid was used – this is justified as shown in bridging studies.
The distribution of the trials in the countries belonging to the maritime climatic zone (as to EPPO 241) is given in the table 6.1.3-1.

Table 6.1.3-1: Site distribution on efficacy trials performed in the "maritime" region

Country	2007	2008	2009	2010	total
France	3	6	4	3	16
Germany			2	8	10
United Kingdom		4	4	4	12
Total	3	10	10	15	38

All trials were carried out by testing facilities or organisations officially recognised as competent to perform efficacy testing in accordance with the requirements of Directive 93/71/EEC, and with the principles of GEP. Trials were conducted across a wide range of sites representative of a wide range of agricultural, plant health and environmental conditions (including climatic conditions) likely to be encountered in practice in the area of proposed use. Trials were located in Germany (10), UK (12) and in the northern part of France (16). France is not part of the central registration zone (zone B) but belongs to the maritime climate EPPO region.
All trials were conducted in accordance with the relevant EPPO standards (PP 1/49, PP 1/135) and the CEB guideline (France). Application rate was 1.5 L/ha in water volumes of 150 to 300 L/ha. The standard reference product was Kerb Flo (750 g propyzamide/ha).
Site details for rate response studies:

- Field size 12-30 square metres
- Layout: RCB

- Replicates: 3 (31 trials) - 4 (8 trials)

Results

Efficacy of weed control with GF-2540 at the final assessment is presented in table 6.1.3-2. It appears that acceptable to excellent performances were achieved for the following weed species: ALOMY, APESV, CENCY, LOLMU, MATSS, PAPRH, POAAN, SENVU, STEME and some *Veronica* species. For VIOAR, in 3 of 9 trial sites the weed control achieved was unsatisfactory while in the other sites efficacy was sufficient.
For some weed species, the efficacy of 1.5 L/ha GF-2540 is not sufficient (e.g. CAPBP, GALAP, LAMSS).

Table 6.1.3-2: Weed control at the last assessment of GF-2540 applied at 758 g a.s./ha (1.5 L/ha)

Weed species	Trials	GF-2540			KERB FLO[1]		
		758 g a.s./ha			750 g a.s./ha		
		mean	min	max	mean	min	max
ALOMY	16	98	92	100	96	75	100
APESV	2	100	100	100	100	100	100
APHAR	1	7			0		
CAPBP	4	42	0	73	56	25	100
CENCY	2	95	90	99	0	0	0
CERGL	1	93			78		
DESSO	1	5			20		
EHIVU	1	9			0		
GALAP	1	53			7		
GERDI	1	80			10		
GERRT	1	86			35		
HORVW	3	76	30	100	78	37	100
LAMAM	2	77	48	91	45	11	78
LAMPU	1	30			100		
LOLMU	4	98	95	100	99	97	100
MATCH	7	97	90	100	40	0	98
MATIN	8	97	86	100	40	13	93
MATSS	1	100			0		
MERAN	1	98			98		
MYOAR	1	15			0		
PAPRH	14	97	82	100	42	0	99
POAAN	2	100	100	100	100	100	100
SENVU	4	86	51	100	31	0	95
SSYOF	1	8			0		
STEME	6	83	32	100	88	53	100
TRZAW	3	98	91	100	97	94	100
TTLWI	1	99			99		
VERAR	2	66	48	93	66	50	90
VERHE	2	92	91	92	81	78	83
VEROF	1	85			91		
VERPE	3	66	33	100	70	57	80
VIOAR	9	73	8	97	48	0	88

[1] for the following weeds in 1 of the trails the comparison treatment was Butisan Top applied at 2 L/ha: PAPRH, ALOMY, MATCH, CHEAL, VIOAR, STEME, LAMPU, CAPBP, MATIN.

The results show that the weed spectrum of solo propyzamide (KERB FLO) applied at the same propyzamide rate as GF-2540 is clearly widened when aminopyralid is added to the formulation:

weed species that clearly demonstrated the benefit of the addition of aminopyralid are: CENCY, CERGL, GALAP, GERDI, GERRT, LAMAM, MATSS, PAPRH, SENVU and VIOAR. The data presented confirm the efficacy of GF-2540 in a large range of annual dicotyledonous and mono-cotyledonous weeds.

Conclusion - Efficacy
For the efficacy evaluation of GF-2540 the applicant has presented a total of 38 efficacy trials. Efficacy is derived from trials carried out in 2007 (3), 2008 (10), 2009 (10) and 2010 (15) in Germany, UK and the northern part of France. The trials were conducted according to GEP and EPPO standards. A sufficient number of trials were submitted for the maritime EPPO zone. Efficacy is demonstrated with an application rate of 1.5 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

Effects on the thousand grain weight were observed. The results shown in table 6.1.4.1-1 confirm that there was no negative effect on the thousand grain weight when GF-2540 is applied on weed-free soils, even at the double dose rate.
In 2 of the trials the oil content of the harvested seeds was tested. In these 2 trial sites no hint of a potential negative impact on oil content was recorded.

Table 6.1.4.1-1: Effects on the 1000 grain value due to the treatment with GF-2540 on weed-free sites. Numbers give the % change versus untreated check = 100%, n = 8

Trial number	**Rating**		**KERB FLO**		**KERB FLO + Aminopyralid**		**GF-2540**	
	Unit	**DAT**	**750**	**1500**	**750+8**	**1500+16**	**758**	**1516**
			g a.s./ha					
Average across all 8 trials with 1000 grain weight info			**99.9 a**	**98.3 a**		**99.8 a**		
Average across 4 trials (at the bottom of this table)			**99.8 a**	**98.2 a**	**97.6 a**	**100 a**	**99.5 a**	**99.9 a**
FR08H2B008ML02C	%UNCK	280	99.8 b	102.4 ab		107.1 a		
GB08H2B008SE01C	%UNCK	252	100.0 a	98.2 a		99.9 a		
GB08H2B008SE02C	%UNCK	249	100.0 a	96.5 a		101.3 a		
GB08H2B008SE03C	%UNCK	278	100.0 a	96.3 a		99.4 a		
FR09H2B007ML01C	%UNCK	248	100.1 a	96.8 a	100.0 a	96.4 a	97.8 a	97.0 a
FR09H2B007ML02C	%UNCK	190	100.5 a	99.7 a	100.0 a	97.8 a	96.8 a	100.7 a
GB09H2B007SE01C	%UNCK	261	99.0 a	101.1 a	100.0 a	98.5 a	102.2 a	103.9 a
GB09H2B007SE02C	%UNCK	265	99.5 a	95.3 a	100.0 a	97.8 a	101.3 a	98.0 a

Conclusion
It can be concluded that GF-2540 applied at 1.5 L/ha (750 g a.s./ha propyzamide + 8 g a.s./ha aminopyralid), should have no negative impact on the quality of plants and plant products.

IIIA1 6.1.4.2 Effects on the processing procedure

The applicant stated that there are no specific studies as they are not deemed necessary because propyzamide and aminopyralid are not present in the tissues of the treated crops (residues below limit of quantification).

IIIA1 6.1.4.3 Effects on the yield of treated plants and plant products

The trials were performed according to the requirements of the EPPO standards on selectivity-testing for herbicides: the trials included at least applications of 2 times the target rate. In these trials a "worst-case scenario" of a 3 l/ha rate of GF-2540 was tested under weed-free conditions. Applications were performed within the time frame set according to application timing in the proposed label.
The results shown in table 6.1.4.3-1 confirm that there was no negative effect on the thousand grain weight when GF-2540 was applied on weed-free soils, even at the double dose rate.

Table 6.1.4.3-1: Yield effects due to the treatment with GF-2540 applied at single (N) and double (2N) target rates. Numbers give the % change versus the untreated check = 100%, n = 10

Trial number	Rating		KERB FLO		KERB FLO + Aminopyralid		GF-2540	
	Unit	DAT	750	1500	750+8	1500+16	758	1516
			g a.s./ha					
Average across all 10 trials with 1000 grain weight info			**100.2 a**	**101.9 a**		**100.9 a**		
Average across 4 trials (at the bottom of this table)			**100.6 bc**	**103.6 a**	**101.3 abc**	**100.0 c**	**103.1 ab**	**102.6 abc**
FR08H2B008ML01C	%UNCK	254	100.0 a	97.6 a		91.9 a		
FR08H2B008ML02C	%UNCK	256	99.4 a	99.6 a		96.9 a		
FR08H2B008ML03C	%UNCK	231	100.0 a	107.0 a		105.3 a		
GB08H2B008SE01C	%UNCK	252	100.0 a	100.8 a		102.3 a		
GB08H2B008SE02C	%UNCK	249	100.0 a	95.0 a		102.8 a		
GB08H2B008SE03C	%UNCK	278	100.0 a	104.2 a		105.1 a		
FR09H2B007ML01C	%UNCK	246	99.5 a	102.2 a	100.0 a	99.4 a	101.4 a	100.2 a
FR09H2B007ML02C	%UNCK	175	101.6 a	106.0 a	100.0 a	103.2 a	102.0 a	104.4 a
GB09H2B007SE01C	%UNCK	261	98.8 a	102.1 a	100.0 a	96.4 a	104.6 a	98.4 a
GB09H2B007SE02C	%UNCK	265	102.4 a	104.2 a	100.0 a	106.2 a	104.4 a	107.3 a

Conclusion
It can be concluded that GF-2540 applied at 1.5 L/ha (750 g a.s./ha propyzamide + 8 g a.s./ha aminopyralid), should have no negative impact on yield.

