REGISTRATION REPORT
Part A

Risk Management

Product code: **BANJO forte/MCW 853**

Active Substance: **Dimethomorph 200 g/L**
Fluazinam 200 g/L

COUNTRY: Germany

Central Zone
Zonal Rapporteur Member State: Germany

NATIONAL ASSESSMENT

Applicant: **ADAMA Deutschland GmbH**

Date: **April 2015**

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PART A – Risk Management

This document describes the acceptable use conditions required for the re-registration of BANJO® FORTE, containing 200 g/L fluazinam and 200 g/L dimethomorph, in Germany. This evaluation was done subsequent to the inclusion of fluazinam and dimethomorph on Annex I.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-8 and Part C of the core assessment for Germany. The information, data and assessments provided in Registration Report, Parts B includes assessment of further data or information as required at national registration by the EU review of both active substances, and where considered essential for the evaluation additional new data that has not previously been considered in the EU review for Annex I inclusion of fluazinam or dimethomorph. It also includes assessments of data an information relating to BANJO® FORTE since this product was not the representative formulation during the Annex I inclusion of fluazinam or dimethomorph. Otherwise assessments for the safe use of BANJO® FORTE have been made using endpoints agreed in the EU review of fluazinam and dimethomorph.

The identical product BANJO® FORTE (KN 007012-00/00) is already registered since 2012. Concerning the active substance dimethomorph the approval was based on the data package of BASF. The BASF-source and the Makhteshim-Agan-source were both registered as sources for the technical substance dimethomorph in the product BANJO® FORTE. The current application is now solely based on applicant's own data package for the active substance dimethomorph which was already positively evaluated for the registration of the applicant's product VinoStar (KN 006947-00/00). Some new data were included in the dossier, merely supporting the risk evaluation and the risk management of this new application compared to the outcome of the former evaluation of BANJO® FORTE. Overall, the evaluation of the already registered BANJO® FORTE (KN 007012-00/00) is completely transferable to this new application of the product and a new evaluation is not considered to be required in principle.

This document describes the specific conditions of use and labelling required for Germany for the registration of BANJO® FORTE.

Appendix 1: due to technical reasons, the authorisation of the final product in Germany will be found under Appendix 4.

Appendix 2: The submitted draft product label has been checked by the competent authority. The applicant is requested to amend the product label in accordance with the decisions drawn by the competent authority. The final version of the label is not available, because the layout is the sole responsibility of the applicant and will not be checked again.

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

Appendix 4: of this document will include the final product authorisation in Germany (later).

1 Details of the application

1.1 Application background

This application was submitted by Feinchemie Schwebda GmbH on 12th April 2013. It has been evaluated in line with the requirements of the zonal assessment under Regulation (EC) No. 1107/2009.
Besides the zonal Rapporteur Member State Germany, authorisations are not applied for in other member states .

1.2 Annex I inclusion

Dimethomorph was included into Annex I of Directive 91/414 (Commission Directive 2007/25/EC of 23 April 2007, entry into force: 01 October 2007) repealed by Commission Implementing Regulation (EU) No 540/2011.

The Annex I Inclusion Directive for dimethomorph (2007/25/EC repealed by Reg. (EU) No 540/2011) provides specific provisions under Part B which need to be considered by the applicant in the preparation of their submission and by the Member State prior to granting an authorisation.

For the implementation of the uniform principles of Annex VI, the conclusions of the review report for **dimethomorph**, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 24 November 2006 shall be taken into account.

In this overall assessment, Member States must pay particular attention to:

- the operators and workers safety. Authorised conditions of use must prescribe the application of adequate personal protective equipment;
- to the protection of birds, mammals and aquatic organisms. Conditions of authorisation should include risk mitigation measures, where appropriate.

These concerns have been addressed within the current submission.

Fluazinam was included into Annex I of Directive 91/414 (Commission Directive 2008/108/EC of 26 November 2008; entry into force: 1 March 2009) repealed by Commission Implementing Regulation (EU) No 540/2011.

The Annex I Inclusion Directive for fluazinam (2008/108/EC repealed by Reg. (EU) No 540/2011) provides specific provisions under Part B which need to be considered by the applicant in the preparation of their submission and by the Member State prior to granting an authorisation.

For the implementation of the uniform principles of Annex VI, the conclusions of the review report for **fluazinam**, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 20 May 2008 shall be taken into account:

Member States must pay particular attention to:

- the protection of the operators' and workers' safety. Authorised conditions of use must prescribe the application of adequate personal protective equipment and risk mitigation measures to reduce the exposure,
- the residues in food of plant and animal origin and evaluate the dietary exposure of consumers,
- the protection of aquatic organisms. In relation to this identified risk, risk mitigation measures, such as buffer zones, should be applied where appropriate.

These concerns have been addressed within the current submission.

The Member States concerned shall request the submission of further studies to confirm the risk assessment for aquatic organisms and soil macro-organisms. They shall ensure that the notifiers at whose request fluazinam has been included in this Annex provide such studies to the Commission within two years from the entry into force of this Directive.

1.3 Regulatory approach

To obtain re-approval/approval the product Banjo Forte 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 was already proven by the approval of the identical product BANJO® FORTE (KN 007012-00/00), registered in Germany since 2012.

The identical product BANJO® FORTE (KN 007012-00/00) is already registered since 2012. Concerning the active substance dimethomorph the approval was based on the data package of BASF. The BASF-source and the Makhteshim-Agan-source were both registered as sources for the technical substance dimethomorph in the product BANJO® FORTE. The current application is now solely based on applicant's own data package for the active substance dimethomorph which was already positively evaluated for the registration of the applicant's product VinoStar. Some new data were included in the dossier, merely supporting the risk evaluation and the risk management of this new application compared to the outcome of the former evaluation of BANJO® FORTE. Overall, the evaluation of the already registered BANJO® is completely transferable to this new application of the product and a new evaluation is not considered to be required in principle.

This application was submitted in order to allow the re-registration of an already approved product in Germany in accordance with the above.

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of Banjo Forte, it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B, sections 1, 5, 6 and 7 and Part C.

1.5 Letters of Access

Letter of Access is not necessary.

2 Details of the authorisation

2.1 Product identity

Product Name	Banjo Forte
Authorization Number (for re-registration)	027012-00/00
Function	fungicide
Applicant	Feinchemie Schwebda GmbH
Composition	200 g/L fluazinam 200 g/L dimethomorph
Formulation type	suspension concentrate [Code: SC]
Packaging	Bottle, Coex, 1 L Canister, Coex, 5 L

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC

The following labelling is proposed in accordance with Directive 1999/45/EC:

Symbol(s)/Indication(s) of danger:	
Xn	Harmful
N	Dangerous for the environment
Risk phrases:	
R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
R63	Possible risk of harm to the unborn child
RA058	Contains fluazinam. May produce allergic reactions.
RA105	Contains 1,2-benzisothiazole-3(2H)-one. May produce allergic reactions.
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.
SP001	To avoid riks to man and the environment, comply with the instructions for use.
Specific labelling requirement:	
To avoid risks to man and the environment, comply with the instructions for use.	
Contains fluazinam (CAS-No. 79622-59-6). May produce an allergic reaction.	
Contains 1,2-benzisothiazol-3(2H)-one (CAS-No. 2634-33-5). May produce an allergic reaction.	

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

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

Hazard classes and categories: (kein Labelling-Requirement!)
Repr. 2
Hazard pictograms:

GHS08	health hazard
GHS09	environment
Signal word:	
Warning	
Hazard statements:	
H361d	Suspected of damaging the unborn child.
H410	Very toxic to aquatic life with long lasting effects.
Precautionary statemtents:	
Not proposed by zRMS Germany, to be decided by applicant	

Special rule for labelling of PPP:	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	
EUH 208 - Contains fluazinam (CAS-No. 79622-59-6). May produce an allergic reaction.	
EUH 208 - Contains 1,2-benzisothiazol-3(2H)-one (CAS-No. 2634-33-5). May produce an allergic reaction.	

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

None

2.2.4 Other phrases

2.2.4.1 Restrictions linked to the PPP under Regulation (EC) No 547/2011

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

Human health protection	
SB001	Avoid any unnecessary contact with the product. Misuse can lead to health damage.
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 Protection and Food Safety must be observed.
SF1891	Re-entering the treated areas/crops are only possible on the day of application wearing personal protective equipment which is specified for applying the particular product. Successive work on/in treated areas/crops may fundamentally not be carried out until 24 hours after applying the product. Within the first 48 hours, protective suits against pesticides and standard protective gloves (plant protection) are to be worn.
SS110	Wear standard protective gloves (plant protection) when handling the undiluted product.
SS120	Wear standard protective gloves (plant protection) when handling/applying the

	product ready for application.
SS2101	Wear a protective suit against pesticides and sturdy shoes (e.g. rubber boots) when handling the undiluted product.
SS2202	Wear a protective suit against pesticides and sturdy shoes (e.g. rubber boots) when applying/handling the product ready for application.
SS530	Wear face protection when handling the undiluted product.
SS610	Wear a rubber apron when handling the undiluted product.
Integrated pest management (IPM)/sustainable use	
WMFC5	Mode of action (FRAC-group): C5 (for fluazinam)
WMFH5	Mode of action (FRAC-group): H5 (for dimethomorph)
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)
NN2002	The product is classified as slightly harmful for populations of relevant beneficial predatory mites and spiders.
Ecosystem protection	
NW 262	The product is toxic for algae.
NW 264	The product is toxic for fish and aquatic invertebrates.
NW 265	The product is toxic for higher aquatic plants.
NW 468	Fluids left over from application and their remains, products and their remains, empty containers and packaging, and cleansing and rinsing fluids must not be dumped in water. This also applies to indirect entry via the urban or agrarian drainage system and to rain-water and sewage canals.

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

Integrated pest management (IPM)/sustainable use	
NN1001	The product is classified as non-harmful for populations of relevant beneficial insects.

The authorization of the use is linked to the following conditions:

Integrated pest management (IPM)/sustainable use	
WW764 for use 001	In order to prevent resistance, alternate with other products from different active substance groups.
NW605-1 for use 001	When applying the product on areas adjacent to surface waters - except only occasionally but including periodically water bearing surface waters - the product must be applied with equipment which is registered in the index of 'Loss Reducing Equipment' of 14 October 1993 ('Bundesanzeiger' [Federal Gazette] No 205, p. 9780) as amended. Depending on the drift reduction classes for the equipment stated below, the following buffer zones must be kept from surface waters. In addition to the minimum buffer zone from surface waters

	stipulated by state law, the ban on application in or in the immediate vicinity of waters must be observed at all times for drift reduction classes marked with "90%/5m, 75%/5m, 50%/5m".
NW606 for use 001	The only case in which the product may be applied without loss reducing equipment is when at least the buffer zone stated below is kept from surface waters - except only occasionally but including periodically water bearing surface waters. Violations may be punished by fines of up to 50 000 Euro. “10m”

2.3 Product uses

date: 2014-04-16

PPP (product name/code) **Banjo forte**
active substance 1 **fluazinam**
active substance 2 **dimethomorph**

Formulation type: **SC**
Conc. of as 1: **200 g/L**
Conc. of as 2: **200 g/L**

Applicant: **Feinchemie Schwebda GmbH**
Zone(s): **central EU**

professional use ☒
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:**
					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		e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
001	DE	Potatoes SOLTU	F	Late blight *(Phytophthora infestans)* PHYTIN	spraying	in case of danger of infection and/or after warning service appeal (BBCH 31 – 91)	a) 4 b) 4 (7 - 10 days)	a) 1.0 L/ha b) 4.0 L/ha	a) as1 : 0.2 kg/ha as2: 0.2 kg/ha b) as1 : 0.8 kg/ha as2 : 0.8 kg/ha	300 - 600	7	NW605-1/606 (90%/5m, 75%/5m, 50%/5m, 10m)

3 Risk management

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

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

Overall Summary:
The appearance of the product is that of an orange homogenious liquid with a faint characteristic odour. It is not explosive, not flammable and has no oxidising properties. The self ignition temperature is 405 °C. In aqueous solution, it has a pH value around 7.6. 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 FAO specifications for dimethomorph or fluazinam.

Compliance with FAO guidelines:
The product Banjo Forte complies with the general requirements according to the FAO/WHO manual (2010).

Compatibility of mixtures:
A complete report regarding physical and chemical compatibility of the tank mixes with Bulldock 25 EC, Agil S, Vondac DG and Dithane Neo Tec has been submitted which has demonstrated compatibility. These tank mixes can therefore be mentioned on the product label for Banjo Forte.

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 Banjo Forte 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 of Banjo forte (MCW-853) can be quantified using the analytical HPLC method described in Part B(2). The method is sufficiently validated.
There is no CIPAC method available for the determination of dimethomorph in SC formulations.
There is no CIPAC method available for the determination of fluazinam.
An analytical HPLC-method for the determination of α-fluazinam in the formulation MCW 853 SC has been sufficiently validated.

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

Adequate analytical methods are available to monitor all compounds given in the respective residue definition of dimethomorph in food of plant and animal origin, soil and water and of fluazinam in food of plant and animal origin, soil, water and air. A method for the determination of dimethomorph in air is not necessary because the substance is not considered to be irritant (Xi), harmful (Xn), toxic or very toxic (T / T+). 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.
New LC-MS/MS methods for the determination of dimethomorph residues in food of plant and animal origin, soil and water were submitted and were found acceptably validated. Methods for body fluids and tissues are not required, because dimethomorph is not considered to be toxic or very toxic (T / T+) nor is it classified according to GHS as acute toxic (cat. 1 - 3), CMR (cat. 1) or STOT (cat. 1).
For the determination of fluazinam in food of plant and animal origin, soil, water and air new LC-MS/MS methods were submitted. These methods were found acceptably validated. Methods for body fluids and tissues are not required, because fluazinam is not considered to be toxic or very toxic (T / T+) nor is it classified according to GHS as acute toxic (cat. 1 - 3), CMR (cat. 1) or STOT (cat. 1).

However, the following minor data gaps have been identified according to the requirements of SANCO/825/00 rev. 8.1:

- Confirmatory methods for the determination of dimethomorph in eggs, meat, soil, drinking and surface water are missing.
- Confirmatory methods for the determination of fluazinam in fat, meat, soil, drinking and surface water are missing.
- An ILV for the determination of fluazinam in liver missing.

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

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

A summary of the toxicological evaluation for BANJO Forte (MCW-853 SC) is given in the following Table. Full summaries of studies on the product are presented in Appendix 2 of Part B Section 3.

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)**
LD_{50} oral, rat (OECD 423)	> 2000 mg/kg bw	Yes	None	None
LD_{50} dermal, rat (OECD 402)	> 2000 mg/kg bw	Yes	None	None
LC_{50} inhalation, rat (OECD 403)	> 4.23 mg/L (highest attain. conc.)	Yes	None	None
Skin irritation, rabbit (OECD 404)	Non-irritant	Yes	None	None
Eye irritation, rabbit (OECD 405)	Non-irritant	Yes	None	None

Skin sensitisation, guinea pig (OECD 406, M&K)	Non-sensitising	Yes	None	None
Supplementary studies for combinations of plant protection products	No data – not required			

Additional toxicological information relevant for classification/labelling of BANJO Forte (MCW-853 SC)

	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 substance(s) (relevant for classification of product)	Fluazinam (17.3 % (w/w))	R43 (≥ 1 %) H317 (≥ 1 %) R63 (≥ 5 %) H361d (≥ 3 %)	Proposal RAC (ECHA/RAC/CLH-O-0000002667-66-01/F, 15 June 2012); MSDS [1)] and RAC proposal (ECHA/RAC/CLH-O-0000002667-66-01/F, 15 June 2012)	"Contains fluazinam (CAS-No. 79622-59-6). May produce an allergic reaction." [2)] EUH208 [2)] R63 H361d
Toxicological properties of non-active substance(s) (relevant for classification of product)	Proxel GXL containing 1,2-benzisothiazol-3(2H)-one (CAS-No. 2634-33-5, 0.03 % (w/w))	R43; RA (≥ 0.005 %); H317; EUH208 (≥ 0.005 %)	Reg. (EC) No 1272/2008 and subsequent regulations amending Reg. (EC) No 1272/2008	"Contains 1,2-benzisothiazol-3(2H)-one (CAS-No. 2634-33-5). May produce an allergic reaction." EUH208
Further toxicological information	No data – not required			

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

Operator exposure was assessed against the AOEL-S agreed in the EU review (dimethomorph 0.15 mg/kg bw/d and fluazinam 0.004 mg/kg bw/d). Dermal absorption data of studies conducted with different but comparable formulations with the single active substances have been used. The detailed evaluation is provided in Part B.
According to the model calculations, it can be concluded that the risk for the operator using BANJO forte in potatoes is acceptable with the use of personal protective equipment described in 2.2.4.1.

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

The bystander and/or resident exposure estimations indicated that the acceptable operator exposure level (AOEL) for dimethomorph and fluazinam will not be exceeded under conditions of intended uses.

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

The risk assessment according to the German model has shown that the estimated exposure towards dimethomorph and fluazinam in BANJO forte will not exceed the particular systemic AOEL for workers if prescribed PPE is worn by operators and workers.

Implications for labelling resulting from operator, worker, bystander assessments:
See 2.2

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

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)

The data available is considered sufficient for risk assessment. An exceedance of the current MRLs for dimethomorph (0.05 mg/kg) and fluazinam (0.05 mg/kg) as laid down in Reg. (EU) 396/2005 is not expected.
Differing from Part B.4 no label restriction excluding the utilization of potatoes as animal feed (VV207) is set. Referring to the EFSA Scientific Report (2008) 137, p. 16-17 and the unprotected metabolism studies with fluazinam in lactating goats and laying hens it is concluded that in both animals the active compound is extensively degraded. No accumulation of the active substance and its metabolites is expected in animal commodities. For the representative use in potatoes no residue definition for food of animal origin was proposed and feeding studies were not deemed necessary. Therefore no label restriction is set.

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

The chronic and the short-term intake of dimethomorph and fluazinam residues are unlikely to present a public health concern.

Dimethomorph	
ADI	0.05 mg/kg bw
TMDI (% ADI) according to EFSA PRIMo	45 % (based on based on WHO cluster diet B)
NTMDI (% ADI) according to NVS II	35 % (based on based on German children 2-4 years)
IEDI (EFSA PRIMo) (% ADI)	not necessary
NEDI (NVS II) (% ADI)	not necessary
Factors included in IEDI and NEDI	none
ARfD	0.6 mg/kg bw
IESTI (EFSA PRIMo) (% ARfD)	potatoes: 0.3 % (based on UK infants)
NESTI (NVS II) (% ARfD)	potatoes: <0.1 % (based on German children 2-4 years)
Factors included in IESTI and NESTI	none

Fluazinam	
ADI	0.01 mg/kg bw
TMDI (% ADI) according to EFSA PRIMo	128 % (based on FR all population)
NTMDI (% ADI) according to NVS II	63 % (based on German children 2-4 years)
IEDI (EFSA PRIMo) (% ADI)	56 % (based on DE child)
NEDI (NVS II) (% ADI)	not necessary
Factors included in IEDI	0.063 (processing factor for wine (Draft evaluation report fluazinam, 2011))
ARfD	0.07 mg/kg bw
IESTI (EFSA PRIMo) (% ARfD)	potatoes: 12.5 % (based on UK infants)
NESTI (NVS II) (% ARfD)	potatoes: 4 % (based on German children 2-4 years)
Factors included in IESTI and NESTI	none

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

A full exposure assessment for the plant protection product Banjo Forte in its intended uses in potatoes is documented in detail in the core assessment of the plant protection product Banjo Forte dated from February 2014 performed by Germany
The following chapters summarise specific exposure assessment for soil and surface water and the specific risk assessment for groundwater for the authorization of Banjo Forte in Germany according to its intended use in potatoes (Use No. 00-001).
Table: Overview uses for risk assessment

Indication	**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)**
00-001	potatoes BBCH 31-91	spraying	4 x, min. interval 7 d, 1. application: 50 % (22 days after emergence) 2. – 4 application: 80 % summer	fluazinam: 4 x 200 = 800, dimethomorph: 4 x 200 = 800	fluazinam 1. 100 2. 40 3. 40 4. 40 = 220 dimethomorph: 1. 100 2. 40 3. 40 4. 40 = 220

Fluazinam

Fluazinam shows a wide range of degradation times in soil under laboratory conditions ranging from 25 to 221 days – geo.mean. 60 days. During aerobic degradation the metabolite HYPA occurs in relevant concentrations, up to 14 % in soil. Hypa is more stable in soil as the parent with a geo.mean. of 93 days. Under field conditions degradation rate for the active substance increases to a maximum DT_{50} of 40.8 days. No accumulation needs to be considered for the active substance but for HYPA background levels are established and considered in the risk assessment.
Fluazinam is well adsorbed to soil with Kfoc mean value 24936. Also the metabolit HYPA is strongly adsorbed to soil with Kfoc mean value 920.
In water/sediment systems dissipation from water phase is quick (DT_{50} 2.7 days). Also Dissiaption in sediment and degradation in the whole system is fast with values of 4.8 and 4.2 days respectively. As metabolites HYPA and AMPA occur which are both more stable with half-life around 34 to 39 days.

Dimethomorph

In soil dimethomorph show similar degradation rates of geo mean DT_{50} of 42.3 days under laboratory and a max. DT_{50} of 60 days under field conditions. No relevant metabolites occur during soil degradation. No accumulation in soil is expected.
Dimethomorph is medium strong adsorbed to soil with a mean Kfoc of 456.
In water/sediment systems dissipation from water phase occurs with a DT_{50} of 8 days. Dissiaption in sediment shows a half-life of 6 days. Concerning the whole system a degradation time of DT_{50} of 15 days is demonstrated. No relevant metabolites occur.

Metabolites

No new study on the fate and behaviour of fluazinam and dimethomorph or Banjo Forte has been performed. Hence no potentially new metabolites need to be considered for environmental risk assessment.

Fluazinam

The risk assessment for the metabolite of fluazinam has already been performed for EU approval (see (SANCO/127/08 – rev.1). The metabolite HYPA is considered ecotoxicologically not relevant and did not penetrate into groundwater. Therefore no new risk assessment hence no exposure assessment for these metabolites is necessary.
However, in the specific groundwater risk assessment for Germany considering the entry path surface run-off and drainage with subsequent bank filtration the soil metabolites of fluazinam are included.
The risk assessment for groundwater by direct leaching for the application of the plant protection product and its intended uses includes the soil metabolite of fluazinam. Additionally, the soil metabolite HYPA of fluazinam was also included in the groundwater risk assessment considering the entry path surface run-off and drainage with subsequent bank filtration.

Dimethomorph

The risk assessment for the metabolites of dimethomorph has already been performed for EU approval (see SANCO/10040/06). The metabolites are considered ecotoxicologically not relevant and did not penetrate into groundwater. Therefore no new risk assessment hence no exposure assessment for these metabolites is necessary.
However, in the specific groundwater risk assessment for Germany considering the entry path surface run-off and drainage with subsequent bank filtration the soil metabolites of dimethomorph are included.

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 Banjo Forte in potatoes according to use No 00-001 PECsoil was calculated for the active substance fluazinam and dimethomorph considering a soil depth of 1 and 2.5 cm, respectively. Due to the fast degradation of the active substances in soil the accumulation potential was not considered. Due to the slow degradation of the metabolite HYPA of the active substance fluazinam in soil the accumulation potential was considered. Therefore PECsoil used for risk assessment comprises background concentration in soil (PECaccu) considering a tillage depth of 20 cm (arable crop) and the maximum annual soil concentration PECact considering the relevant soil depth of 1.0 cm for HYPA,.

Table: Overview PECsoil values

active substance/ preparation	**soil depth (cm)**	**soil relevant application rate (g/ha)**	**PEC_{accu} = PEC_{act} + PEC_{bkgd} (mg/kg)**
Fluazinam	1	100+40+40+40 =220	1.1803
Metabolit HYPA max. 13.9% , MG-ratio 0.96	1	13.3+5.3+5.3+5. 3= 29.21	0.1871 + 0.0038 = 0.1909
Dimethomorph	2.5	100+40+40+40 =220	0.5062
Banjo Forte* 4 x 1l/ha = 4 x 1156 g /ha	1	578+231+231+ 231=1241 (kum)	8.273

The results for PEC soil for the active substance and its metabolites were used for the eco-toxicological risk assessment.

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

1. Direct leaching into groundwater
Results of modelling with FOCUS-PELMO 5.5.3 show that the active substance fluazinam and dimethomorph are not expected to penetrate into groundwater at concentrations of ≥ 0.1µg/L in the intended for uses in potatoes.
For the metabolites HYPAconcentrations of ≥ 0.1µg/L in groundwater can be excluded.

2. Ground water contamination by bank filtration due to surface water exposure via run-off and drainage
According modelling with EXPOSIT 3, groundwater contamination at concentrations ≥ 0.1 µg/L by the active substances fluazinam and dimethomorph due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

Belonging to the same mobility class groundwater contamination at concentrations ≥ 0.1 µg/L by the metabolite HYPA 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 Banjo Forte in potatoes according to use No 00-001 PECsw was calculated for the active substances fluazinam and dimethomorph 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 was based on spray drift data by Rautmann and Ganzelmeier. The vapour pressure at 20 °C of the active substance fluazinam is > 10^{-4} Pa. Hence the active substance fluazinam is regarded as semivolatile (volatilization from soil and plant surfaces).

Therefore, exposure of surface water by the active substance fluazinam due to deposition following volatilization was considered. As higher tier option the experimentally derived deposition values of the windtunnel study (Staffa 2012) was considered for the active substance fluazinam.
The vapour pressure at 20 °C of the active substance dimethomorph is $< 10^{-5}$ Pa. Hence the active substance dimethomorph is regarded as non-volatile. Therefore, exposure of surface water by the active substance dimethomorph due to deposition following volatilization was not considered
The concentration of the active substances fluazinam and dimethomorph in adjacent ditch due to surface run-off and drainage was calculated using the model EXPOSIT 3.0.

Table: Overview PEC surface water values

active substance/ preparation	**Application rates (g/ha) – agriculure**	**PECsw-ditch 1m (µg/l)**	**PECrun-off Ditch – 0 m buffer (µg/l)**	**PECdrainage Autumn/winter/early spring (µg/l)**	**PECdrainage Spring/summer (µg/l)**
Fluazinam*	200 g as/ha– 90 perc**	1.91	0.09	-***	0.03
Dimethomorph	4 x 200 g as/ha	1.85	1.58	-***	0.57
Banjo Forte* 4 x 1l/ha = 4 x 1156 g /ha	4 x 1 l/ha	9.23	-	-***	-

* includes also volatilization/deposition
** due to fast dissipation in water phase
*** Not relevant (since only one application in early spring)
The results for PEC surface water for the active substance and its metabolites were used for the eco-toxicological risk assessment.

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 fluazinam is $> 10^{-4}$ Pa. Hence the active substance fluazinam is regarded as semivolatile (volatilisation from soil and plant surfaces). Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance fluazinam due to volatilization with subsequent deposition should be considered e.g. using the program EVA 2.1.
For photochemical oxidative degradation in air according to EFSA Scientific Report (2008) 137, 1-82, Conclusion on the peer review of fluazinam a DT50 of >2 days cannot be completely excluded (Atkinson method). Long range transport might be possible.
The vapour pressure at 20 °C of the active substance dimethomorph is $< 10^{-5}$ Pa. Hence the active substance dimethomorph is regarded as non-volatile. Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance dimethomorph due to volatilization with subsequent deposition should not be considered.
Photochemical oxidative degradation in air is 3.6 h – no long range transport is to be expected

Implications for labelling resulting from environmental fate assessment: (Phrase **R53** should be added to the label) For the authorization of the plant protection product Banjo Forte following labeling and conditions of use are mandatory:
Classification and labelling
Based on the data on the active substances fluazinam and dimethomorph the plant protection product Banjo Forte is considered to be not readily degradable in the sense of the CLP regulation.
The formulation Banjo Forte is regarded as a candidate for R 53

Further data requirements:

None.

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

A full risk assessment according to Uniform Principles for the plant protection product BANJO FORTE in its intended use in potatoes is documented in detail in the core assessment of the plant protection product BANJO FORTE dated from February 2014 performed by the zRMS Germany. The intended use of BANJO FORTE in Germany is generally covered by the use evaluated in the course of the core assessment.
The following chapters summarise specific risk assessment for non-target organisms and hence risk mitigation measures for the authorization of BANJO FORTE in Germany according to its intended use in poatoes (use No. 00-001).

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).
Both active substances show low chronic endpoints which are relevant for risk assessment.

Table: Overview critical endpoints birds and mammals

Fluazinam			
Exposure System	Species	Endpoint	Result (mg/kg bw)
Reproductive toxicity (long-term)	rat	NOAEL	7.26
Reproductive toxicity (long-term)	*Colinus virginianus*	NOEL	60.4
Dimethomorph			
Reproductive toxicity (long-term)	rat	NOAEL	20
Reproductive toxicity (long-term)	*Colinus virginianus*	NOEL	58.4
BANJO FORTE			
Acute oral toxicity	*Coturnix japonica*	LD_{50}	> 2000
Acute oral toxicity	rat	LD_{50}	> 2000

The preparation indictes no higher toxicity than the expected toxicity based on the active substances.

Based on tier 1 assessment step, the calculated TER values for the acute and long-term risk resulting from

the expected (combined) exposure of birds to the active substances fluazinam and dimethomorph (oral exposure and exposure via drinking water and secondary poisoning) according to the GAP of the formulation BANJO FORTE 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. The results of the assessment indicate an acceptable acute and long-term risk for birds due to the intended use of BANJO FORTE in potatoes according to the label.
Based on tier 1 assessment step (exposure via drinking water and secondary poisoning) and some refinments of exposure, respectively, the calculated TER values for the acute and long-term risk resulting from the expected (combined) exposure of small mammals to the active substances fluazinam and dimethomorph according to the GAP of the formulation BANJO FORTE 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. The results of the assessment indicate an acceptable acute and long-term risk for small mammals due to the intended use of BANJO FORTE in potatoes according to the label.

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

The relevant endpoints for the TER-calculations of the two active substances are as follows:

- **Fluazinam**: SSD-HC_5 (0.00129 mg/L) determined for a number of EC_{10}-values available for aquatic invertebrates considering an adjusted assessment factor of 5.
- **Dimethomorph:** NOEC for fish (ELS) 0.056 mg/L, standard assessment factor of 10

Fluazinam shows a BCF of 1090 but this uncertainty is covered by a FFLC study submitted for fluazinam.
Results of aquatic risk assessment for the intended for uses of BANJO FORTE in potatoes is based on FOCUS Surface Water PEC values is presented in the core assessment, Part B, Section 6, chapter 6.5.
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 risk mitigation measures separately for each entry route.

1. Exposure by spraydrift and deposition following volatilization

Based on the calculated concentrations of the active substances fluazinam and dimethomorph in surface water (EVA 2.1, EXPOSIT 3.0) considering risk mitigation measures applicable in Germany (spray-drift reducing nozzles and no-spray/run-off buffer zones), the calculated TER values for the acute and long-term risk resulting from an exposure of aquatic organisms to fluazinam and dimethomorph according to the GAP of the formulation BANJO FORTE achieve the (modified) acceptability criteria TER ≥ 5 (fluazinam) and TER ≥ 10 (dimethomorph), 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 aquatic organisms due to the intended use of BANJO FORTE in potatoes according to the label.

2. Exposure by surface run-off and drainage

Based on the calculated concentrations of the active substances fluazinam and dimethomorph in surface water (EVA 2.1, EXPOSIT 3.0) considering risk mitigation measures applicable in Germany (spray-drift reducing nozzles and no-spray/run-off buffer zones), the calculated TER values for the acute and long-term risk resulting from an exposure of aquatic organisms to fluazinam and dimethomorph according to the GAP of the formulation BANJON FORTE achieve the (modified) acceptability criteria TER ≥ 5 (fluazinam) and TER ≥ 10 (dimethomorph), 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 aquatic organisms due to the intended use of BANJO FORTE in potatoes according to the label.

Consequences for authorization:
For the authorization of the plant protection product BANJO FORTE the following labelling and conditions of use are mandatory:

Required Labelling

NW 262	Fluazinam Pseudokirchneriella subcapitata NOEC < 0.0.0366 mg/L (as EbC50 = 0.0366 mg/L)
NW 264	Fluazinam NOEC = 0.0125 mg/L (D. magna) and NOEC = 0.0029 mg/L (P. promelas) Dimethomorph NOEC = 0.100 mg/L (D. magna) and NOEC = 0.056 mg/L (O.mykiss)
NW 265	Fluazinam Lemna gibba NOErC < 0.069 mg/L (as ErC50 = 0.069 mg/L)

Safety precautions / Conditions of use

BANJO FORTE	NW 468
use No. 00-001	NW 605-1/606 (conv. – 10 m; 50 % red. – 5 m; 75 % red. – 5 m; 90 % red. – 5 m)

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

Bees

The recommended use pattern for Banjo forte includes application in potatoes at a maximum application rate of up to 1 L product/ha.
Bees may be exposed to Banjo forte 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. Due to the results of laboratory tests Banjo forte 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.

Other non-target arthropods

The risk to non-target arthropods is based on the endpoint for BANJO FORTE obtained from the *T. pyri* study, a vegetation distribution factor has to be considered (study conducted in 2D-design) resulting in ER_{50} of ≥ 2.4 L/ha.
Based on the calculated rates of BANJO FORTE in off-field areas, the calculated TER values describing the risk resulting from an exposure of non-target arthropods to BANJO FORTE according to the GAP of the formulation BANJO FORTE achieve the acceptability criteria of 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 non-target arthropods due to the intended use of BANJO FORTE in potatoes according to the label.

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

Both active substances and all relevant metabolites demonstrated a low acute toxicity towards

earthworms. Relevant for risk assessment are the chronic endpoints.

Table : Overview endpoints for earthworms and other soil organisms

Species	**Substance**	**Exposure System**	**Results**
Eisenia fetida	Dimethomorph	chronic, 56 d	$NOEC_{corr}$ [mg/kg $soil_{dw}$] = 60
Eisenia fetida	HYPA	chronic, 56 d	NOEC [mg/kg $soil_{dw}$] = 15
Eisenia fetida	BANJO FORTE	chronic, 56 d	NOEC [mg/kg $soil_{dw}$] = 92.22 (recalculated from 20.7 L product/ha)
Folsomia candida	HYPA	chronic, 28 d	NOEC [mg/kg $soil_{dw}$] = 6.08
Folsomia candida	BANJO FORTE	chronic, 28 d	NOEC [mg/kg $soil_{dw}$] = 16
Hypoaspis aculeifer	BANJO FORTE	chronic, 14 d	NOEC [mg/kg $soil_{dw}$] = 250

Based on the predicted concentrations of BANJO FORTE and of the fluazinam-metabolite HYPA in soils, the TER values describing the acute and long-term risk for earthworms following exposure to BANJO FORTE and HYPA, respectively, according to the GAP of the formulation BANJO FORTE achieve the acceptability criteria TER $\geq$ 10 resp. TER $\geq$ 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 earthworms due to the intended use of BANJO FORTE in potatoes according to the label.
The Tier-1 TER-value calculated on the basis of the soil-arthropod endpoint available for the formulation BANJO FORTE (*F. candida*, NOEC = 16 mg/kg soil dw) and the German PEC_{act} (8.273mg/kg dw) is 1.9 and thus falls below the trigger (5), requiring a refined risk assessment.
Comparing the results it becomes obvious that fluazinam is clearly dominating the toxicity observed for BANJO FORTE towards *F. candida* (as the product-NOEC of 16 mg/kg soil dw is corresponding to about 3.2 mg a.s./kg for each of the two active substances).
For the purpose of a higher-tier risk assessment regarding the long-term effects of fluazinam, the applicant submitted a soil arthropod field study (see Core assessment, Appendix 2, Ref. IIIA 10.6.6/03: Schulz, L; 2009, internal study code 72808, initially submitted to ZA6899) and a litter bag test (see Core assessment, Appendix 2, Ref. IIIA 10.6.7/01: Lührs, U.; 2009), both conducted with the solo-formulation "BANJO" (synonym MCW 465 500 SC; content: 500 g fluazinam/L).
Considering the results of the soil-arthropod field study and litterbag-study conducted with the mono-formulation "BANJO" (MCW 465 500 SC) containing the active substance fluazinam it can be reasonably concluded that the risk to soil-arthropods from the intended use of BANJO FORTE in potatoes is acceptable.

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

See above.

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

Based on the predicted concentrations of the fluazinam-metabolite HYPA as well as the formulation BANJO FORTE in soils, the risk to soil microbial processes following exposure to both the metabolite and the formulation according to the GAP of the formulation BANJO FORTE 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)

Non-Target Plants

The preparation showed no relevant toxicity towards non-target plants. The risk assessment is based on a ER_{50} of > 1 l/ha detected in a vegetative vigour test with BANJO FORTE.

Based on the predicted rates of BANJO FORTE in off-field areas, the TER values describing the risk for non-target plants following exposure to BANJO FORTE according to the GAP 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. The results of the assessment indicate an acceptable risk for non-target terrestrial plants due to the intended use of BANJO FORTE in potatoes according to the label.

Implications for labelling resulting from ecotoxicological assessment:

For the authorization of the plant protection product BANJO FORTE the following labelling and conditions of use are mandatory:

Classification and labelling

Relevant toxicity	Active substance: Fluazinam (content 17 % - w/w) NOEC = 0.0029 mg/L (Pimephales promelas)
Classification and labelling according to Directive 67/548/EC, 78/631/EC and 1999/45/EC	
Hazard symbol	N, dangerours for the environment
Risk phrases	R 50/53
Classification and labelling according to Regulation 1272/2008	
Hazard sysmbol	GHS09
Signal word	Achtung
Hazard statement	H410

Standard Phrases for special risks and safety precautions under Regulation (EU) 547/2011 Annex II and III / 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.

Use No. 00-001:

NW 605-1	When applying the product on areas adjacent to surface waters - except only occasionally but including periodically water bearing surface waters - the product must be applied with equipment which is registered in the index of 'Loss Reducing Equipment' of 14 October 1993 ('Bundesanzeiger' [Federal Gazette] No 205, p. 9780) as amended. Depending on the drift reduction classes for the equipment stated below, the following buffer zones must be kept from surface waters. In addition to the minimum buffer zone from surface waters stipulated by state law, the ban on application in or in the immediate vicinity of waters must be observed at all times for drift reduction classes marked with "*".Drift reduction by 90% 5 m 75 % 5 m 50% 5 m
NW606	The only case in which the product may be applied without loss reducing equipment is when at least the buffer zone stated below is kept from surface waters - except only occasionally but including periodically water bearing surface waters. Violations may be punished by fines of up to 50 000 Euro. 10 m

Other labels

NW 262	The product is toxic for algae.
NW 264	The product is toxic for fish and aquatic invertebrates.
NW 265	The product is toxic for higher aquatic plants.

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

Banjo forte has been developed for the control of Late Blight of potato caused by *Phytophothora infestans*. The biological assessment is based on field trials conducted in Czech Republic, The Netherlands, Denmark and Germany to prove efficacy and selectivity of Banjo forte.
18 field tests were carried out in the years 2006 to 2008 at a dose rate of 1.0 L/ha. Infestation incidence (percentage of stems/leaves and tubers infested) served as test parameters. In conclusion, in all parameters an adequate efficacy could be achieved. The dose rate of 1.0 L/ha represents the limit of efficacy and should not be reduced as results of 18 minimum dose rate tests confirm. 1.0 L/ha meets the minimum effective dose.

Banjo forte had no relevant adverse effects on quality and quantity of yield.

The test compound shows a slight positive yield effect compared to untreated. In efficacy trials at 1 to 2 L/ha no phytotoxicity was reported.
The evaluation indicates a medium inherent and agronomic risk of resistance development for Banjo forte in potato. Basing on the resistance results the order WW764 is to be labelled: In order to prevent resistance, alternate with other products from different active substance groups.
No unacceptable on plants or plant products used for propagation and on other plants including neighbouring crops were reported in the trials and are not to be expected.

Banjo forte is classified as slightly harmful for populations of relevant beneficial predatory mites and spiders.but not harmful for populations of relevant beneficial insects. Soil quality will not be affected by the use of the product as recommended.

3.2 Conclusions

With respect to physical, chemical and technical properties of the formulation an authorisation can be granted.
With respect to analytical methods (formulation) an authorisation can be granted.
Analytical methods for residues: An authorisation can be granted.

The product shows a sufficient effect against late blight (*Phytophthora infestans*) and no unacceptable effects on plants and plant products, thus, the use can be granted.

The product is classified as non-hazardous to bees, even when the maximum application rate, or concentration if no application rate is stipulated.

With respect to toxicology, residues and consumer protection 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.

An authorisation can be granted.

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

No further information is required.

Appendix 1 – Copy of the product authorisation see Appendix 4

Appendix 2 – Copy of the product label

The submitted draft product label has been checked by the competent authority. The applicant is requested to amend the product label in accordance with the decisions drawn by the competent authority. The final version of the label is not available, because the layout is the sole responsibility of the applicant and will not be checked again.

Appendix 3 – Letter of Access

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

Appendix 4 – Copy of the product authorisation

Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

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

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IHR ZEICHEN
IHRE NACHRICHT VOM

AKTENZEICHEN 200.22100.027012-00/00.81673
(bitte bei Antwort angeben)

DATUM 30. April 2015

ZV1 027012-00/00

BANJO forte

Zulassungsverfahren für Pflanzenschutzmittel

Bescheid

Das oben genannte Pflanzenschutzmittel

mit den Wirkstoffen:	200 g/l	Fluazinam
	200 g/l	Dimethomorph
Zulassungsnummer:	027012-00	
Versuchsbezeichnungen:	ADD-94530-F-0-SC	
Antrag vom:	30. März 2013	

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

Zulassungsende

Die Zulassung endet am 31. Juli 2019.

Festgesetzte Anwendungsgebiete bzw. Anwendungen

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

Anwendungs-nummer	Schadorganismus/ Zweckbestimmung	Pflanzen/-erzeugnisse/ Objekte	Verwendungszweck
027012-00/00-001	Kraut- und Knollen-fäule (Phytophthora infestans)	Kartoffel	

Festgesetzte Anwendungsbestimmungen

Es werden folgende Anwendungsbestimmungen gemäß § 36 Abs. 1 S. 1 des Gesetzes zum Schutz der Kulturpflanzen (Pflanzenschutzgesetz - PflSchG) vom 6. Februar 2012 (BGBl. I S. 148, 1281), zuletzt geändert durch Artikel 4 des Gesetzes vom 2. Dezember 2014 (BGBl. I S. 1928), 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 gegenüber aquatischen Organismen 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 "Banjo Forte" 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 im Sinne der Zweckbestimmung des Pflanzenschutzgesetzes unverzichtbar, der Gefahr, die eine Verbringung von Pflanzenschutzmitteln in Gewässer mit sich bringt, durch die bußgeldbewehrte Anwendungsbestimmung durchsetzbar zu begegnen.

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

Verpackungen

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

Verpackungs-art	Verpackungs-material	Anzahl		Inhalt		
		von	bis	von	bis	Einheit
Flasche	Coex	1	10	1,00		l
Kanister	Coex	1	4	5,00		l

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

Auflagen

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

Kennzeichnungsauflagen:

(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.

(SF1891)
Das Wiederbetreten der behandelten Flächen/Kulturen ist am Tage der Applikation nur mit der persönlichen Schutzausrüstung möglich, die für das Ausbringen des Mittels vorgegeben ist. Nachfolgearbeiten auf/in behandelten Flächen/Kulturen dürfen grundsätzlich erst 24 Stunden nach der Ausbringung des Mittels durchgeführt werden. Innerhalb 48 Stunden sind

dabei der Schutzanzug gegen Pflanzenschutzmittel und Universal-Schutzhandschuhe (Pflanzenschutz) zu tragen.

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

(SS120)
Universal-Schutzhandschuhe (Pflanzenschutz) tragen bei Ausbringung/Handhabung des anwendungsfertigen Mittels.

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

(SS2202)
Schutzanzug gegen Pflanzenschutzmittel und festes Schuhwerk (z.B. Gummistiefel) tragen bei der Ausbringung/Handhabung des anwendungsfertigen Mittels.

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

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

(WMFC5)
Wirkungsmechanismus (FRAC-Gruppe): C5

(WMFH5)
Wirkungsmechanismus (FRAC-Gruppe): H5

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

Vorbehalt

Dieser Bescheid wird mit dem Vorbehalt der nachträglichen Aufnahme, Änderung oder Ergänzung von Anwendungsbestimmungen und 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 63 : Kann das Kind im Mutterleib möglicherweise schädigen.

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 Fluazinam. Kann allergische Reaktionen hervorrufen.

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:

(GHS08) Gesundheitsgefahr

(GHS09) Umwelt

Gefahrenhinweise (H-Sätze):

(EUH 208-0069)
Enthält Fluazinam. Kann allergische Reaktionen hervorrufen.

(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.

(H361d)
Kann vermutlich das Kind im Mutterleib schädigen.

(H410)
Sehr giftig für Wasserorganismen mit langfristiger Wirkung.

Sicherheitshinweise (P-Sätze):
- keine -

Abgelehnte Anwendungsgebiete bzw. Anwendungen

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

Hinweise

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

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

Weitere Hinweise und Bemerkungen
Momentan gibt es seitens des BVL keinen Vorschlag für P-Sätze gemäß Verordnung (EG) Nr. 1272/2008 (CLP-Verordnung).

Zu KIIIA1 6.2.8:
Hinweis und Begründung für die Kennzeichnungsauflage zum Wirkungsmechanismus (WMFC5: Fluazinam und WMFH5: Dimethomorph):
Die FRAC-Klassifizierung ist als neutrale Information direkt jedem einzelnen Wirkstoff (hier: Fluazinam und Dimethomorph) zuzuordnen. Die Kennzeichnung erleichtert der Praxis die Bestimmung des Wirkungsmechanismus von Fungiziden 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.

Hinsichtlich der Gebühren erhalten Sie einen gesonderten Bescheid.

Rechtsbehelfsbelehrung

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

Mit freundlichen Grüßen
im Auftrag

gez. Dr. Martin Streloke
Abteilungsleiter

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

Anlage

Anlage 1 zugelassene Anwendung: 027012-00/00-001

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Kraut- und Knollenfäule (Phytophthora infestans)

Pflanzen/-erzeugnisse/Objekte: Kartoffel

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Anwendungszeitpunkt:	Bei Infektionsgefahr bzw. ab Warndiensthinweis
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	4
- für die Kultur bzw. je Jahr:	4
- Abstand:	7 bis 10 Tage
Anwendungstechnik:	spritzen
Aufwand:	
-	1 l/ha in 300 bis 600 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

(WW764)
Um Resistenzbildungen vorzubeugen, das Mittel im Wechsel mit anderen Mitteln aus anderen Wirkstoffgruppen verwenden.

2.3 Wartezeiten

7 Tage	Freiland: Kartoffel

3 Anwendungsbezogene Anwendungsbestimmungen

(NW605-1)
Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände zu Oberflächengewässern einzuhalten. Für die mit "*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in

jedem Fall zu beachten.
reduzierte Abstände: 50% 5 m, 75% 5 m, 90% 5 m
Begründung:
Das Pflanzenschutzmittel BANJO FORTE bzw. die darin enthaltenen Wirkstoffe Fluazinam und Dimethomorph weisen ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Invertrebarten und Fische auf. Bewertungsbestimmend ist hier die SSD-HC5 für Invertebraten von 1.29 µg/L. Ausgehend von den geltenden Modellen zur Abdrift sowie zur Verflüchtigung von Zielflächen und anschließender Deposition (hier: EVA 2.1) und einem Sicherheitsfaktor von 5 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 605-1/606 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Wirkstoffs Fluazinam / des Mittels BANJO FORTE in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Sektion 6, Kapitel 6.5).

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

REGISTRATION REPORT
Part B

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

Detailed summary of the risk assessment

Product code:	**BANJO forte / MCW-853**	
Active Substance:	**Fluazinam**	**200 g/L**
	Dimethomorph	**200 g/L**

Central Zone
Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant:	**ADAMA Deutschland GmbH**
Date:	**April 2015**

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 BANJO FORTE / MCW-853 containing the active substances dimethomorph and fluazinam which were approved according to Regulation (EC) No 1107/2009.

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

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

Agreed EU End-points

End-Point	**Dimethomorph** (Reg. (EU) No 540/2011)	**Fluazinam** (Reg. (EU) No 540/2011)
Purity of active substance	min 965 g/kg	min 960 g/kg
Relevant impurities	None	5-Chloro-*N*-(3-chloro-5-trifluoro-methyl-2-pyridyl)-α,α,α-trifluoro-4,6-dinitro-*o*-toluidine: max 2 g/kg

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

Information on the detailed composition of BANJO FORTE 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

ADAMA Deutschland GmbH
Edmund-Rumpler-Str. 6
D-51149 Köln
Germany

Contact person: Dr. Isabel Wieland
Registration Manager
Tel.No.: +49 2203 5039 554
Fax No: +49 2203 5039 0554
e-mail: isabel.wieland@fcs-feinchemie.com

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)

Dimethomorph: min 970 g/kg

Fluazinam: min 980 g/kg

Relevant impurity:
5-Chloro-*N*-(3-chloro-5-trifluoro-methyl-2-pyridyl)-α,α,α-trifluoro-4,6-dinitro-*o*-toluidine: max 2 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: BANJO FORTE

Company code number: MCW-853

Alternative names/codes: MCW 853 500 SC, MAC 94530 F, MCW-853SC

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

IIIA 1.4.1 Content of active substance and formulants

The formulation was not the representative formulation.

Pure active substance:

content of pure fluazinam:	200 g/L
content of pure dimethomorph:	200 g/L
limits fluazinam:	188.0- 212.0 g/L
limits dimethomorph:	188.0- 212.0 g/L

Technical active substance:

content of technical fluazinam at minimum purity (98.0 %):	204.08 g/L	(17.65 % w/w)
content of technical dimethomorph at minimum purity (96.9 %):	206.4 g/L	(17.85 % w/w)

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	Dimethomorph	Fluazinam
1.4.3.2	CAS No.	110488-70-5	79622-59-6
1.4.3.2	EINECS No.	–	–
1.4.3.2	CIPAC No.	483	521
1.4.3.2	ELINCS	404-200-2	–
1.4.3.3	Salt, ester anion or cation present	–	–

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

CONFIDENTIAL information - data provided separately (Part C).

IIIA 1.4.5 Formulation process

IIIA 1.4.5.1 Description of formulation process

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

IIIA 1.4.5.2 Discussion of the formation of impurities of toxicological concern

Fluazinam contains < 2 g/kg 5-chloro-N-(3-chloro-5-trifluoromethyl-2-pyridyl)-α,α,α-trifluoro-4,6-dinitro-o-toluidine.
Dimethomorph does 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 fungicide.

IIIA 1.7 Other/Special Studies

None.

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

BANJO FORTE (MCW-853 SC) was not a representative formulation during the EU review of the active substances fluazinam and dimethomorph. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.

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	MCW-853 SC Batch no.: 282-200109-01 Fluazinam: 206 g/L Dimethomorph: 206 g/L	The preparation is an orange homogenious liquid with a faint characteristic odour.	Y	Meinerling, M., Herrmann, S., 2010, 56162204	acceptable
Explosive properties (IIIA 2.2.1)	EEC A 14	MCW-853 SC Batch no.: 175-191107-02 Fluazinam: 211 g/L Dimethomorph: 211 g/L	As a screening method a DSC measurement was conducted. Exothermic effects were detected at temp. of 160 °C and 240 °C with an energy of 561 J/g and 826 J/g respectively, so the main test had to be conducted. Here the formulation showed no thermal or mechanical (shock) sensitivity. Formulation has no explosive properties.	Y	Wielpütz, T., 2008, 0080424.01	acceptable
Oxidizing properties	Expert statement	Theoretical	Formulation has no oxidising	N	Meinerling, M., 2009,	acceptable

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
(IIIA 2.2.2)		evaluation	properties.		42115192	
Flash point (IIIA 2.3.1)	EEC A 9	Batch no.: 175-191107-02	No flash point up to 101 °C. At 101 °C the test item started boiling. No flash point could be observed.	Y	Fieseler, A., 2008, 42120189	acceptable
Flammability (IIIA 2.3.2)	-	-	Not required since the preparation is not a solid.	-	-	acceptable.
Auto-flammability (IIIA 2.3.3)	EEC A 15	Batch no.: 175-191107-02	Auto-ignition at 405 °C.	Y	Wielpütz, T., 2008, 20080424.02	acceptable.
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	Batch no.: 282-200109-01	Before storage: deionised water, 20 °C: 7.6 After 2 weeks, 54 °C: deionised water, 20 °C: 7.3	Y	Meinerling, M., Herrmann, S., 2010, 56162204	acceptable.
Kinematic viscosity (IIIA 2.5.1)	-	-	Not required by regulation (EU) 2011/545.	-	-	acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Dynamic viscosity (IIIA 2.5.2)	CIPAC MT 192 OECD 114	Batch no.: 175-191107-02	non-Newtonian liquid 90 mPa s at 20 °C (shear rate = 100 s^{-1}) 80 mPa s at 40 °C (shear rate = 100 s^{-1})	Y	Fieseler, A., 2008, 42112196 R-23914	acceptable.
Surface tension (IIIA 2.5.3)	EEC A 5 OECD 115	Batch no.: 175-191107-02	35.5 mN/m (20 °C, neat)	Y	Fieseler, A., 2008, 42122184 R-23920	acceptable.
Relative density (IIIA 2.6.1)	EEC A 3 OECD 109	Batch no.: 282-200109-01	Before storage: d_4^{20} = 1.156	Y	Meinerling, M., Herrmann, S., 2010, 56165182	acceptable.
Bulk or tap density (IIIA 2.6.2)	-	-	not required for liquid formulations	-	-	acceptable.
Storage Stability after 14 days at 54° C (IIIA 2.7.1)	CIPAC MT 46.3	Batch no.: 282-200109-01	Storage material: HDPE The content of the active substance does not decrease > 5 %. The changes of the physical and chem-	Y	Meinerling, M., Herrmann, S., 2010, 56162204	acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
			ical properties are negligible. Content of dimethomorph: before storage: 210.8 g/L after storage: 211.5 g/L Content of fluazinam: before storage: 211.4 g/L after storage: 209.2 g/L			
Stability after storage for other periods and/or temperatures (IIIA 2.7.2)	-	-	Not required, since the product was tested for 14 days at 54°C. An appropriate study is available (de Ryckel, B. (2006), report no.: 21230) but not deemed necessary to be submitted.	-	-	statement acceptable. The mentioned study was not submitted for evaluation.
Minimum content after heat stability testing (IIIA 2.7.3)	-	-	Not necessary, since the decrease of the active substance did not exceed 5 %.	-	-	acceptable.
Effect of low temperatures on stability (IIIA 2.7.4)	CIPAC MT 39.3	Batch no.: 282-200109-01	Storage material: glass No separated material, homogeneous liquid. The product shows good low temperature stability, the effects on wet sieve residue and Suspensibility	Y	Meinerling, M., Herrmann, S., 2010, 56163204 R-26492	acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
			are negligible.			
			Storage material: glass bottle After 4 freeze/thaw cycles between 20 °C and -10 °C the appearance, pH, pourability, spontaneity of dispersion, Suspensibility and wet sieve residue of the formulation were nearly unchanged.	Y	Meinerling, M., Herrmann, S., 2010, 56161204 R-26494	acceptable as additional information.
Ambient temperature shelf life (IIIA 2.7.5)	Technical Monograph No. 17	Batch no.: 282-200109-01	Storage material: HDPE The content of the active substance does not decrease > 5 %.: Content of dimethomorph: before storage: 203.5 g/L after storage: 212.1 g/L Content of fluazinam: before storage: 209.6 g/L after storage: 209.5 g/L Content of alpha-fluazinam after storage: < 0.02 % The changes of the physical and chemical properties appearance, pH, pourability, suspensibility, spontaneity of dispersion and wet	Y	Meinerling, M., Herrmann, S., 2012, 56164204	acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
			sieve test are not significant.			
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 2011/545.	-	-	acceptable
Persistence of foaming (IIIA 2.8.2)	CIPAC MT 47.2	Batch no.: 282-200109-01	CIPAC water D, 1.0 %: Before storage 10s: 2 mL 1 min: 2 mL 3 min: 2 mL 12 min: 2 mL	Y	Meinerling, M., Herrmann, S., 2010, 56162204	acceptable.
Suspensibility (IIIA 2.8.3.1)	CIPAC MT 184	Batch no.: 282-200109-01	CIPAC water D, 1.0 %: Before storage Dimethomorph: 98 % Fluazinam e: 94 % After 2 weeks, 54 °C Dimethomorph: 98 % Fluazinam: 93 % CIPAC water D, 0.2 %: Before storage Dimethomorph: 99 % Fluazinam e: 94 %	Y	Meinerling, M., Herrmann, S., 2010, 56162204	acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
			After 2 weeks, 54 °C Dimethomorph: 99 % Fluazinam: 94 %			
		Batch no.: 282-200109-01	CIPAC water D, 1.0 %: Before storage: Dimethomorph: 97 % Fluazinam: 93 % After 2 years, 20 °C: Dimethomorph: 97 % Fluazinam: 93 % CIPAC water D, 0.2 %: Before storage: Dimethomorph: 98 % Fluazinam: 94 % After 2 years, 20 °C: Dimethomorph: 99 % Fluazinam: 94 %	Y	Meinerling, M., Herrmann, S., 2010, 56164204	acceptable.
Spontaneity of dispersion (IIIA 2.8.3.2)	CIPAC MT 160	Batch no.: 282-200109-01	Before storage: Dimethomorph: 89 % Fluazinam: 89 % After 2 weeks, 54°C: Dimethomorph: 91 % Fluazinam: 91 %	Y	Meinerling, M., Herrmann, S., 2010, 56162204	acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
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 185	Batch no.: 282-200109-01	Before storage 0.02 % on 75 µm sieve After 2 weeks, 54 °C 0.05 % on 75 µm sieve	Y	Meinerling, M., Herrmann, S., 2010, 56162204	acceptable.
		Batch no.: 282-200109-01	Before storage 0.08 % on 75 µm sieve After 7 days, 0 °C 0.03 % on 75 µm sieve	Y	Meinerling, M., Herrmann, S., 2010, 56163204	acceptable.
Particle size distribution (IIIA 2.8.6.1)	CIPAC MT 187 / ISO 13320-1	Batch no.: 282-200109-01	Before storage D (v, 0.1) = 0.7 µm D (v, 0.5) = 1.6 µm D (v, 0.9) = 4.4 µm	Y	Smeykal, H., 2010, 20100265.01	acceptable.
Nominal size range of granules (IIIA 2.8.6.2)	-	-	not required for liquid formulations	-	-	acceptable
Dust content	-	-	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
(IIIA 2.8.6.3)						
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
Pourability (including rinsed residue) (IIIA 2.8.8.2)	CIPAC MT 148.1	Batch no.: 282-200109-01	Before storage: remaining residue: 4.1 % residue after rinsing: 0.24 % After 2 weeks, 54 °C: remaining residue: 3.3 % residue after rinsing: 0.24 %	Y	Meinerling, M., Herrmann, S., 2010, 56162204	acceptable.
		Batch no.: 282-200109-01	Before storage: remaining residue: 4.40 % residue after rinsing: 0.31 %	Y	Meinerling, M., Herrmann, S., 2010, 56164204	acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
			After 2 years, 20 °C: remaining residue: 3.97 % residue after rinsing: 0.46 %			
Dustability following accelerated storage (IIIA 2.8.8.3)	-	-	not required for liquid formulations	-	-	acceptable
Physical compatibility of tank mixes (IIIA 2.9.1)	ASTM 1518-99	MCW-853 SC Batch no.: 127-300307-01 Fluazinam: 200 g/L Dimethomorph: 200 g/L	BANJO FORTE (MCW-853) was tested for physical compatibility with 4 WG and EC formulations: Bulldock 25 EC, Agil S, Vondac DG, Dithane Neo Tec. All mixtures were determined to be physically compatible and can be used in spray applications. In all mixtures no lumping, no flocculation occurred, but a running agitator should be used preparing some of them. All mixtures should be used shortly after preparation. The mixtures appeared to be homogeneous.	N	KIIIA1 2.9.1/01: Schnell, R. (2009), report no.: FCS 12/2009	acceptable.
Chemical compatibility of tank	In-house method Examination of	MCW-853 SC Batch no.: 127-	Dimethomorph and fluazinam the active substances of BANJO	N	KIIIA1 2.9.2/01: Schnell, R. (2009),	acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
mixes (IIIA 2.9.2)	individual properties	300307-01	FORTE (MCW-853), are stable in diluted aqueous conditions. Therefore none of the functional groups are likely to react under normal tank mix conditions. BANJO FORTE was tested for physical compatibility with 4 formulations of the types WG and EC: Bulldock 25 EC, Agil S, Vondac DG, Dithane Neo Tec. No indication of any chemical reaction between the mixed products was observed. Therefore BANJO FORTE is apparently chemically compatible with the tested products.		report no.: FCS 13/2009	
Distribution to seed (IIIA 2.10.1)	-	-	Product is not intended for seed treatment.	-	-	acceptable.
Adhesion to seeds (IIIA 2.10.2)	-	-	Product is not intended for seed treatment.	-	-	acceptable.
Miscibility (IIIA 2.11)	-	-	Not required by regulation (EU) 2011/545.	-	-	acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
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 an orange homogenious liquid with a faint characteristic odour. It is not explosive, not flammable and has no oxidising properties. The self ignition temperature is 405 °C. In aqueous solution, it has a pH value around 7.6. 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:

No experimental testing was conducted in the BVl laboratory.

Implications for labelling:

None.

IIIA 3 DATA ON APPLICATION OF THE PLANT PROTECTION PRODUCT

IIIA 3.1 Field of Use

See GAP table

IIIA 3.2 Nature of the Effects on Harmful Organisms

Fungicidal effect

IIIA 3.3 Details of Intended Use

See GAP table

IIIA 3.3.1 Details of existing and intended uses

See GAP table

IIIA 3.3.2 Details of harmful organisms against which protection is afforded

See GAP table

IIIA 3.3.3 Effects achieved

See part B, Section 7

IIIA 3.4 Proposed Application Rates (Active Substance and Preparation)

See GAP table

IIIA 3.5 Concentration of the Active Substance in the Material Used

Insert summary information.

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

See GAP table

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

See GAP table

IIIA 3.7.2 Growth stages of crops or plants to be protected

See GAP table

IIIA 3.7.3 Development stages of the harmful organism concerned

See GAP table

IIIA 3.7.4 Duration of protection afforded by each application

See GAP table

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

See GAP table

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

Not necessary

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

Please refer to Part B Section 7.

IIIA 3.8.2 Limitations on choice of succeeding crops

Please refer to Part B Section 7.

IIIA 3.8.3 Description of damage to rotational crops

Please refer to Part B Section 7.

IIIA 3.9 Proposed Instructions for Use as Printed on Labels

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

IIIA 3.10 Other/Special Studies

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

IIIA 4 FURTHER INFORMATION ON THE PLANT PROTECTION PRODUCT

IIIA 4.1 Packaging and Compatibility with the Preparation

Packaging Summary

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

IIIA 4.1.1 Description and specification of the packaging

Banjo forte / MCW-853 is to be marketed in coextruded high-density polyethylene containers with several inner barriers, e.g., (recycling material/ adhesive layer / EVOH) They are protected by temper proofed screw cap.

1 litre bottle:	material:	COEX 4 layers (HDPE/ recycling material/ adhesive layer / EVOH)
	shape/size:	Cylindrical / approx. 90 mm diameter x 240 mm
	opening:	49 mm outer diameter
	closure:	Temper proofed screw cap and seal
	outer package:	RSC 182 DW cardboard
5 litre canister:	material:	COEX 6 layers (HDPE/ recycling material/ adhesive layer / EVOH/ adhesive layer/ HDPE)
	shape/size:	Square/ approx. 192 mm x 141 mm x 305 mm
	opening:	63 mm outer diameter
	closure:	Temper proofed screw cap and seal
	outer package:	RSC 182 DW cardboard

IIIA 4.1.2 Suitability of the packaging and closures

The 1 L and 5 L bottles meet the ADR (European Agreement concerning the International Carriage of Dangerous Goods by Road) requirements. 10 bottles of 1 L and 4 bottles of 5 L are packed in the respective cardboard boxes. These combination packs meet the following requirements regulations for the transport of hazardous goods: European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) of the Economic Commission for Europe, Inland Transport Committee ECD/TRANS/115 (Vol. I and II) 1997 and TRANSPORT OF DANGEROUS GOODS, Model Regulations, ST/SG/AC.Rev.10, United Nations, 1997.

IIIA 4.1.3 Resistance of the packaging material to its contents

Report:	Meinerling, M., Herrmann, S., 2012
Title:	Determination of the storage stability of MCW 853 SC at 20 °C
Document No:	56164204! R-26892
Guidelines:	CIPAC MT 185, 75.3, 148.1, 160, 184
GLP	Yes

The resistance of the packaging material to its contents was tested in a 2-year shelf life stability study at ambient temperature. The appearance of the container was determined by visual inspection initially, and then after storage. The material appearance showed no modification through 24 months storage period. The packaging material container and lid showed no cracking, fogging discoloration or distortion or change in weight. There is no seepage through the container walls or lid.
Thus, the containers are considered to be resistant to its contents under the tested storage conditions.
Package: 1 L HDPE bottle.

IIIA 4.2 Procedures for Cleaning Application Equipment

IIIA 4.2.1 Procedures for cleaning application equipment and protective clothing

Cleaning procedure as recommended on the label (please refer to Part A):
- Empty the tank, next rinse all equipment of sprayer and empty again
- Fill the tank with water, wash for at least 10 minutes while blending and empty again
- Dismount the parts of the pulveriser, wash and rinse apart in water
- Rinse tank and equipment of sprayer again by clean water

IIIA 4.2.2 Effectiveness of the cleaning procedures

Report:	KIIIA1 4.2.2/01, Meinerling, M., 2010
Title:	Determination of the effectiveness of cleaning prodecures for MCW 853 SC
Testing facility:	IBACON GmbH, Rossdorf, Germany
Document No.:	56167361
Sponsor no.:	R-27393
Guidelines:	PSD, Efficacy Guideline 302
GLP:	Yes

Material and Methods

A small scale test with a 5 L pressure sprayer was conducted. 50 mL of BANJO FORTE were diluted in 5 L water. After mixing the content was sprayed out. Afterwards, the tank was rinsed with 5 L tap water, shaken for 10 minutes and rinsed again with 500 mL of water. The cleaning solution was disposed by spraying through the nozzles. The remaining rinsate was drained from the tank and the nozzle was cleaned with tap water.

After cleaning, the tank was refilled to capacity with 500 mL acetonitrile and 4500 mL tap water. The solution was sprayed through the nozzles. During spraying procedure 3 samples were taken (after draining of 1 L, 2.5 L and 4 L). These samples were analysed for fluazinam and dimethomorph by HPLC-UV.

Results:

	Fluazinam	Dimethomorph
Residue in 20 % of drainage [mg/L]	2.768	2.545
Residue in 50 % of drainage [mg/L]	1.982	2.266
Residue in 80 % of drainage [mg/L]	1.443	2.304
Mean residue [% of initial a.s. conc.]	0.1	0.11

Estimation of the acceptability of the remaining a.s residues in the spray tank

In order to calculate the predicted exposure rate (PER), the following assumptions were made:
It is assumed, that 20 L of rinsate remain in the spray lines and pump of the 2000 L sprayer, assumed to be used for the spraying operations. After rinsing, the spray tank of this sprayer is filled with 2000 L spraying solution for the next operation. The worst case concentration of fluazinam and dimethomorph as given in IIIA 3.5 is used (0.667 g fluazinam and dimethomorph/L water). 0.1% of the initial fluazinam concentration and 0.11% of the initial dimethomorph concentration remain in the rinsate. Furthermore, a range of spray volumes of 100-600 L/ha to be applied to other crops is assumed.

Based on these assumptions and results, the following residues of fluazinam and dimethomorph will be applied to a non-target crop by re-use of the application equipment.
0.00067 – 0.004 mg/ha fluazinam and 0.00073 – 0.0044 mg/ha dimethomorph will be applied to a non-target crop by re-use of the application equipment.

Data on the biological activity of BANJO FORTE are available from the standard test model "vegetative vigour" (a seedling emergence test is not considered to be required for foliar applied fungicide), which is considered to be most relevant for the assessment of effects on non-target plants (including non-target crops) after broadcast spraying of BANJO FORTE and tank residues, respectively. The tests were performed with BANJO FORTE according to OECD 227 (2006)), using six representative plant species

in each test (oilseed rape, soybean, sugar beet, carrot, oat and onion; refer to ref. IIIA 10.8.1.2/01: Bützler, R., Mollandin, G. (2009)).

The acceptability of the predicted residue level of BANJO FORTE can be assessed by comparison of the exposure rate predicted for the re-use of the application equipment with the effect rates in the most sensitive plant species of the plant toxicity tests (TER=ED_{50}/PER). Effects on biomass were considered as reliable endpoints (i.e. effects on shoot fresh weight in the tests of concern). It was not possible to determine the most sensitive species, since all plants tested in the vegetative vigour test (IIIA 10.8.1.2/01: Bützler, R., Mollandin, G. (2009)) showed an ER_{50} > 1000 mL a.s./ha. Thus, the NOEL was set to be 1000 mL a.s./ha. Since the vegetative vigour test was conducted with BANJO FORTE, a direct comparison with a.s. based PER values is not possible, thus the concentration of BANJO FORTE in the remaining rinsate in the spray tank was calculated based on the a.s. concentration.

Maximum predicted exposure rate (PER) of non-target crops with spray residues:

PER = 2.2×10^{-8} L BANJO FORTE/ha
Basis: Results of KIIIA1 4.2.2/01 and calculation acc. to PSD Efficacy guideline 302

Risk from spray residues for non-target plants:

Toxicity endpoints from:
Reference IIIA 10.8.1.2/01: Bützler, R., Mollandin, G. (2009): Effects of BANJO FORTE SC on terrestrial (non-target) plants: vegetative vigour test
Lowest ED_{50} > 1 L BANJO FORTE/ha (all tested plants)
TER (ED_{50}/PER) > 45454545.45

The ED_{50} based TER value for the most sensitive plant species is far above 5[1], a ratio that is defined as trigger for concluding a low risk for terrestrial non-target plants according to the guidance document SANCO/10329/2002 rev.2 (October 17, 2002)[2].

In conclusion, compared to the effect levels for non-target plants, which are most likely to be affected by pesticide residues, residue levels are clearly below concentrations that might pose a risk for the terrestrial flora including non-target crops. Thus, any adverse impact of residues in spray tank on subsequently sprayed crops can widely be excluded, and the cleaning method can be considered to be acceptable.

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

[1] a trigger of 5 can be applied, if at least 6 plant species have been tested.

[2] Guidance Document on Terrestrial Ecotoxicology under Council Directive 91/414/EEC

See section 4.

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

See section 4.

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

See section 4.

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

See section 4.

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

See section 4.

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

See section 4.

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

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

IIIA 4.4.1 Warehouse storage

Refer to the safety data sheet for BANJO FORTE.

IIIA 4.4.2 User level storage

Refer to the safety data sheet for BANJO FORTE.

IIIA 4.4.3 Transport

Refer to the safety data sheet for BANJO FORTE.

IIIA 4.4.4 Fire

Refer to the safety data sheet for BANJO FORTE.

IIIA 4.4.5 Nature of protective clothing proposed

Refer to the safety data sheet for BANJO FORTE.

IIIA 4.4.6 Characteristics of protective clothing proposed

Refer to the safety data sheet for BANJO FORTE.

IIIA 4.4.7 Suitability and effectiveness of protective clothing and equipment

Refer to the safety data sheet for BANJO FORTE.

IIIA 4.4.8 Procedures to minimise the generation of waste

Refer to the safety data sheet for BANJO FORTE.

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

Refer to the safety data sheet for BANJO FORTE.

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

IIIA 4.5.1 Containment of spillages

Refer to the safety data sheet for BANJO FORTE.

IIIA 4.5.2 Decontamination of areas, vehicles and buildings

Refer to the safety data sheet for BANJO FORTE.

IIIA 4.5.3 Disposal of damaged packaging, adsorbents and other materials

Refer to the safety data sheet for BANJO FORTE.

IIIA 4.5.4 Protection of emergency workers and bystanders

Refer to the safety data sheet for BANJO FORTE.

IIIA 4.5.5 First aid measures

Refer to the safety data sheet for BANJO FORTE.

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

BANJO FORTE is neither acidic nor alkaline. Neutralization procedures are therefore not applicable.

IIIA 4.6.1 Details of proposed procedures for small quantities

Not applicable – Neutralization not recommended, see point IIIA 4.6.

IIIA 4.6.2 Evaluation of products of neutralization (small quantities)

Not applicable – Neutralization not recommended, see point IIIA 4.6

IIIA 4.6.3 Procedures for disposal of small quantities of neutralized waste

Not applicable – Neutralization not recommended, see point IIIA 4.6

IIIA 4.6.4 Details of proposed procedures for large quantities

Not applicable – Neutralization not recommended, see point IIIA 4.6

IIIA 4.6.5 Evaluation of products of neutralization (large quantities)

Not applicable – Neutralization not recommended, see point IIIA 4.6

IIIA 4.6.6 Procedures for disposal of large quantities of neutralized waste

Not applicable – Neutralization not recommended, see point IIIA 4.6

IIIA 4.7 Pyrolytic Behaviour of the Active Substance

Justification for non-submission: Information on the pyrolytic behaviour of the active ingredients fluazinam and dimethomorph is not considered to be required, since the halogen content of the preparation BANJO FORTE is below 60 %.

IIIA 4.8 Disposal Procedures for the Plant Protection Product

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

Refer to the safety data sheet for BANJO FORTE.

IIIA 4.8.2 Methods other than controlled incineration for disposal

Refer to the safety data sheet for BANJO FORTE.

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 Banjo forte (MCW-853) 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
Explosivity	Formulation has no explosive properties.	Wielpütz, T., 2008, 0080424.01
Oxidizing properties	Formulation has no oxidising properties.	Meinerling, M., 2009, 42115192
Flammability	Auto-ignition at 405 °C.	Wielpütz, T., 2008, 20080424.02
Content of hydrocarbon	< 10 % (w/w)	

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. (OECD)	**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, 2.4.2, 2.8.2, 2.8.3.1, 2.8.3.2, 2.8.5.2, 2.8.6.1, 2.8.8.2	Meierling, M., Herrmann, S.	2011	Determination of the accelerated storage stability of MCW 853 SC, 56162204! R-26493, GLP: Y, published: N	Y	ADAMA	1
KIIIA1 2.2.1	Wielpütz, T.	2008	MCW-853 SC Explosive properties, 20080424! R-23916, GLP: Y, published: N	Y	ADAMA	1
KIIIA1 2.2.2	Meierling, M.	2009	Expert Statement on the Oxidizing Properties of MCW 853 SC, 42115192! R-23917, GLP: N, published: N	Y	ADAMA	1
KIIIA1 2.3.1	Fieseler, A.	2008	Determination of the Flash Point of MCW-853 SC, 42120189! R-23918, GLP: Y, published: N	Y	ADAMA	1
KIIIA1 2.3.3	Wielpütz, T.	2008	MCW-853 SC: Auto-flammability (determination of the temperature of self-ignition of volatile ligquids and of gases) A.15, 20080424! R-23919, GLP: Y, published: N	Y	ADAMA	1

Annex point/ reference No. (OECD)	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 2.5.2	Fieseler, A.	2008	Determination of the Viscosity of MCW-853 SC, 42112196! R-23914, GLP: Y, published: N	Y	ADAMA	1
KIIIA1 2.5.3	Fieseler, A.	2008	Determination of the Surface Tension of MCW-853 SC, 42122184! R-23920, GLP: Y, published: N	Y	ADAMA	1
KIIIA1 2.6.1	Meinerling, M., Herrmann, S.	2010	Determination of the relative density of MCW 853 SC, 56165182! R-27037, GLP: Y, published: N	Y	ADAMA	1
KIIIA1 2.7.4, 2.8.3.1, 2.8.5.2	Meinerling, M., Herrmann, S.	2010	Determination of the low temperature stability of MCW 853 SC, 56163204! R-26492, GLP: Y, published: N	Y	ADAMA	1
KIIIA1 2.7.4, 2.8.3.1, 2.8.3.2, 2.8.5.2, 2.8.8.2	Meinerling, M., Herrmann, S.	2010	Determination of the freeze/thaw stability of MCW 853 SC (Final Report), 56161204! R-26494, GLP: Y, published: N	Y	ADAMA	1
KIIIA1 2.7.5, 2.8.3.1, 2.8.3.2, 2.8.5.2, 2.8.8.2	Meinerling, M., Hermann, S.	2012	Determination of the storage stability of MCW 853 SC at 20°C, 56164204! R-26892, GLP: Y, published: N	Y	ADAMA	1

Annex point/ reference No. (OECD)	**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 2.8.6.1	Smeykal, H.	2010	MCW 853 SC - Particle size distribution OECD 110, 20100265! R-26892A, GLP: Y, published: N	Y	ADAMA	1
KIIIA1 2.9.1	Schnell, R.	2009	Evaluation of physical compatibility of tank mixtures of MAC 94530 F, FCS 12/2009, GLP: N, published: N	Y	ADAMA	1
KIIIA1 2.9.2	Schnell, R.	2009	Evaluation of chemical compatibility of tank mixtures of MAC 94530 F FCS 13/2009 GLP: N, published: N 2446050 /	Y	ADAMA	1
KIIIA1 4.1.1, 4.1.2	Anonymous	2005	Customer Specification File: 1.0 L Chemicals Container, 4 layers, L7101.11, GLP: N, published: N	Y	ADAMA	1
KIIIA1 4.1.1, 4.1.2	Anonymous	2005	Customer Specification File: 5 L Chemicals Container, 6 layers, L7101-12a, GLP: N, published: N	Y	ADAMA	1

Annex point/ reference No. (OECD)	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 4.1.1, 4.1.2	Anonymous	1999	Statement on cardboard boxes - 10 x 1 litre, 588! 2913114416/2, GLP: N, published: N	Y	ADAMA	1
KIIIA1 4.1.1, 4.1.2	Anonymous	1999	Statement on cardboard boxes - 4 x 5 litres, 588! 2911445/3, GLP: N, published: N	Y	ADAMA	1
KIIIA1 4.1.3	Meinerling, M., Hermann, S.	2012	Determination of the storage stability of MCW 853 SC at 20°C, 56164204! R-26892, GLP: Y, published: N	Y	ADAMA	1
KIIIA1 4.2.2	Meinerling, M.	2010	Determination of the effectiveness of cleaning prodecures for MCW 853 SC, 56167361! R-27393, GLP: Y, published: N	Y	ADAMA	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

date: 2014-04-16

PPP (product name/code)	**BANJO FORTE**	**Formulation type:**	**SC**
active substance 1	**fluazinam**	**Conc. of as 1:**	**200 g/L**
active substance 2	**dimethomorph**	**Conc. of as 2:**	**200 g/L**
Applicant:	**Feinchemie Schwebda 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	Potatoes SOLTU	F	Late blight *(Phytophthora infestans)* PHYTIN	spraying	in case of danger of infection and/or after warning service appeal (BBCH 31 – 91)	a) 4 b) 4 (7 - 10 days)	a) 1.0 L/ha b) 4.0 L/ha	a) as1 : 0.2 kg/ha as2: 0.2 kg/ha b) as1 : 0.8 kg/ha as2 : 0.8 kg/ha	300 - 600	7	

Appendix 3: Physical and chemical properties of the active substance dimethomorph

These following data refer to studies that have been submitted to match protected data.

Section (Annex point)	Study	Purity [%]	Method	Results	Reference	Acceptability / Comments
B.2.1.1.1 (IIA 2.1.1)	Melting point, freezing point or solidification point	99.5	OECD 102 (capillary method)	E/Z: 131.0 - 149.0 °C	Lange, 2007 (BVL no 1937980)	acceptable additional information *LOEP:* *E/Z mixture: 125.2 – 149.2 °C (99.1 %, E/Z 48/52)* *E isomer: 136.8 - 138.3 °C (99.1 %)* *Z isomer: 166.3 - 168.5 °C (99.1 %)*
B.2.1.1.2 (IIA 2.1.2)	Boiling point	99.5	OECD 103 EEC A2	>250 °C at 1048.5 hPa	Lange, 2006 (BVL no 1937981)	acceptable additional information *LOEP:* *not applicable*
B.2.1.1.3 (IIA 2.1.3)	Temperature of decomposition or sublimation	98.6	OECD 113	Decomposition occurs above 350 °C	Horn, 2006 (BVL no 1937982)	acceptable additional information *LOEP:* *E isomer: 280 °C (99.1 %)* *Z isomer: 280 °C (99.1 %)*

Section (Annex point)	Study	Purity [%]	Method	Results	Reference	Acceptability / Comments
B.2.1.2 (IIA 2.2)	Relative density	99.5	OECD 109 EEC A3 (pycnometer)	d_4^{20} = 1.297	Lange, 2006 (BVL no 1937983)	acceptable additional information *LOEP:* *1.3 (20 °C) (99.1%)*
B.2.1.3.1 (IIA 2.3.1)	Vapour pressure	99.5	OECD 104 vapour pressure balance	8.0×10^{-8} Pa (20 °C) 1.8×10^{-7} Pa (25 °C) 6.2×10^{-6} Pa (50 °C)	Horn, 2006 (BVL no 1937984)	acceptable additional information *LOEP:* *$9.7 \cdot 10^{-7}$ (E); $1 \cdot 10^{-6}$ (Z), 25 °C*
B.2.1.3.2 (IIA 2.3.2)	Volatility, Henry's law constant		Calculation	1.30×10^{-5} Pa m³ mol^{-1} (E isomer) 5.75×10^{-5} Pa m³ mol^{-1} (Z-isomer) (20 °C)	O'Brien, 2010 (BVL no 2009468)	acceptable additional information *LOEP:* *$5.4 \cdot 10^{-6}$ (E); $2.5 \cdot 10^{-5}$ (Z)*
				1.66×10^{-7} Pa m³ mol^{-1} (E isomer) 1.61×10^{-7} Pa m³ mol^{-1} (Z-isomer) (20 °C)	Schulze, 2007 (BVL no 1937985)	not acceptable, the water solubility of E/Z-dimethomorph was used to calculate the Henry's law constant of both isomers

Section (Annex point)	Study	Purity [%]	Method	Results	Reference	Acceptability / Comments
B.2.1.4.1 (IIA 2.4.1)	Appearance: physical state	98.6 99.3	Visual assessment	solid, crystalline, powder solid, powder	Schulze, 2007 (BVL no 1937986) Witte, 2009 (BVL no 1937987)	acceptable additional information *LOEP:* *White crystalline solid (98.8%)*
B.2.1.4.2 (IIA 2.4.1)	Appearance: colour	98.6 99.3	Visual assessment	white to beige white	Schulze, 2007 (BVL no 1937986) Witte, 2009 (BVL no 1937987)	acceptable additional information *LOEP:* *White crystalline solid (98.8%)*
B.2.1.4.3 (IIA 2.4.2)	Appearance: odour	98.6 99.3	Olfactory assessment	faint rubber like no discernible odour	Schulze, 2007 (BVL no 1937988) Witte, 2009 (BVL no 1937989)	acceptable additional information
B.2.1.5.1 (IIA 2.5.1)	Spectra of purified active substance	99.5	UV/VIS OECD 101	pH / λ_{max} [nm] / ε [L mol^{-1} cm^{-1}] < 2 / 203 / 43566 < 2 / 244 / 22016 neutral / 204 / 41357 neutral / 244 / 22597 ≥10 / 219 / 24903 ≥10 / 244 / 22171	Lange, 2007 (BVL no 1937990)	acceptable additional information *LOEP:* *λ_{max} [nm] / ε [L mol^{-1} cm^{-1}]* *200 / $4.5 \cdot 10^4$* *205 / $3.0 \cdot 10^4$* *221 / $1.6 \cdot 10^4$* *242 / $2.0 \cdot 10^4$* *286 / $9.1 \cdot 10^3$* *312 / $4.5 \cdot 10^3$*

Section (Annex point)	Study	Purity [%]	Method	Results	Reference	Acceptability / Comments
		99.5	IR, NMR, MS	Spectra are consistent with given structure of dimethomorph.	Roos, 2007 (BVL no 1937991)	acceptable additional information
B.2.1.5.2 (IIA 2.5.2)	Spectra for impurities of toxicological, ecotoxicological or environmental concern		UV/VIS, IR, NMR, MS	Spectra of impurities were submitted although none of them is of toxicological or ecotoxicological concern.	Roos, 2007 (BVL no 1937995) Roos, 2007 (BVL no 1937996) Roos, 2007 (BVL no 1937997)	additional information
B.2.1.6 (IIA 2.6)	Solubility in water	99.5	EEC A 6 OECD 105 (flask method)	Dimethomorph- E, Z: 42.3 mg/L (pH 4.11, 20 °C) 42.9 mg/L (pH 6.86, 20 °C) 37.6 mg/L (pH 8.89, 20 °C)	Lange, 2007 (BVL no 1938004)	acceptable additional information *LOEP:* *20 °C [g/L].*
		99.6	EEC A 6 OECD 105 (flask method)	Isomer- Z : 7.59 mg/L (pH 4.11, 20 °C) 6.75 mg/L (pH 6.61, 20 °C) 7.06 mg/L (pH 8.91, 20 °C)	Lange, 2007 (BVL no 1938005)	*E-isomer: 0.0472* *Z-isomer: 0.0107*
		99.2	EEC A 6 OECD 105 (flask method)	Isomer- E: 31.9 mg/L (pH 4.09, 20 °C) 28.8 mg/L (pH 7.40, 20 °C) 29.3 mg/L (pH 8.89, 20 °C)	Lange, 2007 (BVL no 1938006)	

Section (Annex point)	Study	Purity [%]	Method	Results	Reference	Acceptability / Comments
B.2.1.7 (IIA 2.7)	Solubility in organic solvents	98.6	CIPAC MT 181	acetone 20 - 25 1,2-dichloroethane 160 - 200 ethyl acetate < 10 *n*-heptane < 10 methanol < 10 *p*-xylene < 10 all in g/L, 20 °C	Schulze, 2007 (BVL no 1938007)	acceptable additional information *LOEP:* *Individual isomers E(Z) [g/L; 20°C]* *CH_2Cl_2: 296 (165)* *acetone: 84.1 (16.3)* *ethyl acetate: 39.9 (8.4)* *toluene: 39.0 (10.5)* *methanol: 31.5 (7.5)* *n-hexane: 0.076 (0.036)* *1.2-dichloroethane: 182.5 (92.5)* *xylene: 22.2 (6.4)* *heptane 0.120 (0.053)*
		98.6	OECD 105, EEC A6 (flask method)	*E/Z* mixture [g/L] at 20 °C ethyl acetate: 49.7 *n*-heptane: 0.2 methanol: 36.9 p-xylene: 21.3	Lange, 2008 (BVL no 1938008)	
		97.6	OECD 105, EEC A6 (flask method)	*E/Z* mixture [g/L] at 20 °C 1,2-dichloroethane: 358 acetone: 72.1 Isomer ratio changed from 47:53 (E:Z) in calibration solution to 57:43 and 80:20.	Lange, 2010 (BVL no 2009469)	

Section (Annex point)	Study	Purity [%]	Method	Results	Reference	Acceptability / Comments
B.2.1.8 (IIA 2.8)	Partition coefficient	99.5	OECD 107, EEC A8 (shake flask)	log $P_{O/W}$ = 2.72 (pH 4) log $P_{O/W}$ = 2.75 (pH 7) log $P_{O/W}$ = 2.74 (pH 9) all at 24 °C	Lange, 2007 (BVL no 1938009) Lange, 2010 (BVL no 1985312)	acceptable additional information *LOEP:* *log $P_{O/W}$ = 2.63 (E)* *log $P_{O/W}$ = 2.73 (Z), 20 °C, Milli Q water*
B.2.1.9.1 (IIA 2.9.1)	Hydrolysis rate	99.5	OECD 111 EEC C7	*E, Z*-dimethomorph was stable to hydrolysis at pH 4, 7 and 9. DT_{50} > 1 a (pH 4, 7 and 9)	Lange, 2007 (BVL no 1938011)	acceptable additional information *LOEP:* *After 10 weeks at 70 °C and 90 °C less than 10 % degradation at pH 4, 7 and 9*
B.2.1.9.2 (IIA 2.9.2)	Direct photo-transformation in purified water	99.5	OECD Draft 2000	DT_{50}= 31 d	Lange, 2007 (BVL no 1938012)	acceptable additional information *LOEP:* *DT_{50} 86 d and 107 d (22 °C, pH 5)*
B.2.1.9.3 (IIA 2.9.3)	Quantum yield of direct photo-degradation	99.5	OECD Draft 2000	$\Phi = 2.019 \times 10^{-7}$ (50° N) DT_{50} = 84 d (summer) up to DT_{50} = 759 d (winter)	Lange, 2007 (BVL no 1938013)	acceptable additional information *LOEP:* *$6.71 \cdot 10^{-6}$, pH 7, 20 °C*

Section (Annex point)	Study	Purity [%]	Method	Results	Reference	Acceptability / Comments
B.2.1.9.4 (IIA 2.9.5)	Dissociation constant	99.5	OECD 112	No dissociation was observed between pH 2 and pH 12.	Wielpütz, 2007 (BVL no 1938015)	acceptable additional information *LOEP:* *- 1.3 (calculation)*
B.2.1.10 (IIA 2.10)	Estimated photochemical oxidative degradation	-	Atkinson calculation AOPWIN (v1.65)	DT_{50} = 1.2 h k_{OH} = 106 x 10^{-12} cm^3 s^{-1} (OH-radical conc.: 1.5 x 10^6 cm^{-3})	Jaschke, 2007 (BVL no 1938016)	acceptable additional information
B.2.1.11.1 (IIA 2.11.1)	Flammability	98.6	EEC A 10	Dimethomorph technical was determined to be non-flammable.	Lange, 2006 (BVL no 1938017)	acceptable additional information *LOEP: none*
B.2.1.11.2 (IIA 2.11.2)	Auto-flammability	98.6	EEC A 16	No self ignition and no exothermal reaction was observed up to 401 °C.	Horn, 2006 (BVL no 1938018)	acceptable additional information
B.2.1.12 (IIA 2.12)	Flash point			Not applicable (melting point > 40 °C)		not required
B.2.1.13 (IIA 2.13)	Explosive properties	98.6	EEC A 14	Dimethomorph is not explosive (friction, shock, thermal sensitivity).	Horn, 2006 (BVL no 1938019)	acceptable additional information *LOEP: none*

Section (Annex point)	Study	Purity [%]	Method	Results	Reference	Acceptability / Comments
B.2.1.14 (IIA 2.14)	Surface tension	99.5	EEC A 5	57.7 mN/m (90% saturat. H_2O solution, at a temperature range of 19.6 °C to 19.7 °C) The substance is surface active.	Lange, 2006 (BVL no 1938020)	acceptable additional information *LOEP:* *60.8 mN/m (20 °C, 90% saturated aqueous solution)*
B.2.1.15 (IIA 2.15)	Oxidising properties	98.6	EEC A 17	No oxidising properties were observed.	Lange, 2006 (BVL no 1938021)	acceptable additional information

List of data

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*
KIIA 2.1.1 (OECD)	Lange, J.	2007	MCW 388 pure - Melting point/ melting range 060109MS! CPM107101 GLP: Y, published: N 1937980	Y	MAC	1
KIIA 2.1.2 (OECD)	Lange, J.	2006	MCW 388 pure - Boiling point 060109MS! CPS107101 GLP: Y, published: N 1937981	Y	MAC	1
KIIA 2.1.3 (OECD)	Horn, J.	2006	MCW 388 Technical - Explosive properties A.14 20060358.01! R-20573 GLP: Y, published: N 1937982	Y	MAC	1
KIIA 2.2 (OECD)	Lange, J.	2006	MCW 388 Pure - Determination of the density CPD107101 GLP: Y, published: N 1937983	Y	MAC	1
KIIA 2.3.1 (OECD)	Horn, J.	2006	MCW 388 Pure - Vapour pressure A.4. 20060359.01! R-20582 GLP: Y, published: N 1937984	Y	MAC	1
KIIA 2.3.2 (OECD)	Schulze, M.	2007	MCW 388 Pure - Calculation of Henry Constant CHK10710N! R-21933 GLP: N, published: N 1937985	Y	MAC	2
KIIA 2.3.2 (OECD)	O'Brien, K.	2010	Dimethomorph (MCW 388) Estimation of the Henry's Law constant (Z and E enantiomer) 395249-A2-020302-02! R-27349 GLP: N, published: N 2009468	Y	FSG	1

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*
KIIA 2.4.1 (OECD)	Schulze, M.	2007	MCW 388 Technical - appearance: Physical state, colour and odour CAP107091! R-21932 GLP: Y, published: N 1937986	Y	MAC	1
KIIA 2.4.1 (OECD)	Witte, A.	2009	Appearance (color, odor and physical state) of MCW 388 pure 09M02181-01-AP GLP: Y, published: N 1937987	Y	MAC	1
KIIA 2.4.2 (OECD)	Schulze, M.	2007	MCW 388 Technical - appearance: Physical state, colour and odour CAP107091! R-21932 GLP: Y, published: N 1937988	Y	MAC	1
KIIA 2.4.2 (OECD)	Witte, A.	2009	Appearance (color, odor and physical state) of MCW 388 pure 09M02181-01-AP! R-25887 GLP: Y, published: N 1937989	Y	MAC	1
KIIA 2.5.1.1 KIIA 2.5.1.5 (OECD)	Lange, J.	2007	MCW 388 pure - UV-VIS adsorption spectra CPU107101! R-20577 GLP: N, published: N 1937990 / 1937994	Y	MAC	1
KIIA 2.5.1.2 KIIA 2.5.1.3 KIIA 2.5.1.4 (OECD)	Roos, M.	2007	Characterization of the molecular structure of dimethomorph R-20623! B015/2006 GLP: Y, published: N 1937991 / 1937992 / 1937993	Y	MAC	1

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*
KIIA 2.5.2.2 KIIA 2.5.2.3 KIIA 2.5.2.4 (OECD)	Roos, M.	2007	Characterisation of the molecular structure of Veratrole B063/2006! R-21375 GLP: Y, published: N 1937995 / 1937998 / 1938001	Y	MAC	3
KIIA 2.5.2.2 KIIA 2.5.2.3 KIIA 2.5.2.4 (OECD)	Roos, M.	2007	Characterization of the molecular structure of (E/Z)-4-[3-(Phenyl)-3-(3',4'-dimethoxy-phenyl)-1-oxo-2-propenyl]morpholine B061/2006! R-21373 GLP: Y, published: N 1937996 / 1937999 / 1938002	Y	MAC	3
KIIA 2.5.2.2 KIIA 2.5.2.3 KIIA 2.5.2.4 (OECD)	Roos, M.	2007	Characterization of the molecular structure of MW=429 (imp. of Dimethomorph) B062/2006! R-21374 GLP: Y, published: N 1937997 / 1938000 / 1938003	Y	MAC	3
KIIA 2.6 (OECD)	Lange, J.	2007	MCW 388 Pure - Water solubility in dependence of pH (flask method) CWF107102! R-20583 GLP: Y, published: N 1938004	Y	MAC	1
KIIA 2.6 (OECD)	Lange, J.	2007	Dimethomorph isomer Z water solubility in dependence of pH (flask method) CWF119001! R-22371 GLP: Y, published: N 1938005	Y	MAC	1
KIIA 2.6 (OECD)	Lange, J.	2007	Dimethomorph isomer E water solubility in dependence of pH (flask method) CWF118991! R-22370 GLP: Y, published: N 1938006	Y	MAC	1

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*
KIIA 2.7 (OECD)	Schulze, M.	2007	MCW 388 Technical - solubility in organic solvents CLS107091! R-20584 GLP: Y, published: N 1938007	Y	MAC	1
KIIA 2.7 (OECD)	Lange, J.	2008	MCW 388 Technical - solubility in organic solvents (flask method) CLF107094! R-20584A GLP: Y, published: N 1938008	Y	MAC	1
KIIA 2.7 (OECD)	Lange, J.	2010	MCW 388 Technical solubility in organic solvents (flask method) 100622MS! CLF13832 GLP: N, published: N 2009469	Y	FSG	1
KIIA 2.8.1 KIIA 2.8.2 (OECD)	Lange, J.	2007	MCW 388 Pure partition coefficient (n-octanol / water): Shake flask method COS107101! R-20569 GLP: Y, published: N 1938009 / 1938010	Y	MAC	1
KIIA 2.8.1 KIIA 2.8.2 (OECD)	Lange, J.	2010	1st amendment to the report MCW 388 pure - partition coefficient(n-octanol/water): Shake flask method 060109MS;COS107101 GLP: Y, published: N 1985312 / 1985313	Y	FSG	5
KIIA 2.9.1 (OECD)	Lange, J.	2007	MCW 388 Pure hydrolysis as a function of pH CPH107101 GLP: Y, published: N 1938011	Y	MAC	1

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*
KIIA 2.9.2 KIIA 2.9.3 KIIA 2.9.4 (OECD)	Lange, J.	2007	MCW 388 pure - Phototransformation of chemicals in water- direct photolysis CPP107101! R-20594 GLP: Y, published: N 1938012 / 1938013 / 1938014	Y	MAC	1
KIIA 2.9.5 (OECD)	Wielpütz, T.	2007	MCW 388 pure batch No.: 288-035 Dissociation constant pKa (OECD 112) 20060359.02 GLP: Y, published: N 1938015	Y	MAC	1
KIIA 2.10 (OECD)	Jaschke, S.	2007	Dimethomorph - Estimation of the photochemical oxidative degradation 395249-A2-0210-01 GLP: N, published: N 1938016	Y	MAC	1
KIIA 2.11.1 (OECD)	Lange, J.	2006	MCW 388 Technical - Flammability of solids CPE107091! R-20571 GLP: Y, published: N 1938017	Y	MAC	1
KIIA 2.11.2 (OECD)	Horn, J.	2006	Auto-flammability (solids-determination of relative self-ignition temperature) A.16 20060358.02 GLP: Y, published: N 1938018	Y	MAC	1
KIIA 2.13 (OECD)	Horn, J.	2006	MCW 388 Technical - Explosive properties A.14 20060358.01 GLP: Y, published: N 1938019	Y	MAC	1
KIIA 2.14 (OECD)	Lange, J.	2006	MCW 388 - Surface tension CPT107101! R-20574 GLP: Y, published: N 1938020	Y	MAC	1

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*
KIIA 2.15 (OECD)	Lange, J.	2007	MCW 388 - Oxidizing properties of solids COX107092! R-20575 GLP: Y, published: N 1938021	Y	MAC	1
KIIA 2.16 (OECD)	Bodsch, J.	2008	MCW 388 Technical - Determination of the pH value GLP: Y, published: N 1938022	Y	MAC	3
KIIA 2.17.1 (OECD)	Schulze, M.	2007	MCW 388 Technical - Storage Stability and Corrosion Characteristics GLP: Y, published: N 1938023	Y	MAC	3

* 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 4: Physical and chemical properties of the active substance fluazinam

These following data refer to studies that have been submitted to match protected data.

Section (Annex point)	Study	Purity [%]	Method	Results	Reference	Acceptability / Comments
B.2.1.1.1 (IIA 2.1.1)	Melting point, freezing point or solidification point	99.5	EEC A 1 (capillary method)	110 °C – 117 °C	Lange, 2006 (BVL no 1905202)	acceptable additional information *LOEP:* *117 °C (99.8% w/w)*
B.2.1.1.2 (IIA 2.1.2)	Boiling point	99.5	EEC A 2 (capillary method)	see B.2.1.1.3	Lange, 2006 (BVL no 1905203)	acceptable additional information *LOEP:* *not applicable*
B.2.1.1.3 (IIA 2.1.3)	Temperature of decomposition or sublimation	99.5	EEC A 2 Siwoloboff	148 °C	Lange, 2006 (BVL no 1905204)	acceptable additional information *LOEP:* *test substance not stable >150 °C*
B.2.1.2 (IIA 2.2)	Relative density	99.5	EEC A 3 (pycnometer)	d_4^{20} = 1.741	Lange, 2006 (BVL no 1905205)	acceptable additional information *LOEP:*

Section (Annex point)	Study	Purity [%]	Method	Results	Reference	Acceptability / Comments
B.2.1.3.1 (IIA 2.3.1)	Vapour pressure	99.5	EEC A 4 (vapour pressure balance)	1.7 x 10^{-5} Pa (25 °C) extrapolated from measurements between 47 °C and 100 °C	Horn, 2006 (BVL no 1905206)	acceptable
		99.3	EEC A 4 (weight loss method)	1.72 x 10^{-4} Pa (25 °C) extrapolated from measurements between 70 °C and 140°C	Oudhoff, 2011 (BVL no 2118183)	acceptable
		98.3	EEC A 4 (weight loss method)	1.12 x 10^{-3} Pa (25 °C) extrapolated from measurements between 120 °C and 150°C	Meinerling/Wagner, 2011 (BVL no 2118184)	acceptable
			Statement	Results of different studies are compared. Fluazinam should be characterised as semi-volatile or non-volatile.	Büsing, 2011 (BVL no 2118185)	additional information
		99.3	EEC A 4 (vapour pressure balance)	1.8 x 10^{-5} Pa (20 °C) 3.7 x 10^{-5} Pa (25 °C) 1.0 x 10^{-3} Pa (50 °C) extrapolated from measurements between 37 °C and 98°C	Möller, 2011 (BVL no 2449943)	acceptable
			Statement	Statement that the vapour pressure balance is an adequate method for the determination of the vapour pressure of fluazinam.	Franke, 2012 (BVL no 2449944)	additional information

Section (Annex point)	Study	Purity [%]	Method	Results	Reference	Acceptability / Comments
						additional information *LOEP:* *(7.5 ± 0.8) x 10^{-3} Pa at 20 °C* *(99.8% w/w)*
B.2.1.3.2 (IIA 2.3.2)	Volatility, Henry's law constant		Calculation	0.021 Pa · m^3 / mol	Pagel, 2008 (BVL no 1905207)	acceptable additional information *LOEP:* *25.9 Pa.m^3.mol^{-1} at 20 °C*
B.2.1.4.1 (IIA 2.4.1)	Appearance: physical state	99.0 99.4	Visual assessment	crystalline solid crystalline solid	Schulze, 2007 (BVL no 1905208) Witte, 2009 (BVL no 1905209)	acceptable additional information *LOEP:* *crystalline solid (100% w/w)* *solid (97.7% w/w)*
B.2.1.4.2 (IIA 2.4.1)	Appearance: colour	99.0 99.4	Visual assessment	yellow yellow (Munsell: 5Y 9/8)s	Schulze, 2007 (BVL no 1905208) Witte, 2009 (BVL no 1905209)	acceptable additional information *LOEP:* *yellow (100% w/w)* *yellow (97.7% w/w)*

Section (Annex point)	Study	Purity [%]	Method	Results	Reference	Acceptability / Comments
B.2.1.4.3 (IIA 2.4.2)	Appearance: odour	99.0 99.4	Olfactory assessment	odourless odourless	Schulze, 2007 (BVL no 1905210) Witte, 2009 (BVL no 1905211)	acceptable additional information *LOEP:* *odourless (100% w/w)* *weak aromatic hydrocarbon-like (97.7% w/w)*
B.2.1.5.1 (IIA 2.5.1)	Spectra of purified active substance	99.55	UV/VIS OECD 101	pH λ_{max} [nm] ε [L mol^{-1} cm^{-1}] acidic 244 20837 neutral 265 16163 347 15140 480 2605 alkaline 265 17000 347 19256 480 3628	Lange, 2006 (BVL no 1905212)	acceptable additional information *LOEP: nm L mol^{-1} cm^{-1}* *acidic 238 21900* *neutral 238 21200* *325 5150* *alkaline 260 18100* *341 20100* *479 3710*
		99.5	IR, NMR, MS	Spectra are consistent with given structure of fluazinam.	Petrovic, 2006 (BVL no 1905213)	acceptable additional information

Section (Annex point)	Study	Purity [%]	Method	Results	Reference	Acceptability / Comments
B.2.1.5.2 (IIA 2.5.2)	Spectra for impurities of toxicological, ecotoxicological or environmental concern	97.3	UV/VIS, IR, NMR, MS	Spectra are consistent with given structure of Fluazinam –isomer (5-chloro-*N*-(3-chloro-5-trifluoromethyl-2-pyridyl)-α,α,α-trifluoro-4,6-dinitro-*o*-toluidine).	Roos, 2008 (BVL no 2118181) Witte, 2010 (BVL no 2118182)	acceptable additional information
B.2.1.6 (IIA 2.6)	Solubility in water	99.5	EEC A 6 (column elution)	[mg/L] 10°C 20°C 30°C pH 4 0.0969 0.116 0.151 pH 7 0.113 0.157 0.338 pH 9 2.128 4.629 7.953	Lange, 2006 (BVL no 1905217)	acceptable additional information *LOEP:* *at 20 ± 1 °C (99.8% w/w)* *1.06 x 10^{-4} g/L (at pH 5)* *1.35 x 10^{-4} g/L (at pH 7)* *2.72 x 10^{-3} g/L (at pH 9)*

Section (Annex point)	Study	Purity [%]	Method	Results	Reference	Acceptability / Comments
B.2.1.7 (IIA 2.7)	Solubility in organic solvents	99.0	CIPAC MT 157 (flask method)	acetone 631 1,2-dichloroethane > 250 ethyl acetate 634 *n*-heptane 6.96 methanol 164 xylene > 250 all in g/L, 20 °C	Lange, 2007 (BVL no 1905218)	acceptable additional information *LOEP:* *at 25 °C [g/L] (96.8% w/w)* *acetone 853* *dichloromethane 675* *ethyl acetate 722* *ethyl ether 231* *hexane 8* *methanol 192* *octanol 41* *toluene 451*
B.2.1.8 (IIA 2.8)	Partition coefficient	99.5	EEC A8 (shake flask)	log $P_{O/W}$ = 4.95 (pH 4, 23 °C) log $P_{O/W}$ = 4.87 (pH 7, 23 °C) log $P_{O/W}$ = 3.91 (pH 9, 23 °C)	Lange, 2007 (BVL no 1905219)	acceptable additional information *LOEP:* *log $P_{O/W}$ = 4.03 at 25 °C,* *pH: 5.5 – 7.0 (96.8% w/w)* *data on pH dependency still open*

Section (Annex point)	Study	Purity [%]	Method	Results	Reference	Acceptability / Comments
B.2.1.9.1 (IIA 2.9.1)	Hydrolysis rate	99.5	EEC C7	pH 4 (20 °C): DT_{50} ≈ 100 d pH 7 (20 °C): DT_{50} = 39.7 d pH 9 (20 °C): DT_{50} = 19.3 d degradation product: CAPA CAPA: DT_{50}> 1 a (pH 4, 25 °C) DT_{50}< 1 d (pH 7 and 9, 25 °C)	Geffke, 2007 (BVL no 1905221) Lange, 2007 (BVL no 1905222) Meinerling, 2009 (BVL no 1905223)	acceptable additional information
B.2.1.9.2 (IIA 2.9.2)	Direct photo-transformation in purified water	99.5	OECD	DT_{50} = 8.53 h (pH 5, Suntest 700 W/m^2) corresponding to 28.5 h summer, 50°N No degradation products above 10% were detected. Minor product: 4,9-Dichloro-6-nitro-8-(trifluoromethyl)-pyrido-[1,2-a]benzimidazole-2-carboxylic acid	Lange, 2006 (BVL no 1905224) Lange, 2007 (BVL no 1905225) Lange, 2009 (BVL no 1905226)	acceptable additional information additional information
B.2.1.9.3 (IIA 2.9.3)	Quantum yield of direct photo-degradation	99.5	OECD	$\Phi = 4.5 \times 10^{-5}$ (pH 5)	Lange, 2006 (BVL no 1905227)	acceptable

Section (Annex point)	Study	Purity [%]	Method	Results	Reference	Acceptability / Comments
B.2.1.9.4 (IIA 2.9.5)	Dissociation constant	99	OECD 112 (spectrometric)	pK_a = 7.22	Bodsch, 2009 (BVL no 1905229)	acceptable additional information *LOEP:* *pK_A = 7.34 (20 ± 1 °C)* *(99.9% w/w)*
B.2.1.11.1 (IIA 2.11.1)	Flammability	99.0	EEC A 10	Fluazinam technical was determined to be not highly flammable.	Lange, 2006 (BVL no 1905231)	acceptable additional information *LOEP:* *Not highly flammable* *(96.7% w/w)*
B.2.1.11.2 (IIA 2.11.2)	Auto-flammability	99.0	EEC A 16	no self-ignition up to 400 °C	Horn, 2006 (BVL no 1905232)	acceptable
B.2.1.13 (IIA 2.13)	Explosive properties	99.0	EEC A 14	not explosive (heat: Koenen; shock: fall hammer; friction: friction test apparatus)	Horn, 2006 (BVL no 1905233)	acceptable additional information *LOEP:* *No explosive properties* *(97.8% w/w)*

Section (Annex point)	Study	Purity [%]	Method	Results	Reference	Acceptability / Comments
B.2.1.14 (IIA 2.14)	Surface tension		Statement	not required, water solubility is lower than 1 mg/L	Lange, 2006 (BVL no 1905234)	acceptable additional information *LOEP:* *66.3 mN/m at 20 °C* *(90% saturated solution)* *(95.5% w/w)* *[additional information – water solubility < 1mg/L]*
B.2.1.15 (IIA 2.15)	Oxidising properties	99.0	EEC A 17	non-oxidising	Lange, 2007 (BVL no 1905235)	acceptable additional information *LOEP:* *No oxidising properties* *(97.3% w/w)*

List of data

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*
KIIA 2.1.1 (OECD)	Lange, J.	2006	MCW 465 pure, melting point / melting range R-20529! CPM106921 GLP: Y, published: N 1905202	Y	MAC	1
KIIA 2.1.2 KIIA 2.1.3 (OECD)	Lange, J.	2006	MCW 465 pure, boiling point R-20530! CPS106922 GLP: Y, published: N 1905203 / 1905204	Y	MAC	1
KIIA 2.2 (OECD)	Lange, J.	2006	MCW 465 pure, determination of the density R-20531! CPD106923 GLP: Y, published: N 1905205	Y	MAC	1
KIIA 2.3.1 (OECD)	Horn, J.	2006	MCW 465 pure, vapour pressure A.4 (OECD 104) R-20532! 20060326.01 GLP: Y, published: N 1905206	Y	MAC	1
KIIA 2.3.1 (OECD)	Oudhoff, K.A.	2011	Determination of the vapour pressure of fluazinam 496633 GLP: Y, published: N 2118183	Y	FSG	1
KIIA 2.3.1 (OECD)	Meinerling, M.; Wagner Rivas, V.	2011	Revised final report no. 1: Determination of the vapour pressure of fluazinam by isothermal thermogravimetry 66291183 GLP: Y, published: N 2118184	Y	FSG	1

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*
KIIA 2.3.1 (OECD)	Büsing, A.	2011	Banjo (MCW 465 500 SC, 500 g/L Fluazinam) - Statement on the vapour pressure and volatilisation potential of fluazinam FCS-110620-01 GLP: N, published: N 2118185	Y	MAC	3
KIIA 2.3.1 (OECD)	Möller, M.	2011	Fluazinam (MCW 465): Determination of physico-chemical properties - Vapour pressure (EC A.4., OECD 104) CSL-11-0348.01 GLP: Y, published: N 2449943 /	Y	FSG	1
KIIA 2.3.1 (OECD)	Franke, J.; Möller, M.	2012	Statement: Evaluation of the studies of the vapour pressure of fluazinam with the vapour pressure balance GLP: N, published: N 2449944 /	Y	FSG	3
KIIA 2.3.2 (OECD)	Pagel, J.	2008	Calculation of henry's law constant of MCW 465 MCW-080526-02 GLP: N, published: N 1905207	Y	MAC	1
KIIA 2.4.1 KIIA 2.4.2 (OECD)	Schulze, M.	2007	MCW 465 technical, appearance: Physical state, colour and odour R-21928! CAP106911 GLP: Y, published: N 1905208 / 1905210	Y	MAC	1
KIIA 2.4.1 KIIA 2.4.2 (OECD)	Witte, A.	2009	Appearance (color, odor and physical state) of MCW 465 (Fluazinam) pure R-25888! 09M02182-01-AP GLP: Y, published: N 1905209 / 1905211	Y	MAC	1

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*
KIIA 2.5.1.1 KIIA 2.5.1.5 (OECD)	Lange, J.	2006	MCW 465 pure, UV-VIS absorption spectra R-20528! CPU106921 GLP: Y, published: N 1905212 / 1905216	Y	MAC	1
KIIA 2.5.1.2 KIIA 2.5.1.3 KIIA 2.5.1.4 (OECD)	Petrovic, P.	2006	Characterization of the molecular structure of MCW 465 pure R-20622! B 016/2006 GLP: Y, published: N 1905213 / 1905214 / 1905215	Y	MAC	1
KIIA 2.5.2 (OECD)	Roos, M.	2008	Characterization of the molecular structure of fluazinam a-isomer MW=464 B017/2008 GLP: Y, published: N 2118181	Y	MAC	1
KIIA 2.5.2 (OECD)	Witte, A.	2011	Mass spectrum and UV spectrum of fluazinam impurity 5-chloro-N-(3-chloro-5-trifluoromethyl-2-pyridyl)-a,a,a,-trifluoro-4,6-dinitro-o-toluidine R-28059! 11M04002-01-SP GLP: Y, published: N 2118182	Y	MAC	3
KIIA 2.6 (OECD)	Lange, J.	2006	MCW 465 pure, water solubility (column elution method) R-20533! CWS106921 GLP: Y, published: N 1905217	Y	MAC	1
KIIA 2.7 (OECD)	Lange, J.	2007	MCW 465 technical, solubility in organic solvents (flask method) R-20534! CLF106912 GLP: Y, published: N 1905218	Y	MAC	1

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*
KIIA 2.8.1 KIIA 2.8.2 (OECD)	Lange, J.	2007	MCW 465 pure, partition coefficient (n-octanol / water): shake flask method R-20535! COS106922 GLP: Y, published: N 1905219 / 1905220	Y	MAC	1
KIIA 2.8.2 (OECD)	Mollandin, G.	2010	Determination of the partition coefficient (n-octanol/ water) of HYPA by shake flask method at different pH values (Revised final report no.1 (2nd original)) R-26735! 48362186 GLP: Y, published: N 2449945 /	Y	FSG	3
KIIA 2.9.1 (OECD)	Geffke, T.	2007	MCW 465 pure, hydrolysis as a function of pH R-20519! CPH106923 GLP: Y, published: N 1905221	Y	MAC	1
KIIA 2.9.1 (OECD)	Lange, J.	2007	MCW 465 pure, hydrolysis as a function of pH - scan for major transformation products R-20519A! CPH106921 GLP: Y, published: N 1905222	Y	MAC	5
KIIA 2.9.1 (OECD)	Meinerling, M.	2009	Determination of the abiotic degradation of CAPA (hydrolysis as function of pH) R-23685! 39401193 GLP: Y, published: N 1905223	Y	MAC	3
KIIA 2.9.2 KIIA 2.9.3 KIIA 2.9.4 (OECD)	Lange, J.	2006	MCW 465 pure, phototransformation of chemicals in water - direct photolysis R-20520! CPP106921 GLP: Y, published: N 1905224 / 1905227 / 1905228	Y	MAC	1

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*
KIIA 2.9.2 (OECD)	Lange, J.	2007	MCW 465 pure, phototransformation of chemicals in water - direct photolysis - scan of major transformation products R-20520A! CPP106921 GLP: Y, published: N 1905225	Y	MAC	3
KIIA 2.9.2 (OECD)	Lange, J.	2009	MCW 465 pure, phototransformation of chemicals in water - direct photolysis - scan of major transformation products R-20520! CPP13045 GLP: Y, published: N 1905226	Y	MAC	3
KIIA 2.9.5 (OECD)	Bodsch, J.	2009	MCW 465 Technical (Fluazinam) - Dissociation constants in water - spectrophotometric method (incl. 1st amendment) R-23876! CDC11901 GLP: Y, published: N 1905229	Y	MAC	1
KIIA 2.11.1 (OECD)	Lange, J.	2006	MCW 465 technical, flammability of solids R-20538! CPE106911 GLP: Y, published: N 1905231	Y	MAC	1
KIIA 2.11.2 (OECD)	Horn, J.	2006	MCW 465 technical, auto-flammability (solids-determination of relative self-ignition temperatur) A.16 R-20537! 20060295.02 GLP: Y, published: N 1905232	Y	MAC	1

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*
KIIA 2.13 (OECD)	Horn, J.	2006	MCW 465 technical, explosive properties A.14 R-20539! 20060295.01 GLP: Y, published: N 1905233	Y	MAC	1
KIIA 2.14 (OECD)	Lange, J.	2006	MCW 465 pure, surface tension - Statement R-20540! CPT10692N GLP: N, published: N 1905234	Y	MAC	1
KIIA 2.15 (OECD)	Lange, J.	2007	MCW 465 technical, oxidizing properties of solids R-20541! COX106912 GLP: Y, published: N 1905235	Y	MAC	1
KIIA 2.16 (OECD)	Schulze, M.	2007	MCW 465 Technical (Fluazinam technical), determination of pH value R-22647! CVP119011 GLP: Y, published: N 1905236	Y	MAC	3

* 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)

REGISTRATION REPORT
Part B

Section 2: Analytical Methods
Detailed summary of the risk assessment

Product code: **MCW-853**
BANJO forte

Active Substance: **Dimethomorph 200 g/L**
Fluazinam 200 g/L

Central Zone
Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: **ADAMA Deutschland GmbH**

Date: **April 2015**

Table of Contents

IIIA 5 METHODS OF ANALYSIS

This document summarises the information related to the analytical methods for the product BANJO FORTE (MCW-853) containing the active substances dimethomorph and fluazinam which were approved according to Regulation (EC) No 1107/2009.

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

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

Information on the detailed composition of BANJO FORTE (MCW-853) 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 or the relevant impurity of fluazinam 5-chloro-N-(3-chloro-5-trifluoromethyl-2-pyridyl-α,α,α-trifluoro-4,6-dinitro-o-toluidine < 2 g/kg was performed.

IIIA 5.1.2 Analytical standards for the pure active substance

Analytical standards of dimethomorph and fluazinam were not provided because there was no request.

IIIA 5.1.3 Samples of the active substance as manufactured

No samples were provided because there was no request.

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

No samples were provided because there was no request.

IIIA 5.1.5 Samples of reference substances for relevant impurities

No samples were provided because there was no request.

IIIA 5.2 Methods for the Analysis of the Plant Protection Product

Analytical methods for the determination of dimethomorph and fluazinam 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 BANJO FORTE (MCW-853) 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 BANJO FORTE (MCW-853) 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 BANJO FORTE (MCW-853) has not previously been reviewed. The method is based on the CIPAC method for dimethomorph.

Report:	Meinerling, M., Herrmann, S., 2010
Title:	Determination of the accelerated storage stability of MCW 853 SC
Document No:	56162204; R-26493
Guidelines:	SANCO/3030/99 rev. 4
GLP	Yes

Method description
About 150 mg of the test item were weighed into a 100 mL volumetric flask. Then it was filled up to the mark using acetonitrile, ultrasonicated for 5 minutes and filtered through a syringe filter (0.45 µm PTFE). Determination of the active substances in the test item was performed by HPLC (RP 18 e) with DA detection at 220 nm. Mobile phase is acetonitrile/water (gradient). The quantification was performed by external standard calibration.

Method validation
The validation data of method were determined for the formulation BANJO FORTE (MCW-853). It was with respect to precision, accuracy, linearity and specificity proved that the method is suitable for the determination of dimethomorph and fluazinam in the SC-formulation.

Table containing the methods and validation of the methods (formulation BANJO FORTE (MCW-853))

Analyte	**Linearity n = 5**	**Accuracy n = 2*5 Mean [%]**	**Repeatability n = 1 [%RSD]**	**Specificity/Inteferences**
dimethomorph	50- 450 mg/L r = 0.99995	95 – 102 100 - 101	0.1 (mean content 21.1 %)	No interferences were noted. Chromatograms of formulation without active ingredients present were not submitted.
fluazinam	50- 450 mg/L r = 0.99995	90 – 114 100 - 101	0.2 (mean content 21.0 %) acceptable acc. Horwitz-eqn: 1.71 %	

Summary
The active substances of Banjo forte (MCW-853) can be quantified using the analytical HPLC method described above. The method is sufficiently validated.

IIIA 5.2.3 Applicability of existing CIPAC methods

There is no CIPAC method available for the determination of dimethomorph in SC formulations.
There is no CIPAC method available for the determination of fluazinam.

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

Five batches of technical fluazinam were analysed with a full validated method and the relevant impurity α-fluazinam could not be detected.
Nevertheless, an analytical method was conducted as evidence to demonstrate that α-fluazinam does not exist in the stored formulation. The method is summarised below.

Report:	Meierling, M., 2012
Title:	Development and validation of an analytical method for the determination of α -fluazinam in Formulation MCW-853 SC
Document No:	70371101! R-29528
Guidelines:	SANCO/3030/99 rev. 4
GLP	Yes

Method description
The analyte was determined by HPLC-DAD on a SepServ US ES Phenoxycarb column (250 x 3.0 mm), using external calibration. Injection volume is 5 µl. The separation is achieved by using gradient flow conditions for the detection and quantification of the actives (0.5 ml/min). Detection is performed with a diode array detector at wavelength 254 and 442 nm. The mobile phase consists of acetonitrile and 0.01 M ammonium acetate in pure water (gradient).

Method validation
The validation data of method were determined for the formulation BANJO FORTE (MCW-853). It was with respect to precision, accuracy, linearity and specificity proved that the method is suitable for the determination of α-fluazinam in the SC-formulation.

Table containing the methods and validation of the methods (formulation BANJO FORTE (MCW-853))

Analyte	**Linearity n = 5**	**Accuracy n = 2*5 Mean [%]**	**Repeatability n = 2 [%RSD]**	**Specificity/Inteferences**
α-fluazinam	0.5 - 12.5 mg/L r = 0.9999	101 – 105 % (at 0.016 %) 96 – 97 % (at 0.08 %)	2 % (at 0.016 %) 0.5 % (at 0.08 %) acceptable acc. Horwitz-eqn.: 4.8 %	No interferencesabove 3 %.

Summary

The analytical method is applicable for the determination of α-fluazinam in the formulation MCW 853 SC. For the method validation purpose, the blank formulation of MCW 853 SC was spiked at two concentration levels with α-fluazinam on a HPLC system with UV-DA detection and external calibration. The α-fluazinam content was determined to be below 0.016% w/w in the stored samples.

IIIA 5.2.5 Description of analytical methods for the determination of formulants

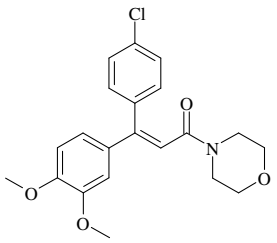
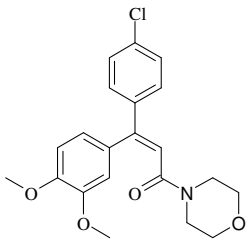
No formulants with toxicological or ecotoxicological relevant compounds are present in the formulation. Therefore, no analytical methods for the determination of formulants are necessary.

IIIA 5.3 Description of Analytical Methods for the Determination of Residues

IIIA 5.3.1 Evaluation of Dimethomorph

The conclusion regarding the peer review of the analytical methods for residues of dimethomorph is summarized in EFSA Scientific report (2006), 82, 1-69 ASB2012-3652.

Table 5.3-1: Information on the active substance dimethomorph

Dimethomorph **(EZ)-4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)acryloyl] morpholine;** **formula** **$C_{21}H_{22}ClNO_4$** **MW 387.9 g/mol**		
	E-Isomer	*Z*-Isomer

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	dimethomorph (sum of isomers)	Regulation (EU) No 668/2013, annex III part A
foodstuff of animal origin	dimethomorph (sum of isomers)	Regulation (EU) No 668/2013, annex III part A
soil	Dimethomorph	EFSA Scientific report (2006), 82, 1-69 ASB2012-3652
Surface water	Dimethomorph	EFSA Scientific report (2006), 82, 1-69 ASB2012-3652
Drinking/ground water	Dimethomorph	minimal requirement of the Drinking Water Act (Trinkwasser-VO)

air	not residue relevant	not classified as T / T+/ Xi / Xn
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	0.05 mg/kg	Regulation (EU) No 668/2013, annex III part A
Plant, acidic commodities	0.05 mg/kg	Regulation (EU) No 668/2013, annex III part A
Plant, dry commodities	0.05 mg/kg	Regulation (EU) No 668/2013, annex III part A
Plant, high oil content	0.05 mg/kg	Regulation (EU) No 668/2013, annex III part A
Plant, difficult matrices (hops, spices, tea)	50 mg/kg	Regulation (EU) No 668/2013, annex III part A
meat	0.05 mg/kg	Regulation (EU) No 668/2013, annex III part A
milk	0.05 mg/kg	Regulation (EU) No 668/2013, annex III part A
eggs	0.05 mg/kg	Regulation (EU) No 668/2013, annex III part A
fat	0.05 mg/kg	Regulation (EU) No 668/2013, annex III part A
liver, kidney	0.05 mg/kg	Regulation (EU) No 668/2013, annex III part A
soil	0.05 mg/kg	common limit
drinking water	0.1 µg/L	general limit for drinking water
surface water	56 µg/L	NOEC *Oncorhynchus mykiss.* EFSA Scientific report (2006), 82, 1-69 ASB2012-3652
air	not necessary	not classified as T / T+/ Xi / Xn
tissue (meat or liver)	not necessary	not classified as T / T+
body fluids	not necessary	not classified as T / T+

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

An overview of the acceptable methods and possible data gaps for analysis of dimethomorph in plant matrices is given in the following tables. For the detailed evaluation of new/additional studies it is referred to 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	Holzer, 2009	Eichler, 2010	Eichler, 2010
acidic	Holzer, 2009	Eichler, 2010	Eichler, 2010
fatty	Holzer, 2009	Eichler, 2010	Eichler, 2010
dry	Holzer, 2009	Eichler, 2010	Eichler, 2010
difficult	not required for the intended GAP	not required for the intended GAP	not required for the intended GAP

Table 5.3-5: Statement on extraction efficiency

	Method for products of plant origin
Required, available from:	Thiele, 1990, RIP2002-744 (RIP2002-745 supplemental data)

Potato plants were treated with 4 x 600 g a.i./ha (10 day intervals). At maturation the plants were harvested and the potato tubers peeled. Peels and peeled tubers were extracted with methanol/water. Only low radioactive residues were found in peel (0.121 mg/kg) and peeled tuber (0.025 mg/kg).
Extraction efficiencies:
Peel: 61 % (46 % parent
Peeled tuber: 47 % (12% parent)

As the extraction solvent used in the monitoring method is isopropanol, comparable extraction efficiency can only be assumed.

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
Holzer, 2009 ASB2010-13637	high water content, acidic, fatty, dry	0.01 mg/kg	LC-MS/MS, Acquity BEH C18 (UPLC), ESI+, m/z 388→301	no confirmation	see appendix 2
Eichler, 2010 ASB2010-13639	high water content, acidic, fatty, dry	0.01 mg/kg	LC-MS/MS, Luna C18, ESI+, m/z 388→301, 388→165	confirmation included, ILV of ASB2010-13637	see appendix 2

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

An overview of the acceptable methods and possible data gaps for analysis of dimethomorph in animal matrices is given in the following tables. For the detailed evaluation of new/additional studies it is referred to Appendix 2.

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	Holzer, 2009	Eichler, 2010	Eichler, 2010
eggs	Holzer, 2009	not required	missing
meat	Holzer, 2009	not required	missing
fat	Holzer, 2009	Eichler, 2010	Eichler, 2010
kidney, liver	Holzer, 2009	Eichler, 2010	Eichler, 2010

Table 5.3-8: Statement on extraction efficiency

	Method for products of animal origin
Required, available from:	van Dijk, 1990, RIP2002-752

Lactating goats were fed twice daily with ^{14}C-Dimethomorph at 25 mg/kg feed for 7 days. After sacrifice, edible tissues were extracted with methanol/water (8+2, v/v) and milk with ethyl acetate.
Only low radioactive residues was found in most edible tissues (0.03 – 0.08 mg/kg in muscle and fat, 0.29 mg/kg in kidney), except for liver (7.1 mg/kg). In milk 0.04 – 0.1 mg/kg was found.

Extractable radioactivity:
Milk: 81 % TRR (74-79 % TRR was characterized: 46-49% metabolite 4, further metabolites between 2-12%, no parent detected)
Muscle: 100 % TRR (parent 18 %)
Fat: 99 % TRR (parent 80 %)
Liver: 90 % TRR (parent 73 %)
Kidney: 95 % TRR (parent 10 %)

Acceptable extraction efficiency was shown for muscle, fat, milk, liver and kidney. As the extraction solvents used in the monitoring method (milk, egg, meat kidney: acetone; liver: acetonitrile, fat: GPC with cyclohexane/ethylacetate, 50/50, v/v) are different, similar extraction efficiency can only be assumed.

Table 5.3-9: Methods suitable for the determination of residues (enforcement) in products of animal origin

Author(s), year	Matrix	Method LOQ	Principle of method	Comment	Evaluated in
Holzer, 2009 ASB2010-13637	milk, egg, fat, meat, kidney, liver	0.01 mg/kg	LC-MS/MS, Acquity BEH C18 (UPLC), ESI+, m/z 388→301	no confirmation	see appendix 2
Eichler, 2010 ASB2010-13640	milk, fat, liver	0.01 mg/kg	LC-MS/MS, Luna C18, ESI+, m/z 388→301, 388→165	confirmation included, ILV of ASB2010-13637	see appendix 2

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

An overview of the acceptable methods and possible data gaps for analysis of dimethomorph in soil is given in the following tables. For the detailed evaluation of new/additional studies it is referred to Appendix 2.

Table 5.3-10: Overview of suitable primary and confirmatory methods for soil

Component(s) of residue definition	Primary method	Confirmatory method
dimethomorph	Holzer, 2009	missing

Table 5.3-11: Methods for soil

Author(s), year	Method LOQ	Principle of method	Comment	Evaluated in
Holzer, 2009 ASB2010-13637	0.01 mg/kg	LC-MS/MS, Acquity BEH C18 (UPLC), ESI+, m/z 388→301	no confirmation	see appendix 2

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

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

Table 5.3-12: Overview of suitable primary and confirmatory methods for water

Component(s) of residue definition	Matrix	Primary method	Confirmatory method
dimethomorph	drinking water/ surface water	Holzer, 2009	missing

Table 5.3-13: Methods for drinking water and surface water

Author(s), year	Method LOQ	Principle of method	Comment	Evaluated in
Holzer, 2009 ASB2010-13637	0.1 µg/L	LC-MS/MS, Acquity BEH C18 (UPLC), ESI+, m/z 388→301	no confirmation	see appendix 2

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

Methods for body fluids and tissues are not required, because dimethomorph is not considered to be irritant (Xi), harmful (Xn), toxic or very toxic (T / T+).

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

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

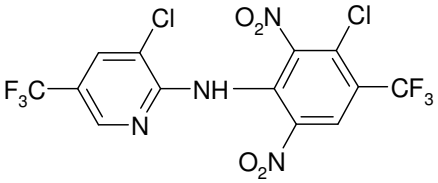
IIIA 5.3.1.8 Other Studies/ Information

none

IIIA 5.3.2 Evaluation of fluazinam

The conclusion regarding the peer review of the analytical methods for residues of fluazinam are summarized in EFSA Scientific Report (2008) 137, 1-82; ASB2012-3623

Table 5.3-14: Information on the active substance fluazinam

Name of component of residue definiton substance code IUPAC name formula	**Structural formula**
Fluazinam 3-chloro-N-(3-chloro-5-trifluoromethyl-2-pyridyl)-α,α,α-trifluoro-2,6-dinitro-p-toluidine $C_{13}H_4Cl_2F_6N_4O_4$ 465.1 g mol-1	

IIIA 5.3.2.1 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 not identical. In the DAR, no residue definition for foodstuff of animal origin was proposed. However, the current legal definition is parent fluazinam.

Table 5.3-15: Relevant residue definitions

Matrix	Relevant residue	Reference Remarks
plant material	fluazinam	Regulation (EC) No 251/2013, annex III part A
foodstuff of animal origin	fluazinam	Regulation (EC) No 251/2013, annex III part A
	not required[1]	EFSA Scientific Report (2008) 137, 1-82; ASB2012-3623
soil	fluazinam	EFSA Scientific Report (2008) 137, 1-82; ASB2012-3623
Surface water	fluazinam	EFSA Scientific Report (2008) 137, 1-82; ASB2012-3623
Drinking/ground water	fluazinam (HYPA + G-504 pending on ecotox. assessment)[2]	EFSA Scientific Report (2008) 137, 1-82; ASB2012-3623

air	fluazinam	classified as Xn EFSA Scientific Report (2008) 137, 1-82; ASB2012-3623
body fluids/tissue	not residue relevant	not classified as T / T+

[1]) This residue definition was not considered in the assessment
[2]) HYPA and G-504 were not considered in the assessment

Table 5.3-16: Levels for which compliance is required

Matrix	MRL	Reference for MRL/level Remarks
Plant, high water content	0.05 mg/kg	Regulation (EC) No 251/2013, annex III part A
Plant, acidic commodities	0.05 mg/kg	Regulation (EC) No 251/2013, annex III part A
Plant, dry commodities	0.05 mg/kg	Regulation (EC) No 251/2013, annex III part A
Plant, high oil content	0.05 mg/kg	Regulation (EC) No 251/2013, annex III part A
Plant, difficult matrices (hops, spices, tea)	0.05 mg/kg	Regulation (EC) No 251/2013, annex III part A
meat	0.05 mg/kg	Regulation (EC) No 251/2013, annex III part A
milk	0.05 mg/kg	Regulation (EC) No 251/2013, annex III part A
eggs	0.05 mg/kg	Regulation (EC) No 251/2013, annex III part A
fat	0.05 mg/kg	Regulation (EC) No 251/2013, annex III part A
liver, kidney	0.05 mg/kg	Regulation (EC) No 251/2013, annex III part A
soil	0.05 mg/kg	common limit
drinking water	0.1 µg/L	general limit for drinking water
surface water	2.9 µg/L	NOEC *Pimephales promelas*, EFSA Scientific Report (2008) 137, 1-82; ASB2012-3623
air	1.2 µg/m^3	AOEL sys: 0.004 mg/kg bw/d, classified as Xn EFSA Scientific Report (2008) 137, 1-82; ASB2012-3623
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 Fluazinam in Plant Matrices (OECD KIII A 5.3.1)

An overview of the acceptable methods and possible data gaps for analysis of fluazinam in plant matrices is given in the following tables. For the detailed evaluation of new/additional studies it is referred to Appendix 2.

Table 5.3-17: 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	Geffke, 2007	Meinerling, 2012	Meinerling, 2009
acidic	Geffke, 2007	not required	Meinerling, 2009
fatty	Geffke, 2007	not required	Meinerling, 2009
dry	Geffke, 2007	Meinerling, 2012	Meinerling, 2009
difficult	not required for the intended GAP	not required for the intended GAP	not required for the intended GAP

Table 5.3-18: Statement on extraction efficiency

	Method for products of plant origin
Required, available from:	Jentoft, 1997, RIP2003-1894

Potato plants were treated with 4 x 0.5 g a.i./ha of phenyl-labelled fluazinam and 4 x 0.43 kg as/ha pyridyl-labelled fluazinam. At maturation the potatoes were harvested and extracted with acetonitrile followed by extraction with acetonitrile/water (50+50, v/v).
Extraction efficiencies:
phenyl-label: 35.7 % TRR (0.004 mg/as-eq/kg), parent 2.3 % TRR (0.0003 mg/as-eq/kg)
pyridyl-label: 46.6 % TRR (0.012 mg/as-eq/kg), parent 5.9 % TRR (0.0015 mg/as-eq/kg).