IIIA1 6.2 Adverse effects

IIIA1 6.2.1 Phytotoxicity to host crop

The trials presented are representative for the use of GF-2540 in Germany. They have been performed according to GEP standards following the EPPO standards in the maritime climate in Germany, the UK and France.

One specific selectivity trial (DE11H2B015UH01C) was performed with 7 different oil-seed rape varieties in Germany: ADRIANA, GALILEO, PR46 W20, VISBY, VISION, NK LINUS. In this test GF-2540 was applied at 1.5 l/ha (758 g a.s./ha). A negative effect of the test varieties was not observed.

Observations in efficacy trials
In all efficacy trial sites, besides weed control efficacy ratings, also the selectivity of the crop was regularly observed and reported. In 5 (3 from France, 1 from Germany and 1 from the UK) of the presented efficacy trials there were assessment timings where some effects were observed and reported. All selectivity ratings of these 5 trials are listed in table 6.2.1-1. Some stand reduction and deformation was assessed for the plots treated with GF-2540. Deformation,

leaf thickening and slight twisting of new leaves were also estimated. In the 3 French trials there were values different to “0”.

Table 6.2.1-1: Efficacy trials with selectivity ratings different to “0”

Trial number	Rating date	Rating			DAT	KERB FLO	GF-2540
		Object	Type	Unit		750 g a.s./ha	758 g a.s./ha
GB08H2B007SE01C	27.11.2008	PLOT	INJURY	%VISUAL	14	0	0
	11.12.2008	PLOT	INJURY	%VISUAL	28	0	0
	25.02.2009	PLOT	STANDRED	%REDUCTN	104	0	10
	25.02.2009	PLOT	DEFORM	%VISUAL	104	0	13.3
	01.06.2009	PLOT	INJURY	%VISUAL	200	0	0
DE10H2B013UB06C	16.11.2010	PLOT	DAMAGE	%VISUAL	15	0	0
	22.03.2011	PLOT	DAMAGE	%VISUAL	47	0	12.5
FR09H2B006ML03C	25.11.2009	PLANT	INJURY	%VISUAL	7	0	0
	04.12.2009	PLANT	INJURY	%VISUAL	16	0	0
	17.12.2009	PLANT	INJURY	%VISUAL	29	0	0
	24.02.2010	PLANT	NECROSIS	%VISUAL	98	0	5
FR10H2B022YL02C	26.11.2010	PLOT	CHLORO	%VISUAL	29	2	5
	26.11.2010	PLOT	REDUCT	%VISUAL	29	0	0
	14.03.2011	PLOT	INJURY	%VISUAL	137	0	0
	07.04.2011	PLOT	INJURY	%VISUAL	161	0	0
09H2B007ML01C	30.11.2009	PLANT	INJURY	%VISUAL	24	0	0
	09.03.2010	PLANT	INJURY	%VISUAL	123	0	0
	12.04.2010	FLOW ER	REDUCT	%VISUAL	157	1.3	1.5
	11.05.2010	PLANT	INJURY	%VISUAL	186	0	0
	28.06.2010	PLANT	INJURY	%VISUAL	234	0	0

Conclusion
It can be concluded that phytotoxicity to the host crop is very limited when GF-2540 is applied at 1.5 L/ha (750 g a.s./ha propyzamide + 8 g a.s./ha aminopyralid).
The label should state that damage is possible to crops.

IIIA1 6.2.2 Adverse effects on health of host animals

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

IIIA1 6.2.3 Adverse effects on site of application

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

IIIA1 6.2.4 Adverse effects on beneficial organisms (other than bees)

Effects on relevant beneficial arthropods
The herbicide GF-2540 (500 g/L propyzamide + 5.3 g/L aminopyralid, DOW-02540-H-0-SC) has been proposed for one treatment from November to February in winter oil-seed rape at an application rate of 1.5 L/ha, corresponding to 750 g/ha propyzamide + 8 g/ha aminopyralid.

Results on the toxicity of the test product were available from laboratory tests with the two indicator species *Aphidius rhopalosiphi* and *Typhlodromus pyri* and from extended laboratory tests with *Typhlodromus pyri* and *Chrysoperla carnea* (table 6.2.4-1).

The predatory mite *Typhlodromus pyri* showed only a marginal lethal effect at 1.13fold the proposed application rate of the test product on artificial substrate, but the fecundity was reduced by 59% (DAS 090221).
At the same rate on a natural substrate, the lethal effect amounted to 36% and thus exceeded the sublethal effect being 12% (DAS 101369).

The test product only marginally affected *Aphidius rhopalosiphi* on an artificial substrate and *Chrysoperla carnea* on a natural substrate up to 1.13 fold the proposed application rate (DAS 090222, DAS 101370).

Table 6.2.4-1: Effects of GF-2540 (436 g/L propyzamide + 5.8 g/L aminopyralid)

Species (Exposed Stage)	Substrate	Rate Product [L/ha]	Corrected Mortality [%]	Sublethal Effect [%]	Reference
T. pyri (PN)	Glass	0.047	-1.2	-7.0 (Re)	DAS 090221
		0.212	2.6	7.0 (Re)	
		0.425	3.9	15.5 (Re)	
		0.85	9	29.6 (Re)	
		1.7	9	59.2 (Re)	
T. pyri (PN)	Bean leaves	0.047	1.8	-7.1 (Re)	DAS 101369
		0.212	25.9	-3.0 (Re)	
		0.425	36.2	22.2 (Re)	
		0.85	20.7	18.2 (Re)	
		1.7	36.2	12.1 (Re)	
A. rhopalosiphi (A)	Glass	0.047	-2.6	11.2 (Re)	DAS 090222
		0.212	7.7	-46.9 (Re)	
		0.425	-2.6	-15.3 (Re)	
		0.85	5.1	-35.7 (Re)	
		1.7	7.7	0.0 (Re)	
C. carnea (La)	Apple leaves	0.094	3.3	-19 (Re)	DAS 101370
		1.7	6.7	16 (Re)	

PN = protonymphs, A = adults, La = larvae, Re = reproduction
The validity criteria were fulfilled.

Conclusion
GF-2540 is considered to be slightly harmful for the predatory mite *Typhlodromus pyri*, due to effects > 25% in the range of the proposed application rate on a natural substrate.
The sensitive indicator species is not a relevant antagonist in the proposed cultures, hence, no classification is proposed for this species.
It can be concluded, that the test product is slightly harmful for other, relevant predatory mites and spiders.

On the basis of the results of valid tests with effects < 25% in the range of the proposed rate, the test product can be classified as not harmful for the insect species *Aphidius rhopalosiphi* and *Chrysoperla carnea*. The lacewing species *Chrysoperla carnea* can be considered as a relevant antagonist for the proposed culture.

Effects on soil quality
Effects on soil macro-organisms being used as indicators of soil quality
Effects on earthworms

Table 6.2.4-2: EU Endpoints - Toxicity to earthworms

Compound	Exposure route	Endpoint	EU agreed endpoints[1]	Endpoints used in risk assessment[2]	
			Value (mg/L)	Value (mg/kg)	Reference
Propyzamide	Acute	$LC50_{corr}$	**> 173**	EU endpoint	SANCO/6502/VI/99
	Sublethal	$NOEC_{corr}$	**34**	EU endpoint	SANCO/6502/VI/99
RH-24644	Acute	$LC50_{corr}$	**>86.9**	EU endpoint	SANCO/6502/VI/99
RH-24644	Sublethal	$NOEC_{corr}$	N/A	**5.5**	GF-2540 IIIA 10.6.3/02
RH-24580	Acute	$LC50_{corr}$	**> 261**	EU endpoint	SANCO/6502/VI/99
Aminopyralid	Acute	LD50	N/A	**>1000**	IIA 8.4.1/01, Ward and Boeri, (2001)
GF-2540	Acute	LD50	N/A	**1000 mg** GF-2540/kg	AIII 10.6.2/01, Stäbler, D (2010)[3]
	Sublethal	NOEC	N/A	**52.1 mg** GF-2540/kg	GF-2540 AIII 10.6.3/01[3]

[1] SANCO/6502/VI/99
[2] Since Annex I inclusion new studies have been performed providing new end-points which are used in the risk assessment.
[3] Full study summary in this dossier.
N/A: Not applicable

Acute and chronic Toxicity Exposure Ratio (TER) values for acute and long term effects were calculated for propyzamide, RH-24644. Due to the low toxicity of RH-24580 only the calculation of the acute TER is necessary it is exceeded 900. In addition, RH-24580 is not persistent in soil with a measured $DT_{50field}$ of only 44.3 days (SANCO/6502/VI/99) so there is negligible long term exposure to this metabolite. Aminopyralid does not form metabolites of ecotoxicological concern in soil hence no assessment is necessary.

The log K_{ow} of propyzamide, RH 24644 and RH 24580 are greater than 2 and hence endpoints have been adjusted. For aminopyralid the log K_{ow} is lower than 2 and hence no adjustment of the endpoints used in the risk assessment is needed.

Proposed use pattern

Table 6.2.4-3: GAP

Use	Number of applications	Application rate L product/ha	Application rate g a.s./ha	Water volume L/ha	Growth stage
Winter oil seed rape	1	1.5	8 + 750	200-300	> 13-29 BBCH

Risk assessment (Toxicity exposure ratios, TER_A and TER_{LT})

Toxicity exposure ratios, TERA and TERLT
The PECs used in the risk assessment assume that propyzamide and its soil metabolites will have an even distribution in the top 1 cm of soil (Koc = 840) to give initial PEC of 5.0 mg/kg with no crop interception. Aminopyralid is assumed to have an even distribution in the top 2.5 cm of soil (Koc = <500) to give initial PEC of 0.02 mg/kg. For the formulation a worst case depth of 1cm was used which will give initial PEC of 10 mg/kg.

Table 6.2.4-4: Maximum PEC_S for propyzamide, RH 24655, RH24644, RH 24580 and aminopyralid after applications of GF-2540

Substance	PEC_S (mg/kg), no foliar interception
GF-2540	10
Propyzamide	5.0
RH 24644	0.96
RH 24580	0.77
Aminopyralid	0.02

Table 6.2.4-5: TERA and TERLT for propyzamide, RH 24655, RH24644, RH 24580 and aminopyralid after applications of GF-2540

Substance	Indicator species	Timescale	Endpoint (mg kg/soil)	PECs (mg kg/soil)	TER	TER risk assessment trigger
GF-2540	*Eisenia fetida*	Acute	1000	10	100	10
	Eisenia fetida	Long-term	52.1	10	5.21	5
Propyzamide	*Eisenia fetida*	Acute	> 173	5.0	34.6	10
	Eisenia fetida	Long term	34	5.0	6.8	5
RH 24580	*Eisenia fetida*	Acute	> 261	0.77	347	10
RH 24644	*Eisenia fetida*	Long term	5.5	0.96	5.73	5
Aminopyralid	*Eisenia fetida*	Acute	> 1000	0.02	50000	10

TERs shown in bold fall below the relevant trigger

Conclusion

Propyzamide, its major soil metabolites and aminopyralid have low toxicity to earthworms and the calculated TERA and TERLT exceed the Annex VI triggers indicating that applications of GF-2540 are low risk to earthworms.

Field tests

Not required as an acceptable risk to earthworms was identified, based on the laboratory studies available.

Effects on other non-target macro-organisms

Tests on other soil non-target organisms are triggered by breaching the soil persistence criteria (DT_{90} > 365 days).
Studies to determine the effects of GF-2540 on other soil non-target macro-organisms are not considered to be necessary because the DT_{90} values for propyzamide and aminopyralid are less than 365 days.

Effects on organic matter breakdown

No tests are required considering the persistence trigger in accordance with the EU Guidance Document, since the field DT_{90} is <365 days for propyzamide and aminopyralid. Furthermore, the TER_{LT} values for earthworms were above the trigger value of 5, and no effects on microorganisms > 25% were observed

Overall conclusion with respect to effects on soil macro-organisms

It is concluded that the proposed use of GF-2540 will not pose an unacceptable risk to populations of earthworms or other soil macro-organisms, when applied according to the recommended use pattern.

Instructions and information: None

Overall conclusion with respect to effects on soil quality

There is no indication of any unacceptable adverse effects on soil macro- or soil micro-organisms relevant for the maintenance of soil quality.

Effects on soil quality
Effects on soil micro-organisms being used as indicators of soil quality
Effects on soil non-target micro-organisms exposed to GF-2540

Table 6.2.4-6: Ecotoxicological endpoints for soil micro-organisms

Test item	Test design[1]	EU agreed endpoints	Reference
GF-2540 SC	C	No significant effect > 25% at day 28 at 2.61 mg or 13.0 mg product/kg d.w. soil (1.7 L or 8.5 L product/ha)	Stäbler, D. (2010) eurofins DAS Study No.: 090218
	N	No significant effect > 25% at day 56 at 1.352 mg a.s./kg d.w. soil (1.7 L or 8.5 L product/ha)	
RH-24644 (propyzamide metabolite)	C	No significant effect > 25% at day 28 at 1.1 mg or 5.5 mg a.s./kg d.w. soil	Rix, S. (2004) DERBI Report 040076, CEMS-2257
	N		

[1] C = Carbon mineralization, N = Nitrogen transformation.

Risk assessment for soil microflora functions

Table 6.2.4-7: Risk assessment for soil microflora functions

Test substance	NOEC (< 25% effect at 28 d)	Maximum PEC_{soil} [mg a.s./kg]	MoS*
GF-2540	13.0 mg/kg d.w. soil	10.0 (no foliar interception; depth of 1 cm for propyzamide, and 2,5 cm for aminopyralid)	1.3
RH-24644	5.5 mg a.s./kg d.w. soil	0.96 (no foliar interception)	5.7

* Margin of Safety

The results of these studies showed no effects of $\geq$ ± 25% compared to the control on soil microbial activity up to a maximum tested concentrations of 8.5 L product/ha. An acceptable risk to soil microbial activity can be concluded for the proposed use of GF-2540.

Overall conclusion with respect to effects on soil quality

There is no indication of any unacceptable adverse effects on soil macro- or soil micro-organisms relevant for the maintenance of soil quality.

IIIA1 6.2.5 Adverse effects on parts of plant used for propagating purposes

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

IIIA1 6.2.6 Impact on succeeding crops

In order to evaluate the effect on crops planted following an oil-seed rape crop treated with GF-2540, a standardised bioassay for the determination of the EC_{10} (NOEL) values was performed in the year 2011 by a GEP-accredited contractor in Germany. In this greenhouse test, the test product GF-2540 was applied and incorporated into the soil (a silty loam sand) at 8 different application rates ranging from 2.058 ml/ha (1.04 g active substance) to 4500 ml/ha (2274 g active substance per ha). In these treated soils the following plant species were transplanted: oat, winter wheat, maize, pea, oilseed rape, white mustard, sugar beet and sunflower. In terms of assessments, visual phytotoxicity, mortality and the effect on the development of fresh biomass were observed over a period of 14 days. The results are summarised in table 6.2.6-1. Phytotoxicity effects were found in all tested plant species. The most sensitive crops are winter wheat and oat. The assessment was done according EPPO standard PP1/207.

Table 6.2.6-1: EC_{10}-values of GF-2540

Plant species	**EC_{10} (µg/kg soil)**
Oat	60.4
Winter Wheat	32.0
Maize	417.0
Pea	479.5
Oilseed Rape	688.4
White Mustard	144.6
Sugar Beet	400.3
Sunflower	229.1

Based on DT_{50} values, PEC-values in soils were calculated. The following residues were calculated six months after application at a soil depth of 2.5 cm:
PEC value propyzamide (DT_{50} 47 days): 140.6 µg/kg soil
PEC value aminopyralid (DT_{50} 35 days): 0.6 µg/kg soil

Based on EC_{10} and PEC values TER values were calculated. TER values smaller than 1 indicate a risk for succeeding crops.
According to the results a damage of oat and winter wheat cannot be ruled out. The applicant had provided additional results from field trials. In 7 of the specific selectivity studies on weed-free sites including the 2 N rates, winter wheat was drilled after the harvest of the treated oil-seed rape in the "normal rotation". These winter wheat crops were assessed in autumn of the year of crop establishment as well as in the spring of the following year for visual crop injury symptoms.
On one site, applications were tested in November 2009 and March 2010 and the following crops were established in the fall after oil-seed rape harvest after minimum soil cultivation: Winter wheat – TRZAW (7.10.11), Lolium – LOLMU (09.09.11), Mustard – SINAR (09.09.11), Phacelia – PHCTA (09.09.11), Crimson Clover - TRFIN (09.09.11). In the following spring after

ploughing, oat – AVESA, spring wheat – TRZAS, maize – ZEAMX, spring oil-seed rape – BRSNS, sugar beet – BEAVA, peas – PIBSA, field beans – VICFX and potatoes – SOLTU were established. For this test with several crops growing in a normal rotation a visual assessment on phytotoxicity was performed as well as a count or a visual estimation of crop density.

No visual negative impact was recorded for any assessment timing in the crop rotation tests with winter wheat as the following crop established in the year of oil-seed rape harvest that was treated with GF-2540. Winter wheat could be established after an oil-seed rape crop treated with GF-2540 even if GF-2540 were treated with double the recommended use rate.
For the test crops established in one trial it appeared that none of the crops showed any damage symptoms or a difference in terms of crop number or crop density at any assessment time.