As the extraction solvent is identical compared to the monitoring method and residues of parent fluazinam are below the LOQ no further proof of extraction efficiency is needed.

Table 5.3-19: 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
Geffke, 2007 ASB2010-7036	high water content, acidic, dry; fatty	0.01 mg/kg 0.02 mg/kg	LC-MS/MS, C18, ESI-, m/z 463→416	no confirmation	see appendix 2
Meinerling, 2012 ASB2013-9885	high water content, dry	0.01 mg/kg	LC-MS/MS, C18, ESI-, m/z 463→416 463→398	confirmation included, ILV of ASB2010-7036	see appendix 2
Meinerling, 2009 ASB2010-7035	high water content, acidic, dry,	0.01 mg/kg	LC-MS/MS, C18, ESI-, m/z 463→416,	confirmation included	see appendix 2

	fatty		463→398		

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

An overview of the acceptable methods and possible data gaps for analysis of fluazinam in animal matrices is given in the following tables. For the detailed evaluation of new/additional studies it is referred to Appendix 2.

Table 5.3-20: 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	Geffke, 2007	Meinerling, 2012	Meinerling, 2012
eggs	Geffke, 2007	Meinerling, 2012	Meinerling, 2012
meat	Holzer, 2009	not necessary [1]	missing
fat	Geffke, 2007	not necessary [1]	missing
kidney, liver	Witte, 2012	missing	Witte, 2012

[1] Geffke, 2007 and Holzer, 2009 are identical

Table 5.3-21: Statement on extraction efficiency

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

Table 5.3-22: Methods suitable for the determination of residues (enforcement) in products of animal origin

Author(s), year	Matrix	Method LOQ	Principle of method	Comment	Evaluated in
Geffke, 2007 ASB2010-7036	milk, eggs, fat	0.01 mg/kg	LC-MS/MS, C18, ESI-, m/z 463→416	no confirmation	see appendix 2
Holzer, 2009 ASB2010-7038	meat, fat	0.01 mg/kg	LC-MS/MS, C18, ESI-, m/z 463→416	no confirmation	see appendix 2
Meinerling, 2012 ASB2013-9885	milk, eggs	0.01 mg/kg	LC-MS/MS, C18, ESI-, m/z 463→416 463→398	confirmation included, ILV of ASB2010-7036	see appendix 2
Witte, 2012 ASB2012-12229	liver	0.01 mg/kg	LC-MS/MS, Thermo Hypurity Aquastar, ESI-,	confirmation included	see appendix 2

Author(s), year	Matrix	Method LOQ	Principle of method	Comment	Evaluated in
			m/z 463→416, 463→398		

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

An overview of the acceptable methods and possible data gaps for analysis of fluazinam in soil is given in the following tables. For the detailed evaluation of new/additional studies it is referred to Appendix 2.

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

Component(s) of residue definition	Primary method	Confirmatory method
fluazinam	Geffke, 2007	missing

Table 5.3-24: Methods for soil

Author(s), year	Method LOQ	Principle of method	Comment	Evaluated in
Geffke, 2007 ASB2010-7036	0.01 mg/kg	LC-MS/MS, C18, ESI-, m/z 463→416	no confirmation, only for fluazinam	see appendix 2

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

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

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

Component(s) of residue definition	Matrix	Primary method	Confirmatory method
fluazinam	drinking water/ surface water	Holzer, 2009	missing

Table 5.3-26: Methods for drinking water and surface water

Author(s), year	Method LOQ	Principle of method	Comment	Evaluated in
Holzer, 2009 ASB2010-7038	0.1 µg/L	LC-MS/MS, C18, ESI-, m/z 463→416	no confirmation, only for fluazinam	see appendix 2

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

An overview of the acceptable methods and possible data gaps for analysis of fluazinam in air is given in the following table. For the detailed evaluation of new/additional studies it is referred to Appendix 2.

Table 5.3-27: Overview of suitable primary and confirmatory methods for air

Component(s) of residue definition	Primary method	Confirmatory method
fluazinam	Holzer, 2011	Holzer, 2011

Table 5.3-28: Methods for air

Author(s), year	Method LOQ	Principle of method	Comment	Evaluated in
Holzer, 2011 ASB2011-9114	0.33 µg/m^3	LC-MS/MS, C18, ESI-, m/z 463→398, 463→416	confirmation included	see appendix 2

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

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

IIIA 5.3.2.8 Other Studies/ Information

none

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

The notifier did not provide sufficiently validated analytical methods for the determination of dimethomorph and fluazinam in all matrices required. At the latest with the application for renewal of approval for the active substances according to Regulation (EC) No 1107/2009 or in context with the review of the existing MRLs for the active substances according to Article 12 of Regulation (EC) No 396/2005 following methods / data have to be submitted:

Dimethomorph:

- In the method by (Holzer, 2009) a second MRM needs to be validated as a confirmatory method for the determination of dimethomorph in egg and meat.
- In the method by (Holzer, 2009) a second MRM needs to be validated as a confirmatory method for the determination of dimethomorph in soil.
- In the method by (Holzer, 2009) a second MRM needs to be validated as a confirmatory method for the determination of dimethomorph in drinking- and surface water.

Fluazinam:

- In the method by (Holzer, 2009) a second MRM needs to be validated as a confirmatory method for the determination of fluazinam in meat.
- In the method by (Geffke, 2007) a second MRM needs to be validated as a confirmatory method for the determination of fluazinam in fat.

- The method by Witte (2012) for the determination of fluazinam in liver needs to be validated by an independent laboratory (ILV).
- A statement regarding the extraction efficiency for products of animal origin needs to be provided.
- In the method by (Geffke, 2007) a second MRM needs to be validated as a confirmatory method for the determination of fluazinam in soil.

In the method by (Holzer, 2009) a second MRM needs to be validated as a confirmatory method for the determination of fluazinam in drinking- and surface water.

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

Annex point/ reference No	Author(s)	Year	Title Source (where different from company) Report-No. GLP or GEP status (where relevant), Published or not	Data protection claimed	Owner	How considered in dRR Study-Status / Usage*
KIIIA1 5.2.2	Meinerling, M., Herrmann, S.	2010	Determination of the accelerated storage stability of MCW 853 SC, 56162204! R-26493, GLP: Yes, unpublished	Y	FSG	1
KIIIA1 5.2.4	Meierling, M.,	2012	Development and validation of an analytical method for the determination of α -fluazinam in Formulation MCW-853 SC, 70371101! R-29528, GLP: Yes, unpublished	Y	FSG	1

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

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
	EFSA	2008	Conclusion regarding the peer review of the pesticide risk assessment of the active substance fluazinam EFSA Scientific Report (2008) 137, 1-82 ASB2012-3623			Add
	EFSA	2008	Conclusion regarding the peer review of the pesticide risk assessment of the active substance dimethomorph EFSA Scientific report (2006), 82, 1-69 ASB2012-3652			Add
KIIA 4.3	Meinerling, M.; Herrmann, S.	2011	Independent laboratory validation of an analytical method for the determination of Fluazinam in food of animal origin and plants (Revised final report no. 2) 44241101 GLP: Open Published: Open BVL-2118186, ASB2011-9113	Yes	MCW	Y
KIIA 4.3	Meinerling, M.; Mollandin, G.	2009	ILV of an analytical method for the determination of Fluazinam in food of animal origin and plants R-23947 ! 44241101 GLP: Open Published: Open BVL-1905253, BVL-1905259, ASB2010-7039	Yes	MCW	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, KIIA 4.5, KIIA 4.7	Holzer, S.	2009	Dimethomorph - Residue analytical method for the determination in water, soil, air, plants, foodstuff of animal origin and body tissues - Part 2, page 86-170. CRA13056! R-25300 GLP: Yes (4) Open (4) Published: Open (4) No (4) BVL-1938030, BVL-1938032, BVL-1938034, BVL-1938036, BVL-2450135, BVL-2450137, BVL-2450139, BVL-2450141, ASB2010-13638	Yes	MAC	Y
KIIA 4.3, KIIA 4.4, KIIA 4.5, KIIIA1 5.3.1, KIIIA1 5.4, KIIIA1 5.6	Meinerling, M.; Eichler, M.	2009	Validation of an analytical method for the determination of AMPA in water, soil and plants R-23943 ! 39394101 GLP: Yes (3) Open (3) Published: Open (3) No (3) BVL-1905254, BVL-1905262, BVL-1905266, BVL-2450097, BVL-2450116, BVL-2450120, ASB2010-7040	Yes	MCW	N
KIIA 4.3, KIIA 6.1.2, KIIA 6.3	Kirchmaier, R.	2009	Determination of residues of Fluazinam after eight applications of MAC 92800 F in potato (outdoor) at 4 Sites in Germany 2008 R-23545 ! S08-01223 GLP: Yes (2) Open (1) Published: Open (1) No (2) BVL-1905255, BVL-2465116, BVL-2469177, ASB2010-7041	Yes	MCW	N
KIIA 4.3, KIIA 6.1.2, KIIA 6.3	Roussel, C. H.	2008	Magnitude of the residues of Fluazinam in potatoes (RAC tubers) following ten applications of MCW 465, France, 2006 R-20936 ! ChR-06-2009 GLP: Open Published: Open BVL-1905256, BVL-1905320, BVL-1905325, ASB2010-7042	Yes	FSG MCW	N
KIIA 4.3, KIIIA1 5.3.1	Holzer, S.	2008	Confirmation of a residue analytical method for the determination of MCW 465 technical (Fluazinam) in plants R-20545B ! CRA11901 GLP: Yes (1) Open (1) Published: Open (1) No (1) BVL-1905251, BVL-2450094, ASB2010-7037	Yes	MCW	N
KIIIA 5.3.1	Dijk van, A.	1990	14C-Dimethomorph (CME 151): Absorption, distribution, metabolism and excretion after repeated oral administration to lactating goats DK-440-005 ! 151AX-652-002 ! 213928 ! 1990/7000056 GLP: Open Published: Open BVL-1968697, RIP2002-752	Yes	BAS	Y
KIIIA 5.3.1	Eichler, M.	2010	Independent laboratory validation of an analytical method for the determination of Dimethomorph in plants - Final report (2nd original) 47281101 ! R-25015 GLP: Yes (1) Open (1) Published: Open (1) No (1) BVL-1985314, BVL-2450142, ASB2010-13639	Yes	FSG MAC	Y

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
KIIIA 5.3.1	Eichler, M.	2010	Independent laboratory validation of an analytical method for the determination of Dimethomorph in food of animal origin - Final report (2nd original) 47282101 ! R-25956 GLP: Yes (1) Open (1) Published: Open (1) No (1) BVL-1985315, BVL-2450143, ASB2010-13640	Yes	FSG MAC	Y
KIIIA 5.3.1 KIIIA 5.4	Geffke, T.	2007	Residue analytical method for the determination of MVW 465 technical in water, soil, plants, animal food / tissue and blood R-20545 ! CRA106911 GLP: Yes (3) Open (6) Published: Open (6) No (3) BVL-1905250, BVL-1905257, BVL-1905260, BVL-1905264, BVL-1905267, BVL-1905269, BVL-2450093, BVL-2450114, BVL-2450118, ASB2010-7036	Yes	MCW	Y
KIIIA 5.3.1 KIIIA 5.6	Holzer, S.	2009	Confirmation of a residue analytical method for the determination in water, soil, air, plants, animal food / tissue and body fluids / tissues - 1st amendment of the report R-25289 ! CRA11901 GLP: Yes (3) Open (6) Published: Open (6) No (3) BVL-1905252, BVL-1905258, BVL-1905261, BVL-1905265, BVL-1905268, BVL-1905270, BVL-2450095, BVL-2450115, BVL-2450119, ASB2010-7038	Yes	MCW	Y
KIIIA 5.3.1 KIIIA 5.4 KIIIA 5.6	Holzer, S.	2009	Dimethomorph - Residue analytical method for the determination in water, soil, air, plants, foodstuff of animal origin and body tissues - Part 1, page 1-85. CRA13056! R-25300 GLP: Yes (4) Open (4) Published: Open (4) No (4) BVL-1938029, BVL-1938031, BVL-1938033, BVL-1938035, BVL-2450134, BVL-2450136, BVL-2450138, BVL-2450140, ASB2010-13637	Yes	MAC	Y
KIIIA 5.3.1	Jentoft, N. H.	1997	14C-IKF-1216 (Fluazinam) plant metabolism study in potatoes 6775-96-0053-EF-001 GLP: Open Published: Open BVL-1953058, RIP2003-1894	No	ISK	Y
KIIIA 5.3.1	Meinerling, M.	2009	Validation of an analytical method for the determination of Fluazinam in various matrices R-25293 ! 43862101 GLP: Yes (1) Open (1) Published: Open (1) No (1) BVL-1905249, BVL-2450092, ASB2010-7035	Yes	MCW	Y
KIIIA 5.3.1	Meinerling, M.; Herrmann, S.	2012	Independent laboratory validation of an analytical method for the determination of Fluazinam in food of animal origin and plants - Revised final report no. 3 R23947 ! 44241101 GLP: Yes Published: No BVL-2449948, BVL-2450131, ASB2013-9885	Yes	MCW	Y

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
KIIIA 5.3.1	Thiele, J.	1990	14C-Dimethomorph (CME 151) (Chlorophenol ring label) - Metabolism and translocation in potato plants DK-640-004 ! SHGR.89.071 ! 151AX-641-008 ! CUE 1/89 ! 1990/7000081 GLP: Open Published: Open BVL-1968680, RIP2002-744	Yes	BAS	Y
KIIIA 5.3.1	Thiele, J.	1991	14C-Dimethomorph (CME 151) (Chlorophenyl ring label) - Metabolism and translocation in potato plants Supplemental data to report SHGR.89.071 DK-640-009 ! SHGR.91.034 ! 151AX-641-009 ! CUE 1/89 ! 1991/7000109 GLP: Open Published: Open BVL-1968683, RIP2002-745	Yes	BAS	Y
KIIIA 5.3.1	Witte, A.	2012	Validation of an analytical method for the determination of residues of Fluazinam in food stuff of animal origin (liver) 12M05036-01-VMAT GLP: Yes (1) Open (1) Published: Open (1) No (1) BVL-2313096, BVL-2450099, ASB2012-12229	Yes	MAC MCW	Y
KIIIA 5.7	Holzer, S.	2011	MCW 465 Technical - Residue analytical method for the determination in air CRA14319 GLP: Yes (1) Open (1) Published: Open (1) No (1) BVL-2118187, BVL-2450123, ASB2011-9114	Yes	MCW	Y

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

Appendix 2 – Detailed evaluation of the additional studies relied upon

A 1.1 Analytical methods for dimethomorph

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:	KIIA 4.3
Report	Dimethomorph - Residue analytical method for the determination in water, soil, air, plants, foodstuff of animal origin and body tissues Holzer, S. 04.09.2009 CRA13056; R-25300, ASB2010-13637 (part 1), ASB2010-13638 (part 2)
Guideline(s):	Yes (SANCO/825/00 rev. 7)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Wheat, peanut: Ethyl acetate was added to samples followed by ultrasound treatment and centrifugation. The supernatant was evaporated using a vacuum rotary evaporator and the residue reconstituted in GPC mobile phase (ethyl acetate/cyclohexane (1/1, v/v)). The solution was filtered and injected onto the GPC column. The fraction containing the analyte was collected and then evaporated to dryness. The residue was dissolved in methanol/water (1+1, v/v) + 0.1 % formic acid.

Cucumber, lemon, potato, wine grape: The homogenized sample was shaken with isopropanol and then centrifuged. The supernatant was filtered over glass wool into a measuring flask and filled up to the mark with demineralized water. The complete volume of each measuring flask was enriched over C18 SPE-cartridges and eluted with isopropanol. The eluate was evaporated to dryness and reconstituted in methanol:water (1+1, v/v) + 0.1 % formic acid.

Final determination was performed by HPLC-MS/MS on an Acquity BEH C18 column. The sample was ionized in ESI+ mode and the transition m/z 388→301 was used for quantification.

Results and discussions

Table A 1: Recovery results from method validation of wheat, peanut, lemon, grape cucumber, potato using the analytical method. Standards were prepared in methanol:water (1+1, v/v) + 0.1 % formic acid

Matrix	Fortification level (mg/kg)	No of samples per fortification level	Mean recovery	RSD (%)	Comments
wheat	0.01 0.1	5 5	77 82	5.7 4.7	m/z 388→301
cucumber	0.01 0.1	5 5	87 78	5.3 7.1	m/z 388→301
peanut	0.01 0.1	5 5	79 79	9.4 12.5	m/z 388→301
lemon	0.01 0.1	5 5	81 95	6.2 4.4	m/z 388→301
potatoes	0.01 0.1	5 5	105 82	0.8 3.8	m/z 388→301
grape	0.01 0.1	5 5	89 80	7.3 4.8	m/z 388→301

Table A 2: Characteristics for the analytical method used for the quantitation of dimethomorph residues in wheat, peanut, lemon, grape cucumber, potato

	dimethomorph (wheat)	dimethomorph (cucumber)
Calibration function	y=243x+101 x in µg/L, r^2=0.99679	y=637x+1842 x in µg/L, r^2=0.9996
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	10-250 µg/L	10-250 µg/L
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.005 – 0.125 mg/kg	0.005 – 0.125 mg/kg
Does the calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/ no)	yes	yes
Assessment of matrix effects is presented (yes/no)	no	no
Interference >30% of LOQ in blank sample is absent (yes/no)	yes	yes

Conclusion

The method is acceptable for the quantification of dimethomorph in plant matrices with a LOQ of 0.01

mg/kg. Confirmation by full validation of a second MRM transition was not provided.

Comments of zRMS:	Acceptable.

A 1.1.1.2 Independent laboratory validation

Reference: KIIA 4.3

Report: Independent laboratory validation of an analytical method for the determination of Dimethomorph in plants - Final report (2nd original)

Eichler, M.

08.03.2010

47281101; R-25015, ASB2010-13639

Guideline(s): Yes (SANCO/825/00 rev. 7)

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods

Same as in the study by Holzer (2009). However, two transitions (m/z 388→301 and 388→165) were monitored for quantification and confirmation, respectively.

Results and discussions

Table A 3: Recovery results from the independent laboratory validation of lemon, peanuts, wheat and potatoes using the analytical method. Standards were prepared in methanol:water (1+1, v/v) + 0.1 % formic acid

Matrix	Fortification level (mg/kg)	No of samples per fortification level	Mean recovery	RSD (%)	Comments
lemon	0.01 0.1	5 5	74 77	5.4 11.1	m/z 388→301
peanuts	0.01 0.1	5 5	100 100	6.5 4.4	m/z 388→301
wheat	0.01 0.1	5 5	103 91	16.0 14.9	m/z 388→301
potatoes	0.01 0.1	4 (1 outlier) 5	87 82	11.8 13.4	m/z 388→301
lemon	0.01 0.1	5 5	74 77	4.9 15.6	m/z 388→165
peanuts	0.01	5	102	6.7	m/z 388→165

	0.1	5	101	4.5	
wheat	0.01 0.1	5 5	103 90	16.9 15.6	m/z 388→165
potatoes	0.01 0.1	4 (1 outlier) 5	93 82	11.5 13.4	m/z 388→165

Table A 4: Characteristics for the analytical method used for the independent laboratory validation of dimethomorph residues in lemon, peanuts, wheat and potatoes

	dimethomorph
Calibration function	y=29367x+14817 x in µg/L, r^2=0.9999
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	2.5 – 250 ng/mL
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.001 mg/kg – 0.125 mg/kg
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 an acceptable ILV of the method by Holzer (2009) for the quantification of dimethomorph in plant matrices with a LOQ of 0.01 mg/kg. Confirmation was provided by a fully validated second MRM transition.

Comments of zRMS:	Acceptable.

A 1.1.2 Methods for enforcement of residues in food and feed of animal origin

A 1.1.2.1 Analytical method 1

Reference: KIIA 4.3

Report: Dimethomorph - Residue analytical method for the determination in water, soil, air, plants, foodstuff of animal origin and body tissues

Holzer, S.

04.09.2009

CRA13056; R-25300, ASB2010-13637 (part 1), ASB2010-13638 (part 2)

Guideline(s): Yes (SANCO/825/00 rev. 7)

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods

Fat: Samples of homogenized fat were melted and mixed with GPC mixture (cyclohexane/ethylacetate, 50+50, v/v). The solution was injected onto the GPC column. The fraction containing the analyte was collected and then evaporated to dryness. The residue was dissolved in methanol/water (1+1, v/v) + 0.1 % formic acid.

Milk, eggs, meat, and kidney: Samples were shaken with acetone on rotary shaker followed by centrifugation. Supernatants were filtered over glass wool into a measuring flask and filled up with demineralized water. The complete volume of each measuring flask was enriched over C18 SPE-cartridges and eluted with isopropanol. The solution was evaporated to dryness and reconstituted in methanol:water (1+1, v/v) + 0.1 % formic acid.

Liver: Acetonitrile was added to samples followed by ultrasound treatment and centrifugation. Supernatants were filtered over glass wool into a measuring flask and filled up with demineralized water. The complete volume of each measuring flask was enriched over C18 SPE-cartridges and eluted with isopropanol. The solution was evaporated to dryness and reconstituted in methanol:water (1+1, v/v) + 0.1 % formic acid.

Final determination was performed by HPLC-MS/MS on an Acquity BEH C18 column. The sample was ionized in ESI+ mode and the transition m/z 388→301 was used for quantification.

Results and discussions

Table A 5: Recovery results from method validation of milk, egg, meat, fat, liver and kidney using the analytical method. Standards were prepared in methanol:water (1+1, v/v) + 0.1 % formic acid

Matrix	Fortification level (mg/kg)	No of samples per fortification level	Mean recovery	RSD (%)	Comments
milk	0.01 0.1	79 80	7..3 6.6	5 5	m/z 388→301
eggs	0.01 0.1	99 100	11.7 5.2	5 5	m/z 388→301
fat	0.01 0.1	83 78	9.4 8.7	5 5	m/z 388→301
meat	0.01 0.1	91 81	6.9 7.0	5 5	m/z 388→301

Matrix	Fortification level (mg/kg)	No of samples per fortification level	Mean recovery	RSD (%)	Comments
kidney	0.01	79	8.0	5	m/z 388→301
liver	0.01 0.1	92 110	6.8 4.2	5 5	m/z 388→301

Table A 6: Characteristics for the analytical method used for the quantitation of dimethomorph residues in milk, egg, meat, fat, liver and kidney

	dimethomorph (milk)	dimethomorph (liver)
Calibration function	y=512x+658 x in µg/L, r²=0.9995	y=309x+614 x in µg/L, r²=0.9995
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	10-250 µg/L	10-250 µg/L
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.005 – 0.125 mg/kg	0.005 – 0.125 mg/kg
Does the calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/ no)	yes	yes
Assessment of matrix effects is presented (yes/no)	no	no
Interference >30% of LOQ in blank sample is absent (yes/no)	yes	yes

Conclusion

The method is acceptable for the quantification of dimethomorph in matrices of animal origin with a LOQ of 0.01 mg/kg. Confirmation by full validation of a second MRM transition was not provided.

Comments of zRMS:	Acceptable.

A 1.1.2.2 Independent laboratory validation

Reference: KIIA 4.3

Report: Independent laboratory validation of an analytical method for the determination of Dimethomorph in food of animal origin - Final report (2nd original)

Eichler, M.

25.05.2010

47282101; R-25956, ASB2010-13640

Guideline(s): Yes (SANCO/825/00 rev. 7)

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods

Same as in the study by Holzer (2009). However, two transitions (m/z 388→301 and 388→165) were monitored for quantification and confirmation, respectively.

Results and discussions

Table A 7: Recovery results from the independent laboratory validation of milk, fat and liver using the analytical method. Standards were prepared in methanol:water (1+1, v/v) + 0.1 % formic acid

Matrix	Fortification level (mg/kg)	No of samples per fortification level	Mean recovery	RSD (%)	Comments
milk	0.01 0.1	5 5	91 100	12.5 4.2	m/z 388→301
liver	0.01 0.1	4 (1 outlier) 5	88 83	2.9 9.0	m/z 388→301
fat	0.01 0.1	5 5	99 90	9.3 8.4	m/z 388→301
milk	0.01 0.1	5 5	90 101	13.1 4.6	m/z 388→165
liver	0.01 0.1	4 (1 outlier) 5	87 81	2.4 8.1	m/z 388→165
fat	0.01 0.1	5 5	97 940	9.4 7.5	m/z 388→165

Table A 8: Characteristics for the analytical method used for the independent laboratory validation of dimethomorph residues in milk, fat and liver

	dimethomorph
Calibration function	y=22735x-25707 x in µg/L, r^2=0.9988
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	2.5 – 250 ng/mL
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.001 mg/kg – 0.125 mg/kg

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 an acceptable ILV of the method by Holzer (2009) for the quantification of dimethomorph in matrices of animal origin with a LOQ of 0.01 mg/kg. Confirmation was provided by a fully validated second MRM transition.

Comments of zRMS:	Acceptable.

A 1.1.3 Description of Methods for the Analysis of Soil

A 1.1.3.1 Analytical method 1

Reference: KIIA 4.4

Report: Dimethomorph - Residue analytical method for the determination in water, soil, air, plants, foodstuff of animal origin and body tissues

Holzer, S.

04.09.2009

CRA13056; R-25300, ASB2010-13637 (part 1), ASB2010-13638 (part 2)

Guideline(s): Yes (SANCO/825/00 rev. 7)

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods

The soil samples (LUFA 2.2 standard soil) were mixed with isopropanol and shaken on a rotary shaker followed by centrifugation. The supernatants were evaporated to dryness using a vacuum rotary evaporator and the residue reconstituted in methanol:water (1+1, v/v) + 0.1 % formic acid. Final determination was performed by HPLC-MS/MS on an Acquity BEH C18 column. The sample was ionized in ESI+ mode and the transition m/z 388→301 was used for quantification.

Results and discussions

Table A 9: Recovery results from method validation of soil using the analytical method. Standards were prepared in methanol:water (1+1, v/v) + 0.1 % formic acid

Matrix	Fortification level (mg/kg)	No of samples per fortification level	Mean recovery	RSD (%)	Comments
Soil (LUFA 2.2)	0.01 0.1	5 5	81 89	3.5 5.3	m/z 388→301

Table A 10: Characteristics for the analytical method used for the quantitation of dimethomorph residues in soil

	dimethomorph
Calibration function	y=563x+278 x in µg/L, r^2=0.9994
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	2.5 – 250 ng/mL
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.005 mg/kg – 0.125 mg/kg
Does the calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)?	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 acceptable for the quantification of dimethomorph in soil with a LOQ of 0.01 mg/kg. Confirmation by full validation of a second MRM transition was not provided.

Comments of zRMS:	Acceptable.

A 1.1.4 Description of Methods for the Analysis of Water

A 1.1.4.1 Analytical method 1

Reference: KIIA 4.5

Report: Dimethomorph - Residue analytical method for the determination in water, soil, air, plants, foodstuff of animal origin and body tissues

Holzer, S.

04.09.2009

CRA13056; R-25300, ASB2010-13637 (part 1), ASB2010-13638 (part 2)

Guideline(s): Yes (SANCO/825/00 rev. 7)

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods

Water samples (tap water, river water) were enriched on C18 SPE-cartridges and the analyte eluted with isopropanol. The eluates were evaporated to dryness using the vacuum rotary evaporator and reconstituted in methanol:water (1+1, v/v) + 0.1 % formic acid. Final determination was performed by HPLC-MS/MS on an Acquity BEH C18 column. The sample was ionized in ESI+ mode and the transition m/z 388→301 was used for quantification.

Results and discussions

Table A 11: Recovery results from method validation of drinking and surface water using the analytical method. Standards were prepared in methanol:water (1+1, v/v) + 0.1 % formic acid

Matrix	Fortification level (µg/L)	No of samples per fortification level	Mean recovery	RSD (%)	Comments
drinking water	0.1 1	5 5	103 104	3.0 1.9	m/z 388→301
surface water	0.1 1	5 5	99 87	7.3 2.2	m/z 388→301

Table A 12: Characteristics for the analytical method used for the quantitation of dimethomorph residues in drinking and surface water

	dimethomorph (drinking water)	dimethomorph (surface water)
Calibration function	y=381x+645	y=286x-1140

	x in µg/L, r^2=0.9995	x in µg/L, r^2=0.9994
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	10 – 250 ng/mL	10 – 250 ng/mL
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.05 mg/kg – 1.25 mg/kg	0.05 mg/kg – 1.25 mg/kg
Does the calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)?	yes	yes
Assessment of matrix effects is presented (yes/no)	no	no
Interference >30% of LOQ in blank sample is absent (yes/no)	yes	yes

Conclusion

The method is acceptable for the quantification of dimethomorph in drinking and surface water with a LOQ of 0.01 µg/L. Confirmation by full validation of a second MRM transition was not provided.

Comments of zRMS:	Acceptable.

A 1.2 Analytical methods for fluazinam

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

A 1.2.1.1 Analytical method 1

Reference: KIIA 4.3

Report: Residue analytical method for the determination of MVW 465 technical in water, soil, plants, animal food / tissue and blood

Geffke, T.

09.07.2007

R-20545 ! CRA106911 ! Project 060109MS, ASB2010-7036

Guideline(s): Yes (SANCO/825/00 rev. 7)

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods

Potatoes, cucumber, lemon and wine grape: Homogenised specimen of potatoes, cucumber, lemon and

wine grape, respectively were shaken with acetonitrile followed centrifugation. Each supernatant was filtered over glass wool into a separate measuring flask and filled up to the mark with water. The complete volume of each measuring flask was enriched over C18 SPE-cartridges, eluted with methanol and diluted with water to obtain methanol/water (1+1, v/v)

Peanuts: Sample were mixed with silica gel and loaded into glass columns. Analytes were eluted first with dichloromethane:n-hexane (20:80; v/v) followed by dichloromethane:n-hexane (40:60; v/v) into the same measuring flask. The eluate was evaporated to near dryness and the residue was reconstituted with GPC mobile phase (cyclohexane:ethyl acetate (50:50; v/v)). The solution was loaded into the sample loop of the GPC and the fraction containing the analyte collected. The fraction was evaporated to dryness and the residue reconstituted in methanol:acetic acid 0.1 % v/v (75:25).

Wheat: Homogenised specimens of wheat were shaken with acetonitrile followed centrifugation. Each supernatant was filtered over glass wool into a separate measuring flask and filled up to the mark with water. The complete volume of each measuring flask was enriched over HLB SPE-cartridges and eluted with methanol. The eluate was evaporated to dryness and reconstituted in methanol:water (50:50; v/v).

Final determination was performed by HPLC-MS/MS on a C18 column. The sample was ionized in ESI- mode and the transition m/z 463→416 was used for quantification.

Results and discussions

Table A 13: Recovery results from method validation of potato, grapes, cucumber, lemon, peanut and wheat using the analytical method. Standards were prepared in methanol/water (1+1, v/v)

Matrix	Fortification level (mg/kg)	No of samples per fortification level	Mean recovery	RSD (%)	Comments
potato	0.02 0.2	5 5	87 75	10.6 3.9	m/z 463→416
grapes	3 30	5 5	98 98	5.1 6.1	m/z 463→416
cucumber	0.01 0.1	5 5	81 76	15.3 4.9	m/z 463→416
lemon	0.01 0.1	5 5	80 76	6.2 3.4	m/z 463→416
peanut	0.02 0.2	5 5	77 84	3.0 1.6	m/z 463→416
wheat	0.01 0.1	5 5	87 91	9.8 6.1	m/z 463→416

Table A 14: Characteristics for the analytical method used for the quantitation of fluazinam residues in potato, grapes, cucumber, lemon, peanut and wheat

	Fluazinam (potato)	Fluazinam (lemon)
Calibration function	y=330x+	y=365x+

	x in µg/L, r^2=0.9997	x in µg/L, r^2=0.9977
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	0.5 – 100 ng/mL	0.5 – 100 ng/mL
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.0005 – 1 mg/kg	0.0005 – 0.2 mg/kg
Does the calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/ no)	yes	yes
Assessment of matrix effects is presented (yes/no)	no	no
Interference >30% of LOQ in blank sample is absent (yes/no)	yes	yes

Conclusion

The method is acceptable for the quantification of fluazinam in lemon, cucumber and wheat with a LOQ of 0.01 mg/kg and in potato and peanut with a LOQ of 0.02 mg/kg, Confirmation by full validation of a second MRM transition was not provided. For grapes the validation was performed above the required LOQ of 0.05 mg/kg and therefore is considered not acceptable.

Comments of zRMS:	Acceptable, except for grapes.

A 1.2.1.2 Independent laboratory validation

Reference: KIIA 4.3

Report: Independent laboratory validation of an analytical method for the determination of Fluazinam in food of animal origin and plants - Revised final report no. 3

Meinerling, M.; Herrmann, S.

06.02.2012

R23947 ! 44241101, ASB2013-9885 (ASB2011-9113 Revised final report no. 2)

Guideline(s): Yes (SANCO/825/00 rev. 7)

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods

Same as in the method by Geffke (2007) for potato and wheat. However, two transitions (m/z 463→416

and 463→398) were monitored for quantification and confirmation, respectively.

Results and discussions

Table A 15: Recovery results from the independent laboratory validation of potato and wheat using the analytical method. Standards were prepared in methanol/water (1+1, v/v)

Matrix	Fortification level (mg/kg)	No of samples per fortification level	Mean recovery	RSD (%)	Comments
wheat	0.01 0.1	5 5	90 93	9 3	m/z 463→416
potatoes	0.01 0.02 0.2	5 5 5	80 73 76	3 5 3	m/z 463→416
wheat	0.01 0.1	5 5	89 94	7 3	m/z 463→398
potatoes	0.01 0.02 0.2	5 5 5	79 72 77	2 6 3	m/z 463→398

Table A 16: Characteristics for the analytical method used for the independent laboratory validation of fluazinam residues in potato and wheat

	Fluazinam (potato, m/z 463→416)	**Fluazinam (wheat, m/z 463→416)**
Calibration function	y=25391x+1383 x in µg/L, r^2=0.9998	y=25268x+5198 x in µg/L, r^2=0.9999
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	0.5 – 100 ng/mL	0.5 – 100 ng/mL
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.0005 – 0.1 mg/kg	0.001 – 0.2 mg/kg
Does the calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/ no)	yes	yes
Assessment of matrix effects is presented (yes/no)	no	no
Interference >30% of LOQ in blank sample is absent (yes/no)	yes	yes

Conclusion

The calibration range is not sufficient for highest fortification level of potato. But nevertheless, the method is an acceptable ILV of the method by Geffke (2007) for the quantification of fluazinam in potato and wheat with a LOQ of 0.01 mg/kg. Confirmation was provided by a fully validated second MRM transition.

Comments of zRMS:	Acceptable.

A 1.2.1.3 Confirmatory method

Reference: KIIA 4.3

Report: Validation of an analytical method for the determination of Fluazinam in various matrices

Meinerling, M.

17.11.2009

R-25293 ! 43862101, ASB2010-7035

Guideline(s): Yes (SANCO/825/00 rev. 7)

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods

Wheat (module E2): Homogenised specimen of wheat was accurately weight and spiked with the reference substance. Deionised water at 40° C was added and the suspension was mixed. Afterwards, the mixture was homogenised with acetone before NaCl and a GPC elution (cyclohexane/ethyl acetate 50:50 v/v) were added. The resulting solution was mixed again before the organic phase was decanted. After that, the aqueous solution was centrifuged. The organic phase was separated again and the combined organic phases were filtered through a plug of glass wool and Na_2SO_4 into a round bottom flask. The filtrate was evaporated and re-dissolved in ethyl acetate. After that, the solution was ultrasonicated and a mixture of Na_2SO_4/NaCl (1:1) and cyclohexane was added to the residue. The suspension was filtered through a 45 µm filter and the extract was injected into GPC. The GPC column was eluted with cyclohexane/ethyl acetate (50:50 v/v) and the relevant fractions (12 to 30 min) were collected. The collected volume was concentrated and re-dissolved in acetonitrile.

Potatoes (module E4): Homogenised specimen of potatoes was accurately weight and spiked with the reference substance. Deionised water was added and the pH value was adjusted to 1 using HCl. Afterwards, the mixture was homogenised with acetone before celite was added and the suspension was mixed. The mixture was filtered (GF-6) and the filtrate was transferred to a separation funnel. NaCl and dichloromethane were added. The solution was shaken for 2 minutes. It was allowed to settle and afterwards the phases were separated. The organic phase was dried over Na_2SO_4 and stand for 30 minutes. Afterwards, the solution was filtered through a cotton pad and Na_2SO_4 into a round bottom flask. The filtrate was evaporated and re-dissolved in ethyl acetate. After that, Na_2SO_4 and cyclohexane were added before the solution was filtrated and the extract was injected into GPC. The GPC column was eluted with cyclohexane/ethyl acetate (50+50, v/v) and the relevant fractions (12 to 30 min) were collected. The collected volume was concentrated and re-dissolved in acetonitrile.

Lemon (module E3): Homogenised specimen of lemon was accurately weight and spiked with the reference substance. Deionised water was added and the mixture was homogenised with acetone before

NaCl and a GPC elution (cyclohexane/ethyl acetate 50+50, v/v) were added. The resulting solution was mixed again. After that, the organic phase was decanted and the aqueous solution was centrifuged. The organic phase was separated again. The combined organic phases were filtered through a plug of glass wool and Na_2SO_4 into a round bottom flask. The filtrate was evaporated and re-dissolved in ethyl acetate. After that, the solution was ultrasonicated and a mixture of Na_2SO_4/NaCl (1:1) and cyclohexane was added to the residue. The suspension was filtered through a 45 µm filter and the extract was injected into GPC. The GPC column was eluted with cyclohexane/ethyl acetate (50+50, v/v) and the relevant fractions (12 to 30 min) were collected. The collected volume was concentrated and re-dissolved in acetonitrile.

Peanuts (module E7): Homogenised specimen of peanuts was accurately weight and spiked with the reference substance. A mixture of acetonitrile and acetone (9+1, v/v) was added and mixed before the suspension was filtered into a flask. The filtrate was rinsed twice with acetone and filtered through a dry filter. The solution was transferred into a tarred round bottom flask, rinsed with acetone and iso-octane (2+1, v/v) and evaporated to dryness. After that, the residue was re-dissolved in GPC elution solvent (cyclohexane/ethyl acetate 50+50, v/v). The extract was injected into GPC and the column was eluted with cyclohexane/ethyl acetate (50+50, v/v). The relevant fractions (12 to 30 min) were collected, concentrated and re-dissolved in acetonitrile.

Final determination was performed by HPLC-MS/MS on a C18 column. The sample was ionized in ESI- mode and the transitions m/z 463→416 and 463→398 were used for quantification and confirmation, respectively.

Results and discussions

Table A 17: Recovery results from the confirmatory method validation of wheat, potato, lemon and peanut using the confirmatory method. Standards were prepared in acetonitrile

Matrix	Fortification level (mg/kg)	No of samples per fortification level	Mean recovery	RSD (%)	Comments
wheat	0.01 0.1	5 5	78 75	5 6	m/z 463→416
potato	0.01 0.1	5 5	81 87	2 5	m/z 463→416
lemon	0.01 0.1	5 5	85 83	5 7	m/z 463→416
peanut	0.01 0.1	5 5	82 85	5 7	m/z 463→416
wheat	0.01 0.1	5 5	78 75	7 6	m/z 463→398
potato	0.01 0.1	5 5	81 88	1 4	m/z 463→398
lemon	0.01 0.1	5 5	84 83	6 7	m/z 463→398
peanut	0.01 0.1	5 5	83 85	6 8	m/z 463→398

Table A 18: Characteristics for the confirmatory method used for the quantitation of fluazinam residues in wheat, potato, lemon and peanut

	Fluazinam
Calibration function	y=39394x-2074 x in µg/L, r^2=1.000
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	0.5 – 100 ng/mL
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.0005 – 0.1 mg/kg
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 acceptable as a confirmatory method for the quantification of fluazinam in wheat, potato, lemon and peanut with a LOQ of 0.01 mg/kg.

Comments of zRMS:	Acceptable.

A 1.2.2 Methods for enforcement of residues in food and feed of animal origin

A 1.2.2.1 Analytical method 1

Reference: KIIA 4.3

Report: Residue analytical method for the determination of MVW 465 technical in water, soil, plants, animal food / tissue and blood

Geffke, T.

09.07.2007

R-20545 ! CRA106911 ! Project 060109MS, ASB2010-7036

Guideline(s): Yes (SANCO/825/00 rev. 7)

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods

Egg, meat: Homogenised specimen of egg and meat were shaken with acetonitrile followed by centrifugation. The supernantants were filtered over glass wool into a measuring flask and filled up to the mark with demineralised water. The complete volume of each measuring flask was enriched over C18 SPE-cartridges, eluted with methanol into a measuring flask again and filled up to the mark with water.

Milk: Homogenised specimen of milk was shaken with isopropanol followed by centrifugation. The supernatant was diluted with 2-propanol and water. Subsequently, the solution was enriched over pre-conditioned HLB cartridges and eluted with methanol. The eluate was evaporated to dryness and the residue was re-dissolved in methanol:water (1+1; v/v).

Fat: Homogenised specimen of fat was dissolved in GPC-mix (cyclohexane:ethyl acetate (1+1; (v/v)). The solution was filled into a disposable syringe and load into the sample loop of the GPC. After injecting the sample onto the GPC –column, the fraction containing the analyte was collected followed by evaporation to dryness and reconstitution of the residue in methanol:acetic acid 0.1 % (75+25, v/v).

Final determination was performed by HPLC-MS/MS on a C18 column. The sample was ionized in ESI-mode and the transition m/z 463→416 was used for quantification.

Results and discussions

Table A 19: Recovery results from method validation of egg, milk, fat and meat using the analytical method. Standards were prepared in methanol/water (1+1, v/v)

Matrix	Fortification level (mg/kg)	No of samples per fortification level	Mean recovery	RSD (%)	Comments
egg	0.01 0.1	5 5	79 76	1.4 3.0	m/z 463→416
milk	0.01 0.1	5 5	82 99	15.7 6.9	m/z 463→416
fat	0.01 0.1	5 5	101 77	7.8 4.7	m/z 463→416
meat	0.01	5	96	11.5	m/z 463→416

Table A 20: Characteristics for the analytical method used for the quantitation of fluazinam residues in egg, milk, fat and meat

	Fluazinam (milk)	Fluazinam (egg)
Calibration function	y=364x x in µg/L, r²=0.9997	y=342x+ x in µg/L, r²=0.9984
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	0.5 – 100 ng/mL	0.5 – 100 ng/mL
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.0005 – 0.2 mg/kg	0.0013 – 0.25 mg/kg

Does the calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/ no)	yes	yes
Assessment of matrix effects is presented (yes/no)	no	no
Interference >30% of LOQ in blank sample is absent (yes/no)	yes	yes

Conclusion

The method is acceptable for the quantification of fluazinam in egg, milk and fat with a LOQ of 0.01 mg/kg. Confirmation by full validation of a second MRM transition was not provided. For meat only the LOQ level (0.01 mg/kg) was validated and is therefore considered not acceptable.

Comments of zRMS:	Acceptable, except for meat.

A 1.2.2.2 Analytical method 2

Reference: KIIA 4.3

Report: Confirmation of a residue analytical method for the determination in water, soil, air, plants, animal food / tissue and body fluids / tissues - 1st amendment of the report

Holzer, S.

29.06.2009

R-25289 ! CRA11901

ASB2010-7038

Guideline(s): Yes (SANCO/825/00 rev. 7)

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods

Same as in the method by Geffke (2007) for meat and fat.

Results and discussions

Table A 21: Recovery results from method validation of meat and fat using the analytical method. Standards were prepared in methanol/water (1+1, v/v)

Matrix	Fortification	No of	Mean	RSD (%)	Comments

	level (mg/kg)	samples per fortification level	recovery		
meat	0.01 0.1	5 5	91 85	5.1 6.3	m/z 463→416
fat	0.01 0.1	5 5	99 71	1.3 10.2	m/z 463→416

Table A 22: Characteristics for the analytical method used for the quantitation of fluazinam residues in meat and fat

	Fluazinam (meat)	Fluazinam (fat)
Calibration function	y=267x x in µg/L, r²=0.9986	y=336x x in µg/L, r²=0.9955
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	2 – 150 ng/mL	1 – 150 ng/mL
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.004 – 0.3 mg/kg	no data available
Does the calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/ no)	yes	yes
Assessment of matrix effects is presented (yes/no)	no	no
Interference >30% of LOQ in blank sample is absent (yes/no)	yes	yes

Conclusion

The method is acceptable for the quantification of fluazinam in meat and fat with a LOQ of 0.01 mg/kg. Confirmation by full validation of a second MRM transition was not provided.

Comments of zRMS:	Acceptable.

A 1.2.2.3 Independent laboratory validation

Reference: KIIA 4.3

Report: Independent laboratory validation of an analytical method for the determination of Fluazinam in food of animal origin and plants - Revised final report no. 3

Meinerling, M.; Herrmann, S.

06.02.2012

R23947 ! 44241101

ASB2013-9885 (ASB2011-9113 Revised final report no. 2)

Guideline(s): Yes (SANCO/825/00 rev. 7)

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods

Same as in the method by Geffke (2007) for milk and egg. However, two transitions (m/z 463→416 and 463→398) were monitored for quantification and confirmation, respectively.

Results and discussions

Table A 23: Recovery results from the independent laboratory validation of milk and egg using the analytical method. Standards were prepared in methanol/water (1+1, v/v)

Matrix	Fortification level (mg/kg)	No of samples per fortification level	Mean recovery	RSD (%)	Comments
milk	0.01 0.1	5 5	83 86	4 10	m/z 463→416
egg	0.01 0.1	5 5	75 81	5 5	m/z 463→416
milk	0.01 0.1	5 5	84 85	4 11	m/z 463→398
egg	0.01 0.1	5 5	75 81	5 4	m/z 463→398

Table A 24: Characteristics for the analytical method used for the independent laboratory validation of fluazinam residues in milk and egg

	Fluazinam (milk, m/z 463→416)	**Fluazinam (egg, m/z 463→416)**
Calibration function	y=22448x+9606 x in µg/L, r^2=0.9997	y=18930x+6889 x in µg/L, r^2=0.9995
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	0.5 – 100 ng/mL	0.5 – 100 ng/mL

	Fluazinam (milk, m/z 463→416)	**Fluazinam (egg, m/z 463→416)**
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.0005 – 0.1 mg/kg	0.0005 – 0.1 mg/kg
Does the calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/ no)	yes	yes
Assessment of matrix effects is presented (yes/no)	no	no
Interference >30% of LOQ in blank sample is absent (yes/no)	yes	yes

Conclusion

The method is an acceptable ILV of the method by Geffke (2007) for the quantification of fluazinam in milk and egg with a LOQ of 0.01 mg/kg. Confirmation was provided by a fully validated second MRM transition.

Comments of zRMS:	Acceptable.

A 1.2.2.4 Analytical method 3

Reference: KIIA 4.3

Report: Validation of an analytical method for the determination of residues of Fluazinam in food stuff of animal origin (liver)

Witte, A.

02.04.2012

12M05036-01-VMAT, ASB2012-12229

Guideline(s): Yes (SANCO/825/00 rev. 8.1)

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods

The homogenised specimens of liver were shaken with acetonitrile followed by centrifugation. Each supernatant was filtered over glass wool into a measuring flask and filled up to the mark with water. The analyte was enriched over C18 SPE-cartridges, eluted with methanol into a measuring flask, adjusted to a define volume with methanol and finally diluted with water. Final determination was performed by HPLC-MS/MS on a Thermo Hypurity Aquastar column. The sample was ionized in ESI- mode and the

transitions m/z 463→416 and 463→398 were used for quantification and confirmation, respectively.

Results and discussions

Table A 25: Recovery results from method validation of liver using the analytical method. Standards were prepared in blank matrix

Matrix	Fortification level (mg/kg)	No of samples per fortification level	Mean recovery	RSD (%)	Comments
liver	0.01 0.1	5 5	91 92	5 3	m/z 463→416
liver	0.01 0.1	5 5	91 92	7 4	m/z 463→398

Table A 26: Characteristics for the analytical method used for the quantitation of fluazinam residues in liver

	Fluazinam (m/z 463→416)	**Fluazinam (m/z 463→398)**
Calibration function	y=320347x+2937920 x in µg/L, r^2=0.9994	y=145518x+1533220 x in µg/L, r^2=0.9992
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	0.2 – 50 ng/mL	0.2 – 50 ng/mL
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.002 – 0.5 mg/kg	0.002 – 0.5 mg/kg
Does the calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/ no)	yes	yes
Assessment of matrix effects is presented (yes/no)	yes	yes
Interference >30% of LOQ in blank sample is absent (yes/no)	yes	yes

Conclusion

The method is acceptable for the quantification of fluazinam in liver with a LOQ of 0.01 mg/kg. Confirmation was provided by a fully validated second MRM transition.

Comments of zRMS:	Acceptable.

A 1.2.3 Description of Methods for the Analysis of Soil

A 1.2.3.1 Analytical method 1

Reference: KIIA 4.4

Report: Confirmation of a residue analytical method for the determination in water, soil, air, plants, animal food / tissue and body fluids / tissues - 1st amendment of the report

Holzer, S.

29.06.2009

R-25289 ! CRA11901, ASB2010-7038

Guideline(s): Yes (SANCO/825/00 rev. 7)

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods

The soil samples (LUFA 2.2 standard soil) were mixed with methanol and shaken on a rotary shaker followed by centrifugation. The supernatant was diluted with water to obtain methanol:water (1+1, v/v). Final determination was performed by HPLC-MS/MS on a C18 column. The sample was ionized in ESI- mode and the transition m/z 463→416 was used for quantification.

Results and discussions

Table A 27: Recovery results from method validation of soil using the analytical method. Standards were prepared in methanol/water (1+1, v/v)

Matrix	Fortification level (mg/kg)	No of samples per fortification level	Mean recovery	RSD (%)	Comments
Soil (LUFA 2.2)	0.01 0.1	5 5	71 70	4.6 0.8	m/z 463→416

Table A 28: Characteristics for the analytical method used for the quantitation of fluazinam residues in soil

	Fluazinam (soil)
Calibration function	y=106x-12 x in µg/L, r^2=0.9998
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	1 – 150 ng/mL
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.005 – 0.75 mg/kg
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	no

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

Conclusion

The method is acceptable for the quantification of fluazinam in soil with a LOQ of 0.01 mg/kg. Confirmation by full validation of a second MRM transition was not provided.

Comments of zRMS:	Acceptable.

A 1.2.4 Description of Methods for the Analysis of Water

A 1.2.4.1 Analytical method 1

Reference: KIIA 4.5

Report: Confirmation of a residue analytical method for the determination in water, soil, air, plants, animal food / tissue and body fluids / tissues - 1st amendment of the report

Holzer, S.

29.06.2009

R-25289 ! CRA11901

ASB2010-7038

Guideline(s): Yes (SANCO/825/00 rev. 7)

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods

Analyts in surface water and tap water were enriched using a C_{18} SPE cartridge and eluted with methanol. The eluate was diluted with water to obtain methanol:water (1+1, v/v). Final determination was performed by HPLC-MS/MS on a C18 column. The sample was ionized in ESI- mode and the transition m/z 463→416 was used for quantification.

Results and discussions

Table A 29: Recovery results from method validation of drinking and surface water using the analytical method. Standards were prepared in methanol/water (1+1, v/v)

Matrix	Fortification level (µg/L)	No of samples per fortification	Mean recovery	RSD (%)	Comments

		level			
drinking water	0.1 1	95 89	3.1 12.2	5 5	m/z 463→416
surface water	0.1 1	101 105	8.0 7.6	5 5	m/z 463→416

Table A 30: Characteristics for the analytical method used for the quantitation of fluazinam residues in drinking and surface water

	Fluzinam
Calibration function	y=50x+16 x in µg/L, r^2=0.9998
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	2 – 150 ng/mL
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.02 – 1.5 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 acceptable for the quantification of fluazinam in drinking and surface water with a LOQ of 0.1 µg/L. Confirmation by a fully validated second MRM transition was not provided.

Comments of zRMS:	Acceptable.

A 1.2.5 Description of Methods for the Analysis of Air

A 1.2.5.1 Analytical method 1

Reference: KIIA 4.7

Report: MCW 465 Technical - Residue analytical method for the determination in air

Holzer, S.

27.05.2011

Study no. CRA14319, Project no. 110222MS, ASB2011-9114

Guideline(s): Yes (SANCO/825/00 rev. 7)

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods

0.33 µg/m3 (LOQ) 3.3 µg/m3 (10 × LOQ): Samples of 360 L air were conducted with a defined flow rate of 1 L/min through polyurethane foam spiked with fluazinam. Subsequently, the foam of each sample was extracted with acetonitrile. The extract was evaporated using a rotary evaporator and reconstituted in methanol/water (1+1, v/v)

33 µg/m3, 330 µg/m3 and 3300 µg/m3 (check for breakthrough): Samples of 360 L air were conducted with a defined flow rate of 1 L/min through polyurethane foam spiked with fluazinam. The second foam was placed behind the first one to check for breakthrough. After sampling the foams, samples were prepared as described above for LOQ and 10 × LOQ. Samples at 100 x LOQ, 1000 x LOQ and 10000 x LOQ were diluted 1:10, 1:100, 1:1000.

Final determination was performed by HPLC-MS/MS on a Symmetry C18 column. The sample was ionized in ESI- mode and the transitions m/z 463→416 and 463→398 were used for quantification and confirmation, respectively

Results and discussions

Table A 31: Recovery results from method validation of air using the analytical method. Standards were prepared in methanol/water (1+1, v/v)

Matrix	Fortification level (µg/m^3)	No of samples per fortification level	Mean recovery	RSD (%)	Comments
warm humid air	0.33	5	75	5.9	m/z 463→416

warm humid air	3.3	5	77	4.2	m/z 463→416
warm humid air	33	1	78	-	m/z 463→416
warm humid air	330	1	100	-	m/z 463→416
warm humid air	3300	1	108	-	m/z 463→416
warm humid air	0.33	5	74	5.8	m/z 463→398
warm humid air	3.3	5	78	3.4	m/z 463→398
warm humid air	33	1	78	-	m/z 463→398
warm humid air	330	1	98	-	m/z 463→398
warm humid air	3300	1	108	-	m/z 463→398

Table A 32: Characteristics for the analytical method used for the quantitation of fluazinam residues in air

	Fluazinam (m/z 463→416)	**Fluazinam (m/z 463→398)**
Calibration function	y=28x x in µg/L, r^2=0.9995	y=16x x in µg/L, r^2=0.9996
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	2 – 150 ng/mL	2 – 150 ng/mL
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.005 – 0.42 µg/m³, dilution of 100 x LOQ – 10000 x LOQ	0.005 – 0.42 µg/m³, dilution of 100 x LOQ – 10000 x LOQ
Does the calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/ no)	yes	yes
Assessment of matrix effects is presented (yes/no)	no	no
Interference >30% of LOQ in blank sample is absent (yes/no)	yes	yes

Conclusion

The method is acceptable for the quantification of fluazinam in air with a LOQ of 0.33 µg/m³. Confirmation was provided by a fully validated second MRM transition.

Comments of zRMS:	Acceptable.

REGISTRATION REPORT
Part B

Section 3: Mammalian Toxicology
Detailed summary of the risk assessment

Product code/name: BANJO forte (MCW-853 SC)
Active Substances: Dimethomorph 200 g/L
Fluazinam 200 g/L

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: ADAMA Deutschland
Date: April 2015

Table of Contents

3 Mammalian Toxicology

3.1 Summary

Table 3.1-1: Information on BANJO Forte (MCW-853 SC)*

Product name and code	BANJO Forte / MCW-853 SC (MAC-94530-F-0-SC)
Formulation type	Suspension concentrate (SC)
Active substance(s) (incl. content)	Dimethomorph; 200 g/L Fluazinam; 200 g/L
Function	Fungicide
Product already evaluated as the 'representative formulation' during the Annex I inclusion	No
Product previously evaluated in an other MS according to Uniform Principles	Yes (Evaluation in DE; authorisation number 007012-00)

* Information on the detailed composition of BANJO Forte (MCW-853 SC) 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(s):	Xn
Indication(s) of danger:	Harmful
Risk phrases:	63
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 fluazinam (CAS-No. 79622-59-6). May produce an allergic reaction.'
	'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(es), categories:	Repr. 2
Signal word:	Warning
Hazard statement(s):	361d
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]
	'Contains fluazinam (CAS-No. 79622-59-6). May produce an allergic reaction.' [EUH208]
	'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 BANJO Forte (MCW-853 SC)

	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 a face shield when handling the undiluted product. - Wear standard protective gloves (plant protection) when handling the undiluted product. - Wear standard protective gloves (plant protection) when handling/applying the product ready for application. - Wear a protective suit against pesticides and sturdy shoes (e.g. rubber boots) when handling the undiluted product. - Wear a protective suit against pesticides and sturdy shoes (e.g. rubber boots) when applying/handling the product ready for application. - Wear a rubber apron when handling the undiluted product.
Workers	Acceptable	- Re-entering the treated areas/crops is only possible on the day of application wearing personal protective equipment which is specified for applying the particular product. Successive work on/in treated areas/crops may fundamentally not be carried out until 24 hours after applying the product. Within the first 48 hours, protective suits against pesticides and standard protective gloves (plant protection) are to be worn.
Bystanders	Acceptable	None
Residents	Acceptable	None

The risk assessment according to the German model has shown that the estimated exposure towards dimethomorph and fluazinam in BANJO Forte will not exceed the particular systemic AOEL for operators, workers, bystanders and residents if prescribed PPE is worn by operators and workers.

The risk assessment according to the UK-POEM has shown that the estimated exposure towards dimethomorph and fluazinam in BANJO Forte will exceed the particular systemic AOEL for operators even if gloves are worn during mixing/loading and application.

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

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

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

1	2	3	4	5	6	7	8			
Crops [1] and situation (e.g. growth stage of crop)	**F/G or I [2]**	**Application**		**Application rate**		**Remarks:** (e.g. surfactant (L /ha))	**Acceptability of exposure assessment**			
		Method / Kind (incl. application technique [3])	**Max. number (min. interval between applications) a) per use b) per crop/ season**	**kg as/ha a) max. rate per appl. b) max. total rate per crop/season**	**Water L/ha min / max**	**critical gap for operator, worker, bystander or resident exposure based on [*Exposure model*]**	**Operator**	**Worker**	**Bystander**	**Residents**
Potatoes	F	LCTM	a) 4 b) 4 (7-10 d)	a) 0.2 kg dimethomorph; 0.2 kg fluazinam b) 0.8 kg dimethomorph; 0.8 kg fluazinam	300 - 600	German model UK POEM				

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

[1] Pooled critical GAPS with the same max. application rate per application and using the same application technique
[2] F: field or outdoor application
[3] LC: low crops, TM: tractor-mounted

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

Dimethomorph

Information on absorption rates of the active ingredient		
	Value	Source
oral	> 90 %	EFSA Scientific Report (2006) 82, 1-69 (2006-06-23)
inhalative	100 %	(default)

Reference doses		
	Value	Source
ADI	0,05	Review Report SANCO/10040/06-rev.3 24 November 2006
AOEL-S	0,15	Review Report SANCO/10040/06-rev.3 24 November 2006
ARfD	0,6	Review Report SANCO/10040/06-rev.3 24 November 2006

Classification and proposed labelling	
with regard to toxicological data (according to the criteria in Dir. 67/548/EEC)	Regulation (EC) No 1272/2008 (Table 3.2): no classification necessary Proposal BfR: none
with regard to toxicological data (according to the criteria in Reg. 1272/2008)	Regulation (EC) No 1272/2008 (Table 3.1): no classification necessary Proposal BfR: none

Fluazinam

Information on absorption rates of the active ingredient		
	Value	Source
oral	35 %	EFSA Scientific Report (2008) 137, 1-82 (2008-03-26)
inhalative	100 %	(default)

Reference doses		
	Value	Source
ADI	0.01 mg/kg bw	Review Report SANCO/127/08-final rev.2 21 November 2011
AOEL-S	0.004 mg/kg bw/d	Review Report SANCO/127/08-final rev.2 21 November 2011
ARfD	0.07 mg/kg bw	Review Report SANCO/127/08-final rev.2 21 November 2011

Classification and proposed labelling	
with regard to toxicological data (according to the criteria in Dir. No 67/548/EEC, as amended)	Regulation (EC) No 1272/2008 (as amended by ATPs, Annex VI, Table 3.2): substance not listed Proposal RAC (ECHA/RAC/CLH-O-0000002667-66-01/F, 15 June 2012): Xn - Harmful R20 - Harmful by inhalation R41 - Risk of serious damage to eyes R43 - May cause sensitisation by skin contact R63 - Possible risk of harm to the unborn child Proposal BfR: *c.f.*, proposal RAC
with regard to toxicological data (according to the criteria in Reg. (EC) No 1272/2008, as amended)	Regulation (EC) No 1272/2008 (as amended by ATPs, Annex VI, Table 3.1): substance not listed Proposal RAC (ECHA/RAC/CLH-O-0000002667-66-01/F, 15 June 2012): Acute toxicity, cat. 4 Serious eye damage, cat. 1 Skin sensitization, cat. 1A Reproductive toxicity, cat. 2 H332 - Harmful if inhaled H318 - Causes serious eye damage H317 - May cause an allergic skin reaction

Classification and proposed labelling	
	H361d - Suspected of damaging the unborn child
	Proposal BfR: *c.f.*, proposal RAC

3.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for BANJO Forte (MCW-853 SC) is given in Table 3.3-1. Full summaries of studies on the product are presented in Appendix 2. MSDS on BANJO Forte (MCW-853 SC) 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 BANJO Forte (MCW-853 SC)

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 423)	> 2000 mg/kg bw	Yes	None	None	[redacted], 2008a
LD_{50} dermal, rat (OECD 402)	> 2000 mg/kg bw	Yes	None	None	[redacted], J., 2008b
LC_{50} inhalation, rat (OECD 403)	> 4.23 mg/L (highest attain. conc.)	Yes	None	None	[redacted], 2009
Skin irritation, rabbit (OECD 404)	Non-irritant	Yes	None	None	[redacted], 2008a
Eye irritation, rabbit (OECD 405)	Non-irritant	Yes	None	None	[redacted], 2008b
Skin sensitisation, guinea pig (OECD 406, M&K)	Non-sensitising	Yes	None	None	[redacted], 2009
Supplementary studies for combinations of plant protection products	No data – not required				

Table 3.3-2: Additional toxicological information relevant for classification/labelling of BANJO Forte (MCW-853 SC)

	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 substance(s) (relevant for classification of product)	Fluazinam (17.3 % (w/w))	R43 (≥ 1 %) H317 (≥ 1 %)	Proposal RAC (ECHA/RAC/CLH-O-0000002667-66-01/F, 15 June 2012);	"Contains fluazinam (CAS-No. 79622-59-6). May produce an allergic reaction." [2)] EUH208 [2)]

		R63 (≥ 5 %) H361d (≥ 3 %)	MSDS [1)] and RAC proposal (ECHA/RAC/CLH-O-0000002667-66-01/F, 15 June 2012)	R63 H361d
Toxicological properties of non-active substance(s) (relevant for classification of product)	Proxel GXL containing 1,2-benzisothiazol-3(2H)-one (CAS-No. 2634-33-5, 0.03 % (w/w))	R43; RA (≥ 0.005 %); H317; EUH208 (≥ 0.005 %)	Reg. (EC) No 1272/2008 and subsequent regulations amending Reg. (EC) No 1272/2008	"Contains 1,2-benzisothiazol-3(2H)-one (CAS-No. 2634-33-5). May produce an allergic reaction." EUH208
Further toxicological information	No data – not required			

[1)] MSDS: material safety data sheet of the applicant

[2)] based on unequivocal study results – therefore used for classification of the product

3.4 Toxicological evaluation of groundwater metabolites

No relevance assessment of groundwater metabolites is required - no data submitted.

3.5 Dermal Absorption

A summary of the dermal absorption endpoints for the active substances in Dimethomorph 500 SC and MCW 465 500SC are presented in Table 3.5-1.

Table 3.5-1: Dermal absorption endpoints for active substances in Dimethomorph 500SC and MCW 465 500SC

	Dimethomorph		**Fluazinam**	
	Value	**Reference**	**Value**	**Reference**
Concentrate	1 %	Van Meeuwen, R.N.C, 2013 ASB2013-9577	1 %	[redacted], 2009 ASB2010-6933
Dilution	17 % (1:2500)	Van Meeuwen, R.N.C, 2013 ASB2013-9577	22 % (1:1667)	[redacted]; 2009 ASB2010-6933

3.5.1 Justification for proposed values - Dimethomorph

The proposed endpoint for dimethomorph is based on a dermal absorption study on an SC formulation containing 500 g/L dimethomoprh similar to BANJO Forte (MCW-853 SC). The study on the dermal absorption of dimethomorph is summarized in the following Table. A full summary of the study is presented in detail in Appendix 2 as the study has not previously been evaluated within an EU peer review process.

Table 3.5-2: Summary of dermal absorption studies for dimethomorph

Test	Concentrate (500 g/L)	Spray dilution (0.2 g/L)	Formulation in study	Acceptability of study	Justification provided on representativity of study formulation for current product	Acceptability of justification	Reference
In vitro (human)	1 %	17 %	Dimethomorph 500 SC	Yes	Yes	Justification accepted. Endpoint can be used for current product.	[redacted], 2013

3.5.2 Justification for proposed values – Fluazinam

The proposed endpoint for fluazinam is based on a dermal absorption study on an SC formulation containing 500 g/L fluazinam similar to BANJO Forte (MCW-853 SC). The study on the dermal absorption of fluazinam is summarized in the following table. A full summary of the study is presented in detail in Appendix 2 as the study has not previously been evaluated within an EU peer review process.

Table 3.5-3: Summary of dermal absorption studies for fluazinam

Test	Concentrate (500 g/L)	Spray dilution (0.3 g/L)	Formulation in study	Acceptability of study	Justification provided on representativity of study formulation for current product	Acceptability of justification	Reference
In vitro (human)	1 %	22 %	MCW 465 500 SC	Yes	Yes	Justification accepted. Endpoint can be used for current product.	[redacted]; 2009

3.6 Exposure Assessment of Plant Protection Product

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

Product name and code	BANJO Forte / MCW-853 SC (MAC-94530-F-0-SC)	
Formulation type	SC	
Category	Fungicide	
Container size(s), short description	1 L bottle (49 mm opening), 5 L bottle (63 mm opening)	
Active substance(s) (incl. content)	**Dimethomorph** 200 g/L	**Fluazinam** 200 g/L
AOEL systemic	0.15 mg/kg bw/d	0.004 mg/kg bw/d
Inhalative absorption	100 %	100 %
Oral absorption	100 %	35 %

Dermal absorption	Concentrate: 1 % Dilution: 17 % (Dilution rate: 1:2500) Dimethomorph 500 SC	Concentrate: 1 % Dilution: 22 % (Dilution rate: 1:1667) MCW 465 500 SC

3.6.1 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.

3.6.2 Operator exposure

3.6.2.1 Estimation of operator exposure

A summary of the exposure models used for estimation of operator exposure to the active substances during application of BANJO Forte (MCW-853 SC) according to the critical use is presented in Table 3.6-2. Outcome of the estimation is presented in Table 3.6-3. Detailed calculations are given in Appendix 3.

Table 3.6-2: Exposure models for intended uses

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

Table 3.6-3: Estimated operator exposure

		Dimethomorph		Fluazinam	
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: 0.2 kg dimethomorph/ha + 0.2 kg fluazinam/ha					
German Model (Geometric mean) Body weight: 70 kg	no PPE[1)]	0.0213	14.2	0.0271	677.7
	+ gloves during mixing/loading and application, coverall during application)	0.0015	1.0	0.0019	47.8
UK POEM (Application volume: 300 L/ha Container: 5 L [3)] Body weight: 60 kg	no PPE[2)]	0.0825	55.0	0.1056	2639.2
	+ gloves during mixing/loading and application	0.0130	8.7	0.0166	415.0

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

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

3) Based on the work rate of 50 ha/day and the proposed maximum application rate of 1 L product /ha, the amount of product required to treat 50 hectares would be 50 litres. It is unrealistic to consider that a 1 litre container would be used throughout a full working day of boom spraying as this would require 50 separate pouring operations/day. Therefore, the 5 litre container gives the realistic worst case dermal exposure during mixing/loading.

3.6.2.2 Measurement of operator exposure

Since the operator exposure estimations carried out indicated that, according to the German model, 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.

3.6.3 Worker exposure

3.6.3.1 Estimation of worker exposure

Table 3.6-4 shows the exposure model(s) used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with BANJO Forte (MCW-853 SC) according to the critical use. Outcome of the estimation is presented in Table 3.6-5. Detailed calculations are in Appendix 3.

Table 3.6-4: Exposure models for intended uses

Critical use(s)	Potatoes (max. 4 x 1 L product/ha)
Model	German re-entry model, Krebs et al. (2000) [Uniform Principles for Safeguarding the Health of Workers Re-entering Crop Growing Areas after Application of Plant Protection Products, Nachrichtenbl. Deut. Pflanzenschutzdienst., 52(1), p. 5-9]

Table 3.6-5: Estimated worker exposure

		Dimethomorph		Fluazinam	
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: 4 x 0.2 kg dimethomorph/ha + 4 x 0.2 kg fluazinam/ha					
2 hours/day [1], TC: 2500 cm^2/person/h [2] Body weight: 60 kg	no PPE [3]	0.0113	7.6	0.0147	366.7 [4]
	with PPE [5]	0.0006	0.4	0.0007	18.3

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) in case of a refinement using 2 applications instead of 4 applications AOEL-S is still exceeded
5) with PPE: see 'Instructions for use'

3.6.3.2 Measurement of worker exposure

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

3.6.4 Bystander and resident exposure

3.6.4.1 Estimation of bystander and resident exposure

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

Table 3.6-6: Exposure models for intended uses

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

Table 3.6-7: Estimated bystander and resident exposure

	Dimethomorph		**Fluazinam**	
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: 4 x 0.2 kg dimethomorph/ha + 4 x 0.2 kg fluazinam/ha				
Bystanders (adult) Drift rate: 2.77 % (1 m) Body weight: 60 kg	0.0016	1.0	0.0020	50.8
Bystanders (children) Drift rate: 2.77 % (1 m) Body weight: 16.15 kg	0.0012	0.8	0.0016	39.7
Residents (adult) Drift rate: 1.85 % (1 m) Body weight: 60 kg	0.0003	0.2	0.0007	16.8
Residents (children) Drift rate: 1.85 % (1 m) Body weight: 16.15 kg	0.0006	0.4	0.0011	28.0

3.6.5 Statement on combined exposure

The product is a mixture of two active substances (see confidential part).

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 *
KIIA 6.3, KIIIA1 7.1.1	[redacted]	2008a	Acute oral toxicity study of MCW-853 SC in rats R-24355 ! 23314 GLP: Yes Published: No BVL-2464950, BVL-2465109, ASB2011-738	Yes	MCW	Y
KIIIA1 7.1.2	[redacted]	2008b	Acute dermal toxicity study of MCW-853 SC in rats R-24357 ! 23316 GLP: Yes Published: No BVL-2464964, ASB2011-739	Yes	MCW	Y
KIIIA1 7.1.3	[redacted]	2009	MCW 853 SC: Acute inhalation toxicity (nose only) study in the rat R-24978 ! 0306/0388 GLP: Yes Published: No BVL-2464992, ASB2011-740	Yes	MCW	Y
KIIIA1 7.1.4	[redacted]	2008a	Acute dermal irritation/corrosion test test (patch test) of MCW 853 SC in rabbits R-24359 ! 23318 GLP: Yes Published: No BVL-1980509, ASB2011-741	Yes	MCW	Y
KIIIA1 7.1.5	[redacted]	2008b	Acute eye irritation/corrosion test of MCW-853 SC in rabbits R-24360 ! 23319 GLP: Yes Published: No BVL-2465039, ASB2011-742	Yes	MCW	Y
KIIIA1 7.1.6	[redacted]	2009	Examination of MCW-853 SC in the skin sensitisation test in Guinea pigs according to Magnusson and Kligman R-24361 ! 23320 GLP: Yes Published: No BVL-2465049, ASB2011-743	Yes	MCW	Y
KIIIA1 7.6.2	[redacted]	2009	In vitro percutaneous absorption of 14C-Fluazinam, formulated as MCW 465 500 SC, through human and rat skin membranes R-25786 ! V8181/02 GLP: Yes Published: No BVL-2465066, ASB2010-6933	Yes	MCW	Y
KIIIA1 7.6.2	[redacted]	2013	In vitro percutaneous absorption of Dimethomorph, formulated as Dimethomorph 500 SC, through human and rat skin membranes V20251 ! R-30646 GLP: Yes Published: No BVL-2465056, ASB2013-9577	Yes	MCW	Y

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

Appendix 2 Detailed evaluation of the studies relied upon

A 2.1 Statement on bridging possibilities

The following studies were performed on the product BANJO Forte (MCW 853 SC). Thus, no bridging is necessary.

A 2.2 Acute oral toxicity

Comments of zRMS:	Acceptable, according to recent guidelines, used in evaluation

Reference: 7.1.1
Report: Acute oral toxicity study of MCW-853 SC in rats, [redacted], 2008a, 23314 (R-24355), ASB2011-738
Guideline(s): OECD 423 (2001), 2004/73/EC - method B.1
Deviations: No
GLP: Yes
Acceptability: Yes

Materials and methods

Test material (Lot/Batch No.)	MCW-853 SC (242-060708-01)
Species	Rat, Crl: CD (SD)
No. of animals (group size)	2 x 3 females
Dose(s)	2000 mg/kg bw
Exposure	Once by gavage
Vehicle/Dilution	None
Post exposure observation period	14 days
Remarks	None

Results and discussions

Table A 1: Results of acute oral toxicity study in rats of MCW-853 SC

Dose [mg/kg bw]	Toxicological results [1)]	Duration of signs	Time of death	LD_{50} [mg/kg bw] (14 days)
Female rats				
2000	0/0/3	--	--	> 2000
2000	0/0/3	--	--	> 2000

[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 of MCW-853 SC

Mortality:	No mortality occurred.
Clinical signs:	No clinical signs of toxicity were observed.
Body weight:	All animals showed body weight gain during the study.

Macroscopic examination:	The necropsies performed at the end of the study revealed no apparent findings.

Conclusion

Under the experimental conditions, the oral LD_{50} of BANJO Forte is higher than 2000 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; according to recent guidelines, used in evaluation

Reference: 7.1.2
Report: Acute dermal toxicity study of MCW-853 SC in rats, [redacted], 2008b, 23316 (R-24357), ASB2011-739
Guideline(s): OECD 402 (1987), 92/69/EEC - method B.3
Deviations: No
GLP: Yes
Acceptability: Yes

Materials and methods

Test material (Lot/Batch No.)	MCW-853 SC (242-060708-01)
Species	Rat, Crl: CD (SD)
No. of animals (group size)	5 males and 5 females
Dose(s)	2000 mg/kg bw
Exposure	24 hours (dermal, semi-occlusive)
Vehicle/Dilution	None
Post exposure observation period	14 days
Remarks	None

Results and discussions

Table A 3: Results of acute dermal toxicity study in rats of MCW-853 SC

Dose [mg/kg bw]	Toxicological results [1)]	Duration of signs	Time of death	LD_{50} [mg/kg bw] (14 days)
Male rats				
2000	0/0/5	--	--	> 2000
Female rats				
2000	0/0/5	--	--	> 2000

[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 of MCW-853 SC

Mortality:	No mortality occurred.
Clinical signs:	No clinical signs of toxicity were observed.
Body weight:	The animals gained body weight as expected.
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 BANJO Forte is higher than 2000 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; according to recent guidelines, used in evaluation

Reference: 7.1.3
Report: MCW 853 SC: acute inhalation toxicity (nose only) study in the rat; [redacted], 2009, 0306/0388 (R-24978), ASB2011-740
Guideline(s): OECD 403 (1981), 92/69/EEC - method B.2
Deviations: No
GLP: Yes
Acceptability: Yes

Materials and methods

Test material (Lot/Batch No.)	MCW 853 SC (242-060708-01)
Species	Rat, Wistar (HsdRccHan: Wist)
No. of animals (group size)	5 males and 5 females
Concentration(s)	4.23 mg/L (max. attainable concentration)
Exposure	4 hours (nose only)
Vehicle/Dilution	Sterile water (MCW 853 SC : sterile water 80 : 20 w/w)
Post exposure observation period	14 days
Remarks	None

Results and discussions

Table A 5: Concentration(s) and exposure conditions

Nominal conc. [mg/L air]	Actual conc. [mg/L air]	MMAD [1)] [µm]	GSD [2)] [µm]
88.1	4.23	3.64	± 2.93

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

Table A 6: Results of acute inhalation toxicity study in rats of MCW 853 SC

Concentration [mg/L air]	Toxicological results [1)]	Duration of signs	Time of death	LC_{50} [mg/L air] (14 days)
Male rats				
4.23	0/5/5	d 1 – d 6	--	> 4.23
Female rats				
4.23	0/5/5	d 1 – d 14	--	> 4.23

[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 of MCW 853 SC

Mortality:	No mortality occurred.
Clinical signs:	The only significant observation noted in all animals was an increased respiratory rate during exposure, on removal from the chamber, one hour post-exposure and one day after exposure. The following observations are considered to be associated with the restraint procedure and, in isolation, are not indicative of toxicity: Signs of hunched posture and pilo-erection were commonly seen in animals for short periods on removal from the chamber following 4-hour exposure. Wet fur was commonly recorded both during and for a short period after exposure. Fur staining by the test item preparation was noted on removal from the test chamber and for several days post-exposure. All animals recovered such that no significant observations were apparent from day 2 after exposure.
Body weight:	Body weight gain was considered to be normal.
Macroscopic examination:	The necropsies performed at the end of the study revealed no apparent findings.

Conclusion

Under the experimental conditions, the inhalation LC_{50} of BANJO Forte is higher than 4.23 mg/L air (highest attainable concentration) 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; according to recent guidelines, used in evaluation

Reference: 7.1.4
Report: Acute dermal irritation/corrosion test (patch test) of MCW-853 SC in rabbits, [redacted], 2008a, 23318 (R-24359), ASB2011-741
Guideline(s): OECD 404 (2002), 2004/73/EC - method B.4
Deviations: No
GLP: Yes
Acceptability: Yes

Materials and methods

Test material (Lot/Batch No.)	MCW-853 SC (242-060708-01)
Species	Rabbit (Himalayan)

No. of animals (group size)	3 males
Initial test using one animal	Yes
Exposure	0.5 mL (4 hours, semi-occlusive)
Vehicle/Dilution	None
Post exposure observation period	4 - 5 days
Remarks	None

Results and discussions

Table A 8: Skin irritation of BANJO Forte

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 0	1 0	1 0	1.0 0	day 5
2	Erythema Oedema	1 0	1 0	1 0	0 0	0.7 0	day 3
3	Erythema Oedema	1 0	1 0	1 0	0 0	0.7 0	day 3

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

Clinical signs:	None.

Conclusion

Under the experimental conditions, BANJO Forte 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; according to recent guidelines, used in evaluation

Reference: 7.1.5
Report: Acute eye irritation/corrosion test of MCW-853 SC in rabbits; [redacted], 2008b; 23319 (R-24360); ASB2011-742
Guideline(s): OECD 405 (2002), 2004/73/EC - method B.5
Deviations: No
GLP: Yes
Acceptability: Yes

Materials and methods

Test material (Lot/Batch No.)	MCW-853 SC (242-060708-01)
Species	Rabbit, Himalayan
No. of animals (group size)	3 males

Initial test using one animal	Yes
Exposure	0.1 mL (single instillation into conjunctival sac)
Irrigation (time point)	Yes (24 hour after application with NaCl solution)
Vehicle/Dilution	None
Post exposure observation period	3 days
Remarks	None

Results and discussions

Table A 9: Eye irritation of MCW-853 SC

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

[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:	None

Conclusion

Under the experimental conditions, BANJO Forte 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 Skin sensitisation

Comments of zRMS:	Acceptable; according to recent guidelines, used in evaluation

Reference:	7.1.6
Report	Examination of MCW-853 SC in the skin sensitisation test in guinea pigs according to Magnusson and Kligman (Maximisation Test); [redacted], 2009; 23320 (R-24361), ASB2011-743
Guideline(s):	OECD 406 (1992), 96/54/EEC - method B.6
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Test material (Lot/Batch No.)	MCW-853 SC (242-060708-01)
Species	Guinea pig, Hartley albino
No. of animals (group size)	Test substance group: 10 male guinea pigs Vehicle control goup: 5 male guinea pigs
Range finding:	Yes
Exposure (concentration(s), no. of applications)	Intradermal induction: 0.5 % Topical induction: 25 % Challenge: 25 %
Vehicle	Aqua ad iniectabilia
Pretreatment prior to topical application	No
Reliability check	Benzocaine (2 % intradermal induction, 5 % topical induction and 5 % challenge)
Remarks	None

Results and discussions

	24 hours	**48 hours**
	After challenge	
MCW-853 SC	0/10	0/10
Test Vehicle Control Group	0/5	0/5
Positive control	20/20	20/20

[1)] Number of animals with positive dermal response (scores of 1-3) /number of animals in dose group

Clinical signs:	None.

Conclusion

Under the experimental conditions, BANJO Forte 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

Not submitted, not necessary.

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

Dimethomorph

Report:	KIIIA1 7.6.2/01, [redacted], R.N.C., 2013, ASB2013-9577
Title:	*In vitro* percutaneous absorption of Dimethomorph, formulated as Dimethomorph 500 SC, through human and rat skin
Testing facility	[redacted]
Document No:	V20251, Sponsor report no. R-30646
Guidelines:	OECD 428 (2004) Deviations: None
GLP	yes

Executive summary

The rate of *in vitro* dermal absorption of ^{14}C-dimethomorph formulated as suspension concentrate was investigated in human and rat skin preparations following single dermal application as either undiluted concentrate (500 g a.s./L), or as representative in-field spray solution (0.2 g a.s./L). After an exposure period of 8 hours, the unabsorbed test item was removed. The post-application period was 24 hours. The study was performed in flow-through diffusion cells. The amount of ^{14}C-dimethomorph in the receptor fluid as well as the residues remaining in and on the skin, and in the *stratum corneum* and in the donor and receptor compartement was determined.

The mean total absorption, defined as the compound-related radioactivity present in the receptor fluid, the receptor compartment wash and the skin membranes (excluding tape strips) was in human skin 0.40 % (concentrate) and 12.6 % (field dilution) of the applied dose. The mean total absorption in rat skin was 2.19 % (concentrate) and 16.03 % (field dilution) of the applied dose. These values do not account for any material recovered in the *stratum corneum*.

However, the material in the lower layers of the *stratum corneum* may be considered as potentially absorbable. Taking into account that less than 75 % of the absorption of dimethomorph from the concentrate and the field dilution through human skin occurred within half of the study duration (i.e. 12 hours), absorption is considered to be not essentially completed and inclusion of *stratum corneum* (excluding strip 1-2) for establishment of dermal absorption values is considered adequate according to EFSA Guidance on Dermal Absorption (2012).

Thus, a proposed dermal absorption rate of 0.73 % and 16.9 % of dimethomorph for the high and low dose levels, respectively, is considered appropriate for use in risk assessment.

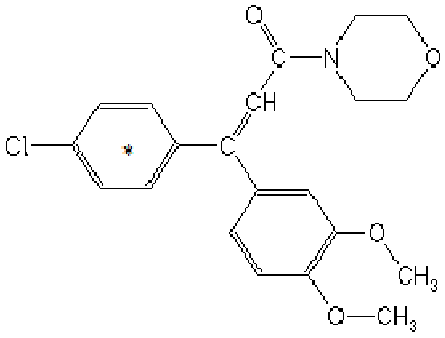
I. Materials and methods

A. Materials

1. Test Material:

Radiolabelled test item:	[^{14}C]-dimethomorph
Lot/Batch no.:	CC-610
Radiochemical purity:	99.7 %
Specific activity:	4.179 MBq/mg (1626 MBq/mmol)
CAS (dimethomorph):	110488-70-5
Stability of test compound:	expiry date: 2 August 2017

The structural formula of [^{14}C]-dimethomorph with the position of the radiolabel (*) is presented below:



Non-radiolabelled test substance:	dimethomorph technical
Batch:	20120323
Purity:	97.65%
Expiry date:	23. March 2014
Formulated test substance:	Dimethomorph 500 SC
Batch No.:	92113364
Concentration of a.i.:	513 g/L
Expiry date:	1. July 2014
Blank formulation:	Dimethomorph 500 SC blank
Batch No:	cq-2
Expiry date:	4. October 2013

The test material for the high dose group was prepared by adding formulation concentrate to the radiolabelled material previously dried under nitrogen. The test material for the low dose group was prepared by adding blank formulation and water to the radiolabelled material previously dried under nitrogen.

2. Vehicle and/or positive control –

Vehicle:	blank mixture Dimethomorph 500 SC and demineralised water
Reference substance:	$^{3}H_2O$ (for testing of the integrity of the skin preparations)

3. Skin preparations –

Human skin:	human skin derived from abdomen and breast was obtained from seven donors (aged 19, 37, 46, 48, 55, 57 and 60 years) directly after surgery
Rat skin:	dorsal and flank skin obtained from two male Wistar WU rats (Harlan, The Netherlands) of approx. 10 weeks old
Skin preparation:	split thickness skin membranes (approx. 200 to 400 µm thick)

4. Test system –

Diffusion cell:	9 mm flow-through diffusion cell (approx. 32°C, 1.6 mL/h flow-rate)
Receptor fluid:	saline (0.9 % sodium chloride (w/v) containing 0.01 % sodium azide supplemented with 5 % bovine serum albumin (w/v)); the solubility in receptor fluid was confirmed

B. Study design and method

1. In life dates: 26 September to 8 October, 2012

2. Experimental design

The study was performed in flow-through diffusion cells at approx. 32°C and a flow through of approx. 1.6 mL/hour of the receptor fluid. After assessment of skin integrity by determination of the permeability coefficient (Kp) in tritiated water, ^{14}C-dimethomorph formulated as suspension concentrate (SC) was applied to the skin preparations (10 µL/cm²) as either undiluted concentrate (500 g a.s./L, high concentration), or as representative in-field spray solution (0.2 g a.s./L, low concentration). A volume of 6.4 µL of the dose preparations was applied on each skin sample (0.64 cm^2). The correctness of the applied concentrations was analytically confirmed by LSC.

After an exposure period of 8 hours, the unabsorbed test item was removed using a mild detergent solution (3 % v/v Teepol in water) and cotton swabs. Receptor fluid samples were collected in the following intervals: 0-1h, 1-2h, followed by 2-h intervals until 24 hours after application. 24 hours after exposure, the diffusion cells were dismantled. Receptor and donor compartments were washed twice with 1.0 mL Ethanol. In addition the donor compartments of group A and C were wiped clean with a cotton swab. The swab was added to the according donor compartment wash vial. The skin membranes were tape stripped 15 times to remove the *stratum corneum* after 24 hours. Skin membranes were digested in 5 mL of a 1.5 M KOH solution with 20 % aqueous Ethanol for at least 24 h.

3. Sampling and analysis of radioactivity

The radioactivity in the collected samples was determined using a Canberra Packard Tricarb 3100 TR scintillation counter. Ultimate Gold™ scintillation liquid (Packard) was added to samples of the receptor fluid, the diffusion cell washes, the cotton swab extracts, the tape strips and to samples of the mock dosing samples. For the determination of radioactivity in digested skin preparations Hionic Fluor™ scintillation liquid was added to an aliquot of each digested skin membrane.

II. Results and discussion

A. Integrity of skin preparations

The permeability coefficient (Kp) was determined in a total of 42 human and rat skin preparations prior to determination of the dermal absorption. Preparations with a Kp value below the cut-off value of 2.5×10^{-3} cm/h (human) or 3.5×10^{-3} cm/h (rat) were selected for the study.

B. Receptor fluid solubility

The solubility of dimethomorph in saline supplemented with 5 % BSA was confirmed in a solubility test. Thus, the receptor fluid is not expected to act as a rate-limiting step in the permeation process.

C. Dermal absorption

The mean recovery of radioactivity ranged from 95.3 to 98.9 % for human skin and from 96.8 to 97.2 % for rat skin.

In human skin, the mean absorption into the receptor fluid at 24 hours was 0.11 % (0.51 µg/cm²/h) for the concentrate and 5.93 % (0.010 µg/cm^2/h) for the spray dilution. The mean total absorption, defined as the radioactivity present in the receptor fluid, the receptor chamber and the skin (excluding stratum corneum) was 0.40 and 12.60 % for the concentrate and spray dilution, respectively. The radioactivity located in the lower stratum corneum layers (strips 3-15) amounted to 0.33 % and 4.30 % of the dose at the high and low dose levels, respectively. Considering the residues in the stratum corneum (excluding tape strip 1-2) as potential absorbable, the total potentially absorbable dose accounts for 0.73 % and 16.90 % for the concentrate and the spray dilution, respectively.

In rat skin, the mean absorption into the receptor fluid at 24 hours was 0.38 % (1.59 µg/cm^2/h) for the concentrate and 11.90 % (0.029 µg/cm^2/h) for the spray dilution. The mean total absorption, defined as the radioactivity present in the receptor fluid, the receptor chamber and the skin (excluding stratum corneum) was 2.19 and 16.03 % for the high and low dose, respectively. The radioactivity located in the lower stratum corneum layers (strips 3-15) amounted to 2.37 % and 9.73 %, resulting to a potential total absorption of 4.56 % and 25.76 % for the concentrate and the spray dilutions, respectively.

A summary of the results is given in the following table.

Table A 10: Distribution of radioactivity following the application of [^{14}C]-dimethomorph to human and rat skin (rounded mean values)

	% of applied dose (mean values)			
	Concentrate (500 g a.s./L)		In-use dilution (0.2 g a.s./L)	
	human [(a)]	rat [(b)]	human [(c)]	rat [(b)]
SURFACE COMPARTMENT				
Skin wash at 8 hours	89.1	90.5	79.2	69.2
Material remaining in donor chamber	3.66	0.67	0.46	0.14
Total non-absorbed	**92.76**	**91.17**	**79.66**	**69.34**
SKIN COMPARTMENT				
Skin (epidermis + dermis)	0.29	1.81	6.62	4.06
Stratum corneum (tape strip 1 + 2)	1.76	1.05	2.34	2.45
Stratum corneum (tape strip 3 and more)	0.33	2.37	4.30	9.73
Total % at dose site (without tape strips 1 + 2)	0.62	4.18	10.92	13.43
RECEPTOR COMPARTMENT				
Receptor fluid total (at 24 hours)	0.11	0.38	5.93	11.9
Receptor chamber	0.00	0.00	0.05	0.07
Total % directly absorbed	0.11	0.38	5.98	11.97
Total recovery (% of applied dose)	95.3	96.8	98.9	97.2
OVERALL ABSORPTION				
Total % absorbed[1]	0.40	2.19	12.60	16.03
Total % potentially absorbed[2]	0.73	4.56	16.90	25.76
75 % absorbed in the receptor fluid in first half of study	No	No	No	Yes
Proposed dermal absorption values	**0.73**	**4.56**	**16.90**	**16.03**

[(a)]: mean value from 7 cells (n = 7)
[(b)]: mean value from 6 cells (n = 6)
[(c)]: mean value from 8 cells (n = 8)
[(1)]: including the amount in the receptor fluid, the receptor compartement wash and the skin
[(2)]: including the amount in the receptor fluid, the receptor compartement wash, the skin and the stratum corneum (excluded strip 1 and 2)

Rat skin membranes showed a higher permeability than human skin. Based on total potentially absorbable dose, the dermal absorption of dimethomorph through rat skin is 6.3-fold higher than compared to human skin from the concentrate (4.56 / 0.73) and 1.5-fold higher from field dilution (25.76 / 16.90), respectively. Based on maximal flux values, the dermal absorption of dimethomorph through rat skin is 3.1-fold higher than compared to human skin from the concentrate (1.59 / 0.51) and 2.9-fold higher from field dilution (0.029 / 0.010), respectively.

C. Deficiencies

None

III. Conclusions

The mean total potentially absorbable dose over 24 hours, considering the compound-related radioactivity present in the receptor fluid, the receptor chamber and the skin compartment and the lower stratum corneum (excluding tape strips 1+2) amounted to 0.73 % and 16.9 % in human skin for the high and low dose levels, respectively.

Taking into account that less than 75 % of the absorption of dimethomorph from the concentrate and the field dilution through human skin occurred within half of the study duration (i.e. 12 hours), absorption is considered to be not essentially completed and inclusion of stratum corneum for establishment of dermal absorption values is considered adequate according to EFSA Guidance on Dermal Absorption (2012).

Thus, a proposed dermal absorption rate of 0.73 % and 16.9 % of dimethomorph for the high and low dose levels, respectively, is considered appropriate for use in risk assessment.

Comments of zRMS:	The study is considered acceptable. However, the calculated value for dermal absorption (in vitro human skin) for the concentrate is not agreed, because the standard deviation of the mean value of absorption is larger than 25%. And according to EFSA Guidance on Dermal Absorption (2012) the preferred approach for such case is the addition of a standard deviation to the mean value. This approach will result in a dermal absorption of 1.3 % rounded to 1%. The dermal absorption of 16.9 % for the dilution is agreed, but has to be rounded to 17 % *Remark:* values of dermal absorption in rat skin (in vitro) were not taken into consideration and therefore not evaluated.
Agreed Endpoints	Dermal absorption: human skin in vitro 1 % for the concentrate and 17 % for the dilution.

Fluazinam

Report:	KIIIA1 7.6.2/02, [redacted], 2009, ASB2010-6933
Title:	*In vitro* percutaneous absorption of [^{14}C]-Fluazinam, formulated as MCW 465 500 SC, through human and rat skin membranes
Testing facility	[redacted]
Document No:	V8181/02, Sponsor report no. R-25786
Guidelines:	OECD 428 (2004) Deviations: None
GLP	yes

Executive summary

The rate of *in vitro* dermal absorption of ^{14}C-fluazinam formulated as suspension concentrate was investigated in human and rat skin preparations following single dermal application as either undiluted concentrate (500 g a.s./L), or as representative in-field spray solution (0.3 g a.s./L). After an exposure period of 8 hours, the unabsorbed test item was removed using cotton swabs moistened with a mild detergent. The post-application period was 24 hours. The study was performed in flow-through diffusion cells. The amount of ^{14}C-fluazinam in the receptor fluid as well as the residues remaining in and on the skin, and in the *stratum corneum* was determined.

The mean total absorption, defined as the compound-related radioactivity present in the receptor fluid, the receptor compartment wash and the skin membranes (excluding tape strips) was in human skin 0.35 % (concentrate) and 14.96 % (field dilution) of the applied dose. The mean total absorption in rat skin was 0.59 % (concentrate) and 42.18 % (field dilution) of the applied dose. These values do not account for any material recovered in the *stratum corneum*.

However, the material in the lower layers of the *stratum corneum* may be considered as potentially absorbable. Taking into account that less than 75% of the absorption of fluazinam from the concentrate and the field dilution through human skin occurred within half of the study duration (i.e. 12 hours) absorption is considered to be not essentially completed and inclusion of *stratum corneum* (excluding strip 1-2) for establishment of dermal absorption values is considered adequate according to EFSA Guidance on Dermal Absorption (2012).

Therefore, the potentially absorbable dose over 24 hours was additionally calculated as the sum of the amounts present in remaining skin, receptor fluid (including compartment wash) and *stratum corneum* tape strips (excluding tape strips 1-2). Whereas the first 3 out of 15 tape strips were subtracted in the original report, only the first 2 tape strips were excluded in this evaluation as very worst-case. This results to a potential dermal absorption of 0.62 % in human skin and 1.10 % in rat skin for the concentrate, and 22.3 % in human skin and 51.95 % in rat skin for the in-use spray dilution.

Based on this, human skin can be assumed to be 1.77 and 2.33 times less permeable for fluazinam than rat skin when exposed to the SC formulation concentrate or its field dilution, respectively.

Overall, a proposed dermal absorption rate of 0.62 % and 22.3 % of fluazinam for the high and low dose levels, respectively, is considered appropriate for use in risk assessment.

Table A 11: Overview table of the *in vitro* percutaneous penetration of [^{14}C]-Fluazinam, formulated as MCW 465 500 SC, through human and rat skin (concentrate)

Concentrate	A – human		D – rat	
Concentration measured [g.L^{-1}]	517.8		517.8	
Dose [ug.cm^{-2}]	4963		4916	
n	6		6	
Penetration into the receptor fluid after 24 h	% of dose	µg.cm^{-2}	% of dose	µg.cm^{-2}
	0.015	0.77	0.017	0.82
Maximal flux [ug.cm^{-2} h^{-1}]	0.030		0.033	
Lag time [h]	0.1		0.5	
Total absorption*	0.35		0.59	
Potential total absorption**	0.59		1.03	

* Total absorption is defined as the amount in the receptor fluid, the receptor compartment wash and skin membrane, excluding tape strips

** Potential total absorption is defined as the amount in the receptor fluid, the receptor compartment wash and skin membrane, excluding tape strips 1 – 3 only

Table A 12: Overview table of the *in vitro* percutaneous penetration of [^{14}C]-Fluazinam through human and rat skin (field dilution)

Field dilution	C – human		F – rat	
Concentration measured [g.L^{-1}]	0.28		0.28	
Dose [µg.cm^{-2}]	2.79		2.83	
n	6		6	
Penetration into the receptor fluid after 24 h	% of dose	µg.cm^{-2}	% of dose	µg.cm^{-2}
	0.19	0.005	2.29	0.065
Maximal flux [µg.cm^{-2} h^{-1}]	0.0003		0.005	
Lag time [h]	7.0		11.2	
Total absorption*	15.0		38.7	
Potential total absorption**	21.1		46.3	

* Total absorption is defined as the amount in the receptor fluid, the receptor compartment wash and skin membrane, excluding tape strips

** Potential total absorption is defined as the amount in the receptor fluid, the receptor compartment wash and skin membrane, excluding tape strips 1 – 3 only

Table A 13: Cumulative absorption of Fluazinam (4963 ± 26 µg.cm^{-2}) through human skin membranes (group A – concentrate)

Group A		Cumulative absorption (µg.cm^{-2})							
Replicate		A – 1	A – 2	A – 3	A – 4	A – 5	A – 6		
Donor no.		H1	H1	H2	H2	H3	H3	**Mean**	**SD**
Time (h)	1	0.10	0.04	0.03	0.05	0.04	0.03	0.05	0.02
	2	0.18	0.07	0.07	0.11	0.06	0.07	0.09	0.04
	4	0.32	0.11	0.10	0.20	0.12	0.13	0.16	0.09
	6	0.45	0.15	0.14	0.27	0.16	0.16	0.22	0.12
	8	0.56	0.21	0.18	0.35	0.21	0.21	0.29	0.15
	10	0.67	0.26	0.22	0.43	0.25	0.25	0.35	0.18
	12	0.77	0.31	0.27	0.49	0.29	0.27	0.40	0.20
	14	0.89	0.35	0.32	0.56	0.34	0.31	0.46	0.23
	16	1.00	0.42	0.35	0.64	0.39	0.36	0.52	0.26
	18	1.11	0.48	0.39	0.73	0.42	0.39	0.59	0.29
	20	1.21	0.56	0.41	0.78	0.46	0.41	0.64	0.32
	22	1.33	0.66	0.45	0.85	0.49	0.43	0.70	0.35
	24	1.44	0.74	0.48	0.93	0.54	0.47	0.77	0.37
Linear range (h)		1-24	1-24	1-24	1-24	1-24	1-24	**Mean**	**SD**
Maximal flux (µg.cm^{-2}.h^{-1})		0.057	0.029	0.020	0.037	0.022	0.018	0.030	0.015
Lag time (h)		**0**	0.5	**0**	**0**	**0**	**0**	0.1	0.2
r^2		0.998	0.982	0.995	0.998	0.997	0.988		

Table A 14: Cumulative absorption of Fluazinam (2.79 ± 0.09 µg.cm^{-2}) through human skin membranes (group C –field dilution)

Group C		Cumulative absorption (µg.cm^{-2})							
Replicate		C – 1	C – 2	C – 3	C – 4	C – 5	C – 6		
Donor no.		H1	H1	H2	H2	H3	H3	**Mean**	**SD**
Time (h)	1	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
	2	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
	4	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
	6	0.000	0.000	0.000	0.001	0.000	0.000	0.000	0.000
	8	0.001	0.000	0.001	0.001	0.001	0.000	0.001	0.000
	10	0.001	0.000	0.001	0.002	0.001	0.001	0.001	0.001
	12	0.001	0.001	0.001	0.003	0.002	0.002	0.002	0.001
	14	0.002	0.001	0.002	0.004	0.002	0.003	0.002	0.001
	16	0.003	0.001	0.002	0.004	0.003	0.004	0.003	0.001
	18	0.003	0.001	0.002	0.005	0.004	0.005	0.003	0.001
	20	0.004	0.002	0.003	0.005	0.004	0.005	0.004	0.001
	22	0.005	0.002	0.003	0.006	0.005	0.006	0.005	0.002
	24	0.006	0.003	0.004	0.007	0.006	0.007	0.005	0.002
Linear range (h)		14-24	14-24	14-24	14-24	14-24	14-24	**Mean**	**SD**
Maximal flux (µg.cm^{-2}.h^{-1})		0.0004	0.0002	0.0002	0.0003	0.0003	0.0004	0.0003	0.0001
Lag time (h)		10.1	9.9	6.7	0.9	7.3	7.3	7.0	3.3
r^2		0.990	0.978	0.998	1.000	0.996	0.999		

Table A 15: Mass balance of Fluazinam in human skin membranes (group A –concentrate)

Group A	% of dose							
Replicate	A – 1	A – 2	A – 3	A – 4	A – 5	A – 6		
Donor no.	H1	H1	H2	H2	H3	H3	**Mean**	**SD**
Receptor fluid	0.03	0.01	0.01	0.02	0.01	0.01	0.02	0.01
Receptor compartment	0.003	0.003	0.002	0.003	0.002	0.002	0.003	0.000
Donor compartment	0.01	0.03	0.07	0.02	0.02	0.02	0.03	0.02
Tape strips	0.16	0.19	1.24	0.53	0.12	0.17	0.40	0.44
Individual tape strips	15	15	15	15	15	15		
1	0.02	0.05	0.31	0.10	0.03	0.08	0.10	0.11
2	0.02	0.03	0.14	0.03	0.02	0.02	0.04	0.05
3	0.02	0.02	0.08	0.03	0.01	0.01	0.03	0.02
4	0.01	0.01	0.06	0.03	0.01	0.01	0.02	0.02
5	0.01	0.01	0.05	0.04	0.01	0.01	0.02	0.02
6	0.01	0.01	0.18	0.06	0.01	0.01	0.05	0.07
7	0.01	0.01	0.09	0.06	0.01	0.01	0.03	0.04
8	0.01	0.01	0.11	0.04	0.00	0.01	0.03	0.04
9	0.01	0.01	0.03	0.03	0.00	0.00	0.01	0.01
10	0.00	0.01	0.03	0.03	0.00	0.00	0.01	0.01
11	0.01	0.01	0.07	0.02	0.00	0.01	0.02	0.03
12	0.00	0.01	0.03	0.02	0.00	0.00	0.01	0.01
13	0.01	0.01	0.04	0.03	0.00	0.01	0.01	0.01
14	0.01	0.00	0.02	0.02	0.00	0.00	0.01	0.01
15	0.01	0.00	0.01	0.01	0.00	0.00	0.01	0.00
Skin wash	112.3	111.0	110.0	110.1	112.1	110.9	111.1	1.0
Skin membrane	0.26	0.17	0.49	0.29	0.43	0.36	0.33	0.12
Total mass balance	112.8	111.4	111.8	110.9	112.7	111.5	111.8	0.7
Total absorption*	0.29	0.19	0.50	0.31	0.45	0.37	0.35	0.11
Potential absorption**	0.38	0.28	1.23	0.68	0.51	0.43	0.59	0.34

* total absorption defined as the amount of compound-related radioactivity present in the receptor fluid, the receptor compartment wash, and the skin membrane (excluding tape strips)

** potential absorption defined as total absorption including tape strips, except for the first 3 tape strips

Table A 16: Mass balance of Fluazinam in human skin membranes (group C – field dilution)

Group C	% of dose							
Replicate	C – 1	C – 2	C – 3	C – 4	C – 5	C – 6		
Donor no.	H1	H1	H2	H2	H3	H3	**Mean**	**SD**
Receptor fluid	0.23	0.10	0.14	0.22	0.21	0.26	0.19	0.06
Receptor compartment	0.03	0.01	0.02	0.01	0.02	0.02	0.02	0.01
Donor compartment	1.74	2.21	0.78	0.72	0.92	0.73	1.18	0.63
Tape strips	11.42	10.46	13.12	13.03	8.64	10.37	11.17	1.73
Individual tape strips	15	15	15	15	15	15		
1	2.43	2.09	2.28	3.06	1.28	2.30	2.24	0.58
2	1.66	1.27	1.59	1.94	1.37	1.71	1.59	0.24
3	1.58	1.23	1.52	1.29	0.91	0.95	1.25	0.28
4	1.16	1.17	1.04	1.21	0.86	0.92	1.06	0.15
5	0.76	0.59	0.78	1.10	0.53	0.73	0.75	0.20
6	0.56	0.53	0.92	0.67	0.43	0.59	0.62	0.17
7	0.53	0.52	1.01	0.68	1.24	0.55	0.75	0.30
8	0.40	0.49	0.84	0.38	0.35	0.62	0.51	0.19
9	0.51	0.49	1.00	0.36	0.32	0.68	0.56	0.25
10	0.40	0.36	0.47	0.30	0.25	0.48	0.38	0.09
11	0.55	0.14	0.28	0.35	0.25	0.16	0.29	0.15
12	0.43	0.27	0.33	0.24	0.26	0.15	0.28	0.09
13	0.19	0.22	0.26	0.18	0.26	0.17	0.21	0.04
14	0.13	0.27	0.46	0.55	0.16	0.18	0.29	0.17
15	0.14	0.81	0.35	0.74	0.16	0.18	0.40	0.30
Skin wash	74.6	82.8	73.2	76.0	81.1	81.3	78.18	4.05
Skin membrane	17.25	14.77	16.08	12.32	14.73	13.32	14.75	1.79
Total mass balance	105.3	110.3	103.4	102.3	105.7	106.1	105.5	2.8
Total absorption*	17.5	14.9	16.2	12.6	15.0	13.6	15.0	1.8
Potential absorption**	23.3	20.7	24.0	19.3	20.0	19.0	21.1	2.1

* total absorption defined as the amount of compound-related radioactivity present in the receptor fluid, the receptor compartment wash, and the skin membrane (excluding tape strips)
** potential absorption defined as total absorption including tape strips, except for the first 3 tape strips

Comments of zRMS:	The study is considered acceptable. However, the calculated value for dermal absorption (in vitro human skin) for the concentrate is not agreed, because the standard deviation of the mean value of absorption is larger than 25%. And according to EFSA Guidance on Dermal Absorption (2012) the preferred approach in such case is the addition of a standard deviation to the mean value. This approach will result in a dermal absorption value of 0.96 % (rounded up to 1 %) for the concentrate. The dermal absorption value for the dilution is agreed, but should be rounded to 22 %. *Remark:* values of dermal absorption in rat skin (in vitro) were not taken into consideration and therefore not evaluated.
Agreed Endpoints	Dermal absorption: human skin in vitro 1 % for the concentrate and 22 % for the dilution.

Appendix 3 Exposure calculations

A 3.1 Operator exposure calculations

A 3.1.1 Calculations for dimethomorph

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

Formulation type:	SC		**Application technique:**	Field Crop Tractor Mounted (FCTM)	
Application rate (AR):	0.2	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):	1	% (concentr.)	**Dermal hands appl. ($D_{A(H)}$):**	0.38	mg/person/kg a.s.
	17	% (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	0.15	mg/kg bw/d	**Inhalation appl. (I_A):**	0.001	mg/person/kg a.s.

Table A 18: Estimation of operator exposure towards dimethomorph using the German model

Without PPE			**With PPE**		
Operators: Systemic dermal exposure after application in potatoes					
Dermal exposure during mixing/loading					
Hands			Hands		
$SDE_{OM(H)} = (D_{M(H)} \times AR \times A \times DA) / BW$			$SDE_{OM(H)} = (D_{M(H)} \times AR \times A \times PPE^{1)} \times DA) / BW$		
(2.4 x 0.2 x 20 x 1%) / 70			(2.4 x 0.2 x 20 x 0.01 x 1%) / 70		
External dermal exposure	9.6	mg/person	External dermal exposure	0.096	mg/person
External dermal exposure	0.137143	mg/kg bw/d	External dermal exposure	0.001371	mg/kg bw/d
Systemic dermal exposure	**0.001371**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000014**	**mg/kg bw/d**
Dermal exposure during application					
Hands			Hands		
$SDE_{OA(H)} = (D_{A(H)} \times AR \times A \times DA) / BW$			$SDE_{OA(H)} = (D_{A(H)} \times AR \times A \times PPE^{1)} \times DA) / BW$		
(0.38 x 0.2 x 20 x 17%) / 70			(0.38 x 0.2 x 20 x 0.01 x 17%) / 70		
External dermal exposure	1.52	mg/person	External dermal exposure	0.0152	mg/person
External dermal exposure	0.021714	mg/kg bw/d	External dermal exposure	0.000217	mg/kg bw/d
Systemic dermal exposure	**0.003691**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000037**	**mg/kg bw/d**
Body			Body		
$SDE_{OA(B)} = (D_{A(B)} \times AR \times A \times DA) / BW$			$SDE_{OA(B)} = (D_{A(B)} \times AR \times A \times PPE^{2)} \times DA) / BW$		
(1.6 x 0.2 x 20 x 17%) / 70			(1.6 x 0.2 x 20 x 0.05 x 17%) / 70		
External dermal exposure	6.4	mg/person	External dermal exposure	0.32	mg/person
External dermal exposure	0.091429	mg/kg bw/d	External dermal exposure	0.004571	mg/kg bw/d
Systemic dermal exposure	**0.015543**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000777**	**mg/kg bw/d**
Head			Head		
$SDE_{OA(C)} = (D_{A(C)} \times AR \times A \times DA) / BW$			$SDE_{OA(C)} = (D_{A(C)} \times AR \times A \times DA) / BW$		
(0.06 x 0.2 x 20 x 17%) / 70			(0.06 x 0.2 x 20 x 17%) / 70		
External dermal exposure	0.24	mg/person	External dermal exposure	0.24	mg/person
External dermal exposure	0.003429	mg/kg bw/d	External dermal exposure	0.003429	mg/kg bw/d
Systemic dermal exposure	**0.000583**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000583**	**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	17.76	mg/person	Total external dermal exposure	0.6712	mg/person
Total external dermal exposure	0.253714	mg/kg bw/d	Total external dermal exposure	0.009589	mg/kg bw/d
Total systemic dermal exposure	**0.021189**	**mg/kg bw/d**	**Total systemic dermal exposure**	**0.001411**	**mg/kg bw/d**
Operators: Systemic inhalation exposure after application in potatoes					
Inhalation exposure during mixing/loading					
$SIE_{OM} = (I_M \times AR \times A \times IA) / BW$			$SIE_{OM} = (I_M \times AR \times A \times IA) / BW$		
(0.0006 x 0.2 x 20 x 100%) / 70			(0.0006 x 0.2 x 20 x 100%) / 70		
External inhalation exposure	0.0024	mg/person	External inhalation exposure	0.0024	mg/person
External inhalation exposure	0.000034	mg/kg bw/d	External inhalation exposure	0.000034	mg/kg bw/d

Systemic inhalation exposure	**0.000034**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000034**	**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 IA) / BW		
(0.001 x 0.2 x 20 x 100%) / 70			(0.001 x 0.2 x 20 x 100%) / 70		
External inhalation exposure	0.004	mg/person	External inhalation exposure	0.004	mg/person
External inhalation exposure	0.000057	mg/kg bw/d	External inhalation exposure	0.000057	mg/kg bw/d
Systemic inhalation exposure	**0.000057**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000057**	**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	0.0064	mg/person	Total external inhalation exposure	0.0064	mg/person
Total external inhalation exposure	0.000091	mg/kg bw/d	Total external inhalation exposure	0.000091	mg/kg bw/d
Total systemic inhalation exposure	**0.000091**	**mg/kg bw/d**	**Total systemic inhalation exposure**	**0.000091**	**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	1.4896	mg/person	Total systemic exposure	0.105144	mg/person
Total systemic exposure	**0.02128**	**mg/kg bw/d**	**Total systemic exposure**	**0.001502**	**mg/kg bw/d**
% of AOEL	**14.2**	**%**	**% of AOEL**	**1.0**	**%**

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

2) reduction factor for protective garment is 0.05 (professional appl.)

Table A 19: Estimation of operator exposure towards dimethomorph using the UK-POEM (no PPE)

Active substance	**Dimethomorph**				
Product	BANJO Forte				
Formulation type	water-based				
Concentration of a.s.	200	mg/mL			
Dose	1	L preparation/ha (0.2 kg a.s./ha)			
Application volume	300	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	1	%			
Dermal absorption from spray	17	%			
EXPOSURE DURING MIXING AND LOADING					
Container size	5	Litres			
Hand contamination/operation	0,01	mL			
Application dose	1	Litres product/ha			
Work rate	50	ha/day			
Number of operations	10	/day			
Hand contamination	0.1	mL/day			
Protective clothing	None				
Transmission to skin	100	%			
Dermal exposure to formulation	0.1	mL/day			
DERMAL EXPOSURE DURING SPRAY APPLICATION					
Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles				
Application volume	300	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	0.1	mL/day	41.55	mL/day
Concen. of a.s. product or spray	200	mg/mL	0.667	mg/mL
Dermal exposure to a.s.	20	mg/day	27.7	mg/day
Percent absorbed	1	%	17	%
Absorbed dose	0.2	mg/day	4.709	mg/day
INHALATION EXPOSURE DURING SPRAYING				
Inhalation exposure	0.01	mL/h		
Duration of exposure	6	h		
Concentration of a.s. in spray	0.667	mg/mL		
Inhalation exposure to a.s.	0.04	mg/day		
Percent absorbed	100	%		
Absorbed dose	0.04	mg/day		
PREDICTED EXPOSURE				
Total absorbed dose	4.949	mg/day		
Operator body weight	60	kg		
Operator exposure	0.082	mg/kg bw/day		
Amount of AOEL	**55.0**	**%**		

Table A 20: Estimation of operator exposure towards dimethomorph using the UK-POEM (gloves mixing/loading and application)

Active substance	**Dimethomorph**			
Product	BANJO Forte			
Formulation type	water-based			
Concentration of a.s.	200	mg/mL		
Dose	1	L preparation/ha (0.2 kg a.s./ha)		
Application volume	300	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	1	%		
Dermal absorption from spray	17	%		
EXPOSURE DURING MIXING AND LOADING				
Container size	5	Litres		
Hand contamination/operation	0,01	mL		
Application dose	1	Litres product/ha		
Work rate	50	ha/day		
Number of operations	10	/day		
Hand contamination	0.1	mL/day		
Protective clothing	Gloves			
Transmission to skin	5	%		
Dermal exposure to formulation	0.005	mL/day		
DERMAL EXPOSURE DURING SPRAY APPLICATION				
Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles			
Application volume	300	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	0.005	mL/day	6.45	mL/day
Concen. of a.s. product or spray	200	mg/mL	0.667	mg/mL
Dermal exposure to a.s.	1	mg/day	4.3	mg/day
Percent absorbed	1	%	17	%
Absorbed dose	0.01	mg/day	0.731	mg/day
INHALATION EXPOSURE DURING SPRAYING				
Inhalation exposure	0.01	mL/h		
Duration of exposure	6	h		
Concentration of a.s. in spray	0.667	mg/mL		
Inhalation exposure to a.s.	0.04	mg/day		
Percent absorbed	100	%		
Absorbed dose	0.04	mg/day		
PREDICTED EXPOSURE				
Total absorbed dose	0.781	mg/day		
Operator body weight	60	kg		
Operator exposure	0.013	mg/kg bw/day		
Amount of AOEL	**8.7**	**%**		

A 3.1.2 Calculations for fluazinam

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

Formulation type:	SC		**Application technique:**	Field Crop Tractor Mounted (FCTM)	
Application rate (AR):	0.2	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):	1	% (concentr.)	**Dermal hands appl. ($D_{A(H)}$):**	0.38	mg/person/kg a.s.
	22	% (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	0.004	mg/kg bw/d	**Inhalation appl. (I_A):**	0.001	mg/person/kg a.s.

Table A 22: Estimation of operator exposure towards fluazinam using the German model

Without PPE			**With PPE**		
Operators: Systemic dermal exposure after application in potatoes					
Dermal exposure during mixing/loading					
Hands			Hands		
$SDE_{OM(H)} = (D_{M(H)} \times AR \times A \times DA) / BW$			$SDE_{OM(H)} = (D_{M(H)} \times AR \times A \times PPE$ [1)] $\times DA) / BW$		
(2.4 x 0.2 x 20 x 1%) / 70			(2.4 x 0.2 x 20 x 0.01 x 1%) / 70		
External dermal exposure	9.6	mg/person	External dermal exposure	0.096	mg/person
External dermal exposure	0.137143	mg/kg bw/d	External dermal exposure	0.001371	mg/kg bw/d
Systemic dermal exposure	**0.001371**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000014**	**mg/kg bw/d**
Dermal exposure during application					
Hands			Hands		
$SDE_{OA(H)} = (D_{A(H)} \times AR \times A \times DA) / BW$			$SDE_{OA(H)} = (D_{A(H)} \times AR \times A \times PPE$ [1)] $\times DA) / BW$		
(0.38 x 0.2 x 20 x 22%) / 70			(0.38 x 0.2 x 20 x 0.01 x 22%) / 70		
External dermal exposure	1.52	mg/person	External dermal exposure	0.0152	mg/person
External dermal exposure	0.021714	mg/kg bw/d	External dermal exposure	0.000217	mg/kg bw/d
Systemic dermal exposure	**0.004777**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000048**	**mg/kg bw/d**
Body			Body		
$SDE_{OA(B)} = (D_{A(B)} \times AR \times A \times DA) / BW$			$SDE_{OA(B)} = (D_{A(B)} \times AR \times A \times PPE$ [2)] $\times DA) / BW$		
(1.6 x 0.2 x 20 x 22%) / 70			(1.6 x 0.2 x 20 x 0.05 x 22%) / 70		
External dermal exposure	6.4	mg/person	External dermal exposure	0.32	mg/person
External dermal exposure	0.091429	mg/kg bw/d	External dermal exposure	0.004571	mg/kg bw/d

Systemic dermal exposure	**0.020114**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.001006**	**mg/kg bw/d**
Head			Head		
$SDE_{OA(C)} = (D_{A(C)} \times AR \times A \times DA) / BW$			$SDE_{OA(C)} = (D_{A(C)} \times AR \times A \times DA) / BW$		
(0.06 x 0.2 x 20 x 22%) / 70			(0.06 x 0.2 x 20 x 22%) / 70		
External dermal exposure	0.24	mg/person	External dermal exposure	0.24	mg/person
External dermal exposure	0.003429	mg/kg bw/d	External dermal exposure	0.003429	mg/kg bw/d
Systemic dermal exposure	**0.000754**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000754**	**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	17.76	mg/person	Total external dermal exposure	0.6712	mg/person
Total external dermal exposure	0.253714	mg/kg bw/d	Total external dermal exposure	0.009589	mg/kg bw/d
Total systemic dermal exposure	**0.027017**	**mg/kg bw/d**	**Total systemic dermal exposure**	**0.001821**	**mg/kg bw/d**
Operators: Systemic inhalation exposure after application in potatoes					
Inhalation exposure during mixing/loading					
$SIE_{OM} = (I_M \times AR \times A \times IA) / BW$			$SIE_{OM} = (I_M \times AR \times A \times IA) / BW$		
(0.0006 x 0.2 x 20 x 100%) / 70			(0.0006 x 0.2 x 20 x 100%) / 70		
External inhalation exposure	0.0024	mg/person	External inhalation exposure	0.0024	mg/person
External inhalation exposure	0.000034	mg/kg bw/d	External inhalation exposure	0.000034	mg/kg bw/d
Systemic inhalation exposure	**0.000034**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000034**	**mg/kg bw/d**
Inhalation exposure during application					
$SIE_{OA} = (I_A \times AR \times A \times IA) / BW$			$SIE_{OA} = (I_A \times AR \times A \times IA) / BW$		
(0.001 x 0.2 x 20 x 100%) / 70			(0.001 x 0.2 x 20 x 100%) / 70		
External inhalation exposure	0.004	mg/person	External inhalation exposure	0.004	mg/person
External inhalation exposure	0.000057	mg/kg bw/d	External inhalation exposure	0.000057	mg/kg bw/d
Systemic inhalation exposure	**0.000057**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000057**	**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	0.0064	mg/person	Total external inhalation exposure	0.0064	mg/person
Total external inhalation exposure	0.000091	mg/kg bw/d	Total external inhalation exposure	0.000091	mg/kg bw/d
Total systemic inhalation exposure	**0.000091**	**mg/kg bw/d**	**Total systemic inhalation exposure**	**0.000091**	**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	1.8976	mg/person	Total systemic exposure	0.133904	mg/person
Total systemic exposure	**0.027109**	**mg/kg bw/d**	**Total systemic exposure**	**0.001913**	**mg/kg bw/d**
% of AOEL	**677.7**	**%**	**% of AOEL**	**47.8**	**%**

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

2) reduction factor for protective garment is 0.05 (professional appl.)

Table A 23: Estimation of operator exposure towards fluazinam using the UK-POEM (no PPE)

Active substance	**Fluazinam**		
Product	BANJO Forte		
Formulation type	water-based		
Concentration of a.s.	200	mg/mL	
Dose	1	L preparation/ha	(0.2 kg a.s./ha)
Application volume	300	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	1	%	
Dermal absorption from spray	22	%	
EXPOSURE DURING MIXING AND LOADING			
Container size	5	Litres	
Hand contamination/operation	0,01	mL	
Application dose	1	Litres product/ha	

Work rate	50	ha/day		
Number of operations	10	/day		
Hand contamination	0.1	mL/day		
Protective clothing	None			
Transmission to skin	100	%		
Dermal exposure to formulation	0.1	mL/day		
DERMAL EXPOSURE DURING SPRAY APPLICATION				
Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles			
Application volume	300	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	0.1	mL/day	41.55	mL/day
Concen. of a.s. product or spray	200	mg/mL	0.667	mg/mL
Dermal exposure to a.s.	20	mg/day	27.7	mg/day
Percent absorbed	1	%	22	%
Absorbed dose	0.2	mg/day	6.094	mg/day
INHALATION EXPOSURE DURING SPRAYING				
Inhalation exposure	0.01	mL/h		
Duration of exposure	6	h		
Concentration of a.s. in spray	0.667	mg/mL		
Inhalation exposure to a.s.	0.04	mg/day		
Percent absorbed	100	%		
Absorbed dose	0.04	mg/day		
PREDICTED EXPOSURE				
Total absorbed dose	6.334	mg/day		
Operator body weight	60	kg		
Operator exposure	0.106	mg/kg bw/day		
Amount of AOEL	**2639.2**	**%**		

Table A 24: Estimation of operator exposure towards fluazinam using the UK-POEM (gloves mixing/loading and application)

Active substance	**Fluazinam**		
Product	BANJO Forte		
Formulation type	water-based		
Concentration of a.s.	200	mg/mL	
Dose	1	L preparation/ha	(0.2 kg a.s./ha)
Application volume	300	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	1	%	
Dermal absorption from spray	22	%	
EXPOSURE DURING MIXING AND LOADING			
Container size	5	Litres	
Hand contamination/operation	0,01	mL	

Application dose	1	Litres product/ha			
Work rate	50	ha/day			
Number of operations	10	/day			
Hand contamination	0.1	mL/day			
Protective clothing	Gloves				
Transmission to skin	5	%			
Dermal exposure to formulation	0.005	mL/day			
DERMAL EXPOSURE DURING SPRAY APPLICATION					
Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles				
Application volume	300	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	0.005	mL/day		6.45	mL/day
Concen. of a.s. product or spray	200	mg/mL		0.667	mg/mL
Dermal exposure to a.s.	1	mg/day		4.3	mg/day
Percent absorbed	1	%		22	%
Absorbed dose	0.01	mg/day		0.946	mg/day
INHALATION EXPOSURE DURING SPRAYING					
Inhalation exposure	0.01	mL/h			
Duration of exposure	6	h			
Concentration of a.s. in spray	0.667	mg/mL			
Inhalation exposure to a.s.	0.04	mg/day			
Percent absorbed	100	%			
Absorbed dose	0.04	mg/day			
PREDICTED EXPOSURE					
Total absorbed dose	0.996	mg/day			
Operator body weight	60	kg			
Operator exposure	0.017	mg/kg bw/day			
Amount of AOEL	**415.0**	**%**			

A 3.2 Worker exposure calculations

A 3.2.1 Calculations for dimethomorph

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

Intended use(s):	Potatoes		**Dislodgeable foliar residues (DFR):**	1	µg/cm²/kg a.s.
Application rate (AR):	0.2	kg a.s./ha	**Transfer coefficient (TC):**	2500	cm²/person/h
Number of applications (NA):	4		**Work rate per day (WR):**	2	h/d
Body weight (BW):	60	kg/person	**PPE**	5	%
Dermal absorption (DA):	17	% ('worst case')			
AOEL	0.15	mg/kg bw/d			

Table A 26: Estimation of worker exposure towards dimethomorph using the German re-entry model

Without PPE [1]			**With PPE** [2]		
Worker (re-entry): Systemic dermal exposure after application in potatoes					
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 2500 x 2 x 0.2 x 4 x 17%) / 60			(1 x 2500 x 2 x 0.2 x 4 x 5% x 17%) / 60		
External dermal exposure	4	mg/person	External dermal exposure	0.2	mg/person
External dermal exposure	0.066667	mg/kg bw/d	External dermal exposure	0.003333	mg/kg bw/d
Total systemic exposure	0.68	mg/person	Total systemic exposure	0.034	mg/person
Total systemic exposure	**0.011333**	**mg/kg bw/d**	**Total systemic exposure**	**0.000567**	**mg/kg bw/d**
% of AOEL	**7.6**	**%**	**% of AOEL**	**0.4**	**%**

[1] acceptable without PPE: Worker wearing long sleeved shirt, long trousers ("permeable") but no gloves (allocation of BVL code SF245-01 for spray applications)

[2] acceptable only with PPE: see 'Instructions for use' (allocation of BVL code SF1891 (cf. Krebs et al., 2000))

A 3.2.2 Calculations for fluazinam

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

Intended use(s):	Potatoes		**Dislodgeable foliar residues (DFR):**	1	µg/cm²/kg a.s.
Application rate (AR):	0.2	kg a.s./ha	**Transfer coefficient (TC):**	2500	cm²/person/h
Number of applications (NA):	4		**Work rate per day (WR):**	2	h/d
Body weight (BW):	60	kg/person	**PPE**	5	%
Dermal absorption (DA):	22	% ('worst case')			
AOEL	0.004	mg/kg bw/d			

Table A 28: Estimation of worker exposure towards fluazinam using the German re-entry model

Without PPE [1]			**With PPE** [2]		
Worker (re-entry): Systemic dermal exposure after application in potatoes					
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 2500 x 2 x 0.2 x 4 x 22%) / 60			(1 x 2500 x 2 x 0.2 x 4 x 5% x 22%) / 60		
External dermal exposure	4	mg/person	External dermal exposure	0.2	mg/person
External dermal exposure	0.066667	mg/kg bw/d	External dermal exposure	0.003333	mg/kg bw/d
Total systemic exposure	0.88	mg/person	Total systemic exposure	0.044	mg/person
Total systemic exposure	**0.014667**	**mg/kg bw/d**	**Total systemic exposure**	**0.000733**	**mg/kg bw/d**
% of AOEL	**366.7**	**%**	**% of AOEL**	**18.3**	**%**

[1] acceptable without PPE: Worker wearing long sleeved shirt, long trousers ("permeable") but no gloves (allocation of BVL code SF245-01 for spray applications)

[2] acceptable only with PPE: see 'Instructions for use' (allocation of BVL code SF1891 (cf. Krebs et al., 2000))

A 3.3 Bystander and resident exposure calculations

A 3.3.1 Calculations for dimethomoprh

Table A 29: Input parameters considered for the estimation of bystander exposure

Intended use(s):	Potatoes		**Drift (D):**	2.77	% (FC, 1 m)
Application rate (AR):	0.2	kg a.s./ha	**Exposed body surface area (BSA):**	1	m² (adults)
	20	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):	17	%	**Area Treated (A):**	20	ha/d (based on FCTM)
Inhalation absorption (IA):	100	%			
AOEL:	0.15	mg/kg bw/d	**Exposure duration (T):**	5	min

Table A 30: Estimation of bystander exposure towards dimethomorph

Adults			**Children**		
Bystander: Systemic dermal exposure during/after application on potatoes (via spray drift)					
SDE_B = (AR x D x BSA x DA) / BW			SDE_B = (AR x D x BSA x DA) / BW		
(20 x 2.77% x 1 x 17%) / 60			(20 x 2.77% x 0.21 x 17%) / 16.15		
External dermal exposure	0.554	mg/person	External dermal exposure	0.11634	mg/person
External dermal exposure	0.009233	mg/kg bw/d	External dermal exposure	0.007204	mg/kg bw/d
Systemic dermal exposure	**0.00157**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.001225**	**mg/kg bw/d**
Bystander: Systemic inhalation exposure during/after application on potatoes (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 0.2 x 20 x 5 x 100%) / 60			(0.000575 / 360 x 0.2 x 20 x 5 x 100%) / 16.15		
External inhalation exposure	0.000056	mg/person	External inhalation exposure	0.000032	mg/person
External inhalation exposure	0.000001	mg/kg bw/d	External inhalation exposure	0.000002	mg/kg bw/d
Systemic inhalation exposure	**0.000001**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000002**	**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	0.094236	mg/person	Total systemic exposure	0.01981	mg/person
Total systemic exposure	**0.001571**	**mg/kg bw/d**	**Total systemic exposure**	**0.001227**	**mg/kg bw/d**
% of AOEL	**1.0**	**%**	**% of AOEL**	**0.8**	**%**

Table A 31: Input parameters considered for the estimation of resident exposure

Intended use(s):	Potatoes		**Drift (D):**	1.85	% (FC, 1 m, 4 appl.)
Application rate (AR):	0.2	kg a.s./ha	**Transfer coefficient (TC):**	7300	cm^2/h (adults)
	0.002	mg/cm^2		2600	cm^2/h (children)
Number of applications (NA):	4		**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):	17	%	**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:	0.15	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 32: Estimation of resident exposure towards dimethomorph

Adults			**Children**		
Residents: Systemic dermal exposure after application on potatoes (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		
(0.002 x 4 x 1.85% x 5% x 7300 x 2 x 17%) / 60			(0.002 x 4 x 1.85% x 5% x 2600 x 2 x 17%) / 16.15		
External dermal exposure	0.10804	mg/person	External dermal exposure	0.03848	mg/person
External dermal exposure	0.001801	mg/kg bw/d	External dermal exposure	0.002383	mg/kg bw/d
Systemic dermal exposure	**0.000306**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000405**	**mg/kg bw/d**
Residents: Systemic inhalation exposure after application on potatoes (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		
			(0.002 x 4 x % x 5% x 50% x 20 x 20 x 2 x 100%) / 16.15		
			External oral exposure	0.00296	mg/person

			External oral exposure	0.000183	mg/kg bw/d
			Systemic oral exposure	**0.000183**	**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		
			(0.002 x 4 x % x 20% x 25 x 100%) / 16.15		
			External oral exposure	0.00074	mg/person
			External oral exposure	0.000046	mg/kg bw/d
			Systemic oral exposure	**0.000046**	**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	0.018367	mg/person	Total systemic exposure	0.010242	mg/person
Total systemic exposure	**0.000306**	**mg/kg bw/d**	**Total systemic exposure**	**0.000634**	**mg/kg bw/d**
% of AOEL	**0.2**	**%**	**% of AOEL**	**0.4**	**%**

A 3.3.2 Calculations for fluazinam

Table A 33: Input parameters considered for the estimation of bystander exposure

Intended use(s):	Potatoes		**Drift (D):**	2.77	% (FC, 1 m)
Application rate (AR):	0.2	kg a.s./ha	**Exposed body surface area (BSA):**	1	m² (adults)
	20	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):	22	%	**Area Treated (A):**	20	ha/d (based on FCTM)
Inhalation absorption (IA):	100	%			
AOEL:	0.004	mg/kg bw/d	**Exposure duration (T):**	5	min

Table A 34: Estimation of bystander exposure towards fluazinam

Adults			**Children**		
Bystander: Systemic dermal exposure during/after application on potatoes (via spray drift)					
SDE_B = (AR x D x BSA x DA) / BW			SDE_B = (AR x D x BSA x DA) / BW		
(20 x 2.77% x 1 x 22%) / 60			(20 x 2.77% x 0.21 x 22%) / 16.15		
External dermal exposure	0.554	mg/person	External dermal exposure	0.11634	mg/person
External dermal exposure	0.009233	mg/kg bw/d	External dermal exposure	0.007204	mg/kg bw/d
Systemic dermal exposure	**0.002031**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.001585**	**mg/kg bw/d**
Bystander: Systemic inhalation exposure during/after application on potatoes (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 0.2 x 20 x 5 x 100%) / 60			(0.000575 / 360 x 0.2 x 20 x 5 x 100%) / 16.15		
External inhalation exposure	0.000056	mg/person	External inhalation exposure	0.000032	mg/person
External inhalation exposure	0.000001	mg/kg bw/d	External inhalation exposure	0.000002	mg/kg bw/d
Systemic inhalation exposure	**0.000001**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000002**	**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	0.121936	mg/person	Total systemic exposure	0.025627	mg/person
Total systemic exposure	**0.002032**	**mg/kg bw/d**	**Total systemic exposure**	**0.001587**	**mg/kg bw/d**
% of AOEL	**50.8**	**%**	**% of AOEL**	**39.7**	**%**

Table A 35: Input parameters considered for the estimation of resident exposure

Intended use(s):	Potatoes		**Drift (D):**	1.85	% (FC, 1 m, 4 appl.)
Application rate (AR):	0.2	kg a.s./ha	**Transfer coefficient (TC):**	7300	cm^2/h (adults)
	0.002	mg/cm^2		2600	cm^2/h (children)
Number of applications (NA):	4		**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):	22	%	**Inhalation Rate (IR):**	16.57	m^3/d (adults)
Inhalation absorption (IA):	100	%		8.31	m^3/d (children)

Oral absorption (OA):	35	%	**Saliva Extraction Factor (SE):**	50	%
AOEL:	0.004	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

* Five vapour pressure studies have been submitted by the applicant (airborne concentration of 0.001 mg/m3 has been used as default value for calculation).