However, the applicant notes that damages on catch crops can occur, in particular leguminous crops like clover, beans and vetches. Possible catch crops are phacelia, mustard and grass mixes.

Early replacement after crop failure
A total of 4 trial results are available where the effect of a GF-2540 treatment at N and 2N rate on an early replacement crop has been evaluated. In 2 trial sites (1 in France 1 in UK) in the year 2008 maize, beans and spring oil-seed rape were established as early replacement crops after a "crop failure". In these 2 sites ploughing and minimum tillage were compared in terms of soil preparation for replacement crop establishment. In the 2 trials in 2009 (1 in France and 1 in the UK) spring barley (1), beets (1), beans (1), spring wheat (1), maize (2), ryegrass (1) and flax (1) were tested as early replacement crops.

The results on the early replacement crops in the 2 trials started in 2008 with ploughing or minimum tillage demonstrate that in the case of crop failure, an oil-seed rape crop treated with GF-2540 can be securely replaced by Maize as well as spring oil-seed rape. This crop replacement can be done after a ploughing activity as well as after a minimum tillage. No obvious differences to the untreated check or the standard comparison treatment KERB FLO were observed.
For beans as a replacement crop, significant deformations as well as leaf rolling and growth inhibition were recorded in the French trial while for the trial performed in the UK no effects were reported.

The applicant recommends no cultivation of spring cereals, grasses, beets, potatoes, legume species (peas, beans, lupines, clover, vetches, and lucernes), sunflower, umbellifer (e.g. carrots) or lettuce in spring after crop failure. Maize, spring rape and cabbage species are possible crops. No results were presented for spring rape and cabbage species.

Due to the trials with succeeding crops, assessments by the applicant, residues of aminopyralid in soil and crop, animal waste, slurry, dung and compost from animals with litter from fields which are sprayed with GF-2540, the use of GF-2540 is only possible under different restrictions. Very low herbicide residues in soil can cause damage to succeeding crops.

Special problems arise with residues of aminopyralid in manure and compost. It is not possible to estimate how aminopyralid residues in fodder (rape straw, pomace) should be assessed concerning the subsequent use of slurry, liquid manure or dung from animals with regard to crop damage following application.

Plant damage may arise with very low residue levels. Results from literature show that some crops react very sensitively to aminopyralid. The applicant did not consider these aspects sufficiently. For reasons of precaution requirements are appropriate.

Conclusion

It can be concluded that GF-2540 applied at 1.5 L/ha (750 g a.s./ha propyzamide + 8 g a.s./ha aminopyralid), can have negative impact on crops under certain conditions. Most affected are leguminous crops in crop rotation and early replacement after crop failure. Sowing of succeeding crops is only possible under certain conditions.
The label should state that damage is possible to succeeding catch crops. Serious damage can occur after early replacement to spring cereals, grasses, beets, potatoes, legume species (peas, beans, lupines, clover, vetches, and lucernes), sunflower, umbellifer (e.g. carrots) and lettuce in spring after crop failure. Maize, spring rape and cabbage species are possible crops.

It is not possible to estimate how aminopyralid residues in fodder (rape straw, pomace) should be assessed concerning the subsequent use of slurry, liquid manure or dung from animals with regard to crop damage following application.

For reasons of precaution requirements are appropriate:
- Damage cannot be excluded for crops other than grassland, cereals or maize when using slurry, liquid manure, dung or compost from animals whose litter comes from treated areas.
- The use of litter as well as slurry, liquid manure, dung and compost from animals whose litter comes from treated areas represents a hazard when used outside the agricultural business.
- Damage can occur to succeeding crops when breaking the field by early replacement. ~~in the year following application:~~ Maize, spring rape and cabbage species are possible crops. ~~cereals, fodder grass or maize are possible crops.~~
- ~~Serious damage can be expected if potatoes, tomatoes, leguminous plants or field vegetable species are replanted within 18 months following treatment.~~

IIIA1 6.2.7 Impact on other plants including adjacent crops

As GF-2540 is a very effective herbicide, drift at application has to be avoided. Drift to adjacent crops may cause severe damage.

The critical endpoints for propyzamide and aminopyralid employed in the risk assessment for non-target plants are indicated in Table 6.2.7-2.

Table 6.2.7-1: PEC-values (drift) – dose rate 1.5 L/ha

Distance (m)	%[1]	drift in ml/ha	drift in g a.s./ha
1	2.77	41.6	21.0
3	0.95	14.3	7.2
5	0.57	8.6	4.3
10	0.29	4.4	2.2
15	0.2	3	1.5

[1] percentage drift (%)

Table 6.2.7-2: Toxicity to terrestrial non-target plants

Compound	Most sensitive species	Endpoint	Endpoint used in risk assessment
			mg a.s./ha
propyzamide (Kerb Flo)	*Avena sativa*	Vegetative vigour (LR50)	2500
	Lolium perenne	Seedling emergence (LR50)	329.9

aminopyralid (GF-1601)	*Glycine max*	Vegetative vigour (LR50)	31.6
	Brassica napus	Seedling emergence (LR50)	3.9

The predicted environmental concentrations (PEC) and the toxicity exposure ratio (TER) by spray drift at the highest recommended application rate may be calculated (Table 6.2.7-3). Exposure assessment should be conducted from a distance of 1 m or 5 m from the field edge for field crops (drift rates of 2.77% and 0.57%). The resulting TER values are given in Table 6.2.7-3. The proposed trigger value for non-target plants is five. The risk assessment for both active ingredients resulted in a 1 and 5 m buffer zone based on ED_{50} values. When based on the estimated toxicity of GF-2540 a 5 m buffer zone was necessary to protect terrestrial non-target plants.

Table 6.2.7-3: TER values for terrestrial non-target plants

Active substance	Application	% drift	PEC	ED_{50}	TER
Vegetative vigour					
propyzamide	750 g/ha	2.77 (1 m)	20.8 g/ha	2500 g/ha	120
aminopyralid	8 g/ha	2.77 (1 m)	0.22 g/ha	31.6 g/ha	143
GF-2540	1500 ml/ha	2.77 (1 m)	41.6 ml/ha	1250 ml/ha	30
Seedling emergence					
propyzamide	750 g/ha	2.77 (1 m)	20.8 g/ha	329.9 g/ha	15.9
aminopyralid	8 g/ha	2.77 (1 m)	0.22 g/ha	3.9 g/ha	17.6
GF-2540	1500 ml/ha	2.77 (1 m)	41.6 ml/ha	165 ml/ha	4.0
		0.57 (5 m)	8.6 ml/ha	165 ml/ha	19.2

Dose response data for GF-2540 were submitted. The methodology for the study was based on OECD guideline 227; Terrestrial (Non-Target) plant test: Vegetative vigour test. The test species consisted of four monocotyledonous and six dicotyledonous species. Applications were made post-emergence to all ten species at growth stage BBCH 12-14. Results are summarised in Table 6.2.7-4. Based on foliar fresh weight reduction barley, with an ER_{50} value of 491.7 ml product/ha, was the most sensitive monocotyledonous species. Tomato was the most sensitive dicotyledonous species.

Table 6.2.7-4: Response data for GF-2540

Species	ER_{50} values (ml product/ha)	propyzamide g a.s./ha	aminopyralid g a.s./ha
ryegrass	>3000	> 1500	>15.9
oats	1041.8	520.9	5.52

barley	491.7	245.85	2.61
onion	>3000	>1500	>15.9
oilseed rape	>3000	>1500	>15.9
soybean	>3000	>1500	>15.9
cucumber	>3000	>1500	>15.9
sugar beet	2982.2	1491.1	15.81
tomato	313.9	156.95	1.66
carrot	>3000	>1500	>15.9

Conclusion
It can be concluded that a 5 m buffer zone is necessary to protect sensitive adjacent crops due to application of GF-2540. Using nozzles with drift reduction will reduce the risk of plant damage.

IIIA1 6.2.8 Possible development of resistance or cross-resistance

Mechanism of resistance
The herbicide GF-2540 contains the active substances propyzamide and aminopyralid. Propyzamide belongs to the benzamides family, a subset of the group K1 (HRAC) microtubule assembly inhibition type of herbicides. The mechanism of resistance for active substances from the HRAC group K1 is unknown. However, both target site resistance and metabolic mechanisms have been proposed to exist in resistant species.
Aminopyralid is classified by the applicant as a synthetic auxin (HRAC group O) closely related to the other pyridine carboxylic acid herbicides clopyralid, triclopyr, fluroxypyr and picloram. Although the mechanism of resistance of group O herbicides has not been determined, resistance may be due to an insensitive target site.