Table A 36: Estimation of resident exposure towards fluazinam

Adults			**Children**		
Residents: Systemic dermal exposure after application on potatoes (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		
(0.002 x 4 x 1.85% x 5% x 7300 x 2 x 22%) / 60			(0.002 x 4 x 1.85% x 5% x 2600 x 2 x 22%) / 16.15		
External dermal exposure	0.10804	mg/person	External dermal exposure	0.03848	mg/person
External dermal exposure	0.001801	mg/kg bw/d	External dermal exposure	0.002383	mg/kg bw/d
Systemic dermal exposure	**0.000396**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000524**	**mg/kg bw/d**
Residents: Systemic inhalation exposure after application on potatoes (via vapour)					
SIE_R = (AC_V x IR x IA) / BW			SIE_R = (AC_V x IR x 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 x NA x D x TTR x SE x SA x Freq x H x OA) / BW		
			(0.002 x 4 x % x 5% x 50% x 20 x 20 x 2 x 35%) / 16.15		
			External oral exposure	0.00296	mg/person
			External oral exposure	0.000183	mg/kg bw/d
			Systemic oral exposure	**0.000064**	**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		
			(0.002 x 4 x % x 20% x 25 x 35%) / 16.15		
			External oral exposure	0.00074	mg/person
			External oral exposure	0.000046	mg/kg bw/d
			Systemic oral exposure	**0.000016**	**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	0.040339	mg/person	Total systemic exposure	0.018071	mg/person
Total systemic exposure	**0.000672**	**mg/kg bw/d**	**Total systemic exposure**	**0.001119**	**mg/kg bw/d**
% of AOEL	**16.8**	**%**	**% of AOEL**	**28.0**	**%**

DRAFT REGISTRATION REPORT
Part B

Section 4: Metabolism and Residues

Detailed summary of the risk assessment

Product code: BANJO forte (MCW-853 SC)

Active Substance: Dimethomorph 200 g/L
Fluazinam 200 g/L

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: ADAMA Deutschland

Date: April 2015

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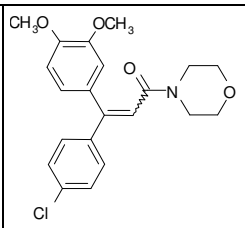
4 METABOLISM AND RESIDUES DATA

4.1 Evaluation of the active substances

4.1.1 Dimethomorph

Table 4.1-1: Identity of the active substance

Structural formula	
Common Name	Dimethomorph
CAS number	110488-70-5

4.1.1.1 Storage stability

A brief summary of the storage stability data on dimethomorph is given in the following table. Data, which has been previously evaluated at EU level is described in detail in the DAR (Germany 2004, ASB2010-10454) and in the conclusion of the peer review (EFSA 2006, ASB2008-3994).

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

Stability of dimethomorph	Plant matrices – grapes (RIP2000-723: 18 months, RIP2000-725: 24 months): ≤-18°C, stable over at least 24 months – grape must, grape pomace, raisins (RIP2000-727): -18°C, stable over at least 16 months (must, pomace) or 14 months (raisins) – potatoes (RIP2002-829): -18°C, stable over at least 24 months

4.1.1.2 Metabolism in plants and plant residue definition

A brief summary of the metabolism of dimethomorph in plants is given in the following table. Data, which has been previously evaluated at EU level is described in detail in the DAR (Germany 2004, ASB2010-10454), in the conclusion of the peer review (EFSA 2006, ASB2008-3994) and in EFSA's Reasoned Opinion concerning the review of the existing MRLs for dimethomorph according to Article 12 of Regulation (EC) No 396/2005 (EFSA 2011, ASB2012-3232).

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	–Potatoes (RIP2002-744; supplement: RIP2002-745): indoors, [^{14}C] chlorophenyl label, 4x0.6 kg/ha, PHI 7 days – Potatoes (RIP2002-747; supplement: RIP2002-748): indoors, [^{14}C] morpholine label, 4x0.6 kg/ha, PHI 7 days – Potatoes (RIP9700382): outdoors, [^{14}C] chlorophenyl label, 3x0.3 kg/ha (in a lysimeter), PHI ca 28 days – Grapes (RIP2002-736, amendment: RIP2002-737): outdoor, [^{14}C] chlorophenyl ring label; 0.9 g/L, PHI 35 days, grapes and leaves treated by syringe – Lettuce (RIP2002-749): outdoor, [^{14}C] chlorophenyl ring label, 4x 1.14 kg/ha, PHI 4 days The degradation of dimethomorph was limited. At harvest, the unchanged parent compound represented the major portion of the radioactive residues in all investigated plant parts (86.5 % and 83 % of the TRR in grapes and grape leaves, respectively; 93 % of the TRR in lettuce; 70.5 % of the TRR in potato green matter and very low TRR in potato tubers: 0.056 mg/kg and 0.003 mg/kg in tuber peels and peeled tubers, respectively). Only relatively small amounts of metabolites were detected; none of them is expected to contribute significantly to the toxicological burden.
Rotational crops	Confined study (RIP2002-821): 4 kg as/ha to bare soil, [^{14}C] chlorophenyl label, PBI 29, 120 and 371 days, rotational crops carrots, pre-cultivated lettuce and wheat, grown under laboratory conditions The residues declined in all samples (both soil and plant) with time. Dimethomorph was the only identified (but not quantified) compound of the residue.
Metabolism in rotational crops similar to metabolism in primary crops? (yes/no)	yes
Distribution of the residue in peel/ pulp	0.13 (peeling factor for oranges according to EFSA's Reasoned Opinion ASB2012-3232)
Processed commodities (nature of residue)	Hydrolysis studies (ASB2010-13802) with unlabelled parent simulating sterilization (20 minutes at 120°C, pH 6), baking, brewing, boiling (60 minutes at 100°C pH 5) and pasteurization (20 minutes at 90°C, pH 4) showed that dimethomorph is hydrolytically stable under these conditions.
Residue pattern in raw and processed commodities similar? (yes/no)	yes
Plant residue definition for monitoring	Reg. (EC) No 396/2005: Dimethomorph (sum of isomers)
Plant residue definition for risk assessment	EFSA Scientific report (2006) 82, 1-69: Dimethomorph EFSA Reasoned Opinion – EFSA Journal 2011;9(8):2348: Dimethomorph
Conversion factor(s) (monitoring to risk assessment)	none

4.1.1.3 Metabolism in livestock and animal residue definition

A brief summary of the metabolism of dimethomorph in livestock is given in the following table. Data, which has been previously evaluated at EU level is described in detail in the DAR (Germany 2004, ASB2010-10454) and in the conclusion of the peer review (EFSA 2006, ASB2008-3994).

Table 4.1-4: Metabolism in livestock (Annex IIA, point 6.2.2 to 6.2.5 and 6.7.1)

Animals covered	Lactating goat (RIP2002-752; amendment: RIP2000-731): [^{14}C] chlorophenyl label, 1 mg/kg bw/d, corresponding to approx. 25 mg/kg feed, 15 doses at 8 consecutive days Total radioactive residues were almost completely extractable from edible tissues and were highest in liver (7.1 mg/kg), while in kidney 0.3 mg/kg and in muscle 0.04 mg/kg were found. There was no accumulation seen. The major component of the extractable residue in kidney, liver, muscle and fat was parent compound, representing 9%, 73% and 75 % of the TRR respectively. The metabolites Z67 and Z69 detected in liver indicate that dimethomorph is initially metabolised via demethylation of one of the phenolic methoxy-groups. In addition morpholine-ring cleavage and degradation, was observed leading to metabolite CUR 7117 which is the only compound identified in milk, representing 48 % of the TRR. Laying hens (RIP2002-770, amendment: RIP2000-730): [^{14}C] chlorophenyl label, 2 mg/kg bw/d, corresponding to approx. 40 mg/kg feed, 15 doses at 8 consecutive days TRR in edible tissues ranged from 0.016 mg/kg (muscle) to 1.05 mg/kg (liver). Extractability of residues was high and parent compound was present in fat only. The metabolic pattern observed in tissues indicates that the degradation pathway in laying hens is similar to that observed in goat, being based on demethylation of the phenolic methoxy groups and on degradation of the morpholine ring.
Time needed to reach a plateau concentration in milk and eggs	4 days (milk) 3 days (eggs)
Animal residue definition for monitoring	Reg. (EC) No 396/2005: Dimethomorph (sum of isomers)
Animal residue definition for risk assessment	EFSA Scientific report (2006) 82, 1-69: Dimethomorph (for poultry and milk, this is to be considered as a default residue definition) EFSA Reasoned Opinion – EFSA Journal 2011;9(8):2348: Dimethomorph
Conversion factor(s) (monitoring to risk assessment)	none
Metabolism in rat and ruminant similar (yes/no)	yes
Fat soluble residue: (yes/no)	no, log $P_{O/W}$ = 2.7; in addition, there was no indication of accumulation in metabolism studies

4.1.1.4 Residues in rotational crops

A brief summary of the field rotational crop studies on dimethomorph is given in the following table. Data, which has been previously evaluated at EU level is described in detail in the DAR (Germany 2004, ASB2010-10454) and in the conclusion of the peer review (EFSA 2006, ASB2008-3994).

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

Field studies	Field studies in Germany, 1991 (RIP2002-822) and 1992 (RIP2002-823): carrots, spinach and beans as follow-up crops sown within 30 days after the last of 3 applications of 180 g as/ha on potatoes. Residues determined in soil were 0.13 mg/kg at planting and 0.006 mg/kg at harvest. In the majority of the harvested samples the dimethomorph residues were seen below LOQ or in a range of <0.01 to 0.09 mg/kg; only in one spinach sample 0.21 mg/kg were found. EFSA concluded on the need for a plant-back restriction to be considered at national level before granting authorizations (ASB2012-3232).

4.1.1.5 Residues in livestock

An actual calculation of the dietary burden (based on residue data reported in the EU and all relevant uses authorized in the Germany) is provided in Table 4.1-6.

Table 4.1-6: Calculation of the dietary burden (based on residue data reported in the EU and all relevant uses authorized in Germany)

Feedstuff	% TM	Percent of daily livestock diet (dry feed basis)				Residues (mg/kg)	Intake (mg/kg, dry feed basis)			
		Chicken	Dairy cattle	Beef cattle	Pig		Chicken	Dairy cattle	Beef cattle	Pig
		1.9 kg bw	550 kg bw	350 kg bw	75 kg bw					
		daily maximum feed (DM) 120 g	daily maximum feed (DM) 20 kg	daily maximum feed (DM) 15 kg	daily maximum feed (DM) 3 kg					
potato	15	20	30	60	60	0.14 [a]	0.067	0.100	0.200	0.200
rape seed	86	10	30	30	20	0.020 [b]	0.002	0.007	0.007	0.005
citrus pomace	23	00	10	30	00	0.48 [C]	0.000	0.209	0.626	0.000
				Intake (mg/kg dry weight feed)			0.189	0.496	1.193	0.565
				Intake (mg/kg bw/d)			0.012	0.018	0.051	0.023
				Intake (mg/animal/d)			0.023	9.913	17.896	1.694

[a] HR, based on cGAP: 3 x 0,18 kg as/ha, PHI: 7 d
[b] STMR, based on cGAP: 1 x 5 g as/kg seed, corresponding to 25 g as/ha, PHI: F
[c)] STMR-P, 2 x 0.41 kg as/ha, PHI 7 days (GAP of SEU, ASB2012-3232)

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

	Ruminant:	**Poultry:**	**Pig:**
Expected intakes by livestock ≥0.1 mg/kg diet (dry weight basis) (yes/no – If yes, specify the level)	yes 1.2 mg/kg	yes 0.19 mg/kg	yes 0.57 mg/kg
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 (liver)	no	yes (liver)

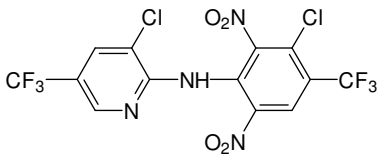
A brief summary of the available livestock feeding studies is given in the following table. Data, which has previously been evaluated at EU level is described in detail in the DAR (Germany 2004, ASB2010-10454) and in the conclusion of the peer review (EFSA 2006, ASB2008-3994).

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

	Ruminant:	**Poultry:**	**Pig:**
Feeding levels (mg/kg feed dry matter) in feeding studies	lactating cows: 2.5, 7.5, 25 (RIP2002-807, supplement: RIP2002-808)	--	--
Relevant dosing levels in feeding study:	2.5	--	2.5
	Expected residue levels in animal matrices (mg/kg):		
Muscle	<0.01	<0.01	<0.01
Liver	<0.01	<0.01	<0.01
Kidney	<0.01	<0.01	<0.01
Fat	<0.01	<0.01	<0.01
Milk	<0.01		
Eggs		<0.01	

4.1.2 Fluazinam

Table 4.1-9: Identity of the active substance

Structural formula	
Common Name	Fluazinam
CAS number	79622-59-6

4.1.2.1 Storage stability

A brief summary of the storage stability data on fluazinam is given in the following table. Data, which has been previously evaluated at EU level is described in detail in the DAR (Austria 2005, ASB2010-10459) and in the conclusion of the peer review (EFSA 2008, ASB2012-3623).

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

Stability of fluazinam	Potato tubers (ASB2010-7046): stable at -20°C for the investigated period of 6 months.

4.1.2.2 Metabolism in plants and plant residue definition

A brief summary of the metabolism of fluazinam in plants is given in the following table. Data, which has been previously evaluated at EU level is described in detail in the DAR (Austria 2005, ASB2010-10459) and in the conclusion of the peer review (EFSA 2008, ASB2012-3623).

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	Root vegetables Potatoes (RIP2003-1894): outdoor, foliar spray, 4x 0.5 kg/ha phenyl-[^{14}C]- or 4x 0.43 kg as/ha pyridyl-[^{14}C]-labelled fluazinam Low TRR in tubers with 0.01 mg/kg (phenyl-label) and 0.025 mg/kg (pyridyl-label). Parent accounted for only 2.3 – 5.9 % TRR but was the main residue. Similar amounts of some structurally related compounds (AMPA-fluazinam, AMGT) were seen. Non-extractable residues were at about 50 % TRR. First steps of the metabolic pathway of fluazinam in plants involve reduction of one or both nitro groups to form AMPA-fluazinam or DAPA, loss of the phenyl-ring chlorine by glutathione conjugation to form AMGT11 and substitution of one nitro group by a hydroxyl group. Further, metabolism proceeds through cleavage of the compound, followed by opening and fragmentation of the resulting pyridyl and nitrophenyl moieties. TFAA was identified as a result of this fragmentation process, present together with other ultimate unidentified degradation products, entering the organic carbon pool of the plant.
Rotational crops	Confined study (RIP2004-1605, addendum: RIP2004-1606, sub-part 1: RIP2004-1608): outdoor, phenyl-[^{14}C]- or pyridyl-[^{14}C]-labelled fluazinam, 2x 1.12 kg/ha applied to bare soil, rotational crops lettuce, carrots, barley sewn/planted at PBIs of 30, 120 and 365 days Parent fluazinam or other related compounds with intact two-ring structure were not found in the rotational crops. Following cleavage and extensive metabolic degradation of the parent molecule the residues in the rotational crops were fragments of containing either the phenyl or the pyridine ring. In confined studies TFAA was present in amounts exceeding 0.05 mg/kg in mature lettuce, carrot roots and barley grain, after application of the total annual rate of fluazinam onto bare soil. ^{14}C was also found to have been reincorporated into natural plant products such as starch.
Metabolism in rotational crops similar to metabolism in primary crops? (yes/no)	To a large extent comparable, with two exceptions: – TFAA occurred in significant amounts in all rotational crops, while in primary treated potatoes it was observed in traces only. – Parent fluazinam was not detected in any extract from any rotational crop sample.
Distribution of the residue in peel/ pulp	no data
Processed commodities (nature of residue)	No processing studies required.
Residue pattern in raw and processed commodities similar? (yes/no)	Not applicable
Plant residue definition for monitoring	Fluazinam (according to EU peer review restricted to potatoes, but MRLs for other commodities with DoR “fluazinam” are in place)

Plant residue definition for risk assessment	Sum of fluazinam, AMPA-fluazinam and AMGT, expressed as fluazinam (provisional, as no risk assessment related to TFAA can be conducted at this stage).
Conversion factor(s) (monitoring to risk assessment)	3 (for potatoes only)

4.1.2.3 Metabolism in livestock and animal residue definition

A brief summary of the metabolism of fluazinam in livestock is given in the following table. Data, which has been previously evaluated at EU level is described in detail in the DAR (Austria 2005, ASB2010-10459) and in the conclusion of the peer review (EFSA 2008, ASB2012-3623).

Table 4.1-12: Metabolism in livestock (Annex IIA, point 6.2.2 to 6.2.5 and 6.7.1)

Animals covered	Livestock metabolism on lactating goat and laying hen were evaluated in the DAR, but the studies were not submitted by the notifier.
Time needed to reach a plateau concentration in milk and eggs	Milk: plateau level reached after 4 days. Eggs: plateau level not reached during the study (4 days).
Animal residue definition for monitoring	Not required In Reg (EC) No 396/2005 MRLs for animal commodities have nevertheless been set for a DoR as fluazinam.
Animal residue definition for risk assessment	Not required
Conversion factor(s) (monitoring to risk assessment)	Not applicable
Metabolism in rat and ruminant similar (yes/no)	Yes
Fat soluble residue: (yes/no)	Yes (log P_{OW} = 4.03 at 25 °C), but accumulation of active substance or metabolites in animal tissues, milk and eggs was not observed.

4.1.2.4 Residues in rotational crops

Field rotational crop studies on fluazinam further to the confined study described above were neither available nor required. This is briefly explained in the following table.

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

Field studies	Fluazinam was not translocated into deeper soil layers but fluazinam or related residues were observed to be persistent in the upper soil layer. In rotational crop studies TRR declined with PBI. Parent fluazinam was not detected in any extract from any crop sample. Structurally related residues still retaining the basic fluazinam two ring moiety remained below relevant levels in edible parts of the crops. The main part of the radioactivity recovered was TFAA (trifluoroacetic acid) at a level of up to 0.27 mg/kg.

4.1.2.5 Residues in livestock

Table 4.1-14: Calculation of the dietary burden

Feedstuff	% DM	Percent of daily livestock diet (dry feed basis)				Residue (mg/kg)	Intake (mg/kg, dry feed basis)			
		Chicken 1,9 kg bw daily maximum feed (DM) 120 g	Dairy cattle 550 kg bw daily maximum feed (DM) 20 kg	Beef cattle 350 kg bw daily maximum feed (DM) 15 kg	Pig 75 kg bw daily maximum feed (DM) 3 kg		Chicken	Dairy cattle	Beef cattle	Pig
Potatoes	15	20	30	60	60	0.057 [a]	0.076	0.114	0.228	0.228
					Intake (mg/kg dry weight feed)		**0.076**	**0.114**	**0.228**	**0.228**
					Intake (mg/kg bw/d)		**0.005**	**0.004**	**0.010**	**0.009**
					Intake (mg/animal/d)		**0.009**	**2.280**	**3.420**	**0.684**

[a] HR, based on the following cGAP: 4x 0.2 kg as/ha, PHI: 7 days

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

	Ruminant:	**Poultry:**	**Pig:**
Expected intakes by livestock ≥0.1 mg/kg diet (dry weight basis) (yes/no – If yes, specify the level)	yes: 0.23 mg/kg	no	yes: 0.23 mg/kg
Potential for accumulation (yes/no):	no	no	no
Metabolism studies indicate potential level of residues ≥0.01 mg/kg in edible tissues (yes/no)	no	no	no

The metabolism study performed with lactating goats only showed very low residues in edible tissues (max. 1.24 % TRR, 0.84 mg as-eq/kg in liver). As the dosing at 11 mg/kg feed was about 50 times higher than the worst case intake, concentrations below the LOQ can be expected in tissues for fluazinam and metabolites. Consequently no feeding study is required.

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

	Ruminant:	**Poultry:**	**Pig:**
Feeding levels (mg/kg feed dry matter) in feeding studies	Feeding studies: not required.		
Relevant dosing levels in feeding study:			
	Expected residue levels in animal matrices (mg/kg):		
Muscle	<0.05	<0.05	<0.05
Liver	<0.05	<0.05	<0.05
Kidney	<0.05	<0.05	<0.05
Fat	<0.05	<0.05	<0.05
Milk	<0.05		
Eggs		<0.05	

4.2 Evaluation of the intended use

4.2.1 Selection of critical use and justification

The only GAP reported for the zone/EU is presented in Table 4.2-1. It has been used for consumer intake and risk assessment.

Table 4.2-1: Critical Use (worst case) used for consumer intake and risk assessment

1	2	3	4	5	6	7	8	9	10	11	12	13
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)** **(a)**	**F G or I** **(b)**	**Pests or Group of pests controlled** **(additionally: developmental stages of the pest or pest group)** **(c)**	**Application**			**Application rate**			**PHI (days) (i)**	**Remarks:** **e.g. safener/synergist per ha** **e.g. recommended or mandatory tank mixtures** **(j)**
					Method / Kind **(d-f)**	**Timing / Growth stage of crop & season** **(g)**	**Max. number (min. interval between applications)** **a) per use** **b) per crop/ season (h)**	**L product / ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**kg as/ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**Water L/ha** **min / max**		
1	DE	Potatoes (0211000)	F	Late blight of potato (*Phytophthora infestans*)	spraying	In case of danger of infection and/or after warning service appeal	a) 4 b) 4 (7-10 days)	a) 1 L/ha b) 4 L/ha	a) 0.2 kg dimethomorph/ha 0.2 kg fluazinam/ha b) 0.8 kg dimethomorph/ha 0.8 kg fluazinam/h	300-600	7	

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 Potatoes

4.2.2.1 Residues in primary crops

The following tables give a brief overview of the supervised residue trials selected for the assessment of dimethomorph and fluazinam in potatoes. For the detailed evaluation of new/additional residue trials, it is referred to Appendix 2.

Table 4.2-2: Overview of the selected supervised residue trials for dimethomorph in potatoes

Commodity	Region [a]	Outdoor/ Indoor	Individual trial results (mg/kg)		STMR (mg/kg) [b]	HR (mg/kg) [c]	Median CF [d]
			Enforcement (dimethomorph)	Risk assessment (dimethomorph)			
potatoes	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.

Additionally a total of 12 overdosed trials with residues below LOQ confirm the results of the selected studies (see Appendix 2).

Table 4.2-3: Overview of the selected supervised residue trials for fluazinam in potatoes

Commodity	Region [a]	Outdoor/ Indoor	Individual trial results (mg/kg)		STMR (mg/kg) [b]	HR (mg/kg) [c]	Median CF [d]
			Enforcement (fluazinam)	Risk assessment (fluazinam, AMPA-fluazinam and AMGT)[e]			
potatoes	NEU	Outdoor	<0.01(9), 0.013, 0.019	<0.03(9), 0.039, 0.057	0.03	0.057	3 (EFSA 2008, ASB2012-3623)

(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.
(e) Values were multiplied with the conversion factor 3

4.2.2.2 Distribution of the residue in peel/pulp

Not relevant.

4.2.2.3 Residues in processed commodities

Not relevant. Due to low residues at harvest, no processing studies are required.

4.2.2.4 Proposed pre-harvest intervals, withholding periods

The proposed PHI of 7 days (see GAP table) is acceptable.

4.3 Consumer intake and risk assessment

4.3.1 Dimethomorph

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

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
potatoes	0.01	STMR	0.01	HR
other commodities	variable	MRL	-	not necessary

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

ADI	0.05 mg/kg bw
TMDI (% ADI) according to EFSA PRIMo	45 % (based on based on WHO cluster diet B)
NTMDI (% ADI) according to NVS II	35 % (based on based on German children 2-4 years)
IEDI (EFSA PRIMo) (% ADI)	not necessary
NEDI (NVS II) (% ADI)	not necessary
Factors included in IEDI and NEDI	none
ARfD	0.6 mg/kg bw
IESTI (EFSA PRIMo) (% ARfD)	potatoes: 0.3 % (based on UK infants)
NESTI (NVS II) (% ARfD)	potatoes: <0.1 % (based on German children 2-4 years)
Factors included in IESTI and NESTI	none

4.3.2 Fluazinam

The consumer intake and risk assessment is based on the appropriate input values given in Table 8.3-3 and the toxicological reference values stated in Table 8.3-4. For the detailed calculation results it is referred to Appendix 3.

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

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
potatoes	0.03	STMR	0.057	HR
Grapes (wine)	0.19	MRL * 0.063 (processing factor)	-	not necessary
other commodities	variable	MRL	-	not necessary

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

ADI	0.01 mg/kg bw
TMDI (% ADI) according to EFSA PRIMo	128 % (based on FR all population)
NTMDI (% ADI) according to NVS II	63 % (based on German children 2-4 years)
IEDI (EFSA PRIMo) (% ADI)	56 % (based on DE child)
NEDI (NVS II) (% ADI)	not necessary
Factors included in IEDI	0.063 (processing factor for wine (Draft evaluation report fluazinam, 2011))
ARfD	0.07 mg/kg bw
IESTI (EFSA PRIMo) (% ARfD)	potatoes: 12.5 % (based on UK infants)
NESTI (NVS II) (% ARfD)	potatoes: 4 % (based on German children 2-4 years)
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. An exceedance of the current MRLs for dimethomorph (0.05 mg/kg) and fluazinam (0.05* mg/kg) as laid down in Reg. (EU) 396/2005 is not expected.

The chronic and the short-term intake of dimethomorph and fluazinam residues are unlikely to present a public health concern.

The notifier did not submit livestock metabolism studies for fluazinam. According to the dietary burden, the trigger value of 0.1 mg/kg feed (DM) was exceeded. It is therefore proposed to implement a label restriction excluding the utilization of potatoes as animal feed (VV207), unless the notifier provides access to the required studies.

As far as consumer health protection is concerned, BfR/Germany agrees with the authorization of the intended use.

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 *
	Austria	2005	fluazinam (Draft Assessment Report) GLP: Open Published: Yes ASB2010-10459			Add
	EFSA	2008	Conclusion regarding the peer review of the pesticide risk assessment of the active substance fluazinam EFSA Scientific Report (2008) 137, 1-82 ASB2012-3623			Add
	EFSA	2011	Reasoned opinion: Review of the existing maximum residue levels (MRLs) for Dimethomorph according to Article 12 of Regulation (EC) No 396/2005 EFSA-Q-2008-528 EFSA Journal 2011;9(8):2348, 1-64 ASB2012-3232			Add
	Germany	2006	EFSA Conclusion regarding the peer review of the pesticide risk assessment of the active substance dimethomorph EFSA Scientific Report (2006) 82, 1-69 ASB2008-3994			Add
	Germany	2004	dimethomorph (Draft Assessment Report) GLP: Open Published: Yes ASB2010-10454			Add
KIIA 6.1.1	Eichler, D.	1991	Storage stability at <= -18°C of Dimethomorph (CME 151) in grapes and soil SHGR.91.009 ! DK-326-002 ! 151AX-545-001 ! CU Li-5-1986 (grape) ! CU 88/525 (soil) ! 1991/7000051 GLP: Open Published: Open BVL-1968665, RIP2000-723	No	BAS	Y
KIIA 6.1.1	Eichler, D.	1991	The storage stability at <= -18°C of Dimethomorph (CME 151) in grapes and soil - Supplemental data to SHGR.91.009 SHGR.91.025 ! DK-326-003 ! 151AX-545-002 ! CU Li-5-1986 (grape) ! CU 88/525 (soil) ! 1991/7000052 GLP: Open Published: Open BVL-1968669, RIP2000-725	No	BAS	Y
KIIA 6.1.1	Eichler, D.	1992	Dimethomorph: Storage stability at <= -18°C in potato DK-326-004 ! SHGR.92.001 ! CU 89/626 ! 1992/7000024 GLP: Open Published: Open BVL-1968670, RIP2002-829	No	BAS	Y
KIIA 6.1.1	Steinhilper, D.	2009	Determination of the storage stability of Fluazinam in potatoes under deep frozen storage condidtions R-23545A ! S08-02055 GLP: Open Published: Open BVL-1905318, BVL-2465102, ASB2010-7046	Yes	FSG MCW	Y

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
KIIA 6.1.1	Weitzel, R.	1997	Dimethomorph (CL 336379): Storage stability of residues of CL 336379 in grape juice (must), grape waste material and raisins at <= -18°C (Germany, 1996) CFS 1997-096 ! DK-326-022 ! DEA862 ! 151AX-545-003 ! 1997/7000110 GLP: Open Published: Open BVL-1968699, RIP2000-727	No	BAS	Y
KIIA 6.2.1	Edwards, V. T.	1992	Dimethomorph (CME 151) (Chlorophenyl Ring-14C) metabolism: The nature of the residue in potato tubers - Supplemental report to report SHRG.89.071 151AX-641-012 ! SHGR.92.015 ! DK-640-014 ! CUB 91/4 ! 1992/7000340 GLP: Open Published: Open BVL-1968663, RIP9700382	No	BAS	Y
KIIA 6.2.1	Goodyear, A.	1995	Dimethomorph (Chlorophenyl ring - 14C): Metabolism in field grown lettuce - Amended final report DK-640-021 ! 460/78-1015 ! 1995/7000162 GLP: Open Published: Open BVL-1968671, RIP2002-749	No	BAS	Y
KIIA 6.2.1	Jentoft, N. H.	1997	14C-IKF-1216 (Fluazinam) plant metabolism study in potatoes 6775-96-0053-EF-001 GLP: Open Published: Open BVL-1953058, RIP2003-1894	No	ISK	Y
KIIA 6.2.1	Schlüter, H.	1990	14C-Dimethomorph (CME 151) - Metabolism and translocation in vines DK-640-005 ! 151AX-641-010 ! CUB 3/87 ! SHGR.89.072 ! 1990/7000082 GLP: Open Published: Open BVL-1968673, RIP2002-736	No	BAS	Y
KIIA 6.2.1	Schlüter, H.	1991	14C-Dimethomorph (CME 151): Metabolism and translocation in vines - Supplemental / Amendment no. 1 to report SHGR.89.072 DK-640-010 ! SHGR.91.035 ! CUB 3/87 ! 1991/7000110 GLP: Open Published: Open BVL-1968674, RIP2002-737	No	BAS	Y
KIIA 6..2.1	Thiele, J.	1990	14C-Dimethomorph (CME 151) (Chlorophenol ring label) - Metabolism and translocation in potato plants DK-640-004 ! SHGR.89.071 ! 151AX-641-008 ! CUE 1/89 ! 1990/7000081 GLP: Open Published: Open BVL-1968680, RIP2002-744	No	BAS	Y
KIIA 6.2.1	Thiele, J.	1990	14C-Dimethomorph (CME 151) (Morpholine ring label) - Metabolism and translocation in potato plants DK-640-006 ! 151AX-641-005 ! SHGR.89.070 ! 1990/7000083 GLP: Open Published: Open BVL-1968685, RIP2002-747	No	BAS	Y
KIIA 6.2.1	Thiele, J.	1991	14C-Dimethomorph (CME 151) (Chlorophenyl ring label) - Metabolism and translocation in potato plants Supplemental data to report SHGR.89.071 DK-640-009 ! SHGR.91.034 ! 151AX-641-009 ! CUE 1/89 ! 1991/7000109 GLP: Open Published: Open BVL-1968683, RIP2002-745	No	BAS	Y

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
KIIA 6.2.1	Thiele, J.	1991	14C-Dimethomorph (CME 151) (Morpholine ring label) - Metabolism and translocation in potato plants - Supplemental data to report SHGR.89.070 DK-640-011 ! 151AX-641-006 ! SHGR.91.033 ! CUE 2/89 ! 1991/7000111 GLP: Open Published: Open BVL-1968684, RIP2002-748	No	BAS	Y
KIIA 6.2.2	[redacted]	1991	14C-Dimethomorph (CME 151): Absorption, distribution, metabolism and excretion after repeated oral administration to laying hens - First amendment to report 151AX-652-001 ! DK-440-007 ! 214740 ! 1991/7000070 GLP: Open Published: Open BVL-1968690, RIP2000-730	No	BAS	Y
KIIA 6.2.3	[redacted]	1990	14C-Dimethomorph (CME 151): Absorption, distribution, metabolism and excretion after repeated oral administration to lactating goats DK-440-005 ! 151AX-652-002 ! 213928 ! 1990/7000056 GLP: Open Published: Open BVL-1968697, RIP2002-752	No	BAS	Y
KIIA 6.2.3	[redacted]	1991	14C-Dimethomorph (CME 151): Absorption, distribution, metabolism and excretion after repeated oral administration to lactating goats - First amendment to report 151AX-652-002 ! DK-440-008 ! 213928 ! 1991/7000262 GLP: Open Published: Open BVL-1968698, RIP2000-731	No	BAS	Y
KIIA 6.3	Baravelli, P. L.	2007	Field and laboratory phase in the determination of Folpet and Dimethomorph in tomato - 2006 Italy IT-DIM-06-4-A ! AGRI012/06 GLP: Open Published: Open BVL-1938052, ASB2010-13806	Yes	FSG	N
KIIA 6.3	Baravelli, P. L.	2007	Field and laboratory phase in the determination of Folpet and Dimethomorph grapevine - 2006 IT-DIM-06-4-B ! R-22591 GLP: Open Published: Open BVL-1938049, ASB2010-13807	Yes	FSG	N
KIIA 6.3	Delcour, B.	2010	Magnitude of the residues of Fluazinam in potatoes (RAS tubers) following ten applications of MCW 465, France, 2007 FR-FLU-09-03 ! BDR-09-5335 GLP: Yes Published: No BVL-2465137, BVL-2468451, ASB2013-9886	Yes	FSG MCW	Y
KIIA 6.3	Fischer, K.	2009	Determination of residues of Fluazinam after eight applications of MAC 92800 F in potato (Outdoor) at 4 Sites in Germany 2008 R-23545 ! S08-01223 GLP: Open Published: Open BVL-1905323, ASB2010-7049	Yes	FSG	Y

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
KIIA 6.3	Huaulme, J.	2011	Magnitude of the residue of Dimethomorph and Mancozeb in potatoes RAW Agricultural Commodity after four applications of MCW 388 M - France - 2009 [4 harvest trials] BPL 09/168/CL ! FR-DIM-08-03 / 3144909 GLP: Yes Published: No BVL-2465141, BVL-2467265, BVL-2469225, ASB2013-9888	Yes	MCW	Y
KIIA 6.3	Huaulme, J.	2012	Magnitude of the residues of Dimethomorph in potatoes (RAC) after four applications of MCW 853, North of France, 2011 BPL 11/394/CL ! R-28971 GLP: Yes Published: No BVL-2465140, BVL-2467270, ASB2013-9887	Yes	MCW	Y
KIIA 6.3	Kirchmaier, R.	2009	Determination of residues of Fluazinam after eight applications of MAC 92800 F in potato (Outdoor) at 4 Sites in Germany 2008 R-23545 ! S08-01223 GLP: Open Published: Open BVL-1905319, BVL-1905324, ASB2010-7047	Yes	FSG	Y
KIIA 6.3	Martinez, M.	2009	Determination of Folpet, Phthalimide and Dimethomorph residues in tomato after four applications with the MCW 685 formulation - 4 sites Italy - 2008 31459 GLP: Open Published: Open BVL-1938054, ASB2010-13803	Yes	FSG	N
KIIA 6.3	Martinez, M.	2009	Determination of Folpet, Phthalimide and Dimethomorph residues in wine grape and table grape, 4 sites in Italy - 2008 R-24623 ! 31462 GLP: Open Published: Open BVL-1938051, ASB2010-13810	Yes	FSG	N
KIIA 6.3	Martínez, M.	2008	Determination of residues of Dimethomorph, Folpet and Phtalimide after five applications of MCW 685 or MCW 388 in grape - 2 sites in Italy 2007 IT-DIM-07-2 ! R-23225 GLP: Open Published: Open BVL-1938050, ASB2010-13808	Yes	FSG	N
KIIA 6.3	Martínez, M.	2008	Determination of residues of Dimethomorph, Folpet and Phtalimide after five applications of MCW 685 in tomato - 2 sites in Italy 2007 R-23227 ! IT-DIF-07-1 GLP: Open Published: Open BVL-1938053, ASB2010-13809	Yes	FSG	N
KIIA 6.3	Roussel, C. H.	2008	Magnitude of the residues of Fluazinam in potatoes (RAC tubers) following ten applications of MCW 465, France, 2006 R-20936 ! ChR-06-2009 GLP: Open Published: Open BVL-1905256, BVL-1905320, BVL-1905325, ASB2010-7042	Yes	FSG MCW	Y

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
KIIA 6.3	Roussel, C. H.	2008	Magnitude of the residues of Fluazinam in potatoes (rac tubers) following ten applications of MCW 465, France, 2007 R-22822 ! ChR-07-3349 GLP: Yes (2) Open (2) Published: Open (2) No (2) BVL-1905321, BVL-1905326, BVL-2465134, BVL-2469188, ASB2010-7048	Yes	FSG MCW	Y
KIIA 6.3	Roussel, C. H.	2008	Magnitude of the residues of Fluazinam in potatoes (RAC tubers) following ten applications of MCW 465, France, 2006 ChR-06-2009 ! R-23545 GLP: Yes Published: No BVL-2465129, BVL-2469186, ASB2013-9890	Yes	MCW	Y
KIIA 6.3, KIIA 6.5.3	Roussel, C. H.	2008	Magnitude of the residues of Dimethomorph in grape vine (RAC bunches and processed fractions) following three applications of MCW685, France, 2007. ChR-07-3314 ! R-22821 GLP: Open Published: Open BVL-1938056, BVL-1938057, ASB2010-13805	Yes (1) No (1)	FSG	N
KIIA 6.3	Schulz, H.	1993	Dimethomorph: Determination of the residues in potatoes following treatment with 500 g/kg wettable powder, SY50574, or 75 + 667 g/kg wettable powder Dimethomorph / Mancozeb, SY50588P, under field conditions in the United Kingdom, 1991 - Vol. I DK-724-017 ! 325350 ! 1993/7000161 GLP: Open Published: Open BVL-1968677, RIP2002-792	No	BAS	Y
KIIA 6.3	Weitzel, R.	1989	Residues of CME 151 (Dimethomorph) in potatoes grown in Germany in 1987 DK-724-003 ! SHGR.89.064 ! 1989/7000089 GLP: Open Published: Open BVL-1968700, RIP2002-799	No	BAS	Y
KIIA 6.3	Weitzel, R.	1991	Residues of CME 151 (Dimethomorph) in potatoes grown in Germany in 1987 - Supplemental data to SHGR.89.064 DK-724-013 ! SHGR.91.019 ! 1991/7000136 GLP: Open Published: Open BVL-1968701, RIP2002-800	No	BAS	Y
KIIA 6.4.2	Cameron, D. M.	1991	CME 151 (Dimethomorph) technical - Residues in milk and tissues of dairy cows (Volume I to Volume III) DK-705-007 ! CMK 61/91644 ! 1991/7000120 ! 151AX-535-001 GLP: Open Published: Open BVL-1968662, RIP2002-807	No	BAS	Y
KIIA 6.4.2	Weitzel, R.	1991	Dimethomorph: Determination of CME 151 residues and metabolites in bovine tissues - Supplemental data to SHGR.91.007 DK-705-006 ! SHGR.91.032 ! CUA 90/663 ! 151AX-535-003 ! 1991/7000119 GLP: Open Published: Open BVL-1968702, RIP2002-808	No	BAS	Y

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
KIIA 6.5.1	Witte, A.	2008	Abiotic degradation (Hydrolysis) of Dimethomorph under typical conditions (pH, temperature and time) of processing 20071310/01-PCHP ! R-22169 GLP: Open Published: Open BVL-1938055, ASB2010-13802	Yes	FSG	Y
KIIA 6.6	Bitz, K.; Weitzel, R.	1994	Dimethomorph: Determination of the residues in field rotational crops (Germany, 1992) DK-790-010 ! CFS 1994-036 ! SHGR.93.024 ! CUA772 ! 1994/7000100 GLP: Open Published: Open BVL-1968661, RIP2002-823	No	BAS	Y
KIIA 6.6	Bitz, K.; Weitzel, R.	1994	Dimethomorph: Determination of Dimethomorph residues in field rotational crops (Germany, 1991) DK-790-011 ! CFS 1994-041 ! SHGR.93.031 ! CUA91/717 ! 1994/7000101 GLP: Open Published: Open BVL-1968660, RIP2002-822	No	BAS	Y
KIIA 6.6	Jentoft, N. H.	1995	Confined rotational crop study on [14C]Fluazinam (IKF-1216) reincorporation of radioactivity into natural products 5032-92-0093-EF-002 ! 92-0093 GLP: Open Published: Open BVL-1953060, RIP2004-1606	No	ISK	Y
KIIA 6.6	Robinson, R. A.; Hoffman, St. L.	1994	Confined rotational crop study on Fluazinam (IKF-1216) - Part 1: Total radioactive residue determination, residue extraction and profiling, and isolation and identification of Trifluroacetic acid 5032-92-0093 ! 92120 ! XBL92071 ! RPT00207 GLP: Open Published: Open BVL-1953059, RIP2004-1608	No	ISK	Y
KIIA 6.6	Robinson, R. A.; Hoffman, St. L.	1995	Confined rotational crop study on Fluazinam (IKF-1216) RPT00244 ! 5032-92-0093 ! 92120 ! XBL92071 ! RPT00207 GLP: Open Published: Open BVL-1953061, RIP2004-1605	No	ISK	Y
KIIA 6.6	Schlüter, H.	1990	14C-Dimethomorph (CME 151): Confined accumulation study on rotational crops DK-640-008 ! SHGR.90.004 ! CUB 2/87 ! 151AX-537-001 ! 1990/7000084 GLP: Open Published: Open BVL-1968675, RIP2002-821	No	BAS	Y
MIIA Sec 4	Anon.	2010	Dimethomorph: Residues in or on treated products, food and feed - Tier 2, IIA-6 MII / Sec. 4 GLP: No Published: No BVL-2463706, BVL-2463707, ASB2010-13572	Yes (1) Open (1)	FSG	Y
MIIA Sec 4	Struck, E.	2009	Fluazinam: Residues in or on treated products, food and feed - Tier 2, IIA-6 MII / Sec. 4 GLP: No Published: No BVL-2463703, BVL-2463704, ASB2010-7012	Yes	FSG	Y

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
MIIIA1 Sec 4	Applicant	2013	Dimethomorph + Fluazinam / BANJO FORTE: Residues in or on treated products, food and feed - Tier 2, IIIA-8 - Draft Registration Report - Part B - Core assessment MIII / Sec. 4 GLP: Open Published: No BVL-2440311, BVL-2442451, ASB2013-9882	Open	FSG	Y

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

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Storage stability

A 2.1.1 Storage stability of residues in plant products

Reference:	K II A 6.1
Report	Determination of the storage stability of Fluazinam in potatoes under deep frozen storage condidtions Steinhilper, D. 26.03.2009 R-23545A ! S08-02055 ASB2010-7046
Guideline(s):	Yes (EC guideline 7032/VI/95 rev. 5)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Samples were homogenized with dry ice and kept at -20°C until further processing. Aliquots of the frozen sample material were fortified with fluazinam in acetonitrile at 0.2 mg/kg and kept under freezing conditions for 6 month. For the analytical determination of fluazinam, the samples were homogenized with acetonitrile/water (80+20, v/v), followed by filtration of a supernatant aliquot. Quantification was performed by LC-MS/MS with a LOQ of 0.01 mg/kg

Results and discussions

After 6 month of deep-freeze storage the mean recovery of fluazinam from potatoes was determined equal to 78%.

Table A 2: Summary of concurrent recoveries of fluazinam from potatoes

Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Recoveries (%)	Mean ± std dev
fluazinam					
	0.01	180	2	91	-
	0.2	180	2	100	-

Table A 3: Stability of fluazinam residues in potatoes following storage at -23°C.

Commodity	Spike level (mg/kg)	Storage interval (days)	Recovered residues (mg/kg)	% recovery
fluazinam				
potatoes	0.2	0	0.201 0.199	100.5 99.5
	0.2	90	0.186 0.171	93 86
	0.2	180	0.161 0.152	81 76

Conclusion

The study successfully demonstrates the stability of fluazinam in potatoes under deep-freeze conditions for up to 6 month.

Comments of zRMS:	acceptable

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 of dimethomorph in potatoes

Reference:	K II A 6.3
Report	RIP2002-792, RIP2002-799, RIP2002-800, ASB2013-9887, ASB2013-9888
Guideline(s):	Yes (US EPA Pesticide Assessment Guidelines, Subdivision 0, 171-4; BBA Merkblatt Nr. 58)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Table A 4: Residues of dimethomorph in potatoes

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) : 200 g/L
Formulation (e.g. WP) : SC
Commercial product (name) : MCW 853
Applicant : Feinchemie Schwebda GmbH

Active ingredient : dimethomorph
Crop / crop group : Potato
Crop Code : SOLTU

Submission date : 2013-07-08

Indoors / Outdoors : Outdoors (European North)
Other a.i. in formulation (content and common name) : 200 g/L fluazinam
Residues calculated as : dimethomorph

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
study BPL 11/394/CL, trial BPL 11/394/CL-01-FR France (FR) 49650 Allonnes 2012-03-19	Charlotte	1) 2011-03-15 (planting) 2) 3)	0.21 0.22 0.21 0.22	250 260 250 260	0.084 0.083 0.084 0.086	2011-06-08[4)] 2011-06-15[4)] 2011-06-23[4)] 2011-06-30[4)]	BBCH 79 (plant)	tuber	<0.010	7	4) spraying analytical method: SOP MA 654 (LC-MS/MS), LOQ(s): 0.01 mg/kg (tuber), max. sample storage 4 months ASB2013-9887

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
study BPL 11/394/CL, trial BPL 11/394/CL-02-FR France (FR) 80340 Herleville 2012-03-19	Babel	1) 2011-03-25 (planting) 2) 3)	0.21 0.21 0.21 0.21	300 300 300 290	0.070 0.069 0.069 0.072	2011-08-26 4) 2011-09-01 4) 2011-09-08 4) 2011-09-15 4)	BBCH 48 (tuber)	tuber	<0.010	7	4) spraying analytical method: SOP MA 654 (LC-MS/MS), LOQ(s): 0.01 mg/kg (tuber), max. sample storage 2 months ASB2013-9887

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) : 90 g/kg
Formulation (e.g. WP) : WG
Commercial product (name) : MCW 388 M
Applicant : Feinchemie Schwebda GmbH

Active ingredient : dimethomorph
Crop / crop group : Potato
Crop Code : SOLTU

Submission date : 2013-07-08

Indoors / Outdoors : Outdoors (European North)
Other a.i. in formulation (content and common name) : 600 g/kg mancozeb
Residues calculated as : dimethomorph

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
study BPL 09/168/CL, trial BPL 09/168/CL-3 France (FR) 49160 Longué 2011-03-29	Nicolas	1) 2009-04-30 (planting) 2) 2009-07-15 - 2009-07-31 3) 2009-09-15 - 2009-09-20	0.18 0.18 0.18 0.18	300 310 310 320	0.059 0.058 0.058 0.056	2009-07-28 4) 2009-08-04 4) 2009-08-11 4) 2009-08-17 4)	BBCH 47 (tuber)	tuber	<0.010 <u>≤0.010</u> <0.010	3 7 14	4) spraying analytical method: MA 654-01 (UPLC-MS/MS), LOQ(s): 0.01 mg/kg (tuber), max. sample storage 9 months ASB2013-9888
study BPL 09/168/CL, trial BPL 09/168/CL-4 France (FR) 80170 Beaufort en Santerre 2011-03-29	Bintje	1) 2009-04-25 (planting) 2) 3) 2009-10-12	0.18 0.18 0.18 0.18	320 330 310 310	0.056 0.055 0.058 0.058	2009-08-04 4) 2009-08-12 4) 2009-08-18 4) 2009-08-25 4)	BBCH 47 (tuber)	tuber	<u>≤0.010</u> <0.010 <0.010	3 8 15	4) spraying analytical method: MA 654-01 (UPLC-MS/MS), LOQ(s): 0.01 mg/kg (tuber), max. sample storage 9 months ASB2013-9888

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) : 500 g/kg
Formulation (e.g. WP) : WP
Commercial product (name) : SY50574
Applicant : Feinchemie Schwebda GmbH

Active ingredient : dimethomorph
Crop / crop group : Potato
Crop Code : SOLTU

Submission date : 2013-07-08

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

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
study 325350, trial SUKF91/226/5 United Kingdom Cilcain, Mould, Clywd 1993-02-25	Maris piper	1) 1991-04-12 (planting) 2) 3)	0.15 0.15 0.15 0.15 0.15 0.15 0.15	200 200 200 200 200 200 200	0.075 0.075 0.075 0.075 0.075 0.075 0.075	1991-06-26 4) 1991-07-11 4) 1991-07-22 4) 1991-08-05 4) 1991-08-16 4) 1991-09-02 4) 1991-09-12 4)	BBCH 87 (plant)	tuber	<0.020	8	4) spraying analytical method: FAMS 002-02 (HPLC-UV), LOQ(s): 0.02 mg/kg (tuber), max. sample storage 15 months RIP2002-792
study 325350, trial SUKF91/226/6 United Kingdom Cilcain, Mould, Clywd 1993-02-25	Maris piper	1) 1991-04-12 (planting) 2) 3)	0.30 0.30 0.30 0.30 0.30 0.30 0.30	200 200 200 200 200 200 200	0.15 0.15 0.15 0.15 0.15 0.15 0.15	1991-06-26 4) 1991-07-11 4) 1991-07-22 4) 1991-08-05 4) 1991-08-16 4) 1991-09-02 4) 1991-09-12 4)	BBCH 87 (plant)	tuber	<0.020	8	4) spraying analytical method: FAMS 002-02 (HPLC-UV), LOQ(s): 0.02 mg/kg (tuber), max. sample storage 15 months RIP2002-792

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
study 325350, trial SUKF91/226/7 United Kingdom Cilcain, Mould, Clywd 1993-02-25	Maris piper	1) 1991-04-12 (planting) 2) 3)	0.50 0.50 0.50 0.50 0.50 0.50 0.50	200 200 200 200 200 200 200	0.25 0.25 0.25 0.25 0.25 0.25 0.25	1991-06-26 4) 1991-07-11 4) 1991-07-22 4) 1991-08-05 4) 1991-08-16 4) 1991-09-02 4) 1991-09-12 4)	BBCH 87 (plant)	tuber	<0.020	8	4) spraying analytical method: FAMS 002-02 (HPLC-UV), LOQ(s): 0.02 mg/kg (tuber), max. sample storage 15 months RIP2002-792
study 325350, trial SUKF91/226/8 United Kingdom Cilcain, Mould, Clywd 1993-02-25	Maris piper	1) 1991-04-12 (planting) 2) 3)	0.15 0.15 0.15 0.15 0.15 0.15 0.15	200 200 200 200 200 200 200	0.075 0.075 0.075 0.075 0.075 0.075 0.075	1991-06-26 4) 1991-07-11 4) 1991-07-22 4) 1991-08-05 4) 1991-08-16 4) 1991-09-02 4) 1991-09-12 4)	BBCH 87 (plant)	tuber	<0.020	8	4) spraying analytical method: FAMS 002-02 (HPLC-UV), LOQ(s): 0.02 mg/kg (tuber), max. sample storage 15 months formulation was applied as a tank mix with an adjuvant: DOBANOL ETHOXYLATE 25-9, 1000 g a.i./ha RIP2002-792

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
study 325350, trial SUKF91/226/9 United Kingdom Cilcain, Mould, Clywd 1993-02-25	Maris piper	1) 1991-04-12 (planting) 2) 3)	0.30 0.30 0.30 0.30 0.30 0.30 0.30	200 200 200 200 200 200 200	0.15 0.15 0.15 0.15 0.15 0.15 0.15	1991-06-26 4) 1991-07-11 4) 1991-07-22 4) 1991-08-05 4) 1991-08-16 4) 1991-09-02 4) 1991-09-12 4)	BBCH 87 (plant)	tuber	<0.020	8	4) spraying analytical method: FAMS 002-02 (HPLC-UV), LOQ(s): 0.02 mg/kg (tuber), max. sample storage 15 months formulation was applied as a tank mix with an adjuvant: DOBANOL ETHOXYLATE 25-9, 2000 g a.i./ha RIP2002-792
study 325350, trial SUKF91/226/10 United Kingdom Cilcain, Mould, Clywd 1993-02-25	Maris piper	1) 1991-04-12 (planting) 2) 3)	0.50 0.50 0.50 0.50 0.50 0.50 0.50	200 200 200 200 200 200 200	0.25 0.25 0.25 0.25 0.25 0.25 0.25	1991-06-26 4) 1991-07-11 4) 1991-07-22 4) 1991-08-05 4) 1991-08-16 4) 1991-09-02 4) 1991-09-12 4)	BBCH 87 (plant)	tuber	<0.020	8	4) spraying analytical method: FAMS 002-02 (HPLC-UV), LOQ(s): 0.02 mg/kg (tuber), max. sample storage 15 months formulation was applied as a tank mix with an adjuvant: DOBANOL ETHOXYLATE 25-9, 2000 g a.i./ha RIP2002-792

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
study 325350, trial SUKF91/227/5 United Kingdom Banbury, Oxon 1993-02-25	Maris baerd + Maris piper	1) 1991-05-06 (planting) 2) 3)	0.15 0.15 0.15 0.15 0.15 0.15 0.15 0.15 0.15	200 200 200 200 200 200 200 200 200	0.075 0.075 0.075 0.075 0.075 0.075 0.075 0.075 0.075	1991-06-27[4)] 1991-07-07[4)] 1991-07-17[4)] 1991-07-25[4)] 1991-08-05[4)] 1991-08-15[4)] 1991-08-26[4)] 1991-09-05[4)] 1991-09-16[4)]	BBCH 87 (plant)	tuber	<0.020	7	4) spraying analytical method: FAMS 002-02 (HPLC-UV), LOQ(s): 0.02 mg/kg (tuber), max. sample storage 15 months RIP2002-792
study 325350, trial SUKF91/227/6 United Kingdom Banbury, Oxon 1993-02-25	Maris baerd + Maris piper	1) 1991-05-06 (planting) 2) 3)	0.30 0.30 0.30 0.30 0.30 0.30 0.30 0.30 0.30	200 200 200 200 200 200 200 200 200	0.15 0.15 0.15 0.15 0.15 0.15 0.15 0.15 0.15	1991-06-27[4)] 1991-07-07[4)] 1991-07-17[4)] 1991-07-25[4)] 1991-08-05[4)] 1991-08-15[4)] 1991-08-26[4)] 1991-09-05[4)] 1991-09-16[4)]	BBCH 87 (plant)	tuber	<0.020	7	4) spraying analytical method: FAMS 002-02 (HPLC-UV), LOQ(s): 0.02 mg/kg (tuber), max. sample storage 15 months RIP2002-792
study 325350, trial SUKF91/227/7 United Kingdom Banbury, Oxon 1993-02-25	Maris baerd + Maris piper	1) 1991-05-06 (planting) 2) 3)	0.50 0.50 0.50 0.50 0.50 0.50 0.50 0.50 0.50	200 200 200 200 200 200 200 200 200	0.25 0.25 0.25 0.25 0.25 0.25 0.25 0.25 0.25	1991-06-27[4)] 1991-07-07[4)] 1991-07-17[4)] 1991-07-25[4)] 1991-08-05[4)] 1991-08-15[4)] 1991-08-26[4)] 1991-09-05[4)] 1991-09-16[4)]	BBCH 87 (plant)	tuber	<0.020	7	4) spraying analytical method: FAMS 002-02 (HPLC-UV), LOQ(s): 0.02 mg/kg (tuber), max. sample storage 15 months RIP2002-792

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
study 325350, trial SUKF91/227/8 United Kingdom Banbury, Oxon 1993-02-25	Maris baerd + Maris piper	1) 1991-05-06 (planting) 2) 3)	0.15 0.15 0.15 0.15 0.15 0.15 0.15 0.15 0.15	200 200 200 200 200 200 200 200 200	0.075 0.075 0.075 0.075 0.075 0.075 0.075 0.075 0.075	1991-06-27 4) 1991-07-07 4) 1991-07-17 4) 1991-07-25 4) 1991-08-05 4) 1991-08-15 4) 1991-08-26 4) 1991-09-05 4) 1991-09-16 4)	BBCH 87 (plant)	tuber	<0.020	7	4) spraying analytical method: FAMS 002-02 (HPLC-UV), LOQ(s): 0.02 mg/kg (tuber), max. sample storage 15 months formulation was applied as a tank mix with an adjuvant: DOBANOL ETHOXYLATE 25-9, 1000 g a.i./ha RIP2002-792
study 325350, trial SUKF91/227/9 United Kingdom Banbury, Oxon 1993-02-25	Maris baerd + Maris piper	1) 1991-05-06 (planting) 2) 3)	0.30 0.30 0.30 0.30 0.30 0.30 0.30 0.30 0.30	200 200 200 200 200 200 200 200 200	0.15 0.15 0.15 0.15 0.15 0.15 0.15 0.15 0.15	1991-06-27 4) 1991-07-07 4) 1991-07-17 4) 1991-07-25 4) 1991-08-05 4) 1991-08-15 4) 1991-08-26 4) 1991-09-05 4) 1991-09-16 4)	BBCH 87 (plant)	tuber	<0.020	7	4) spraying analytical method: FAMS 002-02 (HPLC-UV), LOQ(s): 0.02 mg/kg (tuber), max. sample storage 15 months formulation was applied as a tank mix with an adjuvant: DOBANOL ETHOXYLATE 25-9, 2000 g a.i./ha RIP2002-792

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
study 325350, trial SUKF91/227/10 United Kingdom Banbury, Oxon 1993-02-25	Maris baerd + Maris piper	1) 1991-05-06 (planting) 2) 3)	0.50 0.50 0.50 0.50 0.50 0.50 0.50 0.50 0.50	200 200 200 200 200 200 200 200 200	0.25 0.25 0.25 0.25 0.25 0.25 0.25 0.25 0.25	1991-06-27 4) 1991-07-07 4) 1991-07-17 4) 1991-07-25 4) 1991-08-05 4) 1991-08-15 4) 1991-08-26 4) 1991-09-05 4) 1991-09-16 4)	BBCH 87 (plant)	tuber	<0.020	7	4) spraying analytical method: FAMS 002-02 (HPLC-UV), LOQ(s): 0.02 mg/kg (tuber), max. sample storage 15 months formulation was applied as a tank mix with an adjuvant: DOBANOL ETHOXYLATE 25-9, 2000 g a.i./ha RIP2002-792

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

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Content of a.i. (g/kg or g/l) : 75 g/kg
Formulation (e.g. WP) : WP
Commercial product (name) : SY50588P
Applicant : Feinchemie Schwebda GmbH

Active ingredient : dimethomorph
Crop / crop group : Potato
Crop Code : SOLTU

Submission date : 2013-07-08

Indoors / Outdoors : Outdoors (European North)
Other a.i. in formulation (content and common name) : 667 g/kg mancozeb
Residues calculated as : dimethomorph

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
study 325350, trial SUKF91/226/4 United Kingdom Cilcain, Mould, Clywd 1993-02-25	Maris piper	1) 1991-04-12 (planting) 2) 3)	0.30 0.30 0.30 0.30 0.30 0.30 0.30	200 200 200 200 200 200 200	0.15 0.15 0.15 0.15 0.15 0.15 0.15	1991-06-26 4) 1991-07-11 4) 1991-07-22 4) 1991-08-05 4) 1991-08-16 4) 1991-09-02 4) 1991-09-12 4)	BBCH 87 (plant)	tuber	<0.020	8	4) spraying analytical method: FAMS 002-02 (HPLC-UV), LOQ(s): 0.02 mg/kg (tuber), max. sample storage 15 months formulation was applied as a tank mix with an adjuvant: DOBANOL ETHOXYLATE 25-9, 2000 g a.i./ha RIP2002-792
study 325350, trial SUKF91/226/3 United Kingdom Cilcain, Mould, Clywd 1993-02-25	Maris piper	1) 1991-04-12 (planting) 2) 3)	0.15 0.15 0.15 0.15 0.15 0.15 0.15	200 200 200 200 200 200 200	0.075 0.075 0.075 0.075 0.075 0.075 0.075	1991-06-26 4) 1991-07-11 4) 1991-07-22 4) 1991-08-05 4) 1991-08-16 4) 1991-09-02 4) 1991-09-12 4)	BBCH 87 (plant)	tuber	<0.020	8	4) spraying analytical method: FAMS 002-02 (HPLC-UV), LOQ(s): 0.02 mg/kg (tuber), max. sample storage 15 months formulation was applied as a tank mix with an adjuvant: DOBANOL ETHOXYLATE 25-9, 1000 g a.i./ha RIP2002-792

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
study 325350, trial SUKF91/226/2 United Kingdom Cilcain, Mould, Clywd 1993-02-25	Maris piper	1) 1991-04-12 (planting) 2) 3)	0.30 0.30 0.30 0.30 0.30 0.30 0.30	200 200 200 200 200 200 200	0.15 0.15 0.15 0.15 0.15 0.15 0.15	1991-06-26 4) 1991-07-11 4) 1991-07-22 4) 1991-08-05 4) 1991-08-16 4) 1991-09-02 4) 1991-09-12 4)	BBCH 87 (plant)	tuber	<0.020	8	4) spraying analytical method: FAMS 002-02 (HPLC-UV), LOQ(s): 0.02 mg/kg (tuber), max. sample storage 15 months RIP2002-792
study 325350, trial SUKF91/226/1 United Kingdom Cilcain, Mould, Clywd 1993-02-25	Maris piper	1) 1991-04-12 (planting) 2) 3)	0.15 0.15 0.15 0.15 0.15 0.15 0.15	200 200 200 200 200 200 200	0.075 0.075 0.075 0.075 0.075 0.075 0.075	1991-06-26 4) 1991-07-11 4) 1991-07-22 4) 1991-08-05 4) 1991-08-16 4) 1991-09-02 4) 1991-09-12 4)	BBCH 87 (plant)	tuber	<0.020	8	4) spraying analytical method: FAMS 002-02 (HPLC-UV), LOQ(s): 0.02 mg/kg (tuber), max. sample storage 15 months RIP2002-792
study 325350, trial SUKF91/227/1 United Kingdom Banbury, Oxon 1993-02-25	Maris baerd + Maris piper	1) 1991-05-06 (planting) 2) 3)	0.15 0.15 0.15 0.15 0.15 0.15 0.15 0.15 0.15 0.15	200 200 200 200 200 200 200 200 200 200	0.075 0.075 0.075 0.075 0.075 0.075 0.075 0.075 0.075 0.075	1991-06-27 4) 1991-07-07 4) 1991-07-17 4) 1991-07-25 4) 1991-08-05 4) 1991-08-15 4) 1991-08-26 4) 1991-09-05 4) 1991-09-16 4)	BBCH 87 (plant)	tuber	<0.020	7	4) spraying analytical method: FAMS 002-02 (HPLC-UV), LOQ(s): 0.02 mg/kg (tuber), max. sample storage 15 months RIP2002-792

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
study 325350, trial SUKF91/227/2 United Kingdom Banbury, Oxon 1993-02-25	Maris baerd + Maris piper	1) 1991-05-06 (planting) 2) 3)	0.30 0.30 0.30 0.30 0.30 0.30 0.30 0.30 0.30	200 200 200 200 200 200 200 200 200	0.15 0.15 0.15 0.15 0.15 0.15 0.15 0.15 0.15	1991-06-27[4)] 1991-07-07[4)] 1991-07-17[4)] 1991-07-25[4)] 1991-08-05[4)] 1991-08-15[4)] 1991-08-26[4)] 1991-09-05[4)] 1991-09-16[4)]	BBCH 87 (plant)	tuber	<0.020	7	4) spraying analytical method: FAMS 002-02 (HPLC-UV), LOQ(s): 0.02 mg/kg (tuber), max. sample storage 15 months RIP2002-792
study 325350, trial SUKF91/227/3 United Kingdom Banbury, Oxon 1993-02-25	Maris baerd + Maris piper	1) 1991-05-06 (planting) 2) 3)	0.15 0.15 0.15 0.15 0.15 0.15 0.15 0.15 0.15	200 200 200 200 200 200 200 200 200	0.075 0.075 0.075 0.075 0.075 0.075 0.075 0.075 0.075	1991-06-27[4)] 1991-07-07[4)] 1991-07-17[4)] 1991-07-25[4)] 1991-08-05[4)] 1991-08-15[4)] 1991-08-26[4)] 1991-09-05[4)] 1991-09-16[4)]	BBCH 87 (plant)	tuber	<0.020	7	4) spraying analytical method: FAMS 002-02 (HPLC-UV), LOQ(s): 0.02 mg/kg (tuber), max. sample storage 15 months formulation was applied as a tank mix with an adjuvant: DOBANOL ETHOXYLATE 25-9, 1000 g a.i./ha RIP2002-792
study 325350, trial SUKF91/227/4 United Kingdom Banbury, Oxon 1993-02-25	Maris baerd + Maris piper	1) 1991-05-06 (planting) 2) 3)	0.30 0.30 0.30 0.30 0.30 0.30 0.30 0.30 0.30	200 200 200 200 200 200 200 200 200	0.15 0.15 0.15 0.15 0.15 0.15 0.15 0.15 0.15	1991-06-27[4)] 1991-07-07[4)] 1991-07-17[4)] 1991-07-25[4)] 1991-08-05[4)] 1991-08-15[4)] 1991-08-26[4)] 1991-09-05[4)] 1991-09-16[4)]	BBCH 87 (plant)	tuber	0.025	7	4) spraying analytical method: FAMS 002-02 (HPLC-UV), LOQ(s): 0.02 mg/kg (tuber), max. sample storage 15 months, formulation was applied as a tank mix with an adjuvant: DOBANOL ETHOXYLATE 25-9, 2000 g a.i./ha RIP2002-792

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) : 90 g/kg
Formulation (e.g. WP) : WP (Wettable powder)
Commercial product (name) : CME 15167 F
Applicant : Feinchemie Schwebda GmbH

Active ingredient : dimethomorph
Crop / crop group : Potato
Crop Code : SOLTU

Submission date : 2013-07-08

Indoors / Outdoors : Outdoors (European North)
Other a.i. in formulation (content and common name) : 600 g/kg mancozeb
Residues calculated as : dimethomorph

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
studySHGR.89.064, trial C 870401 Germany (DE) 21409 Oerzen 1989-11-06	Taiga	1) 1987-04-12 (planting) 2) 1987-07-01 - 1987-07-14 3) 1987-10-12	0.18 0.18 0.18 0.18 0.18 0.18 0.18	600 600 600 600 600 600 600	0.030 0.030 0.030 0.030 0.030 0.030 0.030	1987-07-01 4) 1987-07-14 4) 1987-07-29 4) 1987-08-11 4) 1987-08-20 4) 1987-09-07 4)	BBCH 91 (plant)	tuber	0.020 0.020 <0.020 <0.020 <0.020 <0.020	0 7 14 21 29 35	4) spraying analytical method: SFSAMS 002-02 (HPLC-UV), LOQ(s): 0.02 mg/kg (tuber), max. sample storage 23 months RIP2002-799 RIP2002-800 (amendment)
studySHGR.89.064, trial C 870405 Germany (DE) 8381 Münchsdorf/ Arnstorf 1989-11-06	Ulla	1) 1987-04-27 (planting) 2) 1987-07-01 - 1987-07-23 3) 1987-09-17	0.18 0.18 0.18 0.18 0.18 0.18 0.18	600 600 600 600 600 600 600	0.030 0.030 0.030 0.030 0.030 0.030 0.030	1987-06-15 4) 1987-06-29 4) 1987-07-14 4) 1987-07-29 4) 1987-08-08 4) 1987-08-13 4)	BBCH 91 (plant)	tuber	<0.020 <0.020 <0.020 <0.020 <0.020 <0.020	0 7 14 21 28 35	4) spraying analytical method: SFSAMS 002-02 (HPLC-UV), LOQ(s): 0.02 mg/kg (tuber), max. sample storage 25 months RIP2002-799 RIP2002-800 (amendment)

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
studySHGR.89.064, trial C 870406 Germany (DE) 7959 Ingerkingen 1989-11-06	Sieglinde	1) 1987-04-15 (planting) 2) 1987-07-16 - 1987-08-03 3) 1987-09-10	0.18 0.18 0.18 0.18 0.18 0.18	600 600 600 600 600 600	0.030 0.030 0.030 0.030 0.030 0.030	1987-07-06 4) 1987-07-14 4) 1987-07-21 4) 1987-07-28 4) 1987-08-05 4) 1987-08-13 4)	BBCH 91 (plant)	tuber	<0.020 <0.020 <0.020 <0.020 <0.020 <0.020	0 7 14 21 28 35	4) spraying analytical method: SFSAMS 002-02 (HPLC-UV), LOQ(s): 0.02 mg/kg (tuber), max. sample storage 25 months RIP2002-799 RIP2002-800 (amendment)

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 2.2.3 Magnitude of residues of fluazinam in potatoes

Reference:	KIIA 6.3
Report	ASB2010-7047, ASB2010-7048, ASB2010-7049
Guideline(s):	Yes (European Guideline 7029/VI/95 rev. 5, 1997, European Guideline 1607/VI/97 rev. 2, 1999, , SANCO/3029/99 rev. 4, 2000, OECD ENV/JM/MONO(99)22, OECD ENV/JM/MONO(2002)9)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Table A 5: Residues of fluazinam in potatoes

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)	:	500 g/l
Formulation	(e.g. WP)	:	SC
Commercial product	(name)	:	MCW465 (submitted to BANJO **006899-00**) treated with formulation MCW465, SC (500 g/l fluazinam)
Applicant		:	Feinchemie Schwebda GmbH

Active ingredient	:	fluazinam
Crop / crop group	:	Potatoes
Submission date	:	2010-05-31
Indoors / outdoors	:	Outdoors (European North)
Other a.i. in formulation (content and common name)	:	
Residues calculated as	:	fluazinam

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
R-22822, study ChR-07-3349, trial ChR-07-3349 NF01 France 37110 Dame Marie les Bois 2008-06-24	Roseval	1) 2007-07-13 (planting) 2) 2007-08-29 - 2007-09-21 3) 2007-10-12	0.20 0.20 0.23 0.21 0.22 0.22 0.20 0.23 0.21 0.21	300 300 300 300 300 300 300 300 300 300	0.068 0.067 0.077 0.071 0.072 0.074 0.067 0.077 0.071 0.070	2007-08- 092007-08- 162007-08- 242007-08- 31 2007-09-07 2007-09-14 2007-09-21 2007-09-28 2007-10-05 2007-10-12[4)]	BBCH 48 (tuber)	tuber	0.039 <u>0.013</u> <0.01	3 7 14	4) spraying analytical method: GIRPA study STAPH/FLUAZ/07.02 (HPLC-MS/MS), LOQ 0.01 mg/kg, max. sample storage: 4 months ASB2010-7048
R-22822, study ChR-07-3349, trial ChR-07-3349 NF02 France 62860 Inchy en Artois 2008-06-24	Bintje	1) 2007-04-17 (planting) 2) 2007-06-15 - 2007-07-20 3) 2007-09-17	0.18 0.19 0.19 0.20 0.20 0.21 0.20 0.21 0.19 0.20	250 250 250 250 250 250 250 250 250 250	0.073 0.076 0.077 0.080 0.080 0.082 0.080 0.084 0.078 0.080	2007-06-27 2007-07-05 2007-07-12 2007-07-19 2007-07-26 2007-08-02 2007-08-09 2007-08-16 2007-08-23 2007-08-31[4)]	BBCH 49 (tuber)	tuber	<0.01 <u><0.01</u> <0.01	3 7 14	4) spraying analytical method: GIRPA study STAPH/FLUAZ/07.02 (HPLC-MS/MS), LOQ 0.01 mg/kg, max. sample storage: 3 months ASB2010-7048
R-23545, study S08-01223, trial S08-01223-01 Germany 86916 Kaufering 2009-03-06	Kuras	1) 2008-04-21 (planting) 2) 2008-07 - 2008-08 3) 2008-09-08	0.18 0.20 0.21 0.20 0.20 0.20 0.20 0.20 0.20	369 406 417 408 407 394 397 396	0.050 0.050 0.050 0.050 0.050 0.050 0.050 0.050 0.050	2008-07-23 2008-07-28 2008-08-02 2008-08-08 2008-08-13 2008-08-18 2008-08-25 2008-09-01[4)]	BBCH 70 (plant)	tuber	<0.01 <0.01 0.01 <u><0.01</u> <0.01	0 1 3 7 14	4) spraying analytical method: SANCO/3029/99 (HPLC-MS/MS), LOQ 0.01 mg/kg, max. sample storage: 2 months ASB2010-7047 (analytical part), ASB2010-7049 (final report)

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
R-23545, study S08-01223, trial S08-01223-02 Germany 71277 Rutesheim- Perouse 2009-03-06	Nicola	1) 2008-04-30 (planting) 2) 3) 2008-09-02	0.20 0.20 0.20 0.19 0.18 0.20 0.20 0.20	402 398 403 385 363 407 392 407	0.050 0.050 0.050 0.050 0.050 0.050 0.050 0.050	2008-07-16 2008-07-21 2008-07-27 2008-08-01 2008-08-07 2008-08-15 2008-08-21 2008-08-26[4)]	BBCH 91 (plant)	tuber	<0.01 <0.01 <0.01 <u><0.01</u> <0.01	0 1 3 7 13	4) spraying analytical method: SANCO/3029/99 (HPLC-MS/MS), LOQ 0.01 mg/kg, max. sample storage: 3 months ASB2010-7047 (analytical part), ASB2010-7049 (final report)
R-23545, study S08-01223, trial S08-01223-03 Germany 86492 Heinrichshofen 2009-03-06	Producent	1) 2008-04-12 (planting) 2) 2008-06-06 - 2008-08-08 3) 2008-08-25	0.19 0.22 0.19 0.20 0.20 0.20 0.20 0.20	387 430 389 394 407 401 408 398	0.050 0.050 0.050 0.050 0.050 0.050 0.050 0.050	2008-07-03 2008-07-10 2008-07-16 2008-07-23 2008-07-28 2008-08-04 2008-08-11 2008-08-18[4)]	BBCH 74 (plant)	tuber	<0.01 <u><0.01</u>	0 7	4) spraying analytical method: SANCO/3029/99 (HPLC-MS/MS), LOQ 0.01 mg/kg, max. sample storage: 3 months ASB2010-7047 (analytical part), ASB2010-7049 (final report)
R-23545, study S08-01223, trial S08-01223-04 Germany 76297 Stutensee 2009-03-06	Acapella	1) 2008-04-01 (planting) 2) 2008-05 - 2008-06 3) 2008-07-24	0.21 0.22 0.22 0.20 0.21 0.20 0.20 0.22	427 431 436 404 413 393 391 436	0.050 0.050 0.050 0.050 0.050 0.050 0.050 0.050	2008-06-09 2008-06-16 2008-06-21 2008-06-26 2008-07-01 2008-07-07 2008-07-12 2008-07-17[4)]	BBCH 71 (plant)	tuber	<0.01 <u><0.01</u>	0 7	4) spraying analytical method: SANCO/3029/99 (HPLC-MS/MS), LOQ 0.01 mg/kg, max. sample storage: 4 months ASB2010-7047 (analytical part), ASB2010-7049 (final report)

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.

Reference:	K II A 6.3
Report	ASB2013-9886, ASB2013-9890
Guideline(s):	Yes (OECD ENV/MC/CHEM(98)17, OECD ENV/JM/MONO(99)22, OECD ENV/JM/MONO(2002)9)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Table A 6: Residues of fluazinam in potatoes

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) : 500 g/L
Formulation (e.g. WP) : SC
Commercial product (name) : MCW 465
Applicant : Feinchemie Schwebda GmbH

Active ingredient : fluazinam
Crop / crop group : Potato
Crop Code : SOLTU

Submission date : 2013-07-08

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

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
study BDR-09-5335, trial BDR-09 5335/FR02 France (FR) 37110 Dame Marie les Bois 2010-08-13	Charlotte	1) 2009-04-22 (planting) 2) 2009-06-10 - 2009-07-02 3) 2009-08-25	0.20 0.20 0.21 0.21 0.20 0.20 0.21 0.21 0.21 0.21	300 300 300 300 300 300 300 310 310 300	0.067 0.066 0.069 0.069 0.066 0.066 0.069 0.068 0.068 0.069	2009-06-18[4)] 2009-06-25[4)] 2009-07-02[4)] 2009-07-09[4)] 2009-07-15[4)] 2009-07-21[4)] 2009-07-28[4)] 2009-08-04[4)] 2009-08-11[4)] 2009-08-18[4)]	BBCH 48 (tuber)	tuber	<0.010	7	4) spraying analytical method: GIR/MET/FLUAZINA/03V2 (HPLC-MSD), LOQ(s): 0.01 mg/kg (tuber), max. sample storage time in month(s): 5 ASB2013-9886

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
study BDR-09-5335, trial BDR-09-5335/FR03 France (FR) 62860 Inchy en Artois 2010-08-13	Agria	1) 2009-04-27 (planting) 2) 2009-07-01 - 2009-08-10 3) 2009-10-10	0.22 0.20 0.20 0.20 0.20 0.21 0.21 0.21 0.20 0.21	270 250 250 250 250 250 260 260 250 260	0.083 0.079 0.081 0.080 0.081 0.083 0.082 0.080 0.079 0.081	2009-07-29[4)] 2009-08-05[4)] 2009-08-12[4)] 2009-08-19[4)] 2009-08-26[4)] 2009-09-02[4)] 2009-09-09[4)] 2009-09-16[4)] 2009-09-23[4)] 2009-09-30[4)]	BBCH 49 (tuber)	tuber	<0.010	7	4) spraying analytical method: GIR/MET/FLUAZINA/03V2 (HPLC-MSD), LOQ(s): 0.01 mg/kg (tuber), max. sample storage time in month(s): 3 ASB2013-9886
study BDR-09-5335, trial BDR-09-5335/FR05 France (FR) 02700 Mennessis 2010-08-13	Agria	1) 2009-06-03 (planting) 2) 2009-07-20 - 2009-08-20 3)	0.21 0.21 0.21 0.21 0.21 0.20 0.21 0.20 0.20 0.21	310 310 310 310 310 300 310 300 290 310	0.068 0.067 0.068 0.067 0.068 0.066 0.068 0.067 0.068 0.067	2009-07-09[4)] 2009-07-16[4)] 2009-07-23[4)] 2009-07-30[4)] 2009-08-06[4)] 2009-08-13[4)] 2009-08-20[4)] 2009-08-27[4)] 2009-09-03[4)] 2009-09-10[4)]	BBCH 48 (tuber)	tuber	<0.010	7	4) spraying analytical method: GIR/MET/FLUAZINA/03V2 (HPLC-MSD), LOQ(s): 0.01 mg/kg (tuber), max. sample storage time in month(s): 4 ASB2013-9886
study BDR-09-5335, trial BDR-09-5335/FR06 France (FR) 21130 Auxonne 2010-08-13	Monalisa	1) 2009-04-06 (planting) 2) 2009-06-10 3) 2009-07-31	0.21 0.20 0.20 0.20 0.21 0.20 0.21 0.21 0.20 0.20	260 250 250 250 260 250 260 260 250 250	0.081 0.081 0.079 0.081 0.082 0.079 0.082 0.082 0.080 0.081	2009-05-20[4)] 2009-05-27[4)] 2009-06-03[4)] 2009-06-10[4)] 2009-06-17[4)] 2009-06-24[4)] 2009-07-01[4)] 2009-07-08[4)] 2009-07-15[4)] 2009-07-22[4)]	BBCH 49 (tuber)	tuber	<0.010	7	4) spraying analytical method: GIR/MET/FLUAZINA/03V2 (HPLC-MSD), LOQ(s): 0.01 mg/kg (tuber), max. sample storage time in month(s): 5 ASB2013-9886

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment kg a.i./ha	Water l/ha	kg a.i./hl	Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
	(a)	(b)				(c)		(a)		(d)	(e)
study ChR-06-2009, trial ChR-06-2009/NF01 France (FR) 62860 Inchy en Artois 2010-08-13	Ditta	1) 2006-05-03 (planting) 2) 2006-06-30 - 2006-07-21 3) 2006-09-01	0.21 0.22 0.21 0.22 0.20 0.20 0.20 0.20 0.21 0.20	260 270 250 270 250 250 240 250 260 250	0.081 0.082 0.083 0.082 0.080 0.080 0.082 0.080 0.081 0.081	2006-06-23[4)] 2006-06-30[4)] 2006-07-07[4)] 2006-07-14[4)] 2006-07-21[4)] 2006-07-28[4)] 2006-08-04[4)] 2006-08-11[4)] 2006-08-18[4)] 2006-08-25[4)]	BBCH 49 (tuber)	tuber	0.019	7	4) spraying analytical method: GIR/MET/FLUAZINA/03V1 (HPLC-MSD), LOQ(s): 0.01 mg/kg (tuber), max. sample storage time in month(s): 3 ASB2013-9890 ASB2010-7042
study ChR-06-2009, trial ChR-06-2009/NF02 France (FR) 37110 Dame Marie les Bois 2010-08-13	Ditta	1) 2006-05-12 (planting) 2) 2006-07-25 - 2006-08-10 3) 2006-09-05	0.22 0.21 0.21 0.21 0.21 0.22 0.21 0.21 0.22 0.21	330 310 320 310 300 320 310 310 320 320	0.067 0.067 0.066 0.067 0.069 0.069 0.068 0.067 0.069 0.067	2006-06-26[4)] 2006-07-03[4)] 2006-07-10[4)] 2006-07-17[4)] 2006-07-24[4)] 2006-07-31[4)] 2006-08-07[4)] 2006-08-14[4)] 2006-08-21[4)] 2006-08-29[4)]	BBCH 48 (tuber)	tuber	<0.010	7	4) spraying analytical method: GIR/MET/FLUAZINA/03V1 (HPLC-MSD), LOQ(s): 0.01 mg/kg (tuber), max. sample storage time in month(s): 3 ASB2013-9890 ASB2010-7042

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

A 2.3.1 Nature of residues

Reference:	K II A 6.5.1
Report	Abiotic degradation (Hydrolysis) of Dimethomorph under typical conditions (pH, temperature and time) of processing Witte, A. 2008 20071310/01-PCHP ! R-22169 ASB2010-13802
Guideline(s):	Yes (EU 7035/VI/95)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

The hydrolytic stability of dimethomorph was investigated simulating three different conditions:
1) Sterilization (20 minutes at 120°C, pH 6),
2) Baking, brewing, boiling (60 minutes at 100°C pH 5)
3) Pasteurization (20 minutes at 90°C, pH 4).
After equilibration to room temperature, the sample were stabilized with acetonitrile and analyzed by HPLC-UV at 290 nm.

Results and discussions

The study shows that dimethomorph does not hydrolyze under the conditions specified. No other compounds but the active ingredient were observed under any of the hydrolytic conditions specified.

Table A 7: Identification of compounds from high temperature hydrolysis study

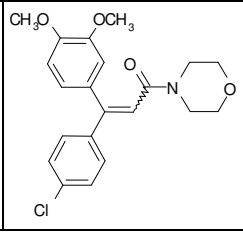
Common name/code ID No.	Chemical name	Chemical structure
Dimethomorph	4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-1-oxo-2-propenyl]morpholine	

Table A 8: High temperature hydrolysis of dimethomorph

Temperature (°C)	Time (min)	pH	Processes represented	Parent	% of initial dose
90	20	4	pasteurization	dimethomorph	100
100	60	5	baking/boiling	dimethomorph	93
120	120	6	sterilization	dimethomorph	99

Conclusion

Dimethomorph is hydrolytically stable under these conditions.

Comments of zRMS:	Acceptable.

A 2.4 Residues in rotational crops

No new study on residues in rotational crops has been submitted.

A 2.5 Residues in livestock

No new study on residues in livestock has been submitted.

A 2.6 Other studies/information

None

Appendix 3 Pesticide Residue Intake Model (PRIMo)

Dimethomorph (sum of isomers)			
Status of the active substance:		Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0,05**	ARfD (mg/kg bw):	**0,6**
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 - refined calculations

	TMDI (range) in % of ADI minimum - maximum
	10 45
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)
45,1	WHO Cluster diet B	10,8	Wine grapes	10,8	Wine grapes	6,2	Tomatoes	
36,9	NL child	5,0	Oranges	4,6	Table grapes	3,8	Head cabbage	
36,6	FR all population	24,0	Wine grapes	2,8	Witloof	2,8	Lettuce	
31,3	IE adult	7,5	Wine grapes	3,8	Celery	2,6	Lettuce	
29,3	DE child	7,6	Table grapes	6,1	Oranges	1,9	Tomatoes	
28,5	WHO regional European diet	11,3	Lettuce	4,4	Head cabbage	2,2	Tomatoes	
26,4	WHO cluster diet E	9,6	Wine grapes	3,1	Head cabbage	2,8	Lettuce	
26,2	ES adult	16,1	Lettuce	2,5	Wine grapes	2,1	Oranges	
24,4	NL general	3,8	Wine grapes	3,6	Lettuce	2,9	Witloof	
23,9	WHO Cluster diet F	9,0	Lettuce	3,6	Wine grapes	3,3	Head cabbage	
23,4	ES child	12,5	Lettuce	3,5	Oranges	2,0	Tomatoes	
23,0	FR toddler	4,0	Broccoli	4,0	Milk and cream,	3,2	Oranges	
21,5	PT General population	14,9	Wine grapes	1,8	Tomatoes	1,7	Table grapes	
20,0	IT adult	11,3	Lettuce	2,3	Tomatoes	0,8	Table grapes	
19,6	SE general population 90th percentile	7,5	Head cabbage	1,5	Tomatoes	1,2	Milk and cream,	
18,4	UK vegetarian	4,9	Wine grapes	4,2	Lettuce	1,4	Oranges	
18,0	WHO cluster diet D	2,2	Head cabbage	2,2	Wine grapes	2,0	Tomatoes	
17,5	IT kids/toddler	8,7	Lettuce	2,9	Tomatoes	0,8	Celery	
16,7	UK Adult	6,5	Wine grapes	3,5	Lettuce	0,9	Oranges	
16,4	UK Toddler	3,2	Oranges	2,3	Sugar beet (root)	2,1	Milk and cream,	
16,4	DK child	4,2	Lettuce	3,3	Cucumbers	1,3	Milk and cream,	
15,1	FR infant	3,0	Broccoli	2,6	Milk and cream,	1,6	Witloof	
13,8	DK adult	8,4	Wine grapes	0,8	Tomatoes	0,7	Head cabbage	
12,1	UK Infant	3,9	Milk and cream,	2,1	Oranges	1,2	Head cabbage	
10,3	PL general population	4,4	Head cabbage	1,9	Table grapes	1,8	Tomatoes	
10,2	LT adult	4,8	Head cabbage	1,9	Lettuce	1,2	Tomatoes	
10,0	FI adult	2,3	Lettuce	1,8	Wine grapes	1,6	Oranges	

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

Fluazinam (F)

Status of the active substance:		Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0,01**	ARfD (mg/kg bw):	**0,07**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2008**	Year of evaluation:	**2008**

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 - refined calculations

	TMDI (range) in % of ADI minimum - maximum
	8 56
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)
56,3	DE child	36,2	Apples	7,1	Milk and cream,	2,1	Wheat	
48,0	NL child	19,0	Apples	14,7	Milk and cream,	2,4	Wheat	
39,3	FR toddler	19,8	Milk and cream,	7,9	Apples	1,5	Potatoes	
37,2	UK Infant	19,4	Milk and cream,	5,0	Sugar beet (root)	4,7	Apples	
35,0	UK Toddler	11,4	Sugar beet (root)	10,3	Milk and cream,	5,1	Apples	
27,7	FR infant	12,9	Milk and cream,	7,5	Apples	1,3	Carrots	
27,5	WHO Cluster diet B	4,3	Wheat	3,4	Wine grapes	3,0	Apples	
25,6	DK child	7,0	Apples	6,3	Milk and cream,	2,8	Wheat	
22,2	IE adult	2,5	Apples	2,4	Wine grapes	1,8	Sweet potatoes	
20,1	ES child	6,3	Milk and cream,	3,4	Apples	2,2	Wheat	
18,1	WHO cluster diet E	3,0	Wine grapes	2,5	Apples	2,0	Wheat	
18,0	SE general population 90th percentile	6,2	Milk and cream,	3,2	Apples	1,6	Wheat	
15,7	FR all population	7,6	Wine grapes	1,6	Wheat	1,4	Apples	
15,4	WHO cluster diet D	3,3	Wheat	2,5	Milk and cream,	2,0	Apples	
15,3	PT General population	4,7	Wine grapes	3,2	Apples	2,0	Wheat	
14,6	NL general	3,5	Apples	3,3	Milk and cream,	1,2	Wine grapes	
14,6	WHO regional European diet	2,4	Milk and cream,	2,0	Apples	1,5	Wheat	
14,4	WHO Cluster diet F	2,0	Milk and cream,	2,0	Apples	1,8	Wheat	
12,3	ES adult	2,5	Milk and cream,	2,3	Apples	1,2	Wheat	
12,2	DK adult	2,7	Milk and cream,	2,6	Wine grapes	2,4	Apples	
12,1	LT adult	5,6	Apples	2,0	Milk and cream,	1,0	Potatoes	
11,2	UK vegetarian	1,9	Sugar beet (root)	1,8	Apples	1,6	Milk and cream,	
10,4	UK Adult	2,0	Wine grapes	2,0	Sugar beet (root)	1,5	Milk and cream,	
10,2	IT kids/toddler	3,3	Wheat	2,7	Apples	0,8	Other cereal	
9,3	PL general population	6,1	Apples	1,0	Potatoes	0,4	Tomatoes	
8,3	FI adult	2,8	Milk and cream,	1,2	Apples	0,6	Wine grapes	
7,9	IT adult	2,4	Apples	2,1	Wheat	0,6	Tomatoes	

Conclusion:

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

REGISTRATION REPORT
Part B

Section 5 Environmental Fate

Detailed summary of the risk assessment

Product code: **BANJO forte**

Active Substance(s): **Fluazinam 200 g/L**
Dimethomorph g/L

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: **ADAMA Deutschland**

Date: **April 2015**

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 Banjo Forte containing the active substances fluazinam and dimethomorph.in its intended uses in potatoes 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 Banjo Forte

Code	MCW-853		
plant protection product	Banjo Forte		
applicant	ADAMA Deutschland		
date of application	March 2013		
Formulation type (WP, EC, SC, …; density)	SC		
active substance	Fluazinam	Dimethomorph	
Concentration of as	200 g/ L	200 g/L	

5.2 Proposed use pattern

The critical GAP used for exposure assessment in the central zone for Banjo Forte is presented in Table 5.2-1. A list of the intended use within the central zone is given in Appendix 3

Table 5.2-1: Critical use pattern of Banjo Forte

Indication	**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)**
00-001	potatoes BBCH 31-91	spraying	4 x, min. interval 7 d, 1. application: 50 % (22 days after emergence) 2. – 4 application: 80 % summer	fluazinam: 4 x 200 = 800, dimethomorph: 4 x 200 = 800	fluazinam 1. 100 2. 40 3. 40 4. 40 = 220 dimethomorph: 1. 100 2. 40 3. 40 4. 40 = 220

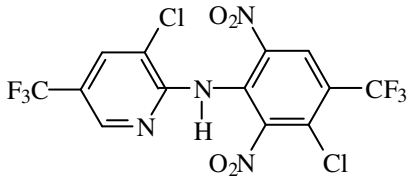
Information on the active substances

5.3 Information on the active substances

5.3.1 Fluazinam

5.3.1.1 Identity, further information of fluazinam

Table 5.3-1: Identity, further information on fluazinam

Active substance (ISO common name)	Fluazinam
IUPAC	3-Chlor-N-(3-chlor-5-trifluormethyl-2-pyridyl)-α,α,α-trifluor-2,6-dinitro-p-toluidin
Function (e.g. fungicide)	contact fungicide
Status under Reg. (EC) No 1107/2009	approved
Date of approval	01/03/2009
Conditions of approval	PART A Only uses as fungicide may be authorised. PART B In assessing applications to authorise plant protection products containing fluazinam for uses other than potatoes, Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorisation is granted. For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fluazinam, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 20 May 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the protection of the operators' and workers' safety. Authorised conditions of use must prescribe the application of adequate personal protective equipment and risk mitigation measures to reduce the exposure, — the residues in food of plant and animal origin and evaluate the dietary exposure of consumers, — the protection of aquatic organisms. In relation to this identified risk, risk mitigation measures, such as buffer zones, should be applied where appropriate
RMS	Austria
Minimum purity of the active substance as manufactured (g/kg)	945
Molecular formula	$C_{13}H_4Cl_2F_6N_4O_4$
Molecular mass	465.1 g/mol
Structural formula	

5.3.1.2 Physical and chemical properties of fluazinam

Physical and chemical properties of fluazinam as agreed at EU level (see SANCO/127/08 – rev.1) and considered relevant for the exposure assessment are listed in Table 5.3-2.

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

	Value	**Reference**
Vapour pressure (at 20 °C) (Pa)	2.9 x 10^{-3} Pa at 20 °C (arithmetic mean from 3 studies, see list)* 7.5 x 10^{-3} Pa (LoEP 2008) 1.12 x 10^{-3} Pa (Meinerling 2011) 1.72 x 10^{-4} Pa (Oudhoff 2011)	**SANCO/127/08 – rev.1**
Henry's law constant (Pa × m³ × mol^{-1})	25.9 Pa.m³.mol^{-1} at 20 °C	
Solubility in water (at 25 °C in mg/L)	at 20 ± 1 °C (99.8 % w/w) 0.106 mg/L in buffered solution (at pH 5) 0.135 mg/L in buffered solution (at pH 7) 2.72 mg/L in buffered solution (at pH 9)	
Partition co-efficient (at 25 °), log Pow	3.56 (4.03)	
Dissociation constant, pKa	7.34	
Hydrolytic degradation	pH 5: stable; pH 7: 46 d (42 d); pH 9: 6 d (5.6 d)	
Photolytic degradation	2.5 d	
Quantum yield of direct phototransformation in water > 290 nm	Φ = 1.7 x 10 $^{-5}$ mol Einstein $^{-1}$ pH 6 destilled water	
Photochemical oxidative degradation in air (calculation according to Atkinson)	A DT_{50} of >2 days cannot be completely excluded (Atkinson method)	
Direct Phototransformation 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.	DT_{50} = 5 d (Maximum for application period May - August)	

5.3.1.3 Metabolites of fluazinam

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

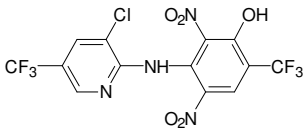
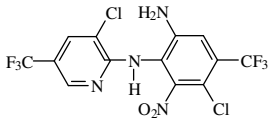
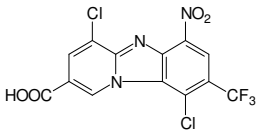
No new study on the fate and behaviour of fluazinam or Banjo Forte has been performed. Hence no potentially new metabolites need to be considered.

The risk assessment for these metabolites has already been performed for EU approval (see (SANCO/127/08 – rev.1).Therefore no new risk assessment hence no exposure assessment for these metabolites is necessary.

Potential ground water contamination by the soil metabolites HYPA was evaluated for EU approval of fluazinam. PECgw modelled with FOCUS PELMO 3.3.2 was less than 0.1 µg/L for the metabolites in all 9 scenarios based on an application of 10 x 200 g ai/ha in potatoes at 4 weeks post emergence …..

However, the leaching potential into groundwater of the soil metabolite HYPA will be assessed for the application of the plant protection product and its intended uses.

Table 5.3-3: Metabolites of fluazinam 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 (SANCO/127/08 – rev.1)
HYPA 5-(3-chloro-5-trifluoromethyl-2-pyridylamino)α,α,α-trifluoro-4,6-dinitro-o-cresol	 $C_{13}H_6F_6N_4O_6$	Soil (aerob): Max. 13.9 % at day 48	Aquatic organism: Water: relevant Sediment: relevant Terrestrial organism: relevant Groundwater: not relevant (Step 2/Step 3-4)[1)]
AMPA 4-chloro-6-(3-chloro-5-trifluoromethyl-2-pyridylamino)α,α,α-trifluoro-5-nitro-m-toluidin	 $C_{13}H_6Cl_2F_6N_4O_2$	Sediment: max. 26.7 % at day 14	Aquatic organism: Water: relevant Sediment: relevant Terrestrial organism : not relevant Groundwater: not relevant (Step 2/Step 3-4)[1)]
G-504 4,9-dichloro-6-nitro-8-(trifluoromethyl)-pyrido-[1,2-a]benzimidazole-2-carboxylic acid	 $C_{13}H_6Cl_2F_3N_3O_4$	aqueous photolysis: max. 17.1 % at day 10	Aquatic organism: Water: relevant Sediment: relevant Terrestrial organism: : not relevant Groundwater: not relevant (Step 2/Step 3-4)[1)]

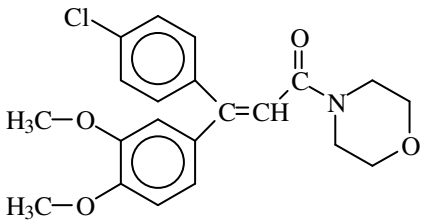
[1)] According to Guidance Document on the assessment of the relevance of metabolites in groundwater of substances regulated under council directive 91/414/EEC (SANCO/221/2000 –rev.10- final - 25 February 2003)

5.3.2 Dimethomorph

5.3.2.1 Identity, further information of dimethomorph

Table 5.3-4: Identity, further information on dimethomorph

Active substance (ISO common name)	Dimethomorph

IUPAC	(*EZ*)-4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)acryloyl]morpholine
Function (e.g. fungicide)	fungicide
Status under Reg. (EC) No 1107/2009	approved
Date of approval	01/10/2007
Conditions of approval	Part A. Only uses as fungicide may be authorised. Part B. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on dimethomorph, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 24 November 2006 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the operators and workers safety. Authorised conditions of use must prescribe the application of adequate personal protective equipment; — to the protection of birds, mammals and aquatic organisms. Conditions of authorisation should include risk mitigation measures, where appropriate.
RMS	Germany
Minimum purity of the active substance as manufactured (g/kg)	920
Molecular formula	$C_{21}H_{22}ClNO_4$
Molecular mass	387.9 g/mol
Structural formula	

5.3.2.2 Physical and chemical properties of Dimethomorph

Physical and chemical properties of dimethomorph as agreed at EU level (see SANCO/10040/06) and considered relevant for the exposure assessment are listed in Table 5.3-5

Table 5.3-5: EU agreed physical chemical properties of dimethomorph relevant for exposure assessment

	Value	**Reference**
Vapour pressure (at 20 °C) (Pa)	9.7 x 10^{-7} Pa (E-Isomer) 1.0 x 10^{-6} Pa (Z-Isomer)	SANCO/10040/06
Henry's law constant (Pa × m^3 × mol^{-1})	5.4 x 10^{-6} Pa m³/mol (E-Isomer) 2.5 x 10^{-5} Pa m³/mol (Z-Isomer)	

Solubility in water (at 25 °C in mg/L)	in deionizated water: *E*-isomer: 37.4 *Z*-isomer: 24.1 as a whole *E/Z:* 61.4 pH 4: *E*-isomer: 40.6 *Z*-isomer: 40.5 as a whole *E/Z:* 81.1 pH 7: *E* -isomer: 31.0 *Z*-isomer: 18.2 **as a whole *E/Z:* 49.2** pH 9: *E*-isomer: 29.3 *Z*-isomer: 12.5 as a whole *E/Z:* 41.8 *E*-isomer: 47.2 (LoEP) *Z*-isomer: 10.7 (LoEP) all values measured at 20 ± 1 °C	
Partition co-efficient (at 25 °), log P_{OW}	log PO/W = 2.63 (*E*-Isomer) log PO/W = 2.73 (*Z*-Isomer) all values measured at 20 ± 1 °C	
Dissociation constant, pKa	-1.305	
Hydrolytic degradation	After 10 weeks at 70 °C and 90 °C less than 10 % of active substance degradation at pH 4, 7 and 9	
Photolytic degradation	DT_{50} = 25 - 28 d (pH 5 at 20 °C)	
Quantum yield of direct phototransformation in water > 290 nm	$\Phi = 6.71 \times 10^{-6}$ (pH 7, 20 °C) DT_{50} = 303.4 ± 6 h (pH 7,.20 ± 2 °C)	
Photochemical oxidative degradation in air (calculation according to Atkinson)	DT_{50} =0.82 d (1.5×10^6 OH radicals/cm³, 12 h day)	

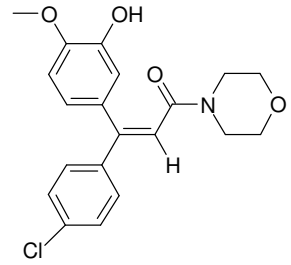
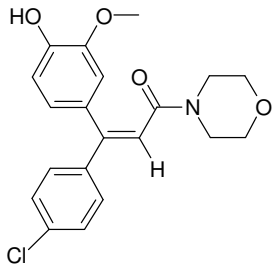
5.3.2.3 Metabolites of Dimethomorph

Environmental occurring metabolites of dimethomorph requiring further assessment according to the results of the assessment of dimethomorph for EU approval are summarized in Table 5.3-6.

No new study on the fate and behaviour of dimethomorph or Banjo Forte has been performed. Hence no potentially new metabolites need to be considered.

The risk assessment for these metabolites has already been performed for EU approval (see SANCO/10040/06Therefore no new risk assessment hence no exposure assessment for these metabolites is necessary.

Table 5.3-6: Metabolites of dimethomorph 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 (SANCO/10040/06)
Mono-desmethyl als Isomerengemisch (meta-desmethyl-Dimethomorph = Z67 =CL900987 und para-desmethyl-Dimethomorph = Z69 = CL900986)	  $C_{20}H_{20}ClNO_4$	Soil (anaerob): max. 14.8 % at day 7 Sediment: max. 7.8 % at 24 h, 6.3 % at 48 h and 6.3 % at day 7	

[1)] According to Guidance Document on the assessment of the relevance of metabolites in groundwater of substances regulated under council directive 91/414/EEC (SANCO/221/2000 –rev.10- final - 25 February 2003)

5.4 Summary on input parameter for environmental exposure assessment

5.4.1 Rate of degradation in soil

5.4.1.1 Laboratory studies

Fluazinam

Three new studies have been submitted regarding route and rate of degradation in soil of fluazinam (Morlock 2008b, Mamouni 2008 and Ponte 2009, see Appendix 2). The environmental exposure assessment is based on the DT_{50} values from the laboratory as summarized in Table 5.4-1.

Table 5.4-1: Summary of aerobic degradation rates for fluazinam as modelling endpoint-laboratory studies

Soil type	pH (H_2O)	DT_{50} (d) 20 °C pF2/10 kPa	Kinetic, Fit	Reference
"18 Acres", sandy loam	6.9	152.6	DFOP, slow phase chi^2 4.7	Barthi 1985
"Frensham", loamy sand	6.4	221.8	SFO **chi^2 =** 6.2	
Sand, Speyer 2.2	6.0	59.9	SFO **chi^2 =** 13.6	Ryan 1992

Pappelacker, sandy loam	7.6	17.1	SFO **r^2** = 0.992	Mawad, 2003
Speyer 2.3, sandy loam	6.9	25.1	SFO r^2 = 0.938	Ponte 2009
LUFA 2.2, loamy sand	6.3	89.3	r^2 = 0.923	Morlock 2008
LUFA 5M, sandy loam	7.9	58.2	r^2 = 0.964	
Vouvry III, sandy loam	7.7	35.9	chi^2 = 3.5	Mamouni 2008
Aggregated DT_{50} (n=8)	**Coefficient of variation (%)**	86		
	Geometric mean/median (d)	59.7/ 59.1		
	90 th percentile	173.4		

The DT_{50} values of fluazinam do not show any pH dependency.

Table 5.4-2: Summary of aerobic degradation rates for metabolite HYPA - laboratory studies

Soil type	**pH (H_2O)**	**T (°C)**	**Moisture**	**DT_{50}/ DT_{90} (d)**	**f.f.**	**DT_{50} (d) 20 °C pF2/10kPa**	**Kinetic, Fit**	**Reference**
Speyer 2.1, sand	5.8	20	40 % of MWHC	148/ 490		148	SFO 0.996	Van der Gauww, 2002
Speyer 2.2, loamy sand	5.6	20	40 % of MWHC	74/ 245		74	SFO 0.958	
Senozan, clay loam	6.2	20	40 % of MWHC	54/ 179		49.3	SFO 0.961	
Clay loam (Chalgrove Farm) Original study	7.4	20	pF2.3	388.8/-		388.8		Johnson, 2000
Speyer 2.2, loamy sand	6.0	20	40-60 %MWHC	81.5/ -		81.5	SFO 0.798	Hiler 2009
Speyer 2.3, sandy loam	6.9	20	40-60 %MWHC	85.6/ 284		85.6	SFO 0.877	
Speyer 6S, clay	7.7	20	40-60 %MWHC	99.0/ 329		62	SFO 0.893	
LUFA 2.2, loamy sand	6.3	20	45 % MWHC	87.0/ 288.9		87.0	SFO 0.971	Morlock 2008b
LUFA 2.3, sandy loam	7.6	20	45 % MWHC	202.7/ 673.3		202.7	SFO 0.914	
LUFA 5M, sandy loam	7.9	20	45 % MWHC	206.3/ 685.3		206.3	SFO 0.903	

Speyer 2.1, sand	5.7	20	pF2-2.5	10.0/ 41.9		12.62	FOMC, DT90/3.32 chi^2 = 7.5	Walther 2008
Speyer 2.2, loamy sand	6.0		pF2-2.5	80.9/ 268.8		80.9	SFO chi^2 = 3.9	
Soil III Senozan, clay loam	7.0	20	pF2-2.5	104.5/		104.5	HSslow phase chi^2 = 4.1	
from degradation study with parent								
Pappelacker, sandy loam	7.6	20	40 % of MWHC	105.2	0.193	105.2	SFO	Mawad 2003
Aggregated DT_{50} (n=14)		**Coefficient of variation (%)**				78		
		Maximum (d) (PECsoil CA)				388		
		Geomeric mean/ median(d) (PECgw and sw CA)				93.1/ 86.3		
		90^{th} percentile (PECgw and PECsoil NA)				205.2		
Formation Fraction from ai → HYPA		**Maximum**			0.193	not determined		

Dimethomorph

One new study has been submitted regarding route and rate of degradation in soil of Dimethomorph (Morlock, 2008a, see Appendix 2). DT_{50} values from the laboratory are summarized in Table 5.4-3.

Table 5.4-3: Summary of aerobic degradation rates for dimethomorph - laboratory studies

Soil type	**pH (H_2O)**	**DT_{50} (d) 20 °C pF2**	**Kinetic, Fit**	**Reference**
Nieder-Ingelheim, DE, Sandy loam	7.5	40.1	SFO	Schlüter, 1990
Woodstock Kent, UK, Silty clay loam	6.4	90.2	SFO	Edwards and Standen, 1990
LUFA Speyer 2.2, DE, Loamy sand	6.3	55.1	SFO	Steinführer, Suchomel and Weis 1998
New Jersey, US, sandy loam	7.3	41.5	SFO	McCullough and Yan, 1998
Ipswich, UK, Sandy loam	6.4	21.0	SFO	Hall and Lowrie, 2001
LUFA 2.2, DE, Sand	6.5	68.7	SFO	Morlock, 2008a
LUFA 5M, DE, Sandy loam	8.7	20.2	SFO	Morlock, 2008a
Aggregated DT_{50} (n= 7)	**Coefficient of variation (%)**	60.1		
	Geometric mean/median (d)	42.3		

	90 th percentile	77.3	

The DT_{50} values of dimethomorph do not show any pH dependency.

5.4.1.2 Field studies

Fluazinam

The field dissipation rates of fluazinam were evaluated during EU assessment. No additional studies have been performed. The DT_{50} values are summarized in Table 5.4-4.

Table 5.4-4: Field degradation studies of fluazinam- persistence endpoint

soil / location	**pH**	**depth (cm)**	**DT_{50} (d)**	**DT_{90} (d)**	**Kinetic, Fit (r^2)**	**DT_{50} (d) 20 °C, pF2**	**Fit, Kinetic**	**Reference**
Cornwall, clay loam, UK	6.6	0-10	35.0		SFO 0.881	-	-	Kennedy 1996
Lincolnshire, sandy clay loam, UK	7.5	0-10	40.8		SFO 0.816	-	-	
"Varendorf", loamy sand, D	6.1	0-10	28.0		SFO 0.975	-	-	Burke 1992
"Klein Zecher", sandy loam, D	6.1	0-10	8.3		SFO 0.984	-	-	
"Ottersweier", clay, D	5.3	0-10	13.4		SFO 0.972	-	-	
"Sollern", clay loam, D	6.8	0-10	16.2		SFO 0.982	-	-	
DT50 aggr. (n = 6)	Maximum		40.8					

Field dissipation studies do not fullfill ctgb criteria because of soil photolysis as relevant degradation pathway, so that DT_{50} values can not be used for PEC_{GW} modeling. The respective DT_{50} values are summarized in Table 5.4-5.

Table 5.4-5: Field degradation studies of fluazinam as modelling endpoints- not fulfilling ctgb criteria (not applicable for PEC_{GW})

soil / location	**pH**	**depth (cm)**	**DT_{50} (d)**	**DT_{90} (d)**	**Kinetic, Fit**	**DT_{50} (d) 20 °C, pF2**	**Kinetic Fit (r^2),**	**Reference**
Cornwall, clay loam, UK	6.6	0-10	35.0		0.881	23.8	SFO 0.882	Kennedy 1996
Lincolnshire, sandy clay loam, UK	7.5	0-10	40.8		0.816	25.7	SFO 0.820	

"Varendorf", loamy sand, D	6.1	0-10	28.0		0.975	20.8	SFO 0.961	Burke 1992
"Klein Zecher", sandy loam, D	6.1	0-10	8.3		0.984	8.4	SFO 0.990	
"Ottersweier", clay, D	5.3	0-10	13.4		0.972	13.5	SFO 0.967	
"Sollern", clay loam, D	6.8	0-10	16.2		0.982	13.6	SFO 0.983	
Geometric Mean (n = 6)						17.2		

The DT_{50} values of fluazinam do not show any pH dependency.

Dimethomorph

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

Table 5.4-6: Field degradation studies of dimethomorph

soil / location	**pH**	**depth (cm)**	**DT_{50} (d)**	**DT_{90} (d)**	**Fit, Kinetic, Parameters**	**DT_{50} (d) 20 °C, pF2**	**Fit, Kinetic**	**Reference**
Sandy loam (Schwabenheim)	7.3	0-10	33.8	112.4	0.951, SFO			Thiele, 1990 a
Sandy loam (Malborn)	5.2	0-10	38.9	129.3	0.889, SFO			Thiele, 1990 b
Clay (Leipertingen)	7.3	0-10	40.1	133.3	0.990, SFO			Thiele, 1991 a
Sandy loam (Schwabenheim)	7.3	0-10	45.7	151.7	0.955, SFO			Thiele, 1991 b
Loamy sand (Krögsberg)	6.6	0-10	52.9	175.7	0.947, SFO			Thiele, 1991 c
Loamy sand (UK-Stratford)	6.7	0-10	61	203	0.831, SFO			Bayer and Zangmeister, 2002
Loamy sand (North-F-Merville)	6.5	0-10	34	112	0.995, SFO			Bayer and Zangmeister, 2002
Sand (Sp-Utrera)	6.5	0-10	10		0.98, SFO			
DT50 aggr. (n = 7)	Maximum (PECsoil)		61					

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 dimethomorph fulfilling ctgb criteria (applicable for PEC_{GW})

soil / location	pH	depth (cm)	DT_{50} (d)	DT_{90} (d)	Kinetic, Fit	DT_{50} (d) 20 °C, pF2	Fit, Kinetic	Reference
Sandy loam (Schwabenheim)	7.3	0-10	33.8	112.4	0.951, SFO	33.8	0.951, SFO	Thiele, 1990 a
Sandy loam (Malborn)	5.2	0-10	38.9	129.3	0.889, SFO	38.9	0.889, SFO	Thiele, 1990 b
Clay (Leipertingen)	7.3	0-10	40.1	133.3	0.990, SFO	40.1	0.990, SFO	Thiele, 1991 a
Sandy loam (Schwabenheim)	7.3	0-10	45.7	151.7	0.955, SFO	45.7	0.955, SFO	Thiele, 1991 b
Loamy sand (Krögsberg)	6.6	0-10	52.9	175.7	0.947, SFO	52.9	0.947, SFO	Thiele, 1991 c
Geometric Mean (n = 5)						41.79		

The DT_{50} values of dimethomorph do not show any pH dependency.

5.4.2 Adsorption/desorption

Fluazinam

One new study has been submitted regarding adsorption/desorption in soil of fluazinam (Geffke 2007b, see Appendix 2). The exposure modeling is based on the K_{foc} values as summarized in Table 5.4-8 and **Fehler! Verweisquelle konnte nicht gefunden werden.**Table 5.4-9.

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

Soil Type	OC (%)	pH (H_2O)	K_f (mL g^{-1})	K_{foc} (mL g^{-1})	1/n (-)	Reference
Speyer 2.1, sand	0.48	6.6	11.12	2317	0.6204	Galicia 1991
Speyer 2.2, loamy sand	2.55	6.6	43.48	1705	0.6813	
Itingen II, silt loam	1.42	8.2	27.19	1915	0.6504	
Diegten, clay loam	2.0	7.6	37.88	1894	0.6492	
Soil 1, clay	3.3	6.3	1056	32000	1.079	Geffke 2007
Soil 2, silt loam	2.4	7.7	1897	79042	1.129	
Soil 3, loam	3.3	6.5	928	28121	1.039	
Soil 4, silt	1.4	7.3	61.4	4386	0.642	

Soil 5, loamy sand	4.4	3.9	3214	73045	1.1635	
Arithmetic mean (n = 9)				24936	0.85	

The K_f values of fluazinam show no pH dependency..

Table 5.4-9: K_f, K_{foc} and 1/n (Freundlich exponent) values for fluazinam metabolite HYPA

Soil Type	**OC (%)**	**pH (H2O)**	**K_f (mL g^{-1})**	**K_{foc} (mL g^{-1})**	**1/n (-)**	**Reference**
Kenny Hill UK, Sandy loam	3.07	7.7	14	450	0.8276	Muller 1993
East Anglia UK, Sandy loam	1.86	8.1	13	700	0.84	
Gayton UK, Loamy sand	1.80	7.9	8.1	450	0.8091	
Lilly field UK, Coarse sand	0.46	5.7	4.3	920	0.7554	
Nebo UK, Silty clay loam	1.45	5.0	19	1300	0.75	
Salmonds bridge UK ,Sandy loam	1.57	4.7	26	1700	0.7631	
Arithmetic mean (n = 6)				918/ (920 EU)	0.7928	

The K_f values of HYPA show no pH dependency.

Dimethomorph

One new study has been submitted regarding adsorption/desorption in soil of Dimethomorph (Geffke 2007a, see Appendix 2). The exposure modeling is based on the K_{foc} values as summarized in Table 5.4-10

Table 5.4-10: K_f, K_{foc} and 1/n (Freundlich exponent) values for dimethomorph

Soil Type	**OC (%)**	**pH, $CaCl_2$**	**K_f (mL g^{-1})**	**K_{foc} (mL g^{-1})**	**1/n (-)**	**Reference**
Schwabenheim, Sandy loamy silt	0.96	5.5	4.94	515	0.834	Haas-Jobelius, 1991
Ingelheim-Moers, Sandy loam	2.26	7.4	8.51	377	0.814	
Speyer 2.1, Sand	0.7	5.8	2.72	389	0.857	
Speyer 2.3, Silty sand	0.96	4.9	3.03	316	0.872	
Lufa-Speyer 2.1, Sand	0.79	5.7	4.47	566	0.887	Eicher, 1988
Lufa-Speyer 2.2, Humus sand	2.90	6.1	11.67	402	0.921	
Lufa-Speyer 2.3, Sandy loam	0.72	5.4	2.09	290	0.814	
Garderen, NL, Sand	0.9	5.7	4.11	457	0.88	

Bidinghuiden, NL, Silty clay loam	1.8	8.2	10.01	556	0.87	McCullough, 1997
Ravenswood, NL, Sand	3.8	5.8	19.5	513	0.88	
Princeton NJ, USA, Sandy loam	1.4	5.7	4.83	345	0.82	
Souli, Peleponnes, GR, Silt loam	2.39	7.2	18	753	0.7723	Geffke, 2007
Radyr, Wales, U.K., Loam	3.32	5.9	15	452	0.8209	
Rots, Normandie, FR, Silt	1.36	6.8	6.2	456	0.8354	
Arithmetic mean (n = 14)				456.2	0.8484	

The K_{foc}/K_f values of dimethomorph do not show any pH dependency.

5.4.3 Rate of degradation in water and sediment

Fluazinam

No new water/sediment study has been submitted. The exposure modeling is based on the results of the water/sediment study of fluazinam (Goodyear 1997) reviewed in the DAR. The DT_{50} values of the water/sediment study are summarized in Table 5.4-11.

Table 5.4-11: Degradation in water/sediment of fluazinam

Water/sediment system	**$DegT_{50}$ / $DegT_{90}$ whole system**	**Kinetic, Fit**	**$DissT_{50}$/ water**	**Kinetic, Fit**	**$DissT_{50}$/ sed.**	**Kinetic, Fit**	**Reference**
Virginia Water	3.1/ 10.3	SFO 0.994	2.4/ 7.9	SFO 0.978	2.9/ 9.6	SFO 0.957	Goodyear 1997
Emperor Lake	5.8/ 19.3	SFO 0.982	3.0/ 10.1	SFO 0.962	7.9/ 26.4	SFO 0.77	
Geometric mean	**4.2/ 13.9**		**2.7/ 8.9**		**4.8/ 15.9**		

Table 5.4-12: Degradation in water/sediment of metabolites HYPA and AMPA of fluazinam

Water/sediment system	**$DegT_{50}$ / $DegT_{90}$ whole system**	**Kinetic, Fit**	**$DissT_{50}$ water**	**Kinetic, Fit**	**$DissT_{50}$ sed.**	**Kinetic, Fit**	**Reference**
Metabolite HYPA							
Virginia Water	27.8/-	SFO 0.837	nd		nd		Goodyear 1997

Emperor Lake	55.5/-	SFO 0.945	nd		nd		
Geometric mean	**39.3/-**						
Metabolite AMPA							
Emperor Lake	nd		nd		34/ 113	SFO 0.930	Goodyear 1997

Dimethomorph

The exposure modeling is based on the results of the water/sediment studies of dimethomorph (Knoch, 1993 and Ebert, 2002) reviewed in the DAR. One new water/sediment study has been submitted (Flörchinger 2009a, see Appendix 2). The DT_{50} values of the water/sediment study are summarized in Table 5.4-11.

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

Water/sediment system	**$DegT_{50}$ / $DegT_{90}$ whole system**	**Kinetic, Fit**	**$DissT_{50}$/ $DegT_{50}$ water**	**Kinetic, Fit**	**$DissT_{50}$/ $DegT_{50}$ sed.**	**Kinetic, Fit**	**Reference**
I Bickenbach, brook (14C(U)-Chlorophenyl)	2.9/ 9.8	SFO	2.7/-	SFO	2.3/-	SFO	Knoch, 1993
II Unter Widdersheim, brook (14C(U)-Chlorophenyl)	2.1/ 7.0	SFO	4.4/-	SFO	2.2/-	SFO	
III Pond Kellmetschweiher	59/ 195	SFO, 1.0	15/-	SFO, 0.97	33/-	SFO, 0.93	Ebert, 2002
IV River Berghäuser Altrhein	16/ 52	SFO, 0.99	5/-	SFO, 0.97	7/-	SFO, 0.94	
V Pond (Chlorobenzene-U-14C]-Dimethomorph)	35/ 116	SFO , 0.983	16/-	SFO , 0.998			Flörchinger, 2009a
V Pond (Morpholine-U-14C]-Dimethomorph)	50/ 166	SFO , 0.982	19/-	SFO , 0.986			
Geometric mean	14.7/ 48.7		8.04/-		5.85/-		

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	Banjo Forte
Use No.:	00-001
Crop	Potatoes
Application rate:	Fluazinam: max. 200 g/ha per application (max. 800 g/ha total per crop/season) Dimethomorph: max. 200 g/ha per application (max. 800 g/ha total per crop/season)
Number of application/interval:	max. 4 application with min. interval 7 days
Crop interception:	50 %, 80 %, 80 %, 80 % (BBCH 31-91)

Table 5.5-2: Input parameter for active substance for PEC_{soil} calculation

Active substance	**DT_{50}**	**value in accordance to EU endpoint**
Fluazinam	40.8 d (Longest unnormalised SFO field value, n = 6)	
Metabolite HYPA	388.8 d (SFO maximum, n = 14, laboratory studies)	
Dimethomorph	61 d (maximum, n = 7 SFO unnormalised $DT_{50field}$)	

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

Due to the slow degradation of the metabolite HYPA in soil (DT90 > 365 d, SFO, laboratory data) the accumulation potential of HYPA needs to be considered. Therefore an accumulated soil concentration (PECaccu) is used for risk assessment that comprises background concentration in soil (PECbkgd) considering a tillage depth of 20 cm (arable crop) or 5 cm (permanent crops) and the maximum annual soil concentration PECact for a soil depth of 5 cm.

Beside PEC_{act} values also PEC_{twa}, 21 d values are required for risk assessment. PEC_{twa},21 d values are also presented in Table 5.5-3

Table 5.5-3: Results of PEC_{soil} calculation for application of Banjo Forte in potatoes (soil bulk density 1.5 g/cm^{-3}, soil depth 5 cm) according to use No. 00-001

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)**

Fluazinam	100+40+40+40= 220	0.2361	0.2060	-	-	-
Metabolit HYPA max. 13.9% , MG-ratio 0.96	13.3+5.3+5.3+5.3 = 29.21	0.0382	0.0375	20	0.0104	0.0487
Dimethomorph	100+40+40+40= 220	0.2531	0.2266	-	-	-
Banjo Forte* 4 x 1l/ha = 4 x 1156 g /ha	578+231+231+ 231=1241 (kum)	1.657	1.6074	-	-	-
1 x 1L/ha (50% interception)	578	0.7707	0.7487	-	-	-

*Relative density D^{20}_4: 1.156 at 20°C

5.6 Estimation of concentrations in surface water and sediment (PECsw/PECsed) (KIIIA1 9.7)

PEC_{sw} and PEC_{sed} calculations are provided according to the recommendations of the FOCUS working group on surface water scenarios in a stepwise approach considering the pathways drainage and runoff.

The relevant input parameters used for $PEC_{sw/sed}$ calculation are summarized in the tables below.

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

Parameter	**Endpoint used for $PEC_{sw/sed}$ calculation**	**Values in accordance to EU endpoint in LoEP**	**Remarks**
Active substance	fluazinam		
Molecular weight (g/mol)	465.1	yes	
Saturated vapour pressure (Pa)	not required for Step 1+2/	yes/no/not stated	
Water solubility (mg/L)	0.135 mg/L in buffered solution (at pH 7)	yes	
Diffusion coefficient in water (m^2/d)	not required for Step 1+2/ 4.3 x 10^{-5}	--	default
Diffusion coefficient in air (m^2/d)	not required for Step 1+2/0.43	--	default
Kf,oc (mL g-1)	24924	no	Arithmetic mean, n = 9 (see Table Table 5.4-8)
Freundlich Exponent 1/n	not required for Step 1+2		Arithmetic mean (see Table …)
Plant Uptake	not required for Step 1+2	-	default for non-systemic substances
Wash-Off factor from Crop (1/mm)	not required for Step 1+2/ 0.05 (MACRO) 0.50 (PRZM)	-	default /oder bei Wasserlöslichkeit < 8000 mg L^{-1}: Berechnung des Wertes nach FOCUS (2001)

DT_{50},soil (d)	59.7	no	Geomean (1st order, pF2.20°C, n = 8) Laboratory data (see Table 5.4-1)
DT_{50},water (d)	4.2 (Step 1, 2, 3)		Geomean of whole system (1st order, 20°C) (see Table 5.4-11)
DT_{50},sed (d)	4.2 (Step 1 + 2) 1000 (Step 3)		Geomean of whole system (1st order, 20°C) (see Table 5.4-11
DT_{50},whole system (d)	4.2 (Step 1 + 2)		Geomean of whole system (1st order, 20°C) (see Table 5.4-11)

Table 5.6-2: Input parameters for dimethomorph for $PEC_{sw/sed}$ calculations

Parameter	**Endpoint used for $PEC_{sw/sed}$ calculation**	**Values in accordance to EU endpoint in LoEP**	**Remarks**
Active substance	Dimethomorph		
Molecular weight (g/mol)	387.9	yes	
Saturated vapour pressure (Pa)	not required for Step 1+2/	yes/no/not stated	
Water solubility (mg/L)	as a whole *E/Z:* 49.2	no	
Diffusion coefficient in water (m^2/d)	not required for Step 1+2/ 4.3 x 10^{-5}	--	default
Diffusion coefficient in air (m^2/d)	not required for Step 1+2/0.43	--	default
Kf,oc (mL g-1)	456.2	no	Arithmetic mean, n = 14 (see Table Table 5.4-10)
Freundlich Exponent 1/n	not required for Step 1+2		Arithmetic mean, n = 14 (see Table Table 5.4-10)
Plant Uptake	not required for Step 1+2	-	default for non-systemic substances
Wash-Off factor from Crop (1/mm)	not required for Step 1+2/ 0.05 (MACRO) 0.50 (PRZM)	-	default /oder bei Wasserlöslichkeit < 8000 mg L^{-1}: Berechnung des Wertes nach FOCUS (2001)
DT_{50},soil (d)	41.79	no	Geomean (1st order, pF2.20°C, n =5), field data (see Table 5.4-7)
DT_{50},water (d)	14.7 (Step 1+ 2) 1000 (Step 3)	no	Geomean of whole system (1st order, 20°C), (see Table 5.4-11)
DT_{50},sed (d)	14.7 (Step 1,2, 3)	no	Geomean of whole system (1st order, 20°C), (see Table 5.4-11)
DT_{50},whole system (d)	14.7	no	Geomean of whole system (1st order, 20°C), (see Table 5.4-11)

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

Plant protection product	Banjo Forte
Use No. .	00-001
Crop:	potatoes
Application rate:	4 x 200 g ai/ha (both active substances)
Number of application/interval:	4 times, minimum interval 7 days
Application method:	spraying
Crop interception:	average crop cover

Table 5.6-4: FOCUS Step 3 Scenario related input parameters for $PEC_{SW/sed}$ calculations for the application of Banjo Forte

Crop	Scenario	Emergence date	Harvest date	Possible window of application (multiple)
	D3	10-May	15_Sept	1-Jun - 22-Jul
	D4	22-May	23_Sept	13-Jun -3-Aug
	D6	10-Apr	15-Jul	2-May - 22-Jun
	R1	5-May	8-Sept	27-May - 17-Jul
	R2	15-Mar	15-Jun	6-Apr - 27-May
	R3	10-Apr	1-Sep	2-May - 22-Jun

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

Table 5.6-5: Maximum FOCUS Step 1 and Step 2 PEC_{sw} and PEC_{sed} of fluazinam for the application of Banjo Forte in potatoes according to use No. 00-001

Fluazinam	**FOCUS Step 1**	**PECsw (µg/L)**	**PECsed (µg/L)**
		15.15	1940
	FOCUS Step 2	**PECsw (µg/L)**	**PECsed (µg/L)**
	North Europe	1.27 (1.84)	181.19 (53.86)
	South Europe	1.45 (1.85)	355.77 (100.98)

(numbers in brackets refer to respective single application)

Table 5.6-6: Maximum FOCUS Step 1 and Step 2 PEC_{sw} and PEC_{sed} of dimethomorph for the application of Banjo Forte in potatoes according to use No. 00-001

Dimethomorph	**FOCUS Step 1**	**PECsw (µg/L)**	**PECsed (µg/L)**
		173.17	756.43
	FOCUS Step 2	**PECsw (µg/L)**	**PECsed (µg/L)**
	North Europe	15.05 (4.96)	65.77 (21.0)
	South Europe	28.2 (8.84)	125.75 (38.69)

(numbers in brackets refer to respective single application)

Table 5.6-7: Global maximum FOCUS Step 3 PEC_{sw} and PEC_{sed} values for fluazinam and dimethomorph for the application of Banjo Forte in potatoes according to use No 00-001

	FOCUS STEP 3 Scenario	Water Body	PEC_{sw} global max (µg/L)	PEC_{sw} (µg/L) twa, 21d	PEC_{SED} global max (µg/kg)
Fluazinam	D3	ditch	0.665 mult **0.992 single**	**0.0492 mult** 0.0244 single	0.321mult **0.344 single**
	D4	pond	0.0291 mult **0.0389 single**	**0.0113 mult** 0.00634 single	**0.0718 mult** 0.0592 single
	D4	stream	0.549 mult **0.774 single**	**0.00366 mult** 0.00156 single	**0.0328 mult** 0.0232 single
	D6	ditch	0.665 mult **0.976 single**	**0.0445 mult** 0.0115 single	**0.287 mult** 0.173 single
	R1	pond	0.0292 mult **0.0389 single**	**0.00885 mult** 0.00636 single	**0.143 mult** 0.0956 single
	R1	stream	0.460 mult **0.687 single**	**0.0128 mult** 0.00770 single	**3.702 mult** 1.377 single
	R2	stream	0.618 mult **0.910 single**	**0.00900 mult** 0.00401 single	**9.215 mult** 2.078 single
	R3	stream	0.650 mult **0.969 single**	**0.0310 mult** 0.0142 single	**1.974 mult** 0.426 single
Dimethomorph	D3	ditch	0.704 multiple **1.046 single**	**0.0982 multiple** 0.0457 single	**0.499 mult.** 0.474 single
	D4	pond	**0.960 mult.** 0.143 single	**0.933 multiple** 0.138 single	**4.569 mult** 0.805 single.
	D4	stream	**1.302 mult.** 0.821 single	**0.646 multiple** 0.0934 single	**2.200 mult.** 0.370 single
	D6	ditch	0.706 multiple **1.029 single**	**0.0946 multiple** 0.0160 single	**0.461 mult.** 0.212 single
	R1	pond	**0.487 mult.** 0.210 single	**0.453 multiple** 0.177 single	**1.891 mult.** 0.601 single
	R1	stream	**5.521 mult.** 2.595 single	**0.278 multiple** 0.108 single	**3.274 mult.** 2.039 single
	R2	stream	**2.638 mult.** 0.960 single	**0.137 multiple** 0.0386 single	**4.436 mult.** 0.759 single
	R3	stream	**7.478 mult.** 3.177 single	**0.806 multiple** 0.152 single	**5.991 mult.** 1.291 single

Table 5.6-8: Global maximum FOCUS Step 4 PEC_{sw} and PEC_{sed} values for fluazinam for the application of Banjo Forte in potatoes according to use No 00-001- 90% nozzle reduction and buffer width 20 m

	FOCUS STEP 4 Scenario	**Water Body**	**PEC_{sw} global max (µg/L)**	**PEC_{sw} (µg/L) twa, 21d**	**PEC_{SED} global max (µg/kg)**
Fluazinam	D3	ditch	0.00558 mult **0.00856 single**	**0.000423 mult** 0.000215single	0.00278mult **0.00304single**
	D4	pond	0.00120mult **0.00157single**	**0.000481mult** 0.000268single	**0.00306mult** 0.00247single
	D4	stream	0.00600 mult **0.00864single**	**0.000040mult** 0.000017 single	**0.000358mult** 0.000258single
	D6	ditch	0.00558 mult **0.00842single**	**0.000384mult** 0.000100single	**0.00247 mult** 0.00150single
	R1	pond	0.00444mult **0.00157 single**	**0.00152mult** 0.000330single	**0.0216 mult** 0.00454 single
	R1	stream	0.0292mult **0.00855single**	**0.00299mult** 0.000554single	**0.200mult** 0.0707single
	R2	stream	0.00947mult **0.0102single**	**0.000509 mult** 0.000108single	**0.466mult** 0.105single
	R3	stream	0.0329mult **0.0108 single**	**0.00359mult** 0.000636single	**0.111 mult** 0.0188 single

5.7 Risk assessment ground water (KIIIA1 9.6)

5.7.1 Predicted environmental concentration in groundwater (PEC_{GW}) calculation for active substances and its metabolites (Tier 1 and 2)

Groundwater contamination by direct leaching of the active substances and its metabolites, degradation or reaction products through soil is generally assessed by groundwater model calculations.

The PEC of fluazinam and dimethomorph and its metabolites in ground water have been assessed with standard FOCUS scenarios to obtain outputs from the FOCUS PELMO 5.5.3. The FOCUS calculations were performed by zRMS using actualized input parameters, mentioned in the following table.

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

plant protection product	Banjo Forte
use No.	00-001
application rate (kg as/ha)	fluazinam and dimethomorph with 4 x 0.200 kg ai/ha
crop (crop rotation)	potatoes
relative application date	22 days after emergence
interception (%)	50, 80, 80, 80
soil moisture	100 % FC
Q10-factor	2.58
moisture exponent	0.7

simulation period (years)	26

Fluazinam

Table 5.7-2: Input parameters related to fluazinam for PEC_{GW} modelling

Parent	**Fluazinam**	**Remarks/Reference**
molecular weight (g/mol)	465.1	
DT_{50} in soil (d)	59.7	Geometric mean, laboratory data, n = 8, see Table 5.4-1
K_{foc}	24936	Arithmetic mean, n = 9, see Table 5.4-8
1/n	0.85	Arithmetic mean, n = 9, see Table 5.4-8
plant uptake factor		0

Table 5.7-3: Input parameters related to the metabolite HYPA of fluazinam for PEC_{GW} modelling

Metabolite 1	**HYPA**	**Remarks/Reference**
molecular mass	428.2	
Formation fraction	0.193	aus Mahwad 2003/DAR 2005
DT_{50} in soil (d)	93.1	Geometric mean, laboratory data, , n = 14, see Table 5.4-1
K_{foc}	920	
1/n	0.7928	
plant uptake factor		

Table 5.7-4: PEC_{GW} at 1 m soil depth for fluazinam and its metabolite HYPA for the application (cumulative) of Banjo Forte in potatoes (based on geom. mean for DT_{50} value and arithm. mean for K_{foc})

Crop/Group/use No.	**Szenario**	**80th Percentile PEC_{GW} at 1 m Soil Depth (µg L^{-1}) groundwater model: FOCUS-PELMO 5.5.3**	
		Fluazinam	**Metabolit HYPA**
Potatoes 00-001	**Châteaudun**	<0.01	<0.01
	Hamburg	<0.01	<0.01
	Jokioinen	<0.01	<0.01
	Kremsmünster	<0.01	<0.01
	Okehampton	<0.01	<0.01
	Piacenza	<0.01	<0.01
	Porto	<0.01	<0.01
	Sevilla	<0.01	<0.01

	Thiva	<0.01	<0.01

According to the PEC_{GW} modelling with FOCUS-PELMO 5.5.3 a groundwater contamination of the active substance fluazinam at a concentration of ≥ 0.1 µg/L is not expected for all 9 FOCUS groundwater scenarios .

For the metabolite HYPA a groundwater concentration of ≥ 0.1 µg/L can be excluded in all 9 FOCUS groundwater scenarios..