Evidence of resistance and cross-resistance
Herbicides representing the HRAC group K1 have been used commercially for more than 35 years and according to the applicant there have been 27 individual species reported showing resistance including three in Europe (International Survey of Herbicide Resistant Weeds). However, this information seems to be incorrect as the International Survey of Herbicide Resistant Weeds (www.weedscience.org, Nov 2012) lists only 11 species with resistance to HRAC group K1 substances worldwide and two in Europe (*Alopecurus myosuroides and Echinochloa crus-galli)*. Only one case of propyzamide resistance has been reported in USA (Oregon) in *Avena fatua* in 1990, the resistance was limited to this site. No resistant case has been reported for propyzamide in Europe.
30 weed species which have developed resistance to HRAC group O herbicides are demonstrated by the international survey of herbicide resistant weeds. Only few species being of importance in European oilseed rape production are reported to have developed resistance to HRAC group O herbicides. Among these species are: *Tripleurospermum inodorum* [2,4-D], *Cirsium arvense* [MCPA], *Stellaria media* [mecoprop], *Papaver rhoeas* [2,4-D] and *Sinapis arvensis* [dicamba]. There are no known cases of resistance to aminopyralid. However, based on HRAC resistance classification, cross resistance should be expected to be likely between aminopyralid and other HRAC group O herbicides. In Europe, cases of multiple resistance in-

cluding HRAC group O herbicides are reported for biotypes of *Papaver rhoeas* (Spain and Italy) and *Sinapis arvensis* (Turkey) with resistance to both HRAC O and HRAC B (only sulfonylureas) substances.

Analysis of the inherent risk

The applicant claims that propyzamide has a complex mode of action and therefore a lower resistance risk. So far, only one case of resistance to propyzamide has been reported in the US and no cases of resistance are known for Europe. Regarding the HRAC group K1, the number of resistant cases is comparatively low worldwide with only two resistant biotypes reported for Europe. The inherent risk of the active substance propyzamide can therefore be regarded as low.

With respect to aminopyralid in general the frequency of the occurrence of resistance to HRAC group O herbicides is very low, especially when only the European observations are taken into consideration. However, some cases of resistance and multiple resistance have already been observed for HRAC group O substances but no resistance to aminopyralid so far.

For propyzamide, the applicant has provided analysis of the inherent risk of the following target species: *Alopecurus myosuroides, Avena fatua* and *Avena ludoviciana Stellaria media.* All three species are annual species which produce many seeds per plant. In addition, the grass weed species produce wind-borne pollen enabling the transfer of (resistant) genetic material over a considerable distance. Blackgrass, wild oats and ryegrass have all shown a propensity to metabolise a range of active substances including those from the ACCase, ureas and amides, dinitroanilines, ALS inhibitors, and arylaminopropionic acid groups of chemistry. Cross-resistance and multiple resistance are widely observed. Both the target grass weed species exhibit a wide range of cross-resistance to some but not necessarily all herbicides within a group of active substances. *Stellaria media* in the UK has been shown to exhibit cross-resistance to the phenoxy herbicides but not all synthetic auxins. Limited cross-resistance to ALS inhibitors has also been reported. *Alopecurus myosuroides* has shown resistance to many different MoA including ACCase, ureas and amides, PS II inhibitors, dinitroanilines, ALS inhibitors and arylaminopropionic acid. *Avena fatua* and *Avena ludoviciana* show resistance to ACCase, dinitroanilines, ALS inhibitors, thiocarbamates and others as well as arylaminopropionic acid. *Stellaria media* has developed resistance to synthetic auxins but more importantly to many ALS inhibitor herbicides.

The assessment by the applicant for aminopyralid concerns the main target weed of aminopyralid in GF-2540, namely *Matricaria* spp. These species produce many seeds per plant and have shown a limited ability to metabolise synthetic auxin herbicides. In the central zone, *Matricaria* spp. has shown resistance to ALS inhibitors, Photosystem II inhibitors and synthetic auxins.

No sensitivity data are provided by the applicant. The applicant refers to efficacy data submitted with the application.

Analysis of the agronomic risk

GF-2540 is intended to be used against annual monocotyledonous and dicotyledonous weeds in oilseed rape.

The major use is in oil-seed rape in the north of Europe. Oil-seed rape is normally grown in rotation with cereal crops allowing a range of cultural and chemical methods to be employed. The herbicide is normally applied once in a crop life. In addition, other control measures for all the major target weeds including various modes of action exist. Since the occurrence of grass species resistant to FOP's, DIM's and sulfonylureas in northern Europe and particularly in the UK, propyzamide is a key tool for the control of these resistant grasses. Most of the FOP's and DIM's herbicides are used for grass control in cereals, hence the appearance of the resistant species. Propyzamide provides an alternative to widely used contact graminicides for control of particularly *Alopecurus myosuroides* in cereal / oil-seed rape rotations. The applicant claims that the agronomic risk is very low. This conclusion can generally be followed.

Summary and conclusion

The applicant claims that the risk of practical resistance for propyzamide and aminopyralid in unrestricted use is very low and the unmodified risk is acceptable. This conclusion can generally be followed. Regarding the low number of weeds with resistance to the concerned HRAC groups K1 and O in Europe and the fact that no resistance to propyzamide and aminopyralid has been reported in Europe, the general resistance risk of GF-2540 is therefore assessed as being low. The applicant has not provided information on the individual agronomic risk for the concerned Member States in the Central Zone but has provided some information especially relevant to the UK.

Management strategy
In view of the acceptable risk of propyzamide no resistance management strategy is deemed necessary; however, the current labelling refers specifically to a strategy for the weed black-grass and we will retain the approved label statement.

PROPOSED LABEL STATEMENT:

RESISTANCE
Strains of some annual grasses (e.g. black grass, wild oats, Italian ryegrass) have developed resistance to herbicides which may lead to poor control. A strategy for preventing and managing such resistance should be adopted. Guidelines have been produced by the Weed Resistance Action Group and copies are available from the HGCA, CPA, your distributor, crop adviser or product manufacturer.

This proposed label statement seems to be created for UK conditions only and therefore has to be adapted to the conditions of the respective member states.

IIIA1 6.3 Economics

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

IIIA1 6.4 Benefits

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

IIIA1 6.4.1 Survey of alternative pest control measures

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

IIIA1 6.4.2 Compatibility with current management practices including IPM

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

IIIA1 6.4.3 Contribution to risk reduction

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

IIIA1 6.5 Other/special studies

There were no other or special studies conducted.

IIIA1 6.6 Summary and assessment of data according to points 6.1 to 6.5

The submission of the present draft Registration Report (dRR) serves the core registration of GF-2540 in the central registration zone (B) of the European Union. The applicant applies for a herbicide containing the active ingredients propyzamide and aminopyralid. The evaluation of the test compound is based on results from field trials conducted in Germany, UK and the northern part of France during the years 2009 to 2010.

Minimum effective dose
Dose response was assessed in trials treated at post-emergence of weeds. Efficacy data from weeds, sprayed in post-emergence, allow the requested 1.5 L/ha as GF-2540 effective registration dose rate against annual monocotyledonous and dicotyledonous weeds in winter oil-seed rape. Reduction of the application rate below the proposed target rate will result in an obvious reduction of weed control performance.

Efficacy
Efficacy tests were conducted in winter oil-seed rape in the maritime EPPO climate zone regarding the control of annual mono- and dicotyledonous weeds. GF-2540 was tested in all trials in comparison to the commercial standard reference products. The trials presented are relevant for judging efficacy of GF-2540 in Germany. They were performed in Germany, UK and the maritime part of France under GEP conditions by GEP certified contractors.

Assessments performed in an April/May timeframe demonstrated satisfying control levels for the following weed species: ALOMY, APESV, CENCY, LOLMU, MATSS, PAPHR, POAAN, SENVU, STEME, VIOAR and some *Veronica* species. The achieved efficacy is not related to the application timings (early or late winter). The inclusion of aminopyralid in the propyzamide formulation is justified: an obvious efficacy increase versus the solo application of propyzamide was demonstrated for: CENCY, CERGL, GALAP, GERDI, GERRT, LAMAM, MATSS, PAPRH, SENVU and VIOAR.

Yield effects
Even under the extreme conditions of applications of GF-2540 at 2N rate on weed-free sites, no relevant negative impact on yield or 1000 grain weight was found due to the treatment with GF-2540. Applications as recommended on the label will not result in negative impact on yield for the crop.

Phytotoxicity to host crop
The trials presented are representative for the use of GF-2540 in Germany. They have been performed according to GEP standards following the EPPO standards in the maritime climate in Germany, the UK and France.
Observations for visual phytotoxicity symptoms were performed in a set of specific selectivity trials applied at target rate (N-rate) and double the target rate (2N-rate) as well as in all efficacy trials plus in a variety screen of 6 varieties where GF-2540 was applied at N-rate (758 g a.s./ha).

It can be concluded that phytotoxicity to the host crop is very limited when GF-2540 is applied at 1.5 L/ha (750 g a.s./ha propyzamide + 8 g a.s./ha aminopyralid). The label should state that damage is possible to crops.