Dimethomorph

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

Parent	**Dimethomorph**	**Remarks/Reference**
molecular weight (g/mol)	387.9	
DT_{50} in soil (d)	41.79	Geometric mean, field data, n = 5, see Table 5.4-7
K_{foc}	456.2	Arithmetic mean, n = 14, see Table 5.4-11
1/n	0.8484	Arithmetic mean, n = 14, see Table 5.4-11
plant uptake factor	0	

Table 5.7-6: PEC_{GW} at 1 m soil depth for dimethomorph for the application of Banjo Forte in potatoes (based on geom. mean for DT_{50} value and arithm. mean for K_{foc})

Crop/Group/use No.	**Szenario**	**80th Percentile PEC_{GW} at 1 m Soil Depth (µg L^{-1}) groundwater model: FOCUS-PELMO 5.5.3**

		Dimethomorph
Potatoes 00-001	**Châteaudun**	<0.01
	Hamburg	<0.01
	Jokioinen	<0.01
	Kremsmünster	<0.01
	Okehampton	<0.01
	Piacenza	<0.01
	Porto	<0.01
	Sevilla	<0.01
	Thiva	<0.01

According to the PEC_{GW} modelling with FOCUS-PELMO 5.5.3 a groundwater contamination of the active substance dimethomorph at a concentration of ≥ 0.1 µg/L is not expected for all 9 FOCUS groundwater scenarios.

5.7.2 Summary of risk assessment for ground water

Results of modelling with FOCUS-PELMO 5.5.3 show that the active substance fluazinam and dimethomorph are not expected to penetrate into groundwater at concentrations of ≥ 0.1 µg/L in the intended uses in potatoes.

For the metabolite HYPA of fluazinam concentrations of ≥ 0.1 µg/L in groundwater can be excluded in all 9 FOCUS groundwater scenarios in the intended uses.

5.8 Potential of active substance for aerial transport

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

As higher tier option the experimentally derived deposition values of the windtunnel study (Staffa 2012) can be considered for the active substance fluazinam.

The vapour pressure at 20 °C of the active substance dimethomorph is < 10^{-5} Pa. Hence the active substance dimethomorph is regarded as non-volatile. Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance dimethomorph due to volatilization with subsequent deposition should not 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 <annex point>	<author>	<year>	<title> <report number> <Authority registration No>			
OECD: KIIA <annex point>	<author>	<year>	<title> <report number> <Authority registration No>			

*

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

KIIA 7.2.1 Morlock, 2008a

Reference:	KIIA 7.2.1
Author:	Morlock, G.
Report:	DEGRADATION OF DIMETHOMORPH IN 2 SOILS UNDER AEROBIC CONDITIONS AT 20°C IN THE DARK Report-no. R-22170
Date:	15/05/2008
Guideline(s):	OECD 307
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

The study was conducted with two German standard soils. A summary of the physical and chemical properties of the soils is provided in Table Table A 2

Table A 2: Physical, chemical and microbiological properties of the soils used

Soil Property	Test Soil Name	
	2.2	5M
Classification (USDA)	Sand	Sandy loam
Organic carbon (%)	2.32	1.32
Cation exchange capacity (mval/100 g soil)	8.12	11.1
pH ($CaCl_2$)	5.9	7.6
Maximum water holding capacity (w/w %)	42.2	40.1

Portions of soil (50 g dry weight) were treated with Dimethomorph. All soil samples were adjusted to 45% maximum water holding capacity (MWHC) and were preincubated in darkness at 20 ±2 °C up to 8 days. The water content of the samples was controlled regularly and losses were added if necessary.

Soil samples were taken at time intervals 0, 1, 3, 7, 14, 21, 30, 62, 90 and 120 days for subsequent analysis. Two replicates of the treated samples were taken on all dates.

As extracting agent 50 mL acetonitrile was added to 50 g soil (dry weight). For the quantification of Dimethomorph, HPLC-analysis with UV -detection and the following HPLC-solvents were used: acetonitrile:water (70:30 v/v).

Results and discussions

No significant differences in biomass of the treated samples were observed in comparison to the untreated samples during the entire period of the test.

The concentrations of Dimethomorph as percentage of the initial content at day 0, over 120 days aerobic incubation were summarised in Table Table A 3. The data were analysed by non-linear regression of the original data to the recommendations of a first order kinetic. The results are given in Table Table A 4. The mean recoveries ranged from 86 % to 103% for all fortification levels.

Table A 3: Concentration of Dimethomorph over 120 days aerobic incubation of treated test soils

Days after application	Test Soil Name			
	2.2 (sand)		5M (silty sand)	
	µg a.s./50 g dry soil	Conc. as a percentage of t = 0 days analysed concentration	µg a.s./50 g dry soil	Conc. as a percentage of t = 0 days analysed concentration
0	60.6	101	60.6	101
1	60.3	99.9	60.04	100.1
3	59.43	99.1	59.46	99.1
7	55.65	92.8	49.66	82.8
14	53.04	88.4	41.89	69.8
21	45.52	75.9	34.24	57.1
30	44.04	73.5	27.15	45.3
62	30.5	50.8	15.5	25.8
90	24.53	40.9	7.74	12.9
120	24.9	41.5	4.76	7.9

Table A 4: Degradation rate constant calculation

Test Soil	Number of data points	r^2	DT_{50}(days)	DT_{90} (days)
2.2 (sand)	10	0.965	74.0	245.7
5M (silty sand)	10	0.992	27.7	92.1

Conclusion

The DT50 values for Dimethomorph for the test soils 2.2 and 5M amounted to 74 and 27.7 days, respectively, each following first order kinetics.

Comments of zRMS

The study was considered fully reliable.

KIIA 7.2.1 Morlock, 2008b

Reference:	KIIA 7.2.1
Author:	Morlock, G.
Report:	Degradation of Fluazinam, in 2 different soils under aerobic conditions at 20 °C in the dark

	Rreport No. S08-00336 Document No. R-23507
Date:	29/09/2008
Guideline(s):	OECD 307
Deviations:	Yes (No transformation products were analysed in this study and the volatile products were not trapped.)
GLP:	Yes
Acceptability:	Yes

Materials and methods

Two German standard soils 2.2 and 5M delivered by LUFA Speyer, a weak loamy sand and a medium loamy sand soil, were used.

Table A 5: Soil physicochemical properties

Origin and name	1	2
Soil description	LUFA 2.2 F2.20608	LUFA 5M F5M0708
soil texture	weak loamy sand	medium loamy sand
< 2 µm [%][1]	6.2	11.3
2 – 6.3 µm [%][1]	3.5	4.3
6.3 – 20 µm [%][1]	5.2	8.9
20 – 63 µm [%][1]	8.1	21.3
63 – 200 µm [%][1]	34.6	38.1
200 – 630 µm [%][1]	41.7	15.1
630 µm – 2 mm [%][1]	0.7	1.0
total organic carbon [%]	1.82	1.07
pH	5.69	7.38
CEC [mval/100 g]	9.88	15.88
Water capacity [%]	47.9	43.3
Soil density [g/L]	1188	1189
Soil type (USDA)	loamy sand	sandy loam
(< 0.002 mm)[2]	6.2	11.3
(0.002 – 0.050 mm)[2]	14.5	26.5
(0.05 – 2.00 mm)[2]	79.3	62.2

[1]: particle size distribution according to German DIN [%]
[2]: particle size distribution according to USDA [%]

50 g samples (dry weight equivalent) of the two soils were filled in 300 ml glass flasks and closed with cotton wool. They were pre-incubated in the dark for 20 days under aerobic conditions at 20 °C ± 2 °C and with a moisture content of 45 % of their maximum water holding capacity. 24 untreated (control) and 24 treated samples were established for each soil type to allow for double vessels to be sampled at 10 sample times with four additional spare vessels. Fluazinam was prepared in acetone at a nominal concentration of 1944 mg/L and after acclimatisation of the soils an aliquot of this solution (100 µl) was applied drop by drop to the soil surface at a concentration per vessel of about 194.4 µg/50 g dry, approximately equivalent to an application rate of 200 g a.i./ha based on a uniform distribution in a 2.5 cm soil layer. The control flasks received the same kind and amount of solvent as the treated samples.

After application the test vessels were re-incorporated into their incubation systems in darkness at 20 °C ± 2 °C under aerobic conditions.

10 untreated and 10 treated 250 ml glass flasks for each soil type were filled with 100 g (dry weight equivalent) of soil for determination of the microbial biomass. These soils were incubated under the same conditions as above.

Double soil samples from the treated and the untreated flasks of each system were taken for analysis immediately after test substance application (T0) and at 1, 3, 7, 14, 21, 30, 59, 91 and 120 days after application. At each sampling point and for each soil test item was applied to one of the untreated flasks for verification of the stability and recovery during analytical procedure.

The soil microbial biomass was determined in untreated soil on the day before application and at 1, 30 and 120 days after application and in the treated soil at day 1, 30 and 120 (2 samples/each).

Results and discussions

Determination of biomasses showed no significant differences between biomass of treated and untreated samples during study period.

Table A 6 shows the mean Fluazinam contents of the treated LUFA2.2 soils at the different time points. The recovery of the samples fortified with the test item at time of sampling ranged from 83-99 %. In Table A 7 the Fluazinam content of the LUFA 5M soil is presented. The recovery was between 62-108 % in the samples fortified at sampling time. The determined values of blank samples were less than 30 % of the assigned LOQ of test item at any time in both soils.

Table A 6: Degradation of Fluazinam in soil LUFA 2.2 [µg/50 g dry soil] and [%] of the nominal amount and mean of two samples

Time [d]	Mean conc. [µg]	Std. Dev. [µg]	Mean [%]	Std. Dev. [%]
0	187.94	6.92	96.9	3.54
1	171.36	4.59	88.4	2.33
3	181.97	2.86	93.8	1.41
7	168.67	13.40	87.0	6.86
14	158.37	4.96	81.6	2.55
21	164.21	12.22	84.7	6.29
30	147.11	2.29	75.9	1.20
59	131.50	8.09	67.8	4.17
91	73.49	0.10	37.9	0.07
120	73.35	11.57	37.8	5.94

Table A 7: Degradation of Fluazinam in soil LUFA 5M [µg/50 g dry soil] and [%] of the nominal amount and mean of two samples

Time [d]	Mean conc. [µg]	Std. Dev. [µg]	Mean [%]	Std. Dev. [%]
0	190.06	1.94	98.0	0.99
1	197.34	0.18	101.8	0.07
3	188.44	2.19	97.1	1.13
7	189.36	5.26	97.6	2.69

14	163.29	9.98	84.2	5.16
21	143.18	12.47	73.9	6.43
30	148.29	8.14	76.5	4.17
59	83.88	6.13	43.3	3.18
91	60.64	2.52	31.3	1.34
120	61.48	2.67	31.7	1.41

Untreated soil samples were spiked with standard solution prior to extraction to determine the recovery. Five recovery samples were analysed prior to extracts from the soil degradation test. The mean recoveries ranged from 102 – 106 %.

In the soil LUFA 2.2 Fluazinam declined from 96.9 % of the applied dose at time zero to 37.8 % at day 120. In the second soil LUFA 5M Fluazinam decreased from 98.0 % at day 0 to 31.7 % of the applied dose at day 120.

Simple first order kinetics (SFO) described the measured concentrations appropriately as the visual fit was good for both soils without any systematic errors. This is supported by the coefficient of determination > 0.85. The calculation of the rate constant and the initial concentration was performed using iterative modelling (Marquardt) following the principle of minimizing the differences between the determined and proposed values using the non-linear procedure within the SAS computer program. DT_{50} and DT_{90} values were derived from the regression curve.

Table A 8: $DegT_{50}$ and $DegT_{90}$ values of Fluazinam with the 95 % confidence limit (1st order) in two soils

Rep Table Bold	First order kinetic		
	$DegT_{50}$ [days]	**$DegT_{90}$ [days]**	**R^2**
LUFA 2.2	89.3	296.7	0.9287
LUFA 5M	58.2	193.5	0.9642

The degradation times were calculated from the kinetic constant k and the predicted initial mean concentration. In the laboratory study Fluazinam was degraded moderately to slowly.

Conclusion

The aerobic degradation of Fluazinam in soil incubated at a moisture content of 45 % of the maximum water holding capacity and 20 °C ± 2 °C in the dark was moderate to slow in both tested soils LUFA 2.2 and LUFA 5M. SFO $DegT_{50}$ values of 89.3 days (LUFA 2.2), and 58.2 days (LUFA 5M) were derived, describing the degradation pattern appropriately. The biomass examinations lead to the conclusion that the reduction within the study period will not have affected the degradation pattern of Fluazinam. Fluazinam was degraded from 96.9 % of the applied dose at time zero to 37.8 % at day 120 in the LUFA 2.2 soil and from 98.0 % at day 0 to 31.7 % of the applied dose at day 120 in the LUFA 5M soil.
The mean recoveries ranged from 102 – 106 % of the initial concentrations.

Comments of zRMS

The study was considered fully reliable.

KIIA 7.2.1 Mamouni, 2008

Reference: KIIA 7.2.1

Author:	A. Mamouni
Report:	^{14}C-FLUAZINAM Degradation and Metabolism in one Soil Incubated Under Aerobic Conditions Report No. B50062
Date:	05/12/2008
Guideline(s):	OECD 307
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

The rate of degradation and metabolism of the test item, ^{14}C-Fluazinam, i.e. 3-chloro-N-(3-chloro-S-trifluoromethyl-2-pyridyl)-α,α,α-trifluoro-2,6-dinitro-p-toluidine, were investigated in a fresh agricultural soil under aerobic conditions at 20°C for a period of 160 days. The soil samples were treated with two labels of the test item, i.e. [benzene ring-U-^{14}C]Fluazinam (B)and [pyridine-2,6-^{14}C]Fluazinam (P)-labels, tested separately.

The treated soil samples (one per label) were incubated at 20 ± 2°C in the dark under continuous ventilation with moistened air. The exhaust air was passed through a trapping system consisting of flasks of ethylene glycol and sodium hydroxide in series to trap organic volatiles and $^{14}CO_2$, respectively. Prior to treatment and at the end of the incubation period, the microbial biomass was determined. The results showed that the soil was viable during the study.

Duplicate soil samples were taken for extraction and analysis immediately after treatment (time 0), and after 7, 14, 28, 60, 120 and 160 days of incubation. All soil samples were exhaustively extracted with methanol/phosphoric acid (99.5/0.5; v/v). From sampling interval 14 onwards, additional Soxhlet extraction with acetonitrile/water (4:1; v/v) was performed for at least four hours. The extracts were then pooled and concentrated under reduced pressure and analysed by TLC and/or HPLC for the test item and degradation products. In order to investigate the non-extractable residues, the samples from the end of the study were submitted to organic matter fractionation. A total balance of radioactivity, the nature of extracted radioactivity and pattern of metabolites were established for each sampling interval.

Table A 9 Soil properties

Soil / Soil type (USDA)	CEC, mmol/ 100 g soil	Conc. of a.i. (ppm)	pH ($CaCl_2$)	% OC	WHC at pF2 2.0 (%)
Vouvry III, sandy loam	6.78	1	7.23	1.14	25.4

Results and discussions

As an indicator of the microbial activity of the soil, the microbial biomass was determined at the start (just prior to treatment) and end of the incubation period (9.1 and 15.9 mg microbial C/100 g soil dry wt. respectively). The results show that the soil was viable throughout the study.

The mean recoveries of radioactivity were 101.5 ± 4.5% and 97.5 ± 5.6% of applied radioactivity for the samples treated with [benzene ring-U-14C]Fluazinam (B)- and [pyridine-2,6-14C]Fluazinam (P)-labels, respectively. The same distribution and metabolic pattern of radioactivity was obtained for both labels of the test item, therefore the results in the following expressed as the mean of both labels.
The amount of total extractable radioactivity decreased from 102.2% of the applied radioactivity immediately after treatment (time 0) to 49.2% by the end ofthe study on day 160.

The amount of non-extractable radioactivity increased from 3.8% of the applied radioactivity immediately after treatment (time 0) to 39.2% after 160 days. Of the non-extractable radioactivity, organic matter fractionation indicated that the major part of the non-extractable radioactivity was bound to the immobile humic acids and humin fraction, accounting for mean amounts of 44.3% and 29.2%, respectively. The corresponding value for non-extractable radioactivity bound to fulvic acids was on average 26.5%.

Some mineralization of the radioactive residues was observed with radioactive carbon dioxide reaching a maximum of 5.3% of applied by the end of the study. The formation of organic volatile compounds reached a maximum of 0.9% of applied by the end of the study.

The amount of Fluazinam in the aerobic soil samples declined with time, from an initial mean level of 102.2% of applied to 4.4% after 160 days. Besides the parent compound, one major fraction M3 (HYPA, EPP/OS 394.7) was first observed on day 7 and steadily increased with time to reach its peak of 12.9% on day 160. Additionally, numerous minor metabolites were detected none individually exceeding 5% of applied. One of minor metabolites (M18) was identified as AMPA (EPP/JIA 076.32).

The following DT50, and DT90 values were calculated for Fluazinam based on single first-order (SFO) kinetics using the Origin calculation software.

Table A 10: DT_{50} of active substance

Soil name / Soil type	pH, H_2O	T (°C)	Moisture	DT_{50} (d)	DT_{90} (d)	DT_{50} (d) 20 °C, pF2	Fit, r^2	Kinetic
Vouvry III / sandy loam	7.7	20	pF2-2.5	35.9	119.3	35.9	0.991	SFO

Conclusion

Degradation of ^{14}C-Fluazinam in soil incubated under aerobic conditions proceeds via the formation of one major metabolite, HYPA (EPP/OS 394.7), and numerous minor metabolites (all below 5% of applied), some radioactive carbon dioxide and significant amounts of bound residues.

Comments of zRMS

The study was considered fully reliable.

KIIA 7.2.1 Ponte, 2009

Reference:	KIIA 7.2.1
Author:	Marian Ponte
Report:	Rate of Degradation of 14C-Fluazinam in One Soil Incubated Under Aerobic Conditions Report No. 1796W
Date:	21.01.2009
Guideline(s):	OECD 307
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

A rate of degradation of fluazinam in aerobic soil study was conducted on one European field soil (Speyer 2.3) using [^{14}C]fluazinam ([2-pyridinamine, 3-chloro-N-[3-chloro-2,6-dinitro-4-(trifluoromethyl)phenyl]-5 -(trifluoromethyl)-], uniformly labeled in the benzffie ring).

Table A 11 Soil properties

Soil / Soil type (USDA)	CEC, mval/ 100 g soil	Conc. of a.i. (ppm)	pH ($CaCl_2$)	% OC	WHC at pF2 2.0 (%)
Speyer 2.3 / sandy loam	8	1.07	6.49	0.98	34.4

Individual samples were treated at a dose rate of 1.07 µlg/g and incubated in the dark at 20 ± 2°C and a pF of between 2.0 and 2.5 for up to 91 days. The soil samples were continuously aerated throughout the incubation period. Traps for volatiles included an ethylene glycol (EG) trap for organic volatiles and two 10% aqueous NaOH traps for carbon dioxide.

Soil samples were extracted twice with 0.5% phosphoric acid in methanol with one-hour shaking each time. Soil extracts were combined and radioassayed by liquid scintillation counting (LSC) for recovery. Extracted soils were combusted to determine levels of unextracted residues in the soils. Fluazinam was quantified by high performance liquid chromatography (HPLC) of the soil extracts with co-injection with analytical standard. The presence of fluazinam in soil extracts was confirmed by two-dimensional thin layer chromatography (TIC).

Results and discussions

The material balance was based on the sum of the radiocarbon recovered in the soil extracts, bound residues and trapped volatiles, and calculated based on percent of applied radiocarbon (AR). Mass balance averaged 101.6 ± 3.9% AR for the study. Extractable radiocarbon declined from 102.9% at T_0 to an average of 43.3% AR after 91 days of incubation. Bound residues increased from an average of 3.4 % AR at T_0 to an average of 44.7% AR at the end of the study period. Radiocarbon trapped in NaOH traps averaged up to 9.1 % AR during the study, while EG traps recoveries were below detection for all samples tested.

Table A 12: DT_{50} of active substance

Soil / Soil type (USDA)	pH, H_2O	T (°C)	Moisture	DT_{50} (d)	DT_{90} (d)	Fit, r^2	Kinetic
Speyer 2.3 / sandy loam	6.9	20	pF2-2,5	25,1	83,3	0.938	SFO

Conclusion

Fluazinam degraded rapidly in Speyer 2.3 aerobic soil and represented an average of 64.3% AR after 14 days of incubation. At the end of the study fluazinam declined to an average of 8.3% AR. The degradation rate of fluazinam in aerobic soil was calculated based on the percent fluazinam recovered in the soil extracts, using pseudo-first order kinetics. The half-life and DT_{90} of fluazinam were determined as 25.1 days and 83.3 days, respectively ($r^2 = 0.938$).

Comments of zRMS

The study was considered fully reliable.

KIIA 7.4.1 Geffke, 2007a

Reference:	KIIA 7.4.1
Author:	Geffke, T.
Report:	MCW388 PURE ADSORPTION/DESORPTION USING A BATCH EQUILIBRIUM METHOD Report No. CADl07101 Document No. R-20592
Date:	07/09/2007

Guideline(s):	OECD 106
Deviations:	Yes (2 of 5 soils cannot be used for evaluation purposes, see details below)
GLP:	Yes
Acceptability:	Yes

Materials and methods

The study was conducted with five different soils. A summary of the physical and chemical properties of the soils is provided in Table Table A 13.

Table A 13 Physical and chemical properties of the soils

Pedological parameter	**(I) Clay**	**(II) Silt loam**	**(III) Loam**	**(IV) Silt**	**(V) Loamy sand**
Soil site	Aluminusa, Silicy, I*	Souli, Peleponnes, GR	Radyr, Wales, U.K.	Rots, Normandie, F	Gudow, Schl.-Holst., D**
Sand total [%]	3.3	13.4	46.4	4.11	71.6
Silt total [%]	21.9	64.1	36.8	75.7	12.7
Clay total [%]	75.0	22.6	17.0	20.3	6.0
pH in 0.01 M $CaCl_2$	5.7	7.2	5.9	6.8	3.2
Total carbon	3.5	10.9	3.6	1.7	3.7
Organic carbon	3.29	2.39	3.32	1.36	4.43
Cation exchange capacity [mval/100 g]	32.4	28.9	16.6	17.3	24.1

* Clay content too high (must be <65 % according to OECD 106)
** pH value too low (must be ≥4.0 according to OECD 106)

All soils samples were placed in a centrifuge for 5 min at 3000 rpm for coarse separation of soil and aqueous phase. Afterwards, all samples were passed through a 0.2 µm filter. Subsequently the equivalent of 1 g of each soil was added to each test vessel. During the study, the test vessels were maintained at 20°C.

Adsorption and desorption experiments were conducted in 50 mL PE centrifugation tubes with screw cap. A stock solution of 5000 mg MCW 388 Pure/L in acetonitrile was prepared. Dilutions of this stock solution were made in acetonitrile and used as spiking solutions for all test item applications. Subsequently aliquots of the stock solutions and dilutions, respectively were dispensed into the test flasks to reach a known volume, giving nominal final concentrations of 0.5 mg/L, 1.0 mg/L, 2.0 mg/L, 4.0 mg/L and 5.0 mg/L. The concentration of MCW 388 Pure in each dose solution was determined by the water solubility and on the results of the preliminary study.

Aliquots of 0.01 M aqueous calcium chloride solution were added to each vessel to give the target soil:solution ratio. Soil/solution ratios were used depending on the different soil properties: 1 : 25 for soils 2, 3 and 4 and 1 : 50 for soils 1 and 5. After shaking the samples 24 hours soil for reaching adsorption equilibrium the aqueous phase was decanted after analysis. The aqueous phase of the samples were replaced with an identical volume of fresh 0.01 M $CaCl_2$ and shaken for 24 hours. As well as for the adsorption step, the aqueous phase was decanted for the desorption step and replaced once more for the extraction of the soil.

Pilot investigations were carried out to determine the optimum soil: solution ratio for adsorption of MCW 388 Pure. In order to determine the appropriate time for equilibration, single vessels for each soil type

containing a concentration of MCW 388 Pure of 5.0 mg/L were taken for analysis after intervals of2, 4, 24 and 48 hours. Furthermore the possibility of adsorption of the test substance to the vessel surfaces was investigated as well as the mass balance to establish the stability of the test item.

Results and discussions

Recoveries of radioactivity after adsorption and desorption were in the range 87 - 97% of the amounts applied.

Freundlich adsorption constants (K_F^{ads}) ranged from 6.2 to 58. Therefore MCW 388 Pure showed a moderate to low tendency to adsorb to the five test soils. Most of adsorption constants appear to correlate reasonably with soil organic carbon content. K_F^{ads} values ranged from 452 to 1309. Soils 2 and 4 have nearly the same content of silt and clay, whereas the organic carbon content for soil 2 is higher than for soil 4 resulting in higher values for KFOC for soil 2. Soil 5 has the lowest content of silt and clay, but the highest content of organic carbon and a high value of K_F^{ads}. For each soil type, the K_F^{des} value (desorption) was greater than the K_F^{ads} value (adsorption). This indicates that MCW 388 Pure is not strongly desorbed. Besides, the results of the control experiment indicated there was no significant adsorption of MCW 388 Pure to the vessels or the filter material.

The adsorption constants for each soil are given in Table Table A 14resulting from a soil to solution ratio of 1:25 (soils 2,3, and 4) respectively 1:50 (soils 1 and 5). Desorption constants for each soil are given in Table Table A 15. Adsorption ofMCW 388 Pure is not completely reversible since desorption was moderate (30 - 41 %) in the desorption kinetics and ≤61 % (overall mean for each soil) for desorption isotherms.

Table A 14: Results of adsorption isotherm

Test Soil	Organic carbon [%]	r^2	K_F^{ads}	K_{FOC}	1/n
I	3.29	0.9951	41	1246	0.921
II	2.39	0.9844	18	753	0.7723
III	3.32	0.9932	15	452	0.8209
IV	1.36	0.9361	6.2	456	0.8354
V	4.43	0.9793	58	1309	0.6846

Table A 15: Results of desorption isotherm

Test Soil	Organic carbon [%]	r^2	K_F^{des}	1/n
I	3.29	0.9382	92	0.7117
II	2.39	0.9938	31	0.942
III	3.32	0.9808	25	0.7586
IV	1.36	0.9308	18	1.0282
V	4.43	0.882	101	0.7651

Conclusion

MCW 388 Pure showed a moderate tendency to adsorb to the five test soils. A correlation between the degree of adsorption and the organic carbon content of the soil can be assumed. MCW Pure 388 can be considered to have a medium to low mobility in soil (according to McCall mobility classification scheme). Adsorption of MCW 388 Pure is not completely reversible, since desorption was moderate (30 - 41 %) in the desorption kinetics and ≤61 % (overall mean for each soil) for desorption isotherms. MCW Pure 388 has not shown any tendency for the formation of irreversible bound residues.

Comments of zRMS

Two of the five soils (I and V) cannot be used in evaluation process due to violation of OECD 106 guidelines (too high clay content and too low pH respectively).

KIIA 7.4.1 Geffke, 2007b

Reference:	KIIA 7.4.1
Author:	Geffke, T.
Report:	MCW 465 pure - Adsorption/Desorption using a batch equilibrium method Report No. CAD 106921 Document No. R-20543
Date:	09.07.2007
Guideline(s):	OECD 106
Deviations:	Yes (The soil to solution ratio was higher than 1:100 as recommended in the guideline due to the very high adsorption rate of MCW 465 pure. The recovery was partly below and above the recommended range of 70 – 110 % of applied amount in 3 of the 5 soils, however the overall recovery remained within the range.)
GLP:	Yes
Acceptability:	Yes

Materials and methods

Five different soils (Standard EURO soils no. 1, 2, 3, 4 and 5) with pH values (in 0.01 M $CaCl_2$) between 3.2 – 7.2, organic carbon content between 1.36 – 4.43 % and cation exchange capacity between 16.6 – 32.4 mval/100 g were used. All soils were air dried and sieved ≤ 2 mm.

Table A 16: Soil physico-chemical properties

Origin and name	EURO-Soil 1	EURO-Soil 2	EURO-Soil 3	EURO-Soil 4	EURO-Soil 5
Use of site	meadow	deciduous forest	pasture	agriculture	coniferous forest
Soil texture	clay	silty loam	loam	silt	loamy sand
Clay[1] [%]	75.00	22.60	17.00	20.30	6.00
Silt[1] [%]	21.90	64.10	36.80	75.70	12.70
Sand[1] [%]	3.30	13.40	46.40	4.11	71.60
Organic carbon [%]	3.29	2.39	3.32	1.36	4.43
pH (0.01 M $CaCl_2$)	5.7	7.2	5.9	6.8	3.2
CEC [mval/100g]	32.4	28.9	16.6	17.3	24.1
Dry mass [%]	97.3	98.4	98.6	98.0	98.7
MWHC [g/100g dry weight]	not stated	not stated	not stated	not stated	not stated

[1]: particle size distribution not stated

Preliminary experiments were performed to check the stability of the test substance, the pH value of the aqueous phase, equilibration time for adsorption/desorption and the amount substance adsorbed to soil at equilibrium. Furthermore, the optimal soil/solution ratio was determined. The adsorption of MCW 465 Pure to the test vessel surfaces was investigated directly after preparation with and without filtration in vessels with no soil present. For the preliminary tests 20 µg test item/L $CaCl_2$ was used.

Based on the results of preliminary assays an equivalent of 1 g of each soil was added to 200 ml 0.01 M $CaCl_2$-solution for soils 1-4 (ratio 1:200) and to 500 ml $CaCl_2$-solution for soil 5 (ratio 1:500). A stock solution of 100 mg test item/L in methanol was mixed. For the determination of the adsorption and desorption coefficient a concentration of 20 µg test item/L was prepared for each soil in duplicate. The test was performed according to the serial method. For determination of the adsorption and desorption isotherms an aliquot of the MCW 465 Pure stock solution was added to the duplicate vessels of each soil type resulting in a final concentration of 2.0, 6.0, 10.0, 14.0 and 20.0 µg/L. A $CaCl_2$-solution treated with the lowest test item concentration as a control without soil and a blank trial containing $CaCl_2$-solution with soil and without test item were prepared as single replicates.

The test vessels were incubated (shaken at approx. 110 rpm) at 20±2 °C in the dark until reaching the adsorption equilibrium, i.e. 48 hours. After decanting the aqueous phase of the adsorption test, the same volume of 0.01 M $CaCl_2$-solution was added to the soils and the vessels were incubated for another 48 hours under the same conditions for the desorption experiment.

After the adsorption step, as well as after the desorption step, the aqueous solutions were separated from the soils. The solutions were centrifuged to separate particles with a diameter > 0.2 µm and aliquots were analysed by HPLC-MS/MS.

After the desorption test, the soil samples were extracted with 25 ml methanol by shaking for 30 minutes after decanting the aqueous phase. Following centrifugation the soil extract was diluted with HPLC water (factor 2). Aliquots of the aqueous solution and soil extracts were analysed by LC-MS/MS. Results from the soil extracts were used for mass balance determination.

The results from the aqueous phase analyses of adsorption and desorption steps were used for calculation of the test item content in the soil (indirect method).

The LOQ (limit of quantification) was defined as 0.6 µg test item/L. The LOD was calculated via signal-to-noise ratio to be 0.090 µg/L.

Results and discussions

The stability test during the preliminary study showed a recovery rate (RR) of 88 % for the test item after application of 20 µg/L in 0.01 M $CaCl_2$ and 48 h incubation. No adsorption of MCW 465 Pure to the test vessel and 36 % adsorption to the filter material was observed. Therefore particles >0.2 µm were separated during the study. An adsorption and desorption equilibration time of 48 hours and an optimal soil to solution ratio of 1:200 for the soil 1-4 and 1:500 for soil 5 were selected.

Preliminary mass balance was measured in samples following the adsorption step after 2 extraction steps with acetone. The initial nominal mass of test item applied was 4.00 µg for soils 1-4 and 10 µg for soil 5. The total recovery rates after adsorption were between 71 and 99 % for all soils. Thus the test substance can be regarded as stable under test conditions.

The recovery rate ranged from 69 – 113 % of applied test substance in soil 1-3 and 5, with exception of the lowest concentration trial of soil 5 where only 52 % a.i. were found. In the trials of soil 4 the recovery rates were between 16 – 79 % a.i.

For the determination of the adsorption and desorption coefficients the initial concentration of the test item applied was 0.0200 µg a.i./cm^3 (20 µg/L), resulting in an amount of 4.00 µg MCW 465 Pure in each test vessel of soil 1-4 and 10.0 µg for soil 5. The adsorption equilibration time was set 48 hours for each trial.

The amount of test item in the aqueous phase was determined by HPLC-MS/MS analysis. The quantity of test item in the soil after adsorption phase was calculated as difference between applied amount and amount test item in aqueous solution (indirect method).

The amount of adsorption was found to be between 53 – 88 % a.i. at equilibration for the tested soils. Adsorption coefficients of 233 to 1841 cm^3/g and K_{OC} values between 17132 and 46717 show a strong adsorption of MCW 465 Pure to all of the 5 tested soils.

The desorption level accounted for 3 - 35 % of applied material at equilibration time. Desorption coefficients between 384 and 8092 were calculated after 48 h incubation of the soil samples from the adsorption test with fresh $CaCl_2$-solution. A low proportion of test item which was adsorbed to the soil after adsorption step was dissolved in the solution during desorption test. The adsorption appears to be nearly non-reversible.

Adsorption coefficients according to Freundlich (K_F^{ads}-values) were determined from the equilibrium concentrations of the test item, which was applied in the 5 different concentrations to each soil type. It ranged from 61.4 – 3214 indicating high tendency for adsorption of MCW 465 Pure to the test soils. Corresponding coefficients corrected for organic carbon content K_{FOC}^{ads} values accounted for 4515 - 79372. Freundlich exponents (l/n) varied from 0.64 – 1.16. A significant correlation between the degree of adsorption and the organic carbon content of the soil is indicated. Likewise, a pH dependency of adsorption was observed.

Table A 17: Freundlich coefficients and regression constants for adsorption of the test item MCW 465 Pure

Soil	Log K_F^{ads}	l/n	r^2	K_F^{ads}	OC [%]	K_F^{OC}
EURO soil 1	3.0235	1.0797	0.9886	1056	3.29	32097
EURO soil 2	3.2780	1.1292	0.9999	1897	2.39	79372
EURO soil 3	2.9674	1.0390	0.8805	928	3.32	27952
EURO soil 4	1.7879	0.6420	0.9606	61.4	1.36	4515
EURO soil 5	3.5070	1.1635	0.9926	3214	4.43	72551

Desorption coefficients determined according to Freundlich (K_F^{des}-values) ranged from 28100 – 50315 for soil 3 and 4. For soil 1, 2 and 5 no K_F^{des}-values could be calculated as the test item concentration in solution at equilibrium was below the LOQ. Values of exponent l/n varied from 1.48 – 1.62 for soil 3 and 4.

Table A 18: Freundlich coefficients and regression constants for desorption of the test item MCW 465 Pure

Soil	Log K_F^{des}	l/n	r^2	K_F^{des}
EURO soil 1	n.e.	n.e.	n.e.	n.e.
EURO soil 2	n.e.	n.e.	n.e.	n.e.
EURO soil 3	4.4487	1.4818	0.8918	28100
EURO soil 4	4.7017	1.6153	0.7030	50315
EURO soil 5	n.e.	n.e.	n.e.	n.e.

MCW 465 Pure is immobile in soils 1, 2, 3 and 5 and slightly mobile in the agriculture soil 4 according to McCall classification. Adsorption of the test item is considered to be not reversible, since the desorption was very low with values between 3 - 35 % and the desorption isotherms were mostly not evaluable. MCW 465 Pure shows a tendency for the formation of irreversible bound residues.

Values of relevant soil parameters differ from proposed ranges in 4 of the 5 soils selected. However, these deviations are only minor in 3 of the 4 soils and therefore deemed to be acceptable. In addition, only 1 soil was considered to be representative with regard to the typical sites of application considered for the use of Fluazinam in agriculture. A soil to solution ratio higher than 1:100 (as recommended in the guideline) was used (1:200, 1:500). This was due to the very high adsorption rate of MCW. This circumstance is considered to be an acceptable justification. The recovery rate in the main experiment is

considerably lower for soil 4 compared to the remainder 4 soils. The recovery was partly slightly below and above the recommended range of 70 – 110 % of applied amount in 3 of the 5 soils, however the overall recovery remained within the range.

Conclusion

The adsorption behaviour of MCW 465 Pure has been studied in five EURO-soils. Equilibrium conditions in soil were reached after 48 hours. Freundlich adsorption coefficients (K_F^{ads}) were in the range 61.4 – 3214. A strong adsorption of MCW 465 Pure to all five soils was observed, indicated by K_{FOC}^{ads}-values of 4515 - 79372. A significant correlation between the degree of adsorption and the organic carbon content of the soil was observed. Furthermore, a clear pH dependency was detected showing increased adsorption with decreasing pH values. Desorption of the test item from soil was very poor ranging from 3 – 35 % a.i., with no evaluable low concentrations in soil 1. Adsorption is considered to be not reversible as desorption remained below 35 % in the desorption kinetics and desorption isotherms were mostly not evaluable. According to the McCall scale classifying a chemical's potential for mobility, MCW 465 Pure is immobile in soils 1, 2, 3 and 5 and slightly mobile in the agricultural soil 4 (based on K_{FOC}^{ads}). Freundlich exponents (1/n values) for adsorption of 1.039 - 1.164 testify a nearly-linear sorption behaviour for soil 1-3 and soil 5. Soil 4 shows a lower Freundlich exponent with 0.642. In all five soils, the tendency of MCW 465 Pure to form irreversible bound residues was observed.

Comments of zRMS

The study was considered fully reliable.

KIIA 7.8.3 Florchinger, 2009a

Reference:	KIIA 7.8.3
Author:	Martin Florchinger
Report:	Degradation and Metabolism of [Chlorobenzene-U-^{14}C]- and [Morpholine-U-^{14}C]-Dimethomorph in one Water/Sediment System (Pond) under Aerobic Conditions – Laboratory Test Report No. S08-02149 Document No.R-23937
Date:	26/06/2009
Guideline(s):	OECD 308
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Water and sediment were sampled from location known to be not influenced by effluents or human activity in Emst Maurer See, Illingen, Germany.

The sediment and water characteristics are summarized in Table Table A 19.

Table A 19: Characterisation of water and sediment at time of sampling

Compartment	Parameter	Emst Maurer See
Water	Temperature [°C]*	22.7

	pH*	7.69
	Redox potential [mV]*	+212
	Oxygen [mg/L]*	8.40
	Total organic carbon [mg C/L]	10
Sediment	pH	7.7
	Redox potential [mV]*	-184
	Total organic carbon [mg C/L]	1.45
	Cation exchange capacity [mval/100g]	12.9
	Sediment classification	Silty loam
	Clay [%]	27.9
	Silt [%]	66.2
	Sand [%, > 50 µm]	5.8

* detennined at sampling site; all other values are taken after sieving of sediment and water

Experimental conditions

Water was filtered through a 0.2 mm sieve and the sediment was sieved through a 2.0 mm mesh. After a storage period of up to 15 days wet sediment (approx. 300g) was transferred into each metabolism flask to establish a layer of 2.5 cm. Afterwards the flasks were filled with water until additional height of 7.5 cm (approx. 500 mL) was reached. Acclimatisation under aerobic conditions was then started for a period of up 46 days at 20 ± 3°C in the dark until an equilibrium based on measured variables (oxygen concentration, pH and redox potential - in water and sediment) was reached.

System consisted of a closed gas-flow-system in a 1000 mL all-glass metabolism flask (inner diameter: ≈ 10.1 cm; surface: ≈ 80 cm^2). The system was aerated by gently shaking the flasks. Any organic volatiles generated in the flasks were trapped by Tenax as an adsorbent. Any carbon dioxide generated in the flasks was trapped by a sodium hydroxide reservoir. The vessels were closed. The oxygen content inside the test vessels was determined by a pressure transducer system on two biomass flasks. The pressure reduction caused by any binding of carbon dioxide to soda lime gave exact information about the oxygen consumption of the test system. If a reduction of more than 10 % of the initial oxygen content occurred, the system was intermediately aerated.

The field rate (0.300 kg a.i./ha) assuming 30 cm depth of water with an equi-distribution of the test item was applied. Regarding the field rate, the surface of the first 22 test vessels would have be treated with 60 µg test item 1 ([Chlorobenzene-U-14C]-Dimethomorph), equivalent to 0.300 kg/10.000 m^2 and 0.3 m depth. To be able to follow the metabolite formation a radioactivity of about 10 µCi per vessel had to be applied. Assuming a specific activity of 62 mCi/mmol, this corresponds to more than 60 µg test item per vessel. The application rate was up to 11.37 µCi ([Chlorobenzene-U-14C]-Dimethomorph which corresponds to 72.3 µg unlabelled test item. For [Morpholine-U-14C]-Dimethomorph, the application rate was up to 9.17µCi which corresponds to 58.7 µg unlabelled test item. Each biomass flask was treated with 60 µg non-labelled test item.

Sampling

Duplicate samples per test system were taken for analysis immediately after application (time 0) and on days 1, 2, 4, 7, 14, 29, 62, 99 and 120 of incubation. At each sampling date or at least after 4 weeks, the traps for volatiles were monitored for radioactivity by LSC. The actual volume of sodium hydroxide solutions was determined and their radioactivity content was measured separately for each trap.

At each sampling, the height of the sediment and water layer, the redox potential in water and sediment, the pH in water and the oxygen concentration in water were determined. 120 days after treatment, the sediment in the control vessels was analyzed for microbial activity, pH and redox potential. The water phase was analyzed for pH, redox potential, total N and P, concentration of oxygen and total organic carbon (TOC).

Results and discussions

Mass balance

During incubation, there were no significant changes observed in redox potential, pH and dissolved oxygen content for both pond and creek systems.

The microbial biomass in the sediment measured prior to, during and at the end of the test showed that both systems were viable throughout the study. Values in µg C per g dry matter were 1111 at the beginning of the study and 370 at the end of the study on day 120. The mean recoveries from the water/sediment system during the whole study were 92 - 103 % AR for [Chlorobenzene-U-^{14}C]-Dimethomorph and 91 – l04 % for [Morpholine-U-^{14}C]-Dimethomorph.

Table A 20 Distribution of Dimethomorph and its degradates in the water phase, sediment extracts and the entire aerobic test system. Mean values are given in percent of the applied radioactivity.

% of applied radioactivity		Incubation Time [Days]								
		0	1	2	7	14	29	62	99	120
[Chlorobenzene-U-14C]-Dimethomorph	Water	95	89	86	68	52	27	9	*	4
	Sediment	4	12	14	25	32	27	16	*	12
	Total system	99	101	99	93	84	54	25	*	16
Metabolite	Water	0	0	0	0	0	0	2	*	4
	Sediment	0	0	0	0	0	0	2	*	1
	Total system	0	0	0	0	0	0	4	*	5
[Morpholine-U-14C]-Dimethomorph	Water	98	88	84	67	55	31	15	8	7
	Sediment	4	11	15	29	34	31	25	18	20
	Total system	102	99	99	96	89	62	40	25	27
Metabolite	Water	0	0	0	0	0	0	3	3	4
	Sediment	0	0	0	0	0	0	2	2	0
	Total system	0	0	0	0	0	0	5	4	4

* sample not used for evaluation

Half-life times

The following dissipation half-lives and DT_{90} values were calculated for ^{14}Dimethomorph using the experimentally derived values and single first order (SFO) kinetics.

Table A 21 DT_{50} of active substance

[Chlorobenzene-U-14C]-Dimethomorph	**Water**	**Total System**
DT50 [days]	16	35
DT90 [days]	55	116
r^2	0.998	0.983
[Morpholine-U-14C]-Dimethom orph		

DT50 [days]	19	50
DT90 [days]	65	166
r^2	0.986	0.982

Conclusion

The route and rate of degradation of ^{14}Dimethomorph under aerobic conditions were investigated at 20°C in the dark. Dimethomorph was seen to degrade moderately from the water phase with half lives of 16 and 19 days. Half lives in the whole water/sediment system were 35 and 50 days. No metabolites in relevant amounts were found in the sediment or water phase or in the total system.

In aerobic aquatic system, ^{14}C-Dimethomorph moderately dissipates from the water phase by adsorption to the sediment. Once in the sediment, its degradation proceeds at a slower rate.

Comments of zRMS

The study was considered fully reliable.

KIIIA1 9 Fate and Behaviour in the Environment – Plant protection product

Appendix 3 Table of Intended Uses justification and GAP tables

PPP (product name/code) **BANJO FORTE** **Formulation type:** **SC**
active substance 1 **fluazinam** **Conc. of as 1:** **200 g/L**
active substance 2 **dimethomorph** **Conc. of as 2:** **200 g/L**

Applicant: **ADAMA Deutschland** **professional use** ☒
Zone(s): **central EU** **non professional use** ☐

Crop and/ or situation (a)	Zone	Product code	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	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**		
Potatoes SOLTU	central EU	BANJO FORTE	F	Late blight *(Phytophthora infestans)* PHYTIN	SC	200 g ai/L both fluazinam and dimetho morph	Foliar spraying	in case of danger of infection and/or after warning service appeal BBCH 31 - 91	4	7 days	a) 1.0 L/ha b) 4.0 L/ha	a) as1 : 0.2 kg/ha as2: 0.2 kg/ha b) as1 : 0.8 kg/ha as2 : 0.8 kg/ha	300 - 600	7	

Remarks:

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

REGISTRATION REPORT
Part B

Section 5 Environmental Fate

Detailed summary of the risk assessment

Product code: **BANJO forte**

Active Substances: **Fluazinam 200 g/L**
Dimethomorph 200 g/L

Central Zone
Zonal Rapporteur Member State: Germany

NATIONAL ADDENDUM – Germany

Applicant: **ADAMA Deutschland**

Date: **April 2015**

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FATE AND BEHAVIOUR IN THE ENVIRONMENT (KIIIA 9)

The exposure assessment of the plant protection product Banjo Forte in its intended uses in potatoes is documented in detail in the core assessment of the plant protection product Banjo Forte dated from Januar 2014 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 Banjo Forte 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 Banjo Forte

Code	MCW-853		
plant protection product	Banjo Forte		
applicant	ADAMA Deutschland		
date of application	30.03.2013		
Formulation type (WP, EC, SC, …; density)	SC		
active substances (as)	Fluazinam	Dimethomorph	
Concentration of as	200 g/L	200 g/L	

Data pool/task force	
letter of access/cross reference	
existing authorisations in DE	7012-00/00

5.2 Proposed use pattern

The intended uses in Germany classified according the soil effective application rate (cumulative, disregarding degradation in soil) is presented in
Table 5.2-1. Full details of the proposed uses that will be assessed is included in Appendix 3.
The intended uses in Germany (use No. 00-001) are covered by the core assessment performed by Germany

Table 5.2-1: Classification of intended uses in Germany for Banjo Forte

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)

02-001	potatoes/ BBCH 31-91	spraying	4 x, 7 d, 01.06 1. 50 % 2. 80 % 3. 80 % 4. 80 %	Fluazinam: 4 x 200 = 800 Dimethomorph: 4 x 200 = 800	Fluazinam: 1. 100 2. 40 3. 40 4. 40 = 220 Dimethomorph: 1. 100 2. 40 3. 40 4. 40 = 220

* 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 Fluazinam

Please refer to the core assessment (November 2013), part B, section 5, point 5.3.1.

5.3.2 Dimethomorph

Please refer to the core assessment (November 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

Fluazinam

Please refer to the core assessment (November 2013), part B, section 5, point 5.4.1.

Dimethomorph

Please refer to the core assessment (November 2013), part B, section 5, point 5.4.1.

5.4.2 Adsorption/desorption

Fluazinam.

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

Soil Type	OC	pH	K_f	K_{foc}	1/n	Reference

	(%)	(H_2O)	(mL g^{-1}	(mL $g^{-1)}$	(-)	
Speyer 2.1, sand	0.48	6.6	11.12	2317	0.620	Galicia 1993
Speyer 2.2, loamy sand	2.55	6.6	43.48	1705	0.681	
Itingen II, silt loam	1.42	8.2	27.19	1915	0.650	
Diegten, clay loam	2	7.6	37.88	1894	0.649	
Soil 1, clay	3.3	6.3	1056	32000	1.079	Geffke, 2007
Soil 2, silt loam	2.4	7.7	1897	79042	1.129	
Soil 3, loam	3.3	6.5	928	28121	1.039	
Soil 4, silt	1.4	7.3	61.4	4386	0.642	
Soil 5, loamy sand	4.4	3.9	3214	73045	1.164	

Table 5.4-2: Statistic values according to INPUT DECISION 3.2 for Fluazinam for PEC_{GW} modelling

Does the active substance dissociate ?	yes, pKs =7.22	
correlation K_{foc} and pH	Kendall-τ:-0.310 p-value:0.295	not significant
correlation K_f and pH	Kendall-τ:-0.423 p-value:0.142	Not significant
correlation K_f and oc	Kendall-τ:0.648 p-value:0.011	positiv significant (p-Wert < significance level)
coefficient of variation K_{foc}	126	not relevant/ sufficiently low (≤ 60%)/ too high (> 60%)
coefficient of variation Kf	139	not relevant/ sufficiently low (≤ 100%)/ too high (> 100%)
Correlation K_f and other soil parameters (clay, CEC)	-	not relevant
K_{foc}/K_f for PEC_{GW}	24936	arithmetic mean all soils, n= 9
1/n PECgw	0.85	arithmetic mean all soils, n= 9

Metabolite HYPA

Table 5.4-3: K_f, K_{foc} and 1/n (Freundlich exponent) values for HYPA

Soil Type	**OC (%)**	**pH (H_2O)**	**K_f (mL g^{-1}**	**K_{foc} (mL $g^{-1)}$**	**1/n (-)**	**Reference**

Kenny Hill UK Sandy loam	3.07	7.7	14	450	0.8276	Müller 1993
East Anglia UK Sandy loam	1.86	8.1	13	700	0.84	
Gayton UK Loamy sand	1.8	7.9	8.1	450	0.8091	
Lilly field UK Coarse sand	0.46	5.7	4.3	920	0.7554	
Nebo UK Silty clay loam	1.45	5.0	19	1300	0.75	
Salmonds bridge UK Sandy loam	1.57	4.7	26	1700	0.7631	
arithmetisches Mittel (n = 6) EU			14	(918) **920** EU	0.7928	

Table 5.4-4 Statistic values according to INPUT DECISION 3.2 for HYPA for PEC_{GW} modelling

Does the active substance dissociate ?	yes, pKs =7.22	
correlation K_{foc} and pH	Kendall-τ:-0.733 p-value:0.060	not significant
correlation K_f and pH	Kendall-τ:-0.467 p-value:0.260	not significant
correlation K_f and oc	Kendall-τ:0.200 p-value: 0.354	not significant (p-Wert < significance level)
coefficient of variation K_{foc}	53 %	sufficiently low (≤ 60%)
coefficient of variation Kf	55 %	sufficiently low (≤ 60%)
Correlation K_f and other soil parameters (clay, CEC)	-	not relevant
K_{foc} for PEC_{GW}	918 **920 (EU-endpoint)**	arithmetic mean all soils, n= 6
1/n PECgw	0.7928	arithmetic mean all soils, n= 6

Dimethomorph

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 5.4-5: K_f, K_{foc} and 1/n (Freundlich exponent) values for dimethomorph

Soil Type	**OC (%)**	**pH (H_2O)**	**K_f (mL g^{-1}**	**K_{foc} (mL g^{-1})**	**1/n (-)**	**Reference**

Sandy loamy silt	0.96	6.1	4.94	515	0.834	Haas-Jobelius, 1991
Sandy loam	2.26	7.9	8.51	377	0.814	
Sand	0.7	6.4	2.72	389	0.857	
Silty sand	0.96	5.5	3.03	316	0.872	
Sand	0.79	6.3	4.47	566	0.887	Eichler, 1988
Humus sand	2.90	6.7	11.67	402	0.921	
Sandy loam	0.72	6.0	2.09	290	0.814	
Sand	0.9	6.3	4.11	457	0.88	McCullough, 1997
Silty clay loam	1.8	8.7	10.01	556	0.87	
Sand	3.8	6.4	19.5	513	0.88	
Sandy loam	1.4	6.3	4.83	345	0.82	
Silt loam	2.39	7.7	18	753	0.7723	Geffke, 2007
Loam	3.32	6.5	15	452	0.8209	
Silt	1.36	7.3	6.2	456	0.8354	

Table 5.4-6: Statistic values according to INPUT DECISION 3.2 for dimethomorph for PEC_{GW} modelling

does the active substance dissociate ?	No (pKa = -1.305)	
correlation K_f and oc	Kendall-τ: 0.796 p-value: 0.000	positiv significant (p-value < significance level)
coefficient of variation K_{foc}	27	sufficiently low (≤ 60%)
correlation K_f and pH	Kendall-τ: 0.438 p-value: 0.036	not significant
correlation K_f and other soil parameters (clay, CEC)	Clay: Kendall-τ: 0.275 p-value: 0.189 CEC: Kendall-τ: 0.663 p-value: 0.001	Clay: not significant CEC: significant
K_{foc}	456	arithmetic mean all soils
1/n PEC_{GW}	0.848	arithmetic mean all soils

5.4.3 Rate of degradation in water/sediment

Fluazinam

Please refer to the core assessment (November 2013), part B, section 5, point 5.4.3.

Accumulation of active substance and relevant metabolites in the sediment

active substance	Fluazinam
accumulation potential in sediment	no ($DT_{90,whole\ system}$ < 1 year, see core assessment, part B, section 5, chapter 5.4.3)

Dimethomorph

Please refer to the core assessment (November 2013), part B, section 5, point 5.4.3.

Accumulation of active substance and relevant metabolites in the sediment

active substance	Dimethomorph
accumulation potential in sediment	no ($DT_{90,whole\ system}$ < 1 year, see core assessment, part B, section 5, chapter 5.4.3)

5.5 Estimation of concentrations in soil (KIIIA1 9.4)

Results of PECsoil calculation for Banjo Forte according to EU assessment considering 5 cm soil depth are given in the core assessment November 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 the active substances fluazinam and dimethomorph in soil (DT_{90} < 365 d, SFO, field data) the accumulation potential of fluazinam and dimethomorph does not need to be considered.

Due to the slow degradation of the metabolite HYPA of fluazinamin soil (DT_{90} > 365 d, SFO, laboratory data) the accumulation potential of HYPA is need to be considered. Therefore PEC_{soil} used for risk assessment comprises background concentration in soil (PEC_{accu}) considering a tillage depth of 20 cm (arable crop) or 5 cm (permanent crops) and the maximum annual soil concentration PEC_{act} considering the relevant soil depth of 2.5 cm or 1.0 cm, respectively.

The PEC_{soil} calculations were performed with ESCAPE 2.0 based on the input parameters for fluazinam as presented in Table 5.5-1.

Table 5.5-1: Input parameters Banjo Forte for PEC_{soil} calculation

Active substance	**DT_{50}**

Fluazinam	40.8 d (SFO, Maximum, field studies, see core assessment, chapter 5.4.1.2)
Fluazinam metabolite HYPA	205.2 d (SFO, 90th percentile, laboratory data)
Dimethomorph	61 d (SFO, maximum unnormalised $DT_{50field}$, n = 7)

Additional $PEC_{soil,act}$ was calculated for the formulation Banjo Forte for a soil depth 1 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 fluazinam, HYPA and dimethomorph and for the formulation Banjo Forte are summarized in Table 5.5-2.

Table 5.5-2: Results of PEC_{soil} calculation for the intended use in potatoes used for German risk assessment

plant protection product:		Banjo Forte				
use:		00-001				
Number of applications/intervall		4 , minimum interval 7 days				
application rate:		200 g ai/ha				
crop interception:		50, 80, 80, 80 % (BBCH 31-91)				
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)**
Fluazinam	100+40+40+40= 220	1	1.1803	-	-	-
HYPA max. 13.9% , MG-ratio 0.96	13.3+5.3+5.3+5.3 = 29.21	1	0.1871	20	0.0038	0.1909
Dimethomorph	100+40+40+40= 220	2.5	0.5062	-	-	-
Banjo Forte	578+231+231+ 231=1241 (kum)	1	8.273			

*Relative density D^{20}_4: 1.156 at 20°C

5.6 Estimation of concentrations in surface water and sediment (KIIIA1 9.7)

Results of PECsw calculation of fluazinam for the intended for uses of Banjo Forte in potatoes using FOCUS Surface Water are given in the core assessment from November 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 3.0.

The German surface water exposure assessment is outlined in the following chapters.

5.6.1 PEC_{SW} after exposure by spraydrift and deposition following volatilization

Fluazinam

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 fluazinam is > 10^{-4} Pa. Hence the active substance fluazinam is regarded as semivolatile (volatilization from soil and plant surfaces). Therefore exposure of surface water by the active substance fluazinam 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 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.

However, for the active substance fluazinam the thus calculated peak PECsw for multiple applications is lower than for one application. Thus, PECsw for one single application are used as highest PECsw here/ However, the dissipation of the active substance fluazinam from the water phase between the application events as described by a $DissT_{50}$ value of 3 days (SFO, worst case for dissipation from the water phase) is significantly shorter than the application interval of 7 days, application events are regarded as independently from each other and exposure assessment is consequently based on a single application. As higher tier option the experimentally derived deposition values of the windtunnel study (Staffa 2012) was considered for the active substance fluazinam.

The endpoints used for modelling surface water exposure via spray drift and volatilization with subsequent deposition with EVA 2.1 are summarized in Table 5.6-1.

Table 5.6-1 Endpoints of fluazinam used for the PEC_{SW} calculations with EVA 2.1

Parameter	**Active substance fluazinam**		**Reference**
Vapour pressure at 20 °C (Pa)	2.9 x 10^{-3} Pa at 20 °C		See core assessment, section 5, point 5.3.1.1
Solubility in water (mg/L)	0.135 mg/L in buffered solution (at pH 7)		See core assessment, section 5, point 5.3.1.1
$DissT_{50}$ water (d)	3 (maximum)		See core assessment, section 5, point 5.4.3
DT_{50} water/sediment study, total system (d)	5.8 (maximum)		See core assessment, section 5, point 5.4.3
DT_{50} hydrolysis/photolysis (d)	1000 (default)		
Windtunnel study (Staffa 2012)			
	Distance (m)	% of applied rate	
	1	0.11	
	3	0.07	
	5	0.06	
	10	0.03	
	15	0.02	
	20	0.02	

*SFO, worst case

**SFO, worst case

The calculated PECsw values after exposure via spray drift and volatilization with subsequent deposition for the active substance fluazinam for the intended use in potatoes (worst case application rate) are summarized in Table 5.6-2.

Table 5.6-2 PEC_{SW} for the active substance fluazinam after exposure via spray drift and volatilization with subsequent deposition modelled with EVA 2.1

active substance	Fluazinam
use pattern/gap:	00-001
application rate/number of applications / interval	200 g ai/ha (1.0 L product/ha) (single application as worst case)
DissT50 (SFO) in water	3
relevant PEC if applicable twa-interval	PECinitial
scenario/percentile:	agriculture (90th percentile), 80 % Interzeption auf Kulturpflanzen (Anteil für Verflüchtigung)

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	66.67			66.67	6.67	16.67	33.33
1	2.770	1.847	0.095	0.064	1.910	0.25	0.53	0.99
5	0.570	0.380	0.052	0.035	0.415	0.07	0.13	0.22
10	0.290	0.193	0.026	0.017	0.211	0.04	0.07	0.11
15	0.200	0.133	0.017	0.012	0.145	0.02	0.04	0.08
20	0.150	0.100	0.017	0.012	0.112	0.02	0.04	0.06

Dimethomorph

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 dimethomorph is $< 10^{-5}$ Pa. Hence the active substance dimethomorph is regarded as non. Therefore exposure of surface water by the active substance fluazinam due to deposition following volatilization does not need to be considered.

The calculation of PECsw after exposure via spray drift and volatilization with subsequent deposition is performed using the model EVA 2.1. 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.

However, for the active substance dimethomorph the thus calculated peak PECsw for multiple applications is lower than for one application. Thus, PECsw for one single application are used as highest PECsw here/ However, the dissipation of the active substance dimethomorph from the water phase between the application events as described by a $DissT_{50}$ value of 15 days (SFO, worst case for dissipation from the water phase) is significantly longer than the application interval of 7 days, application events are regarded as dependently from each other and exposure assessment is consequently based on a cumulative application rate.

The endpoints used for modelling surface water exposure via spray drift and volatilization with subsequent deposition with EVA 2.1 are summarized in Table 5.6-3.

Table 5.6-3 Endpoints of ... used for the PEC_{sw} calculations with EVA 2.1

Parameter	Dimethomorph	Reference
Vapour pressure at 20 °C (Pa)	9.7 x 10^{-7} Pa (E-Isomer) 1.0 x 10^{-6} Pa (Z-Isomer)	See core assessment, section 5, point 5.3.2.2
Solubility in water (mg/L)	as a whole E/Z isomers mixture: 49.2 (pH 7)	See core assessment, section 5, point 5.3.2.2
DissT50 water (d)	19 (maximum)	See core assessment, section 5, point 5.4.3
DT50 water/sediment study, total system (d)	59 (maximum)	See core assessment, section 5, point 5.4.3
DT50 hydrolysis/photolysis (d)	1000 (default)	

*SFO, worst case

**SFO, worst case

The calculated PECsw values after exposure via spray drift and volatilization with subsequent deposition for the active substance dimethomorph for the intended use in potatoes (worst case application rate) are summarized in Table 5.6-4.

Table 5.6-4 PEC_{sw} for the active substance dimethomorph after exposure via spray drift and volatilization with subsequent deposition modelled with EVA 2.1

active substance	Dimethomorph
use pattern/gap:	00-001
application rate/number of applications / interval	200 g ai/ha (1.0 L product/ha) (cumulative application rate as worst case)
$DissT_{50}$ (SFO) in water	19
relevant PEC **if applicable twa-interval**	PECinitial
scenario/percentile:	agriculture (90th percentile), 80 % Interzeption auf Kulturpflanzen (Anteil für Verflüchtigung)

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	66.67			66.67	6.67	16.67	33.33
1	2.770	1.847			1.847	0.18	0.46	0.92
5	0.570	0.380			0.380	0.04	0.10	0.19
10	0.290	0.193			0.193	0.02	0.05	0.10
15	0.200	0.133			0.133	0.01	0.03	0.07
20	0.150	0.100			0.100	0.01	0.03	0.05

5.6.2 PEC_{sw} after exposure by surface run-off and drainage

Fluazinam

The concentration of the active substance fluazinam in adjacent ditch due to surface runoff and drainage is calculated using the model EXPOSIT 3.0.

The parameters for fluazinam used for modelling surface water exposure via run-off and drainage in an adjacent ditch with EXPOSIT 3.0 are summarized in Table 5.6-5.

Table 5.6-5 Input parameters for fluazinam used for PEC_{SW} calculations with EXPOSIT 3.0

Parameter	Fluazinam	Reference
$K_{foc, Runoff}$	24936	arithm. mean (see core assessment, section 5, chapter 5.4.2)
$K_{foc, mobility class}$	24936	arithm. mean (see core assessment, section 5, chapter 5.4.2)
DT_{50} soil (d)	40.8	
Solubility in water (mg/L)	0.135 (pH7)	see core assessment, section 5, point 5.3.1.1
Reduction by bank filtration (only relevant for PECgw see 5.7.2)	100 %	
Metabolite	HYPA	
molecular weight (g/mol)	446.7	
max. observed (%)	13.9	
Solubility in water (mg/L)	10.45	
DT50 in soil (d)	205.2	
Kfoc	920	arithm. mean (see core assessment, section 5, chapter 5.4.2)
$K_{foc, mobility class}$	920	arithm. mean (see core assessment, section 5, chapter 5.4.2)

The calculated PEC_{SW} in an adjacent ditch due to surface run-off and drainage for the active substance fluazinam for the intended for use in potatoes (worst case application rate) are summarized in Table 5.6-6.

Table 5.6-6 PEC_{SW} of fluazinam in an adjacent ditch due to surface run-off and drainage

Active substance:	Fluazinam	
Use pattern/GAP:	00-001	
Application rate:	4 x 200 g ai/ha (worst case), minimum Interval 7 days	
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	0.09	1.97
5	0.08	1.71
10	0.07	1.47
20	0.05	1.03
Exposure by drainage		
time of application	PECsw in adjacent ditch (µg/L)	
autuum/winter/early spring	0.08	
Spring/summer	0.03	

PEC_{SW} of fluazinam in an adjacent ditch due to surface run-off and drainage

Active substance:	Metabolite HYPA	
Use pattern/GAP:	00-001	
Application rate:	4 x 26.7 g ai/ha (worst case), minimum Interval 7 days (MG-ratio 0.96, max. 13.9% observed)	
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	0.20	0.22
5	0.17	0.19
10	0.15	0.15
20	0.10	0.11
Exposure by drainage		
time of application	**PECsw in adjacent ditch (µg/L)**	
autuum/winter/early spring	0.01	
Spring/summer	0.00	

Dimethomorph

The concentration of the active substance dimethomorph in adjacent ditch due to surface runoff and drainage is calculated using the model EXPOSIT 3.0.

The parameters for dimethomorph used for modelling surface water exposure via run-off and drainage in an adjacent ditch with EXPOSIT 3.0 are summarized in Table 5.6-7.

Table 5.6-7 Input parameters for dimethomorph used for PEC_{SW} calculations with EXPOSIT 3.0

Parameter	Dimethomorph	Reference
$K_{foc,\ Runoff}$	456	arithm. mean (see core assessment, section 5, chapter 5.4.2)
$K_{foc,\ mobility\ class}$	456	arithm. mean (see core assessment, section 5, chapter 5.4.2)
DT_{50} soil (d)	61	core assessment, section 5, chapter 5.4.1
Solubility in water (mg/L)	pH 7: *E* -isomer: 31.0 *Z*-isomer: 18.2 as a whole *E/Z:* 49.2	core assessment, section 5, chapter 5.3.2.2
Reduction by bank filtration (only relevant for PECgw see 5.7.2)		

The calculated PEC_{SW} in an adjacent ditch due to surface run-off and drainage for the active substance dimethomorph for the intended for use in potatoes (cumulative application rate) are summarized in Table 5.6-8.

Table 5.6-8 PEC_{SW} of dimethomorph in an adjacent ditch due to surface run-off and drainage

Active substance:	Dimethomorph	
Use pattern/GAP:	00-001	
Application rate:	4 x 200 g ai/ha (worst case), minimum Interval 7 days	
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	1.58	1.61
5	1.37	1.39
10	1.17	1.18
20	0.82	0.83
Exposure by drainage		
time of application	**PECsw in adjacent ditch (µg/L)**	
autuum/winter/early spring	1.76	
Spring/summer	0.57	

5.7 Risk assessment for groundwater (KIIIA1 9.6)

Results of PECgw calculation of fluazinam and dimethomorph for the intended uses of Banjo Forte in potatoes according to EU assessment using FOCUS PELMO 5.5.3 are given in the core assessment from November 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.

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 Banjo Forte in potatoes according to

Table 5.2-1 (see also Appendix 3).

Table 5.7-1 Input parameters related to application for PEC_{GW} modelling with FOCUS PELMO 5.5.3

use evaluated	00-001
application rate (kg as/ha)	4 x 0.2 kg ai/ha
crop (crop rotation)	potatoes
date of application	22 days after first emergence
interception (%)	50, 80, 80, 80 %
soil moisture	100 % FC
Q10-factor	2.58
moisture exponent	0.7
plant uptake	0
simulation period (years)	26

Fluazinam

The endpoints used for groundwater modelling for fluazinam and its metabolite HYPA according to INPUT DECISION 3.3 are summarized in Table 5.7-2.

Table 5.7-2 Input parameters related to fluazinam for PEC_{GW} modelling

Parent	**Fluazinam**	**Remarks/Reference to core assessment, part B, section 5**
molecular weight (g/mol)	465.1	
DT_{50} in soil (d)	59.7	
K_{foc}	24936	
1/n	0.85	
metabolite	HYPA	
molecular weight (g/mol)	446.7	
Formation fraction	0.193	
DT_{50} in soil (d)	205.2	
K_{foc}	920	
1/n	0.865	

The results of the groundwater simulation are presented in Table 5.7-3.