Succeeding crops
For succeeding crops in a normal rotation, field trials have shown that TRZAW, LOLMU. SINAR, PHCTA, TRFIN, AVESA, TRZAW, ZEAMX, BRSNS, BEAVA, PIBSA, VICFX and SOLTU can be drilled in a normal rotation. For early replacement crops in the case of the failure of a treated oil-seed rape crop, it appeared that the establishment of ZEAMX and BRSNS are secure.

After intensive soil cultivation in fall or spring following the harvest of a treated oil-seed rape crop, there is no restriction in terms of crops to be planted. Catch crops after a treated oil-seed rape might show damage symptoms. In terms of catch crops established after a treated crop phacelia, mustard and grass mixes are possible. Leguminosae (clover, beans, and vetches) should not be used as catch crops.

In the case of early replacement in spring, deep ploughing is required to establish maize, spring oil-seed rape or cabbage crops. It is not possible to establish spring cereals, grasses, beets, potato or crops from the leguminosae or umbellifer group.

It can be concluded that GF-2540 applied at 1.5 L/ha (750 g a.s./ha propyzamide + 8 g a.s./ha aminopyralid), can have a negative impact on catch crops under certain conditions. Most affected are leguminous crops in crop rotation and early replacement after crop failure.

The label should state that damage is possible to succeeding catch crops. Serious damage can occur after early replacement to spring cereals, grasses, beets, potatoes, legume species (peas, beans, lupines, clover, vetches, and lucernes), sunflower, umbellifer (e.g. carrots) and lettuce in spring after crop failure. Maize, spring rape and cabbage species are possible crops.

It is not possible to estimate how aminopyralid residues in fodder (rape straw, pomace) should be assessed concerning the subsequent use of slurry, liquid manure or dung from animals with regard to crop damage following application

Information for herbicides containing aminopyralid:
- Damage cannot be excluded for crops other than grassland, cereals or maize when using slurry, liquid manure, dung or compost from animals whose litter comes from treated areas.
- The use of litter as well as slurry, liquid manure, dung and compost from animals whose litter comes from treated areas represents a hazard when used outside the agricultural business.
- Damage can occur to succeeding crops when breaking the field by early replacement. Maize, spring rape and cabbage species are possible crops.~~in the year following application: cereals, fodder grass or maize are possible crops.~~
- ~~Serious damage can be expected if potatoes, tomatoes, leguminous plants or field vegetable species are replanted within 18 months following treatment.~~

Impact on other plants including adjacent crops

GF-2540 is a very effective herbicide; drift at application has to be avoided. Drift to adjacent sensitive crops may cause severe damage. Calculations of TER values showed that a 5 m buffer zone is necessary to protect terrestrial non-target plants due to application of GF-2540. Using nozzles with drift reduction will reduce the risk of plant damage.

Adverse effects on beneficial organisms (other than bees)

Effects on relevant beneficial arthropods

GF-2540 is considered to be slightly harmful for the predatory mite *Typhlodromus pyri*, due to effects > 25% in the range of the proposed application rate on a natural substrate.
The sensitive indicator species is not a relevant antagonist in the proposed cultures, hence, no classification is proposed for this species.
It can be concluded, that the test product is slightly harmful for other, relevant predatory mites and spiders.

On the basis of the results of valid tests with effects < 25% in the range of the proposed rate, the test product can be classified as not harmful for the insect species *Aphidius rhopalosiphi* and *Chrysoperla carnea*. The lacewing species *Chrysoperla carnea* can be considered as a relevant antagonist for the proposed culture.

Effects on soil quality

There is no indication of any unacceptable adverse effects on soil macro- or soil micro-organisms relevant for the maintenance of soil quality.

Resistance risk

The applicant claims that the risk of practical resistance for propyzamide and aminopyralid in unrestricted use is very low and the unmodified risk is acceptable. This conclusion can generally be followed. Regarding the low number of weeds with resistance to the concerned HRAC groups K1 and O in Europe and the fact that no resistance to propyzamide and aminopyralid has been reported in Europe, the general resistance risk of GF-2540 is therefore assessed as being low. The applicant has not provided information on the individual agronomic risk for the concerned Member States in the central zone but has provided some information especially relevant to the UK.

IIIA1 6.7 List of test facilities including the corresponding certificates

AGRARTEST GmbH, DE	Palmbachstraße 37 D 65326 Aarbergen-Panrod Germany
AGRO-CHECK, DE	Dorfstraße 15 16+833 Lenzke Germany
ARMSTRONG FISHER LTD, UK	Hill crest, main street ufford stamford lincolnshire pe9 3bh United Kingdom
ASTRIA PHYTO, FR	Chemin des chirouzes st paul les romans 26750 France
BIOCHEM AGRAR	Kupferstraße 6 D-04827 Machern, OT Gerichshain Germany
BIOTEK AGRICULTURE, FR	Route De Vielaines 10120 St Pouange France
DOW AgroSciencess France	790 avenue du Dr. Donat Marco Polo BAT. B BP 1220 06254 MOUGINS Cedex France
DOW AgroSciencess Germany	Truderinger Strasse 15 81677 München Germany
EUROFINS SARL, FR	Les Herbonnes 82290 Meauzac France
EUROFINS, UK	Slade Lane Wilson Melbourne Derby DE73 8AG United Kingdom
NDSM LTD. UK.	Unit 2b

	Dove Way Kirby Mills Industrial Estate Kirkbymoorside York North Yorkshire YO62 6NR United Kingdom
OXFORD AG TRIALS, UK	West Farm Barns, Launton Road, Stratton Audley, Bicester, Oxfordshire OX27 9AS United Kingdom
PRESTAGRO. FR	11 impasse Gaz des mulets 38300 RUY France
Syntech Research France (SRF) FR	613, route du Bois de Loyse 71570 La Chapelle de Guinchay France

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

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
MIIIA1 Sec 6	Dow AgroSciences	Draft Registration Report - Part B - Mittelname - MS - Section 6 - Ecotoxicology - National addendum	2012	285842
MIIIA1 Sec 6	Dow AgroSciences	Draft Registration Report - Part B - Mittelname - MS - Section 6 - Ecotoxicology - National addendum	2012	285843
MIIIA1 Sec 7	Dow AgroSciences	Draft Registration Report - Part B - GF-2540 - DE - Section 7 - Efficacy Data and Information - National addendum	2012	285844
MIIIA1 Sec 7	Dow AgroSciences	Draft Registration Report - Part B - GF-2540 - DE - Section 7 - Efficacy Data and Information - National addendum	2012	285845
MIIIA1 Sec 7	Dow AgroSciences	Draft Registration Report - Part B - GF-2540 - DE - Section 7 - Efficacy Data and Information - National addendum	2012	285846
KIIIA1 10.5.1	Klug, T.	GF-2540 - Toxicity to the Aphid Parasitoid, Aphidius rhopalosiphi De Stefani Perez (Hymenoptera, Braconidae) in the laboratory (Rate Response Test)	2009	090222 ! S09-00695 285852
KIIIA1 10.5.1	Klug, T.	GF-2540 - Toxicity to the Predatory Mite, Typhlodromus pyri Scheuten (Acari, Phytoseiidae) in the laboratory (Rate Response Test)	2009	090221 ! S09-00694 285853
KIIIA1 10.5.2	Höhn, P.	GF-2540 - Toxicity to the Predatory Mite, Typhlodromus pyri Scheuten (Acari, Phytoseiidae) using an Extended Laboratory Test (Rate Response Test)	2010	101369 ! S10-01125 285854
KIIIA1 10.5.2	Höhn, P.	GF-2540 - Toxicity to the Green Lacewing, Chrysoperla carnea Steph. (Neuroptera, Chrysopidae) under Extended Laboratory Conditions	2010	101370 ! S10-01126 285855
KIIIA1 10.6.2	Stäbler, D.	Acute toxicity of GF-2540 on Earthworms, Eisenia fetida using an Artificial Soil Test	2010	090216 ! S09-00689 285856
KIIIA1 10.6.3	Stäbler, D.	Sublethal toxicity of GF-2540 to the Earthworm Eisenia fetida in Artificial Soil	2010	090217 ! S09-00690 285857
KIIA 8.9.2	Davies, N.	RH-24644 Metabolite - Effects on reproduction and growth in the Earthworm Eisenia fetida	2004	040077 ! CEMS-2253 285858

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 10.7.1	Stäbler, D.	Assessment of the side effects of GF-2540 on the Activity of the Soil Microflora	2010	090218 ! S09-00691 285859
KIIIA1 6.2.6	Friedemann, A., Brockmann, A., Teresiak, H.	Standardized Bioassay for the Determination of ED10 (NOEL) and ED50 values for GF-2540 (aminopyralid potassium + propyzamide 5.3 g ae/l + 500 g ai/l SC) and selected Following Crops in Soil - Europe 2011	2011	AC/11/128 285865
KIIIA1 6.1.3	Litt, M.	EFFICACY OF GF-1601 APPLIED IN WINTER OILSEED RAPE, GERMANY 2009	2010	DE09A2A043ML01 285866
KIIIA1 6.1.3	Schulz, T.	EFFICACY OF GF-1601 APPLIED IN WINTER OILSEED RAPE, GERMANY 2009	2010	DE09A2A043TS02 285867
KIIIA1 6.1.2	Schnieder, F.	Efficacy of Propyzamide + aminopyralid in OSR, Germany 2010	2011	DE10H2B013FS02 285868
KIIIA1 6.1.3	Schnieder, F.	Efficacy of Propyzamide + aminopyralid in OSR, Germany 2010	2011	DE10H2B013FS02 285869
KIIIA1 6.1.2	Dzikowski, M.	Efficacy of Propyzamide + aminopyralid in OSR, Germany 2010	2011	DE10H2B013MD01 285870
KIIIA1 6.1.3	Dzikowski, M.	Efficacy of Propyzamide + aminopyralid in OSR, Germany 2010	2011	DE10H2B013MD01 285871
KIIIA1 6.1.2	Dzikowski, M.	Efficacy of Propyzamide + aminopyralid in OSR, Germany 2010	2011	DE10H2B013MD02 285872
KIIIA1 6.1.3	Dzikowski, M.	Efficacy of Propyzamide + aminopyralid in OSR, Germany 2010	2011	DE10H2B013MD02 285873
KIIIA1 6.1.2	Dzikowski, M.	Efficacy of Propyzamide + aminopyralid in OSR, Germany 2010	2011	DE10H2B013MD03 285874
KIIIA1 6.1.3	Dzikowski, M.	Efficacy of Propyzamide + aminopyralid in OSR, Germany 2010	2011	DE10H2B013MD03 285875
KIIIA1 6.1.2	Schulz, T.	Efficacy of Propyzamide + aminopyralid in OSR, Germany 2010	2011	DE10H2B013TS01 285876

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 6.1.3	Schulz, T.	Efficacy of Propyzamide + aminopyralid in OSR, Germany 2010	2011	DE10H2B0 13TS01 285877
KIIIA1 6.1.2	Schulz, T.	Efficacy of Propyzamide + aminopyralid in OSR, Germany 2010	2011	DE10H2B0 13TS02 285878
KIIIA1 6.1.3	Schulz, T.	Efficacy of Propyzamide + aminopyralid in OSR, Germany 2010	2011	DE10H2B0 13TS02 285879
KIIIA1 6.1.2	Bernhard, U.	Efficacy of Propyzamide + aminopyralid in OSR, Germany 2010	2011	DE10H2B0 13UB06C 285880
KIIIA1 6.1.3	Bernhard, U.	Efficacy of Propyzamide + aminopyralid in OSR, Germany 2010	2011	DE10H2B0 13UB06C 285881
KIIIA1 6.2.6	Bernhard, U.	WHAT IS THE CARRY OVER EFFECT OF GF-2540 ON A RANGE OF CROPS FOLLOWING	2012	DE10H2B0 15UB01C 285883
KIIIA1 6.2.1	Homa, U.	SELECTIVITY OF GF-1633 STRAIGHT AND IN COMBINATIONS IN OSR AUTUMN APPLIED. GERMANY 2011	2012	DE11H2B0 15UH01C 285884
KIIIA1 6.1.3	Luras, M.	Efficacy of aminopyralid alone or in mixture with KERB FLO against Papaver r. in oil seed rape crop - autumn 2007	2008	FR07L1B1 09ML01C 285888
KIIIA1 6.1.3	Luras, M.	Efficacy of aminopyralid alone or in mixture with KERB FLO against Papaver r. in oil seed rape crop - autumn 2007	2008	FR07L1B1 09ML02C 285890
KIIIA1 6.1.3	Luras, M.	Efficacy of KERB FLO alone or in mixture with aminopyralid against grasses (alomy, lolmu) in oil seed rape crop - autumn 2007	2008	FR07L1B1 10ML01C 285891
KIIIA1 6.1.3	Luras, M.	Efficacy of Propyzamide + aminopyralid in OSR-AUTUMN 2008	2009	FR08H2B0 07ML02C 285892
KIIIA1 6.1.3	Luras, M.	Efficacy of Propyzamide + aminopyralid in OSR-AUTUMN 2008	2009	FR08H2B0 07ML04C 285893
KIIIA1 6.1.3	Bailey, A.	Efficacy of Propyzamide + aminopyralid in OSR-AUTUMN 2008	2009	FR08H2B0 07ML05C 285894
KIIIA1 6.1.3	Luras, M.	Efficacy of Propyzamide + aminopyralid in OSR-AUTUMN 2008	2009	FR08H2B0 07ML06C 285895

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 6.1.3	Charlot, Y.	Efficacy of Propyzamide + aminopyralid in OSR-AUTUMN 2008	2009	FR08H2B0 07YC03 285896
KIIIA1 6.1.3	Lourdet, Y.	Efficacy of Propyzamide + aminopyralid in OSR-AUTUMN 2008	2009	FR08H2B0 07YL01 285897
KIIIA1 6.1.4	Luras, M.	Selectivity of aminopyralid+propyzamid combinations in oil seed rape ,UK & France 2008-2009	2010	FR08H2B0 08ML01C 285898
KIIIA1 6.2.1	Luras, M.	Selectivity of aminopyralid+propyzamid combinations in oil seed rape ,UK & France 2008-2009	2010	FR08H2B0 08ML01C 285899
KIIIA1 6.1.4	Luras, M.	Selectivity of aminopyralid+propyzamid combinations in oil seed rape ,UK & France 2008-2009	2010	FR08H2B0 08ML02C 285900
KIIIA1 6.2.1	Luras, M.	Selectivity of aminopyralid+propyzamid combinations in oil seed rape ,UK & France 2008-2009	2010	FR08H2B0 08ML02C 285901
KIIIA1 6.1.4	Luras, M.	Selectivity of aminopyralid+propyzamid combinations in oil seed rape ,UK & France 2008-2009	2010	FR08H2B0 08ML03C 285902
KIIIA1 6.2.1	Luras, M.	Selectivity of aminopyralid+propyzamid combinations in oil seed rape ,UK & France 2008-2009	2010	FR08H2B0 08ML03C 285903
KIIIA1 6.2.6	Luras, M.	Selectivity of aminopyralid+propyzamid combinations in oil seed rape ,UK & France 2008-2009	2010	FR08H2B0 08ML03C 285904
KIIIA1 6.2.6	Luras, M.	Selectivity of aminopyralid+propyzamid combinations in oil seed rape ,UK & France 2008-2009	2010	FR08H2B0 08ML01C 285905
KIIIA1 6.2.6	Luras, M.	Selectivity of aminopyralid+propyzamid combinations in oil seed rape ,UK & France 2008-2009	2010	FR08H2B0 08ML02C 285906
KIIIA1 6.2.6	Luras, M.	Crops to be sown after a winter oil seed rape crop failure sprayed with GF-2545, GF-1601, GF-1633, GF-2040 FRANCE- AUTUMN 2009	2010	FR09A2A0 79ML01C 285907
KIIIA1 6.1.3	Luras, M.	Efficacy of Propyzamide + aminopyralid as GF-2540 in OSR AUTUMN 2009 FRANCE	2010	FR09H2B0 06ML01C 285908
KIIIA1 6.1.2	Luras, M.	Efficacy of Propyzamide + aminopyralid as GF-2540 in OSR AUTUMN 2009 FRANCE	2010	FR09H2B0 06ML01C 285909

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 6.1.2	Luras, M.	Efficacy of Propyzamide + aminopyralid as GF-2540 in OSR AUTUMN 2009 FRANCE	2010	FR09H2B006ML02C 285910
KIIIA1 6.1.3	Luras, M.	Efficacy of Propyzamide + aminopyralid as GF-2540 in OSR AUTUMN 2009 FRANCE	2010	FR09H2B006ML02C 285911
KIIIA1 6.1.2	Luras, M.	Efficacy of Propyzamide + aminopyralid as GF-2540 in OSR AUTUMN 2009 FRANCE	2010	FR09H2B006ML03C 285912
KIIIA1 6.1.3	Luras, M.	Efficacy of Propyzamide + aminopyralid as GF-2540 in OSR AUTUMN 2009 FRANCE	2010	FR09H2B006ML03C 285913
KIIIA1 6.1.2	Lourdet, Y.	Efficacy of Propyzamide + aminopyralid as GF-2540 in OSR AUTUMN 2009 FRANCE	2010	FR09H2B006ML04C 285914
KIIIA1 6.1.3	Lourdet, Y.	Efficacy of Propyzamide + aminopyralid as GF-2540 in OSR AUTUMN 2009 FRANCE	2010	FR09H2B006ML04C 285915
KIIIA1 6.1.4	Luras, M.	Selectivity of GF-2540 and aminopyralid+propyzamid combinations in oil seed rape ,UK & France 2009-2010	2010	FR09H2B007ML01C 285916
KIIIA1 6.2.1	Luras, M.	Selectivity of GF-2540 and aminopyralid+propyzamid combinations in oil seed rape ,UK & France 2009-2010	2010	FR09H2B007ML01C 285917
KIIIA1 6.1.4	Lourdet, Y.	Selectivity of GF-2540 and aminopyralid+propyzamid combinations in oil seed rape ,UK & France 2009-2010	2010	FR09H2B007ML02C 285918
KIIIA1 6.2.1	Lourdet, Y.	Selectivity of GF-2540 and aminopyralid+propyzamid combinations in oil seed rape ,UK & France 2009-2010	2010	FR09H2B007ML02C 285919
KIIIA1 6.1.2	Lourdet, Y.	Efficacy of Propyzamide + aminopyralid as GF-2540 against MATSS in OSR	2011	FR10H2B016YL03C 285920
KIIIA1 6.1.3	Lourdet, Y.	Efficacy of Propyzamide + aminopyralid as GF-2540 against MATSS in OSR	2011	FR10H2B016YL03C 285921
KIIIA1 6.1.3	Lourdet, Y.	Efficacy of reduced rates of GF-2540 against ALOMY and LOLMU on oil seed rape France 2010	2011	FR10H2B022YL02C 285922
KIIIA1 6.1.3	Lourdet, Y.	Efficacy of reduced rates of GF-2540 against ALOMY and LOLMU on oil seed rape France 2010	2011	FR10H2B022YL05C 285923

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 6.1.3	Egerton, S.	Efficacy of Propyzamide + aminopyralid in OSR	2009	GB08H2B007SE01C 285924
KIIIA1 6.1.3	Egerton, S.	Efficacy of Propyzamide + aminopyralid in OSR	2009	GB08H2B007SE02C 285925
KIIIA1 6.1.3	Egerton, S.	Efficacy of Propyzamide + aminopyralid in OSR	2009	GB08H2B007SE06C 285926
KIIIA1 6.1.3	Egerton, S.	Efficacy of Propyzamide + aminopyralid in OSR	2009	GB08H2B007SE07C 285927
KIIIA1 6.1.4	Egerton, S.	Selectivity of aminopyralid+propyzamid combinations in oil seed rape ,UK & France 2008-2009	2010	GB08H2B008SE01C 285928
KIIIA1 6.2.1	Egerton, S.	Selectivity of aminopyralid+propyzamid combinations in oil seed rape ,UK & France 2008-2009	2010	GB08H2B008SE01C 285929
KIIIA1 6.2.6	Egerton, S.	Selectivity of aminopyralid+propyzamid combinations in oil seed rape ,UK & France 2008-2009	2010	GB08H2B008SE01C 285930
KIIIA1 6.1.4	Egerton, S.	Selectivity of aminopyralid+propyzamid combinations in oil seed rape ,UK & France 2008-2009	2010	GB08H2B008SE02C 285931
KIIIA1 6.2.1	Egerton, S.	Selectivity of aminopyralid+propyzamid combinations in oil seed rape ,UK & France 2008-2009	2010	GB08H2B008SE02C 285932
KIIIA1 6.2.6	Egerton, S.	Selectivity of aminopyralid+propyzamid combinations in oil seed rape ,UK & France 2008-2009	2010	GB08H2B008SE02C 285933
KIIIA1 6.1.4	Egerton, S.	Selectivity of aminopyralid+propyzamid combinations in oil seed rape ,UK & France 2008-2009	2010	GB08H2B008SE03C 285934
KIIIA1 6.2.1	Egerton, S.	Selectivity of aminopyralid+propyzamid combinations in oil seed rape ,UK & France 2008-2009	2010	GB08H2B008SE03C 285935
KIIIA1 6.2.6	Egerton, S.	Selectivity of aminopyralid+propyzamid combinations in oil seed rape ,UK & France 2008-2009	2010	GB08H2B008SE03C 285937
KIIIA1 6.1.2	Egerton, S.	Efficacy of Propyzamide + aminopyralid in OSR, UK & France 2009	2010	GB09H2B006SE04C 285938

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 6.1.3	Egerton, S.	Efficacy of Propyzamide + aminopyralid in OSR, UK & France 2009	2010	GB09H2B0 06SE04C 285940
KIIIA1 6.1.2	Egerton, S.	Efficacy of Propyzamide + aminopyralid in OSR, UK & France 2009	2010	GB09H2B0 06SE05C 285941
KIIIA1 6.1.3	Egerton, S.	Efficacy of Propyzamide + aminopyralid in OSR, UK & France 2009	2010	GB09H2B0 06SE05C 285942
KIIIA1 6.1.4	Egerton, S.	Selectivity of GF-2540 and aminopyra-lid+propyzamid combinations in oil seed rape ,UK & France 2009-2010	2011	GB09H2B0 07SE01C 285943
KIIIA1 6.2.1	Egerton, S.	Selectivity of GF-2540 and aminopyra-lid+propyzamid combinations in oil seed rape ,UK & France 2009-2010	2011	GB09H2B0 07SE01C 285944
KIIIA1 6.2.6	Egerton, S.	Selectivity of GF-2540 and aminopyra-lid+propyzamid combinations in oil seed rape ,UK & France 2009-2010	2011	GB09H2B0 07SE01C 285945
KIIIA1 6.1.4	Egerton, S.	Selectivity of GF-2540 and aminopyra-lid+propyzamid combinations in oil seed rape ,UK & France 2009-2010	2011	GB09H2B0 07SE02C 285946
KIIIA1 6.2.1	Egerton, S.	Selectivity of GF-2540 and aminopyra-lid+propyzamid combinations in oil seed rape ,UK & France 2009-2010	2011	GB09H2B0 07SE02C 285947
KIIIA1 6.2.6	Egerton, S.	Selectivity of GF-2540 and aminopyra-lid+propyzamid combinations in oil seed rape ,UK & France 2009-2010	2011	GB09H2B0 07SE02C 285948
KIIIA1 6.2.6	Egerton, S.	Crops to be sown after a winter oil seed rape crop failure sprayed with GF-2545, GF-2040 UK - AUTUMN 2009	2010	GB09H2B0 10SE01C 285949
KIIIA1 6.1.3	Egerton, S.	Efficacy and selectivity of GF-2540 in oilseed rape against ALOMY, MATSS and PAPRH	2010	GB09H2B0 13SE03C 285950
KIIIA1 6.1.3	Egerton, S.	Efficacy and selectivity of GF-2540 in oilseed rape against ALOMY, MATSS and PAPRH	2010	GB09H2B0 13SE04C 285951
KIIIA1 6.1.2	Egerton, S.	Efficacy of Propyzamide + aminopyralid as GF-2540 against MATSS in OSR	2011	GB10H2B0 16SE01C 285952
KIIIA1 6.1.3	Egerton, S.	Efficacy of Propyzamide + aminopyralid as GF-2540 against MATSS in OSR	2011	GB10H2B0 16SE01C 285953

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 6.1.2	Egerton, S.	Efficacy of Propyzamide + aminopyralid as GF-2540 against MATSS in OSR	2011	GB10H2B0 16SE02C 285954
KIIIA1 6.1.3	Egerton, S.	Efficacy of Propyzamide + aminopyralid as GF-2540 against MATSS in OSR	2011	GB10H2B0 16SE02C 285955
KIIIA1 6.1.2	Egerton, S.	Demonstration of the efficacy of Propyzamide + aminopyralid as GF-2540 against MATSS and PAPRH in OSR	2011	GB10H2B0 19SE01C 285956
KIIIA1 6.1.3	Egerton, S.	Demonstration of the efficacy of Propyzamide + aminopyralid as GF-2540 against MATSS and PAPRH in OSR	2011	GB10H2B0 19SE01C 285957
KIIIA1 6.1.2	Egerton, S.	Demonstration of the efficacy of Propyzamide + aminopyralid as GF-2540 against MATSS and PAPRH in OSR	2011	GB10H2B0 19SE03C 285958
KIIIA1 6.1.3	Egerton, S.	Demonstration of the efficacy of Propyzamide + aminopyralid as GF-2540 against MATSS and PAPRH in OSR	2011	GB10H2B0 19SE03C 285959

Appendix 2: GAP table

GAP-Table of intended uses for Germany

GAP rev. BVL, date: 2012-10-05

PPP (product name/code) GF-2540
active substance 1 Propyzamid
active substance 2 Aminopyralid

Formulation type: SC
Conc. of as 1: 500 g/L
Conc. of as 2: 5.3 g/L

Applicant: DOW AgroSciences GmbH
Zone(s): central/EU

professional use X
non professional use

Verified by MS: Y

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**	**Remarks:**
					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 a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max	(days)	e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
001	DE	Winter oil-seed Rape (BRSNW)	F	annual monocotyle-donous weeds (TTTMS), annual dicotyledonous weeds (TTTDS) (post emergence of weeds)	Spraying	> BBCH 14 Late autumn to winter, November to February	a) 1 b) 1	a) 1.5 b) 1.5	a) 750 g/ha Propyzamid 7.95 g/ha Aminopyralid b) 750 g/ha Propyzamid 7.95 g/ha Aminopyralid	20 0 - 300		