Table 5.7-3 PEC_{GW} at 1 m soil depth of fluazinam and its metabolite HYPA considered relevant for German exposure assessment

Use No.	Szenario	80th Percentile PEC_{GW} at 1 m Soil Depth (µg L^{-1}) modeled by FOCUS PELMO 5.5.3		
		Fluazinam	Metabolite HYPA	
00-001	Hamburg	<0.001	<0.001	

Dimethomorph

The endpoints used for groundwater modelling for dimethomorph according to INPUT DECISION 3.3 are summarized in Table 5.7-4.

Table 5.7-4 Input parameters related to dimethomorph for PEC_{GW} modelling

Parent	Dimethomorph	Remarks/Reference to core assessment, part B, section 5
molecular weight (g/mol)	387.9	
DT_{50} in soil (d)	41.8	
K_{foc}	456.2	
1/n	0.8484	

The results of the groundwater simulation are presented in Table 5.7-5.

Table 5.7-5 PEC_{GW} at 1 m soil depth of dimethomorph considered relevant for German exposure assessment

Use No.	Szenario	80th Percentile PEC_{GW} at 1 m Soil Depth (µg L^{-1}) modeled by FOCUS PELMO 5.5.3
		Dimethomorph
00-001	Hamburg	<0.001

According to the results of the groundwater simulation with FOCUS-PELMO 5.5.3, a groundwater contamination of the active substances fluazinam and dimethomorph in concentrations of ≥ 0.1 µg/L is not expected for the intended use in potatoes.

For the metabolite HYPA of fluazinam a groundwater concentration of ≥ 0.1 µg/L can be excluded for the application in potatoes according to the results of the groundwater simulation with FOCUS-PELMO 4.4.3.

5.7.1.2 Summary on risk assessment for groundwater after direct leaching

Results of modelling with FOCUS-PELMO 5.5.3 show that the active substance fluazinam and dimethomorph are not expected to penetrate into groundwater at concentrations of ≥ 0.1µg/L in the intended for uses in potatoes.

For the metabolites HYPAconcentrations of ≥ 0.1µg/L in groundwater can be excluded.

Consequences for authorization:

none

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

Fluazinam

The input parameters for fluazinam used for modelling surface water exposure via run-off and drainage in an adjacent ditch with subsequent bank filtration into the groundwater with EXPOSIT 3.0 are summarized in Table 5.7-6.

Table 5.7-6 Input parameters for fluazinam used for PEC_{GW} calculations with EXPOSIT 3.0

Parameter	Fluazinam	Reference
$K_{foc, Runoff}$	24936	arithm. mean (see core assessment, section 5, chapter 5.4.2)
$K_{foc, mobility class}$	24936	arithm. mean (see core assessment, section 5, chapter 5.4.2)
DT_{50} soil (d)	40.8	
Solubility in water (mg/L)	0.135	
Mobility class	1	
Reduction by bank filtration	100	

The calculated PECgw for fluazinam after surface run-off and drainage with subsequent bank filtration are summarized in Table 5.7-7.

Table 5.7-7 PEC_{gw} for fluazinam after surface run-off and drainage with subsequent bank filtration (modelled with EXPOSIT 3.0)

Active substance		**Fluazinam**			
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)**
00-001	4 x 200 g /ha, interval 7 days, 50, 80, 80, 80 % 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, groundwater contamination at concentrations ≥ 0.1 µg/L by the active substance fluazinam due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

Metabolites

The soil metabolites of fluazinam (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.

Belonging to the same mobility class groundwater contamination at concentrations ≥ 0.1 µg/L by the metabolite HYPA due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

Dimethomorph

The input parameters for dimethomorph used for modelling surface water exposure via run-off and drainage in an adjacent ditch with subsequent bank filtration into the groundwater with EXPOSIT 3.0 are summarized in Table 5.7-8.

Table 5.7-8: Input parameters for dimethomorph used for PEC_{GW} calculations with EXPOSIT 3.0

Parameter	Dimethomorph	Reference
$K_{foc, Runoff}$	456.2	arithm. mean (see core assessment, section 5, chapter 5.4.2)
$K_{foc, mobility class}$	456.2	arithm. mean (see core assessment, section 5, chapter 5.4.2)
DT_{50} soil (d)	61	
Solubility in water (mg/L)	49.2	
Mobility class	2	
Reduction by bank filtration	75	

The calculated PECgw for dimethomorph after surface run-off and drainage with subsequent bank filtration are summarized in Table 5.7-9.

Table 5.7-9: PEC_{gw} for dimethomorph after surface run-off and drainage with subsequent bank filtration (modelled with EXPOSIT 3.0)

Active substance		**Dimethomorph**			
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)**
00-001	4 x 200 g /ha, interval 7 days, 50, 80, 80, 80 % interception	0	0.032	autumn/winter/ early spring	0.035
		5	0.027		
		10	0.023	spring/summer	0.011
		20	0.016		
required labelling		none			

According modelling with EXPOSIT 3, groundwater contamination at concentrations ≥ 0.1 µg/L by the active substance dimethomorph due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

Consequences for authorization:

None.

Appendix 1 List of data submitted in support of the evaluation

No additional data for national assessment submitted.

Appendix 2 Detailed evaluation of studies relied upon

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

KIIIA1 9 Fate and Behaviour in the Environment

KIIIA1 9.6. Staffa 2012

Reference:	
Author	Staffa, C.
Report:	Large outdoor wind tunnel study with a fluazinam-containing formulation (500 g a.s./L) to investigate the volatilisation, short range transport and deposition of fluazinam, Study No: AS257
Date:	28.11.2012
Guideline(s):	Assessment scheme for the short range transport of plant protection products- environmental exposure by airborne routes (Spray drift, votalisation and deposition BVL report 110 (2002) Braunschweig, Germany Sieber, Fent (2012) Empfehlungen zur experimentellen Bestiummung der verflüchtigungsbedingten Deposition von Pflanzenschutzmittel-Wirkstoffen auf Nichtzielpflächen
Deviations:	none
GLP:	Yes
Acceptability:	Yes

Materials and methods

At the time of application the growth-stage of lettuce was BBCH 45. The non-treated area was grown with local green fallow. To exclude influences of changing wind speed and wind direction the experiment was carried out under controlled conditions in a wind tunnel with a length of approximately 55 m, a width of 6.5 m and a height of 3.1 m. At one end of the tunnel a wind engine with 26 synchronic working fans was installed. Between the wind engine and the target area, there was a 5 m air equilibrium distance. The target area had a width of 4 m and a length of 25 m. The distance from the edges of the field to the wind tunnel was 1.25 m on each side. The sampling points were located in the non-target area at defined distances.

The application was carried out with a portable 4 m carbon boom sprayer with eight drift reducing nozzles at a pressure of approximately 3 bar and a speed of about 2.3 km/h.

Fluazinam was applied at a target concentration of 200 g/ha. The application rate of the reference item Lindane amounted to 400 g/ha. The total volume of application solution was 400 L/ha.

Sampling points were located in distances of 1, 3, 5, 10, 15, and 20 m away from the target area. Stainless steel bowls (length 100 cm, width 50 cm, depth 12 cm) were placed on the non-target area short time after application. Afterwards they were filled with 25 L tap water acidified to pH 4 with hydrochloric acid. After filling of the steel bowls the wind engine was started (corresponds to 10 minutes after spray application). The average wind speed during the 24 hours study time was 2.08 m/s and the mean air temperature was 16.9 °C. Water sampling was carried out 0.5, 2, 12 and 24 hours after spray application. Specimens were stored at <-18 °C in the dark until further analysis.

Results and discussions

For BANJO, 100.3 % of the planned application rate was actually applied on the field

The deposition (%) of the test and reference item in water at the 24 h sampling is given as follows:

	Deposition (% of applied) at the following downwind distance from the target area					
(m)	1	3	5	10	15	20
Fluazinam	**0.11**	**0.07**	**0.06**	**0.03**	<LOQ	<LOQ
Lindane	1.65	1.11	0.97	0.48	0.31	0.21

LOQ: Limit of quantification, corresponding to 0.02 %a. for fluazinam and 0.01 %a. for lindane.

Conclusion

As a result, the analysed concentrations of Fluazinam were low and ranged from 0.11 % of applied at the 1 m distance to values below limit of quantification (0.02 % a.) at the 15 and 20 m distances.

The deposition of the reference item Lindane resulted in the same range as determined for arable crops in other studies. This demonstrates the validity of the experiment.

For both compounds the deposition was a function of distance from the treated crop and a continuous decrease with increasing distance from the treated crop can be observed.

The bold values in the table above can be used as input values in EVA 2.1.xls model for a higher tier refined aquatic risk assessment of fluazinam.

Comments of zRMS

The study is considered to be acceptable. The results of the study can be used as higher tier input parameters in EVA 3 to refine the aquatic risk assessment.

Appendix 3 Table of Intended Uses in Germany (according to BVL 08.07.2013)

PPP (product name/code) BANJO FORTE **Formulation type**: SC

active substance 1 Fluazinam **Conc. of as 1**: 200 g /L
active substance 2 Dimethomorph **Conc. of as 2**: 200 g/L

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**			**Application rate**			**PHI** (days)	**Remarks:** e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
00-001	DE	Potatoes	F	Late blight (Phytophthora infestans) PHYTIN	Foliar spraying	Summer applications BBCH 31-91	a) 4 b) 4	a) 1.0 L/ha b) 4.0 L/ha	a) as1 : 0.2 kg/ha as2: 0.2 kg/ha b) as1 : 0.8 kg/ha as2 : 0.8 kg/ha	300-600	7	

DRAFT REGISTRATION REPORT
Part B

Section 6: Ecotoxicological studies
Detailed summary of the risk assessment

Product code: **BANJO forte**

Active Substance: **Fluazinam 200 g/L**
Dimethomorph 200 g/L

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: **ADAMA Deutschland**
Date: **April 2015**

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Sec 6 ECOTOXICOLOGICAL STUDIES (MIIIA 10)

This document reviews the ecotoxicological studies for the product BANJO FORTE (also referred to as MCW-853 SC) containing the active substances fluazinam (200 g/L) and dimethomorph (200 g/L) which were included into Annex I of Directive 91/414 (Fluazinam: Commission Directive 2008/108/EC of 26 November 2008, date of inclusion 01 March 2009; Dimethomorph: Commission Directive 2007/25/EC of 23 April 2007, date of inclusion 01 October 2007). A full risk assessment according to Uniform Principles is provided which demonstrates that the product is safe for the environment.

Where appropriate this document refers to the conclusions of the EU review of fluazinam and dimethomorph. This will be where:

- the active substance data is relied upon in the risk assessment of the formulation; *or*
- the EU review concluded that additional data/information should be considered at national re-registration.

Note: This Part B document for Section 6 reviews both Annex II data that has previously been considered within the EU review process (identified as EU agreed endpoints in the context of the Annex I inclusion decision) and Annex III data on BANJO FORTE, the formulation for which authorisation is sought. New Annex II data available since Annex I inclusion were included if they are considered essential for the evaluation and in this case a full study summary is provided. Detailed study summaries for the studies performed with the formulated product BANJO FORTE and for other new studies (metabolites) are presented in Appendix 2.

The completeness of the AII data and information matching protected Annex II data for **fluazinam** was confirmed by the RMS Austria's letter dated 06 July 2009. Since all points of the list of essential Annex II-studies, for which the main submitter ISK has claimed data protection, are adequately addressed by alternative studies of Makhteshim Chemical Works Ltd., reference can be made without restriction to all studies which were considered for the Annex inclusion. Thus, explicit reference is made to the corresponding documents and results summarised in the Draft Assessment Report on fluazinam (public version, July 2006, final addendum February 2008) and especially to the EFSA Scientific Report (2008) 137 (fluazinam) and the appended list of endpoints.

A check list of AII data and information matching protected Annex II data for **dimethomorph** and the underlying studies were submitted in November 2006 and are evaluated by RMS Germany and MS. The data demonstrate access to a complete Annex II data package. Since all points of the list of essential Annex II-studies, for which the main submitter BASF has claimed data protection, are adequately addressed by alternative studies of Makhteshim Chemical Works Ltd., reference can be made without restriction to all studies which were considered for the Annex I inclusion. Thus, explicit reference is made to the corresponding documents and results summarised in the Draft Assessment Report (DAR) on dimethomorph (2004), the EC review report SANCO/10040/06-rev.3 (2006) and especially to the EFSA Scientific Report (2006) 82 (dimethomorph) and the appended list of endpoints.

The Annex I Inclusion Directives for fluazinam and dimethomorph (Commission Directive 2008/108/EC and Commission Directive 2007/25/EC) provide specific provisions under Part B which need to be considered by the applicant in the preparation of their submission and by the Member State prior to granting an authorisation.

For the implementation of the uniform principles of Annex VI, the conclusions of the review report for **fluazinam**, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 20 May 2008 shall be taken into account.

In this overall assessment, Member States must pay particular attention to:

- the protection of the operators' and workers' safety. Authorised conditions of use must prescribe the application of adequate personal protective equipment and risk mitigation measures to reduce the exposure *(not pertaining to this section)*,
- the residues in food of plant and animal origin and evaluate the dietary exposure of consumers *(not pertaining to this section)*,
- the protection of aquatic organisms. In relation to this identified risk, risk mitigation measures, such as buffer zones, should be applied where appropriate.

These concerns have been addressed within the current submission in the corresponding sections.

In addition, the following concerns related to ecotoxicological data and information are raised in the EFSA Scientific Report (2008) 137 and have been addressed in the current submission:

- A refined risk assessment to earthworm eating mammals is required (addressed in point IIIA 10.3.0).
- Final aquatic toxicity studies with the soil metabolite HYPA for fish and *Daphnia* and algae are required (addressed in point IIIA 10.2.0, IIIA 10.2.2.1 and IIIA 10.2.2.2).
- A refined aquatic risk assessment for HYPA is required including revised PEC_{sw} concentration (addressed in point IIIA 10.2.0).
- A data gap was identified at the expert meeting for toxicity data for G-504 for all groups of aquatic organisms (addressed in point IIIA 10.2.0).
- A data gap for a study on logKow for HYPA was identified at the experts' meeting on physical-chemical properties to decide if further risk assessment is triggered for the metabolite (addressed in point IIIA 10.2.0).
- A data gap for a new higher tier study, in which the new PEC_{soil} plateau is covered and the presence of and effects on macro organisms are monitored (addressed in point IIIA 10.6.0).

For the implementation of the uniform principles of Annex VI, the conclusions of the review report for **dimethomorph**, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 24 November 2006 shall be taken into account.

In this overall assessment, Member States must pay particular attention to:

- the operators and workers safety. Authorised conditions of use must prescribe the application of adequate personal protective equipment *(not pertaining to this section)*;

- to the protection of birds, mammals and aquatic organisms.

Conditions of authorisation should include risk mitigation measures, where appropriate.

These concerns have been addressed within the current submission in the corresponding sections.

6.1 GAP and overall conclusions

6.1.1 Table of intended uses

Table 6.1-1: GAP and overall conclusions

Intended use	F/G	Timing (months, BBCH)	Max number appl. (interval in days)	Application per treatment		Overall conclusions						
				kg a.s./ha max	Rate/season [kg a.s./ha] max	Birds	Aquatic organisms	Mammals	Bees	Non-target arthropods	Soil organisms	Non-target plants
Potatoes	F	BBCH 31-91	4 (7 d)	4 x 0.2 (fluazinam) 4 x 0.2 (dimetho-morph)	0.8 (fluazinam) 0.8 (dimetho-morph)		"X1"					

F: Field use; G: Glasshouse use

Remarks:
- Safe use identified
- Further refinement and/or risk mitigation measures are needed
- No safe use identified and considered possible

Explanations:

The colours in the Table 6-1 are intended to reflect the outcome of the assessments including the available and valid refinement steps and risk mitigations measures.

"X1": Risk mitigation measures for the protection of surface water required at member state level (since no EU harmonized legally binding measures in force).

6.1.2 Grouping of intended uses for risk assessment

The risk assessments for terrestrial, aquatic and soil organisms presented in this document were performed for the only intended use in potatoes the application was made for, i.e. there is no need for defining a risk envelope for other intended uses. This intended GAP use is summarised in the table below (copied from Part B Section 5, chapter 5.2). The soil relevant application rate is based on the effective cumulative application rate including interception. Full details of the intended GAP use in Germany are included in Part B Section 5, Appendix 3.

Table 6.1-2: Critical use pattern of BANJO FORTE

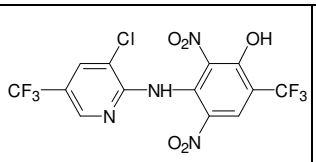
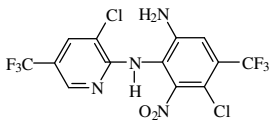
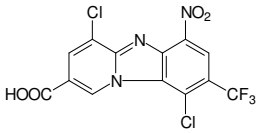
Indication	Crop/growth stage	Application method / Drift scenario	Number of applications, Minimum application interval, interception, application time (season)	Application rate, cumulative (g as/ha)	Soil effective application rate (g as/ha)
00-001	potatoes BBCH 31-91	spraying	4 x, min. interval 7 d, 1. application: 50 % (22 days after emergence) 2. – 4 application: 80 % summer	fluazinam: 4 x 200 = 800, dimethomorph: 4 x 200 = 800	fluazinam: 1. 100 2. 40 3. 40 4. 40 = 220 dimethomorph: 1. 100 2. 40 3. 40 4. 40 = 220

6.1.3 Consideration of metabolites

The metabolites which require an ecotoxicological assessment according to the endpoint list are given below (copied from Part B Section 5 chapter 5.3.1.3 and chapter 5.3.2.3).

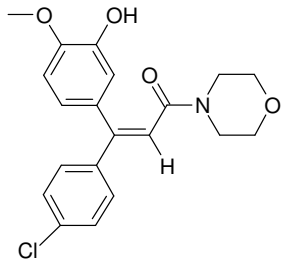
Table 6.1-3: Metabolites of fluazinam potentially relevant for exposure assessment (> 10 % of as or > 5 % of as in 2 sequential measurements or > 5 % of a.s. and maximum of formation not yet reached at the end of the study)

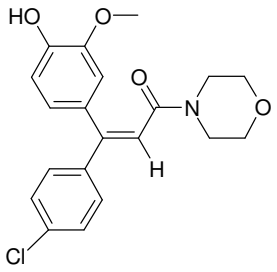
Metabolite	Structural formula/Molecular formula	occurrence in compartments (Max. at day/	Status of Relevance (SANCO/127/08 – rev.1)

HYPA 5-(3-chloro-5-trifluoromethyl-2-pyridylamino)α,α,α-trifluoro-4,6-dinitro-o-cresol	 $C_{13}H_6F_6N_4O_6$	Soil (aerob): Max. 13.9 % at day 48	Aquatic organism: Water: relevant (due to run-off and drainage) Sediment: not relevant Terrestrial organism: relevant Groundwater: not relevant (Step 2/Step 3-4)[1)]
AMPA 4-chloro-6-(3-chloro-5-trifluoromethyl-2-pyridylamino)α,α,α-trifluoro-5-nitro-m-toluidin	 $C_{13}H_6Cl_2F_6N_4O_2$	Sediment: max. 26.7 % at day 14	Aquatic organism: Water: not relevant Sediment: relevant Terrestrial organism: not relevant Groundwater: not relevant (Step 2/Step 3-4)[1)]
G-504 4,9-dichloro-6-nitro-8-(trifluoromethyl)-pyrido-[1,2-a]benzimidazole-2-carboxylic acid	 $C_{13}H_6Cl_2F_3N_3O_4$	aqueous photolysis: max. 17.1 % at day 10	Aquatic organism: Water: relevant Sediment: not relevant Terrestrial organism: not relevant Groundwater: not relevant (Step 2/Step 3-4)[1)]

[1)] According to Guidance Document on the assessment of the relevance of metabolites in groundwater of substances regulated under council directive 91/414/EEC (SANCO/221/2000 –rev.10- final - 25 February 2003)

Table 6.1-4: Metabolites of dimethomorph potentially relevant for exposure assessment (> 10 % of as or > 5 % of as in 2 sequential measurements or > 5 % of a.s. and maximum of formation not yet reached at the end of the study)

Metabolite	**Structural formula/Molecular formula**	**occurrence in compartments (Max. at day/**	**Status of Relevance (SANCO/10040/06)**
Mono-desmethyl als Isomerengemisch (meta-desmethyl-Dimethomorph = Z67 =CL900987 und para-desmethyl-Dimethomorph		Soil (anaerob): max. 14.8 % at day 7 Sediment: max. 7.8 % at 24 h, 6.3 % at 48 h and 6.3 % at day 7	Aquatic organism: Water: not relevant Sediment: not relevant Terrestrial organism: not relevant Groundwater: not relevant

= Z69 = CL900986)	 $C_{20}H_{20}ClNO_4$		

[1)] According to Guidance Document on the assessment of the relevance of metabolites in groundwater of substances regulated under council directive 91/414/EEC (SANCO/221/2000 –rev.10- final - 25 February 2003)

6.2 Effects on birds (MIIIA 10.1, KPC 10.1, KPC 10.1.1)

Annex II data on the toxicity of the active substances fluazinam and dimethomorph to birds are available in the context of the respective EU evaluation process resulting in the Annex I inclusion of each of the active substances. Thus, explicit reference is made to the corresponding results (EU agreed endpoints) summarised in the EFSA Scientific Report 137 for fluazinam (2008) and 82 for dimethomorph (2006). EU agreed endpoints for the active substances fluazinam and dimethomorph relevant for the risk assessment for birds are outlined in table below.

Table 6.2-1: Endpoints used for risk assessment for birds

Test system	Species	Results [mg a.s./kg bw(/d)]		Reference	Internal code
Fluazinam					
Acute oral toxicity	*Colinus virginianus*	LD_{50}	1782	[redacted] 1991 ISK 48/91161	26639
Dietary toxicity (short-term)	*Anas platyrhynchos*	LDD_{50}	> 1230	[redacted] 1991 ISN 25BT/841208	26638
Reproductive toxicity (long-term)	*Colinus virginianus*	NOEL	60.4	[redacted] 1996 Project No. 272-116	46384
Dimethomorph					
Acute oral toxicity	*Anas platyrhynchos*,	LD_{50}	> 2000	[redacted] 1986 DK-505-003 CMK15/86919	25867

Dietary toxicity (short-term)	*Colinus virginianus*	LDD_{50}	> 728.3	[redacted] 1987 DK-505-002 CMK18/871027	25870
Reproductive toxicity (long-term)	*Colinus virginianus*	NOEL	58.4	[redacted] 1997 029606	38998
BANJO FORTE					
Acute oral toxicity	*Coturnix japonica*	LD_{50}	> 2000*	[redacted] 2008 R-24358, 23317	75303

* New study submitted

6.2.1 Justification for new endpoints

An acute toxicity study with BANJO FORTE was performed with Japanese quails. The determined LD50 > 2000 mg prod./kg bw demonstrates the low oral toxicity of the formulated product (Ref. IIIA 10.1.6/01: [redacted]., 2008). A summary of this study is given in Appendix 2.

6.2.2 Risk assessment (MIIIA 10.1.1, MIIIA 10.1.2) for spray applications

The product BANJO FORTE (also referred to as MAC 94530 F or MCW-853 SC) is a suspension concentrate (SC) containing 200 g/L fluazinam and 200 g/L dimethomorph as active substances. BANJO FORTE is a fungicide applied as a spray after dilution in water on infested potato foliage. It is used up to 4 times per growing season with a maximum single treatment rate of 1.0 L prod./ha (corresponding to 200 g fluazinam and 200 g dimethomorph/ha) and a minimum spray interval of 7 days. The timing of application is at crop growth stages BBCH 31 - 91 when the first symptoms of a respective fungal disease become visible or after official warnings. For a detailed summary of the critical use scenario of BANJO FORTE, please refer to **Fehler! Verweisquelle konnte nicht gefunden werden.**.

Birds are typically exposed to dry residues on their food items following the dilution and spraying of the formulated product. During these processes, much of the formulation constituents are likely to be lost by volatilisation. Since oral exposure is the main route of exposure, toxicity data for the active substances are therefore used in preference to data from tests with the formulated material. On this basis, the risk to birds from the proposed uses of BANJO FORTE will be assessed using data on the active substances.

Nevertheless, an acute toxicity study with BANJO FORTE was performed with Japanese quails. The determined LD_{50} > 2000 mg prod./kg bw demonstrates the low oral toxicity of the formulated product (Ref. IIIA 10.1.6/01: [redacted]., 2008). A summary of this study is given under Annex point IIIA 10.1.6 in Appendix 2.

According to the current guidance document provided by EFSA, a separate short-term risk assessment is not intended and hence, it is recommended that the short-term dietary toxicity test is no longer part of the

core data packet. Instead, dietary effects are covered by the acute oral toxicity test resulting in a LD_{50} as relevant endpoint which should be used for the TER_A calculations. However, short-term dietary toxicity tests conducted with the active substances are available and relevant endpoints (expressed in daily dose: LDD_{50}) derived from these studies are nominally lower than the acute LD_{50} values. For maximum conservatism, the lower LDD_{50} (instead of the acute LD_{50}) was used for the acute risk assessment based on TER_A calculations.

In summary, for each time-frame (acute and long-term), the lowest available endpoints expressed as daily dose were considered for the risk assessment. Thus, the dietary LDD_{50} > 1230 mg/kg bw/d and the reproductive NOEL = 60.4 mg/kg bw/d determined for fluazinam and the dietary LDD_{50} > 728.3 mg/kg bw/d and the reproductive NOEL = 58.4 mg/kg bw/d determined for dimethomorph were used for the TER calculations.

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438).

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, but that they feed exclusively in the treated area and on a single food type. Factors PT and PD are therefore equal to 1.

The acute and reproductive risk for terrestrial vertebrates (considering direct dietary exposure to contaminated food items) was assessed using a tiered approach which is in line with current guidance. According to EFSA Journal 2009; 7(12): 1438 a screening step based on absolute worst-case assumptions can be used in order to identifiy those substances and associated uses that do not pose a risk to terrestrial vertebrates. As the screening step is not mandatory and thus only an option for the risk assessment, more realistic Tier-1 exposure scenarios as provided by EFSA Journal 2009; 7(12): 1438 were considered for an initial evaluation of the risk of fluazinam and dimethomorph to birds and mammals.

Mixture toxicity

According to Appendix B of 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. For the acute risk assessment of formulations containing more than one active substance it is proposed to calculate a "surrogate LD_{50}" assuming dose/concentration additivity of the components (active substances) per default. Sublethal effects and effects on reproduction are assessed on a case-by-case basis according to Appendix B of the guidance document.

The following formula is used to derive a surrogate LD_{50} for the mixture of active substances with known toxicity assuming dose additivity (occasionally called Finney`s formulae; Finney 1948 and 1971).:

$$LD_{50}(mix) = \left(\sum_i \frac{X(a.s._i)}{LD_{50}(a.s._i)} \right)^{-1}$$

where:

X(a.s. *i*)= relative fraction of active substance (i) in the mixture
LD_{50}(a.s. *i*) = acute toxicity value for active substance (*i*)

Comparing the results of the acute toxicity study conducted with the formulation BANJO FORTE (see chapter 6.2.1., LD_{50} > 2000 mg prod./kg bw, i.e. no mortality was observed at the limit dose tested, recalculation to the sum of active ingredients disregarding the density of the formulation yields a LD_{50} > 800 mg sum of a.s./kg bw) with the "surrogate LD_{50}" calculated by the formula above (LD_{50} > 1884 mg sum of a.s./kg bw) does not point at a relevant more-than-additive mixture toxicity of the formulation (the factor between calculated and experimental LD_{50} is 2.35). Hence, the risk assessment is conducted based on the residues of the individual active substances, however assuming dose/concentration additivity.

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:

$$\text{TER(mix)} = \left(\sum_i \frac{1}{\text{TER(a.s.}_i\text{)}} \right)^{-1}$$

where:

$TER_{(a.s.i)}$= calculated TER for the active substance *i*

Regarding long-term risk assessment NOELs for reproduction are considered as relevant endpoints for TER(mix) calculations (thus, again assuming dose/concentration additivity as realistic worst case and additionally assuming that the NOELs of the individual active substances do refer to a similar no- or low effect level).

6.2.2.1 Screening assessment

As the screening step is not mandatory and thus only an option for the risk assessment, more realistic Tier-1 exposure scenarios as provided by EFSA Journal 2009; 7(12): 1438 were considered for an initial evaluation of the risk of fluazinam and dimethomorph to birds and mammals.

6.2.2.2 Tier 1 risk assessment

In the Tier 1 risk assessment step, the defined daily dietary doses and TER values were calculated for so-called generic focal species (see EFSA 1438/2009, Annex I). As for the indicator species, the generic focal species are considered to be representative for all species potentially at risk. In the Tier 1 assessment, a mixed diet approach is followed when appropriate and interception of the spray by the crop is taken into account for the calculation of residue levels for different food types.

If more than one generic focal species is relevant for the crop, the one that is relevant in terms of time of application or growth stage should be selected. If more than one generic focal species is relevant in terms of application time and growth stage, then the risk should be assessed for all relevant generic focal species. If the same generic focal species is relevant for several application times according to the BBCH growth stages, the risk assessment for this generic focal species is conducted once using the highest mean short-cut value, since this mirrows a realistic worst case scenario.

A summary of the critical GAP use and relevant avian indicator species is given in the table below.

Table 6.2-2: Critical GAP use and relevant generic focal species

Crop	Worst-case application scenario	Tier-1 scenario	Generic focal species (representative)	Shortcut value for TER_A/TER_{LT}
Potato	4× 1.0 L prod./ha (interval: min. 7 d) BBCH ≥ 31	BBCH 10 - 39	Small omnivore (Woodlark)	24.0 / 10.9
		BBCH ≥ 40	Small omnivore (Woodlark)	7.2 / 3.3
		BBCH ≥ 20	Small insectivore (Yellow wagtail)	25.2 / 9.7

For the acute exposure assessment, shortcut values for 90th percentile RUDs (SV_{90th}) were taken into account as recommended in EFSA Journal 2009; 7(12): 1438. Considering the worst-case application scenario, i.e. 4× 1 L prod./ha applied to potato, a Multiple Application Factor (MAF_{90th}) of 1.8 was taken into account.

For long-term exposure estimates, a time-frame of a few weeks after application is considered. Since the area of birds feeding on contaminated diet will be largely compared to the spatial scale of residue variation, shortcut values for mean percentile RUDs (SV_m) should be used. Furthermore, time-weighted average residues are considered to reflect long-term exposure in a more realistic manner in view of a residue decrease in relevant food over time. According to the recommendations of current guidance, i.e. in consideration of a residue decline with a default first order DT_{50} of 10 days (recommended for herbal food items as well as insects) and a time scale of 21 days, the time-weighted average factor is f_{twa} = 0.53. Considering the worst-case application scenario, i.e. 4× 1 L prod./ha applied to potato, a Multiple Application Factor (MAF_m) of 2.2 was taken into account.

For the Tier-1 standard risk assessment, PT, PD and AV were set to 1, and thus not considered for exposure mitigation; i.e. animals satisfy their entire food demand in the exposed area, feed on a single food type and contaminated diet will not be avoided representing overall a worst-case scenario.

The results of the acute and reproductive Tier 1 risk assessments are summarized in the following tables.

Table 6.2-3: Tier 1 risk assessment for birds (TER a.s.)

Generic focal species	Exposure	A [kg a.s./ha]	SV	MAF	f_{twa}	DDD [mg/kg	Endpoint [mg/kg bw/d]		TER(a.s.)	TER trigger
Fluazinam										
Small omnivore BBCH 10 - 39	acute	0.2	24	1.8	1	8.6	LDD_{50}	> 1230	> 142.4	10
	long-term	0.2	10.9	2.2	0.53	2.5	NOEL	60.4	23.8	5
Small omnivore BBCH ≥ 40	acute	0.2	7.2	1.8	1	2.6	LDD_{50}	> 1230	> 474.5	10
	long-term	0.2	3.3	2.2	0.53	0.8	NOEL	60.4	78.5	5
Small insectivore BBCH ≥ 20	acute	0.2	25.2	1.8	1	9.1	LDD_{50}	> 1230	> 135.6	10
	long-term	0.2	9.7	2.2	0.53	2.3	NOEL	60.4	26.7	5
Dimethomorph										
Small omnivore BBCH 10 - 39	acute	0.2	24	1.8	1	8.6	LDD_{50}	> 728.3	> 84.3	10
	long-term	0.2	10.9	2.2	0.53	2.5	NOEL	58.4	23.0	5
Small omnivore BBCH ≥ 40	acute	0.2	7.2	1.8	1	2.6	LDD_{50}	> 728.3	> 281.0	10
	long-term	0.2	3.3	2.2	0.53	0.8	NOEL	58.4	75.9	5
Small insectivore BBCH ≥ 20	acute	0.2	25.2	1.8	1	9.1	LDD_{50}	> 728.3	> 80.3	10
	long-term	0.2	9.7	2.2	0.53	2.3	NOEL	58.4	25.8	5

Table 6.2-4: Tier 1 risk assessment for birds (TERmix)

Generic focal species	Exposure	TER fluazinam	TER dimethomorph	TER(mix)	TER trigger
	acute	> 142.4	> 84.3	> 52.9	10

Small omnivore BBCH 10 - 39	long-term	23.8	23.0	11.7	5
Small omnivore BBCH ≥ 40	acute	> 474.5	> 281.0	> 176.5	10
	long-term	78.5	75.9	38.6	5
Small insectivore BBCH ≥ 20	acute	> 135.6	> 80.3	> 50.4	10
	long-term	26.7	25.8	13.1	5

In conclusion, all calculated TER values are above the Annex VI trigger values of 10 and 5, respectively, indicating an acceptable risk for acute and long-term exposure of birds. Thus, further refinement steps are not required.

Furthermore, it should be noted that potato leaves are inedible for terrestrial vertebrates, and hence the crop itself is very unlikely to be attractive as food item. On this account, it can be concluded that birds (especially herbivores and omnivores) satisfy at least a certain part of their food demand in the untreated off-crop area. It can thus reasonably be supposed that the PT value is below 1 resulting in even higher TER values.

6.2.2.3 Higher tier risk assessment for birds

As the relevant acute and long-term TER trigger values in the Tier 1 risk assessment are met, there is no need for a refinement.

6.2.2.4 Drinking water exposure

Puddle scenario

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals (see below), according to EFSA Journal 2009; 7(12): 1438 no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/kg).

A comparison of the relevant endpoints with the effective application rates for fluazinam and dimethomorph is presented below.

Table 6.2-5: Application rate to endpoint ratios for birds exposed to fluazinam and dimethomorph

Intended use	**Exposure Scenario**	**Cumulative application rate [g a.s./ha]**	**Koc [L/kg]**	**LD_{50}/NOEL [mg a.s./kg bw]**	**Ratio Application Rate : endpoint**
Fluazinam					
	Acute	800 (4 x 200)	23936	>1230	<0.65

Potatoes	Long-term			60.4	13.24
Dimethomorph					
Potatoes	Acute	800 (4 x 200)	456	>728.3	<1.1
	Long-term			58.4	13.7

In conclusion, an acceptable risk is indicated for birds drinking water from puddles.

Leaf scenario

According to EFSA guidance, leaf whorl exposure is relevant only for the following crop types and growth stages:

- Leaf vegetables (forming heads, e.g. cabbage, lettuce and endive) at principal growth stage 4 until harvest (classification according to BBCH)
- Other leaf vegetables (e.g. cauliflower) at principal growth stage 4 or later, with a morphology that facilitates collection of rain/irrigation water in reservoirs that are large enough and easily accessible to attract birds and sufficiently stable over some hours

Since BANJO FORTE is not intended to be sprayed on crops forming heads or at relevant growth stages that induce the formation of water collecting structures, this scenario is not actually relevant to the proposed GAP crop

6.2.2.5 Effects of secondary poisoning (MIIIA 10.1.9)

Based on a $logK_{OW}$ of 4.03 for the active substance fluazinam that is above the relevant threshold of 3, a potential for bioaccumulation has to be considered for this compound. Thus, appropriate risk assessments were performed for exposure from accumulation in food chains in agreement with SANCO/4145/2000 (2002). This modeling approach is just the same as the Tier 1-"Dry soil approach" suggested by the most recent guidance document (EFSA Journal 2009; 7(12): 1438).

As outlined in the underlying residue definitions given in Part B, Section 5, the following metabolites in soil and aquatic systems have to be considered for these assessments:

- AMPA-fluazinam: $logK_{OW}$ = 3.99
- G-504: $logK_{OW}$ = 4.89
- HYPA: $logK_{OW}$ = 1.5

Based on model calculations using BCFWIN (version 2.17, SRC 2000) provided by the applicant, the $logK_{OW}$ values were determined at 3.99, 4.89 and 2.55 for AMPA-fluazinam, G-504 and HYPA, respectively. In addition to the model calculations, a laboratory study on the $logK_{OW}$ of HYPA was conducted. Accordingly, the $logK_{OW}$ of HYPA was determined to be 1.5 (Ref. IIIA 2.15/02: Mollandin, G., 2010). These results indicate a potential of AMPA-fluazinam and G-504 for bioaccumulation in fish. However, it should be noted that AMPA-fluazinam is the sole major metabolite in sediment, but it appears

in amounts below 10 % in the water phase and thus, critical exposure of fish (and other aquatic organisms) and subsequently of fish-eating terrestrial vertebrates is considered negligible.

As stated in the EFSA Scientific Report (2006) 82 for dimethomorph, the $logK_{OW}$ for the second active ingredient contained in BANJO FORTE was determined at 2.73 (Z-isomer). This value is below the relevant trigger of 3 and thus, a low potential for bioaccumulation is indicated and no deterministic risk assessments by calculating TER values have to be conducted.

Furthermore, the parent dimethomorph is degraded without the formation of any major metabolites in aerobic soil and aquatic systems as outlined in the residue definitions given in Part B, Section 5.

In conclusion, a potential for bioaccumulation may be expected for the active substance fluazinam (earthworm-eating and fish-eating birds) and its metabolite G-504 (only fish-eating birds). Consequently, deterministic risk assessments by calculating TER values were performed only for these compounds of concern.

Risk assessment for earthworm-eating birds via secondary poisoning

Dry soil approach

Table 6.2-6: Assessment of the risk for earthworm eating birds from an exposure to fluazinam through secondary poisoning for the intended use in potatoes

Parameter	Fluazinam	comments
PEC_{soil} (twa = 21 d) [mg/kg soil]	0.206	See Part B Section 5 core assessment, chapter 5.5, table 5.5-3
K_{ow}	10715	= log Kow of 4.03
K_{oc}	24936	Arithmetic mean, N = 9 (see Part B Section 5 core assessment, chapter 5.4.2, table 5.4-8)
F_{oc}	0.02	Default
BCF_{worm}	0.259	$BCF_{worm} = (PEC_{worm}/PEC_{soil})$ $= (0.84 + 0.012 \times K_{ow})/ f_{oc} \times K_{oc}$
PEC_{worm}	0.053	$PEC_{worm} = PEC_{soil} \times BCF$
Daily dietary dose (mg/kg bw/d)	0.056	$DDD = PEC_{worm} \times 1.05$
NOEL (mg/kg bw/d)	60.4	See Part B section 6 core assessment, chapter 6.2, table 6.2-1
TER_{lt}	1078	Risk acceptable

TER values shown in bold fall below the relevant trigger.

Risk assessment for fish-eating birds via secondary poisoning

Data on bioconcentration of the active substance fluazinam in fish are available in the context of the EU evaluation process. Explicit reference is made to the underlying results summarised and evaluated in the Draft Assessment Report for fluazinam (2006) and stated as agreed endpoint in the EFSA Scientific Report

(2008) 137 for fluazinam. Accordingly, a BCF of 1090 (whole fish) was taken into account for this risk assessment.

Table 6.2-7: Assessment of the risk for fish eating birds from an exposure to fluazinam through secondary poisoning for the intended use in potatoes

Parameter	Fluazinam	comments
PEC_{sw} [mg/L]	0.00145	FOCUS Step 2 South Europe (i.e. worst case scenario), see Part B Section 5 chapter 5.6 table 5.6-6
BCF_{fish}	1090	whole fish (EFSA Scientific Report (2008) 137)
PEC_{fish} [mg/kg]	1.58	$PEC_{fish} = PEC_{water}$ x BCF_{fish}
Daily dietary dose (mg/kg bw/d)	0.25	DDD = PEC_{fish} x 0.159
NOEL (mg/kg bw/d)	60.4	See Part B section 6 core assessment, chapter 6.2, table 6.2-1
TER_{lt}	242	Risk acceptable

TER values shown in bold fall below the relevant trigger (5).

A respective quantitative secondary poisoning risk assessment for fish eating birds following exposure towards the metabolite G-504 is hampered by the lacking of robust entry data. The applicant proposed to consider a modelled BCF of 3.16 which was estimated by the QSAR-program BCFWIN (version 2.17, SRC 2000). However, the validity of these QSAR estimations (both log Kow and BCF) cannot be finally proven. Still, if a maximum building rate of 17.1 % and a molecular weight ratio (G-504/fluazinam) of 0.849 is considered, a PEC_{water} (FOCUS Step 2 South Europe) of 0.00021 mg G-504/L can be estimated. Assuming - in a realistic-worst-case approach - an identical BCF of the metabolite as the parent (i.e. 1090) instead of the clearly lower value (3.16 see above) proposed by the applicant, yields a PEC_{fish} of 0.229 mg G-504/kg. The daily dietary dose then calculates as 0.036 mg G-504/kg bw/d. As no empirical chronic bird and mammal toxicity data for G-504 are available, it is assumed that G-504 is 10 times toxic than the parent compound (i.e. NOEL = 6.04 mg/kg bw/d). The TERlt thus finally calculates as 168 indicating an acceptable risk for the metabolite, too.

Regarding the fluazinam metabolite AMPA, the EFSA conclusion (EFSA Scientific Report (2008) 137, 1-82, Conclusion on the peer review of fluazinam) on page 26 states: “Fluazinam was extensively metabolised in fish organisms to AMPA-FLUAZINAM, without any evidence of accumulation. Thus, the risk of AMPA-FLUAZINAM to bioconcentrate in fish and to bio-accumulate in aquatic systems is expected to be low.”

6.2.3 Biomagnification in terrestrial food chains

Not relevant.

6.2.4 Risk assessment (MIIIA 10.1.3, MIIIA 10.1.4, MIIIA 10.1.5) for baits, pellets, granules, prills or treated seed

Not relevant.

6.2.5 Overall conclusions

Based on tier 1 assessment step, the calculated TER values for the acute and long-term risk resulting from the expected (combined) exposure of birds to the active substances fluazinam and dimethomorph (oral exposure and exposure via drinking water and secondary poisoning) according to the GAP of the formulation BANJO FORTE 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. The results of the assessment indicate an acceptable acute and long-term risk for birds due to the intended use of BANJO FORTE in potatoes according to the label.

6.3 Effects on Terrestrial Vertebrates Other Than Birds (MIIIA 10.3, KPC 10.1, KPC 10.1.2)

Table 6.3-1: EU agreed endpoints and new endpoints

Species	Substance	Exposure System	Results	Reference	Internal code
Rat	fluazinam	Acute toxicity	LD_{50} 4100 mg/kg bw	[redacted] 1988 881246D/ISK20/AC	72545
Rat	fluazinam	Reproductive toxicity	NOAEL 7.26 mg/kg bw/d**	[redacted] 1987 87/ISK068/097	72547
Rat	dimethomorph	Acute toxicity	LD_{50} 3900 mg/kg bw	[redacted] 1985 DK-411-004 ! 1985/7000027	71567
Rat	dimethomorph	Reproductive toxicity	NOAEL 20 mg/kg bw/d	[redacted] 1990 DK-430-001 ! 1990/7000052	71569
Rat	BANJO FORTE	Acute toxicity	LD_{50} > 2000 mg/kg bw*	[redacted] 2008 R-24355, 23314	75288

* New study submitted

** NOAEL as reported on page 11 of the EFSA Scientific Report (2008) 137, 1-82, Conclusion on the peer review of fluazinam

6.3.1 Justification for new endpoints

An acute toxicity study with BANJO FORTE was performed with rat. The determined LD50 > 2000 mg prod./kg bw demonstrates the low oral toxicity of the formulated product (Ref. IIIA 7.1.1/01: Haferkorn, J., 2008). A summary of this study is given in Part B Section 3 Core Assessment.

6.3.2 Risk assessment (MIIIA 10.3.1) for spray applications

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438). Please see 6.2.2 for detailed information on the estimation of daily intake rates and the assessment of mixture toxicity.

The results of the acute toxicity study conducted with the formulation BANJO FORTE with an LD50 > 2000 mg prod./kg bw (see Ref. IIIA 7.1.1/01: [redacted], J., 2008, Part B Section 3 Core Assessment) recalculated to the sum of active ingredients disregarding the density of the formulation yields a LD_{50} > 800 mg sum of a.s./kg bw. Comparing this figure with the "surrogate LD_{50}" of 3997 mg sum of a.s./kg bw calculated by the formula given in chapter 6.2.2 does not point at a relevant more-than-additive mixture toxicity of the formulation: The numerical difference (factor 5) between calculated and experimental LD_{50} is considered of limited relevance given that no mortality occurred at the limit dose tested in the formulation study. Hence, the risk assessment is conducted based on the residues of the individual active substances, however assuming dose/concentration additivity.

Also the long-term risk assessment is conducted based on the residues of the individual active substances, what is in line with the respective EU assessments (EFSA Scientific Report (2008) 137, 1-82, Conclusion on the peer review of fluazinam, EFSA Scientific Report (2006) 82, 1-69, Conclusion on the peer review of dimethomorph).

6.3.2.1 Screening assessment

As the screening step is not mandatory and thus only an option for the risk assessment, more realistic Tier-1 exposure scenarios as provided by EFSA Journal 2009; 7(12): 1438 were considered for an initial evaluation of the risk of fluazinam and dimethomorph to birds and mammals.

6.3.2.2 Tier-1 risk assessment

It is well noted that potato foliage is inedible for terrestrial vertebrates, and hence the crop itself is very unlikely to be attractive as food item. Furthermore, potato fields do not produce grains or seeds and are kept weed free until groundcover of developed plants prevent weeds from emerging. Thus, it is unlikely that grass weeds or leafy weeds are present in significant amounts beneath potato crops within the timeframe when applications are sought. These facts indicate that herbivorous vertebrates satisfy their food demand in the untreated off-crop area and therefore, the exposure of herbivorous vertebrates in potato fields is considered not relevant. Instead, the risk assessment is reasonably focussed on insectivorous and omnivorous/earthworm-eating mammals. This conclusion is also confirmed by several subject-specific documents/publications. The most relevant information are outlined in the following:

- In the EFSA Scientific Report (2008) 137 for fluazinam, it was peer-reviewed that *it is not considered necessary to calculate the risk to herbivorous birds and mammals in potatoes as potato leaves are considered unpalatable. Therefore the risk to herbivorous birds and mammals is considered to be low*.

- The attractiveness of potato fields for herbivorous mammals was investigated within the framework of a generic field study carried out in Western Germany (ref. IIIA 10.3/01: [redacted], 2003). Some larger herbivorous mammals like rabbits or hares were occasionally seen in potato fields, but all these larger or medium sized mammals seemed to spend only short times in the fields. For the purpose of a definition of more relevant species foraging in potato fields, three herbivorous species were radio tracked: the bank vole, the common vole (both species are almost wholly herbivorous) and the wood mouse (omnivorous). The bank vole was not found on potato fields at all, whereas common voles spent only a small portion of time on potato fields. In contrast, it could be demonstrated that wood mice spent up to 83 % of their time in the fields. Furthermore, the average speed of movements was calculated resulting in the following: In potato fields wood mice moved with an average speed of 81 m/h, whereas they made only 12 m/h in the surrounding and 30 m/h in adjacent woods and bushes. These results indicate that wood mice may search for rare food items like weeds seeds or invertebrates partially present in the off-crop habitat. In conclusion, the wood mouse better defined as omnivore rather than herbivore was identified as most relevant species foraging in potato fields.

A summary of the critical GAP use and relevant mammal indicator species is given in the table below.

Table 6.3-2: Critical GAP use and relevant generic focal species

Crop	Worst-case application scenario	Tier-1 scenario	Generic focal species (representative)	Shortcut value for TER_A/TER_{LT}
Potato	4× 1.0 L prod./ha (interval: min. 7 d) BBCH ≥ 31	BBCH ≥ 20	Small insectivore (Common shrew)	5.4 / 1.9
		BBCH 10 - 39	Small omnivore (Wood mouse)	17.2 / 7.8
		BBCH ≥ 40	Small omnivore (Wood mouse)	5.2 / 2.3

For the estimation of Daily dietary doses (DDD) and the calculation of TER values, please see 6.2.2.2.

The results of the acute and reproductive Tier 1 risk assessments are summarized in the following tables.

Table 6.3-3: Tier 1 risk assessment for mammals (TER a.s.)

Generic focal species	Exposure	A [kg a.s./ha]	SV	MAF	f_{twa}	DDD [mg/kg	Endpoint [mg/kg bw/d]		TER(a.s.)	TER trigger
Fluazinam										
	acute	0.2	5.4	1.77	1	1.91	LD_{50}	4100	2142	10

Small insectivore BBCH ≥ 20	long-term	0.2	1.9	2.2	0.53	0.586	NOAEL	7.26	12.4	5
Small omnivore BBCH 10 - 39	acute	0.2	17.2	1.77	1	6.1	LD_{50}	4100	672	10
	long-term	0.2	7.8	2.2	0.53	2.4	NOAEL	7.26	**3.0**	5
Small omnivore BBCH ≥ 40	acute	0.2	5.2	1.77	1	1.84	LD_{50}	4100	2224	10
	long-term	0.2	2.3	2.2	0.53	0.71	NOAEL	7.26	10.2	5
Dimethomorph										
Small insectivore BBCH ≥ 20	acute	0.2	5.4	1.77	1	1.91	LD_{50}	3900	2038	10
	long-term	0.2	1.9	2.2	0.53	0.58	NOAEL	20	24.1	5
Small omnivore BBCH 10 - 39	acute	0.2	17.2	1.77	1	6.1	LD_{50}	3900	640	10
	long-term	0.2	7.8	2.2	0.53	2.4	NOAEL	20	8.3	5
Small omnivore BBCH ≥ 40	acute	0.2	5.2	1.77	1	1.84	LD_{50}	3900	2116	10
	long-term	0.2	2.3	2.2	0.53	0.71	NOAEL	20	28.2	5

Bold: below the relevant trigger value

Table 6.3-4: Tier 1 risk assessment for mammals (TER mix)

Generic focal species	Exposure	TER fluazinam	TER dimethomorph	TER(mix)	TER trigger
Small insectivore BBCH ≥ 20	acute	2142	2038	1044	10
	long-term	12.4	24.1	8	5
Small omnivore BBCH 10 - 39	acute	672	640	328	10
	long-term	**3.0**	8.3	**2.0**	5
Small omnivore BBCH ≥ 40	acute	2124	2116	1060	10
	long-term	10.2	28.2	7	5

Bold: below the relevant trigger value

The TER_A values calculated are above the Annex VI trigger of 10, indicating an acceptable risk for acute exposure of mammals. Furthermore, all $TER_{long\text{-}term}$ values are above the trigger value of 5 except the TER_{LT}(fluzinam) and TER_{LT}(mix) for small omnivores (represented by the wood mouse) exposed at crop growth stages BBCH 10 - 39. Consequently, a refined risk assessment considering the wood mouse as relevant species is presented in the following chapter.

6.3.2.3 Higher tier long-term risk assessment for small omnivorous mammals (here: wood mouse) (KPC 10.1.2.2)

In accordance with the EFSA Guidance Document (2009) the following refinement options are considered:

- Consideration of a more realistic exposure taking the intended application pattern of BANJO FORTE into account, with the application starting not earlier than at BBCH ≥ 31 and an interval of 7 days interval between applications, i.e. only one application will be at crop growth stage BBCH 10 – 39. At this early stage potato plants do not yet entirely cover potential food items such as under-growing weeds and seeds (making 75 % of the share of the food items of the wood mouse), what is why in Appendix E of the EFSA guidance (EFSA Journal 2009; 7(12): 1438) a deposition factor of 1 (i.e. no interception by the potato plants) is assumed in the short-cut value suggested for wood mouse as generic focal species a this stage. For the later stage (BBCH ≥ 40), Appendix E of the EFSA guidance does suggest a nearly complete crop cover expressed in a deposition factor of 0.3 for under-growing weeds and seeds (i.e. 70 % interception by the potato plants). Thus, consideration of only one application at BBCH 10 – 39 (deposition factor 1) and the following three applications at BBCH ≥ 40 (deposition factor 0.3) yields a MAF x twa factor of 0.69 for refinement of the DDD calculation as presented in the table below.
- Consideration of a more realistic PT-value for the generic focal species wood mouse based on the generic field study (ref. IIIA 10.3/01: [redacted], 2003) submitted by the applicant. The attractiveness of potato fields for the wood mouse (beside other small and medium mammal species) was monitored by a radio telemetry field study. The four study sites in Western Germany are located in a typical central European potato growing area with moderate climate conditions during the growing period. All fields were situated within an agricultural landscape, surrounded by different fields (e.g. beets or wheat) and three of them on one side by hedges or stripes of wood. Observations were conducted from mid July to mid August which is in compliance with the intended use of BANJO FORTE at BBCH 31 – 91 (i.e. about end of May until mid of September, under typical climate conditions of Germany). Four wood mouse individuals were radio tracked for 24 hours, during which the position of each individual was recorded every 15 to 30 minutes. The average time of wood mouse spent in potato fields was determined as 52 %, while the maximum value observed for one animal was 83%. In view of the rather narrow database (i.e. only 4 individuals studied), the consideration of the average value is not supported. Instead, the maximum PT value as observed will be taken into the DDD calculation. This more cautious interpretation of this potato field study results is generally in line with an opinion of the EFSA scientific panel on methamidophos (The EFSA Journal (2004) 144, 1-50), however, the conclusion there was even more restrictive since the acute risk assessment was concerned.
- (Additional note for the refined risk assessment: In cases where the relevant model species for the risk assessment is a mouse or a vole, the German authorities allow the TER acceptability criterion according to Annex VI of Directive 91/414/EEC to be modified for the following reason: In terms of size and potential exposure, mice and voles already represent the ‘worst case’ for agricultural areas in Europe’s middle zone. Furthermore, the toxicological endpoints and effect values for the assessment are determined on phylogenetically closely related species. Hence, a TER ≥ 5 in the acute exposure scenario and a TER ≥ 2 in the long-term exposure scenario may be accepted as sufficient. It should additionally be noted that there are currently no indications for a significant impact of pesticides on the population dynamics of mice or voles in the agricultural landscape,

which are apparently determined by other biological factors (e.g. periodical increases in vole populations creating the necessity for control measures).

Table 6.3-2: Refinement of reproductive risk assessment for small omnivorous mammals (here: wood mouse) exposed to fluazinam and dimethomorph according to EFSA Journal (2009) following application of BANJO FORTE in potatos. For details see text.

Generic focal species	A [kg a.s./ha]	SV	MAFx f_{twa}	PT	DDD [mg/kg	Endpoint [mg/kg bw/d]		TER(a.s.)	TER trigger
Fluazinam									
Small omnivore BBCH 10 - 39 long-term	0.2	7.8	0.69	0.83	0.89	NOAEL	7.26	8.1	5
Dimethomorph									
Small omnivore BBCH 10 - 39 long-term	0.2	7.8	0.69	0.83	0.89	NOAEL	20	22.4	5

Table 6.3-8: Refined reproductive risk assessment for small omnivorous mammals (here: wood mouse) exposed to fluazinam and dimethomorph following application of BANJO FORTE in potatos (TER mix)

Generic focal species	Exposure	TER-refined fluazinam	TER-refined dimethomorph	TER(mix)	TER trigger
Small omnivore BBCH 10 - 39	long-term	8.1	22.4	5.9	5

The TER_{LT} values (a.s. and mixture) calculated are above the Annex VI trigger of 5, indicating an acceptable risk for long-term exposure of mammals.

6.3.2.4 Drinking water exposure

Leaf scenario

A leaf scenario is not deemed relevant for small mammals.

Puddle scenario

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals (see below), according to EFSA Journal 2009; 7(12): 1438 no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/kg).

A comparison of the relevant endpoints with the effective application rates for fluazinam and dimethomorph is presented in the table below.

Table 6.3-3: Application rate to endpoint ratios for mammals exposed to fluazinam and dimethomorph

Intended use	**Exposure Scenario**	**Cumulative application rate [g a.s./ha]**	**Koc [L/kg]**	**LD_{50}/NOEL [mg a.s./kg bw]**	**Ratio Application Rate : endpoint**
Fluazinam					
Potatoes	Acute	800 (4 x 200)	23936	4100	0.19
	Long-term			7.26	110
Dimethomorph					
Potatoes	Acute	800 (4 x 200)	456	3900	0.2
	Long-term			20	40

In conclusion, an acceptable risk is indicated for mammals drinking water from puddles.

6.3.2.5 Effects of secondary poisoning (MIIIA 10.3.2.3)

The same approach as explained for birds in chapter 6.2.2.5 is followed for mammals.

Risk assessment for earthworm-eating mammals via secondary poisoning

Dry soil approach

Table 6.3-4: Assessment of the risk for earthworm eating mammals from an exposure to fluazinam through secondary poisoning for the intended use in potatos

Parameter	**Fluazinam**	**comments**
PEC_{soil} (twa = 21 d) [mg/kg soil]	0.206	See Part B Section 5 core assessment, chapter 5.5, table 5.5-3
K_{ow}	10715	= log Kow of 4.03
K_{oc}	24936	Arithmetic mean, N = 9 (see Part B Section 5 core assessment, chapter 5.4.2, table 5.4-8)
F_{oc}	0.02	Default

BCF_{worm}	0.259	$BCF_{worm} = (PEC_{worm}/PEC_{soil})$ $= (0.84 + 0.012 \times K_{ow})/ f_{oc} \times K_{oc}$
PEC_{worm}	0.053	$PEC_{worm} = PEC_{soil} \times BCF$
Daily dietary dose (mg/kg bw/d)	0.067	$DDD = PEC_{worm} \times 1.28$
NOEL (mg/kg bw/d)	7.26	See Part B section 6 core assessment, chapter 6.3, table 6.3-1
TER_{lt}	108	Risk acceptable

Risk assessment for fish-eating birds via secondary poisoning

Table 6.3-5: Assessment of the risk for fish eating birds from an exposure to fluazinam through secondary poisoning for the intended use in potatoes

Parameter	**Fluazinam**	**comments**
PEC_{sw} [mg/L]	0.00145	FOCUS Step 2 South Europe (i.e. worst case scenario), see Part B Section 5 chapter 5.6 table 5.6-6
BCF_{fish}	1090	whole fish (EFSA Scientific Report (2008) 137)
PEC_{fish} [mg/kg]	1.58	$PEC_{fish} = PEC_{water} \times BCF_{fish}$
Daily dietary dose (mg/kg bw/d)	0.22	$DDD = PEC_{fish} \times 0.142$
NOEL (mg/kg bw/d)	7.26	See Part B section 6 core assessment, chapter 6.3, table 6.3-1
TER_{lt}	33	Risk acceptable

TER values shown in bold fall below the relevant trigger (5).

A respective quantitative secondary poisoning risk assessment for fish eating mammals following exposure towards the metabolite G-504 is hampered by the lacking of robust entry data. The applicant proposed to consider a modelled BCF of 3.16 which was estimated by the QSAR-program BCFWIN (version 2.17, SRC 2000). However, the validity of these QSAR estimations (both log Kow and BCF) cannot be finally proven. Still, if a maximum building rate of 17.1 % and a molecular weight ratio (G-504/fluazinam) of 0.849 is considered, a PEC_{water} (FOCUS Step 2 South Europe) of 0.00021 mg G-504/L can be estimated. Assuming - in a realistic-worst-case approach - an identical BCF of the metabolite as the parent (i.e. 1090) instead of the clearly lower value (3.16 see above) proposed by the applicant, yields a PEC_{fish} of 0.229 mg G-504/kg. The daily dietary dose then calculates as 0.032 mg G-504/kg bw/d. As no empirical chronic mammalian toxicity data for G-504 are available, it is assumed that G-504 is 10 times toxic than the parent compound (i.e. NOEL = 0.726 mg/kg bw/d). The TERlt thus finally calculates as 22.7 indicating an acceptable risk for the metabolite, too.

Regarding the fluazinam metabolite AMPA, the EFSA conclusion (EFSA Scientific Report (2008) 137, 1-82, Conclusion on the peer review of fluazinam) on page 26 states: “Fluazinam was extensively metabolised in fish organisms to AMPA-FLUAZINAM, without any evidence of accumulation. Thus, the risk of AMPA-FLUAZINAM to bioconcentrate in fish and to bio-accumulate in aquatic systems is expected to be low.”

6.3.3 Biomagnification in terrestrial food chains

According to the ADEM section of conclusion on the peer review of fluazinam (EFSA Scientific Report (2008) 137, 1-82), there is no evidence for accumulation of fluazinam.

According to the ADEM section of conclusion on the peer review of dimethomorph (EFSA Scientific Report (2006) 82, 1-69, Conclusion on the peer review of dimethomorph), there is a low potential for accumulation of dimethomorph.

Consequently, the EFSA bird and mammal guidance (2009) does not require an assessment of the risk arising from biomagnifications of both active substances in terrestrial food chains.

6.3.4 Risk assessment (MIIIA 10.3.1) for baits, pellets, granules, prills or treated seed

Not relevant.

6.3.5 Overall conclusions

Based on tier 1 assessment step (exposure via drinking water and secondary poisoning) and some refinements of exposure, respectively, the calculated TER values for the acute and long-term risk resulting from the expected (combined) exposure of small mammals to the active substances fluazinam and dimethomorph according to the GAP of the formulation BANJO FORTE 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. The results of the assessment indicate an acceptable acute and long-term risk for small mammals due to the intended use of BANJO FORTE in potatoes according to the label.

6.4 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KPC 10.1.3)

Not yet considered.

6.5 Effects on aquatic organisms (MIIIA 10.2, KPC 10.2, KPC 10.2.1)

Table 6.5-1: Endpoints used for risk assessment for aquatic organisms for fluazinam and its relevant metabolites (most sensitive species / lowest endpoint for each organism group as available in the database of zRMS)

Species	Substance	Exposure System	Results [mg/L]	Reference	Internal code
Oncorhynchus mykiss	Fluazinam	96 h, flow-through	LC_{50} = 0.036*	[redacted]. 1992 5099-91-0422-TX-002	53577

				Submitted with dossier to ZA4092	
Oncorhynchus mykiss	HYPA	96 h, static	LC_{50} = 2.09*	[redacted]. 16.01.2009 C09083 Submitted with dossier to ZA?(lacking ICS-entry)	72684
Danio rerio	AMPA	96 h, static	LC_{50} > 0.089	[redacted] 21.10.1997 662512 Submitted with dossier to ZA4092	53585
Oncorhynchus mykiss	G-504	96 h, static	LC_{50} > 100*	[redacted]. 21.01.2009 C09061 Submitted with dossier to ZA6897	77206
Pimephales promelas	Fluazinam	278 d (FLC), flow-through	NOEC (Growth and Reproduction F1) = 0.0029	[redacted] 1995 94-1-5123, 12073.0392.6113.122	54565
Daphnia magna	Fluazinam	48 h, static	EC_{50} = 0.165*	Noack, M. 2006 R-20525 ! DAI106911 Submitted with dossier to ZA?(lacking ICS-entry)	72857
SSD Invertebrates (based on EC_{10})	Fluazinam	96 h, static	HC_5 = 0.00129	Arts, G.H.P. et al. 15.03.2004 072003 Submitted with dossier to ZA4092	55116
Daphnia magna	HYPA	48 h, static	EC_{50} = 0.876*	Peither, A. 2009 C09072!103FZI Submitted with dossier to ZA6897	72562
Daphnia magna	AMPA	48 h, static	EC_{50} > 0.260	Hertl, J. 24.10.1997 662490 Submitted with dossier to ZA4092	53971
Daphnia magna	G-504	48 h, static	EC_{50} > 98	Ref. IIIA 10.2.2.2/03:	83585

				Kuhl, R.; Wydra, V. (2011)	
Daphnia magna	Fluazinam	21 d, semi-static	NOEC = 0.0125	Van den Bogaert, M.; Farrelly, E. and Hamer, M.J. 1991 RJ 0974B	26633
Chironomus riparius	Fluazinam	28 d, spiked water test	NOEC = 0.00625 nominal-initial (water)	Stewart, K.M. and Shillabeer, N. 1997 Report No.BL6115/B	37545
Pseudo-kirchneriella subcapitata	Fluazinam	72 h, static	E_rC_{50} > 0.0705* E_bC_{50} = 0.0366	Scheerbaum, D. 2006 R-20524 ! SPO106911 Submitted with dossier to ZA?(lacking ICS-entry)	72889
Pseudo-kirchneriella subcapitata	HYPA	72 h, static	E_rC_{50} = 26.47* E_yC_{50} = 7.81	Ref. IIIA 10.2.2.3/02: Böttcher, M.; Deierling, T. (2010)	83586
Pseudo-kirchneriella subcapitata	AMPA	72 h, static	E_rC_{50} = 0.334* E_bC_{50} = 0.14	Pupp, A., Wydra, V. 2008 R-23886 ! 39392210 Submitted with dossier to ZA?(lacking ICS-entry)	72891
Pseudo-kirchneriella subcapitata	G-504	72 h, static	E_rC_{50} > 50* E_yC_{50} = 20	Ref. IIIA 10.2.2.3/03: Kuhl, R.; Wydra, V. (2011)	83587
Lemna gibba	Fluazinam	7 d, semi-static	E_rC_{50} > 0.069* NOErC = 0.0359*	Boeri, R. L. and Ward, T. J. 2001 2129-SK Submitted with dossier to ZA4092	53593
Lemna gibba	HYPA	7 d, semi-static	E_rC_{50} > 69.1*	Boeri, R. L., Ward, T. J. 18.06.2001 2129-SK ! 013022 Submitted with dossier to ZA7411	79670

* Endpoint differing from LoEP / New study submitted

Table 6.5-2: Endpoints used for risk assessment for aquatic organisms for dimethomorph (most sensitive species / lowest endpoint for each organism group as available in the database of zRMS)

Species	Substance	Exposure System	Results [mg/L]	Reference	Internal code
Oncorhynchus mykiss	Dimethomorph	96 h, static	LC_{50} = 3.4 (nominal) LC_{50} = 6.2 (real)	[redacted]. 068152	45772
Oncorhynchus mykiss	Dimethomorph	60 d (ELS), flow-through	NOEC (growth/weight) = 0.056	[redacted] 1997 DK-512-002 ! 1997/7000205	45781
Daphnia magna	Dimethomorph	48 h, static	EC_{50} > 10.6	Mitchell, G. C., Boeri, R. L., Wyskiel, D. C. and Ward, T. J. 2001 ECO-00-314	45689
Daphnia magna	Dimethomorph	21 d, semi-static	NOEC (reproduction) = 0.1	Memmert & Knoch 1993 DK-524-001 ! 1993/7000130	25862
Chironomus riparius	Dimethomorph	24 d, spiked water test	NOEC (growth) = 4.1 (initial-nominal)	England, D. C., Leak, T. and Mitchell, G. C. 1997 43063	37165
Pseudokirchneriella subcapitata	Dimethomorph	72 h, static	E_bC_{50} = 24.4	Ellgehausen, H. 1986 068141	25859

* Endpoint differing from LoEP / New study submitted

Table 6.5-3: Endpoints used for risk assessment for aquatic organisms for BANJO FORTE (most sensitive species / lowest endpoint for each organism group as available in the database of zRMS)

Species	Substance	Exposure System	Results [mg/L]	Reference	Internal code
Oncorhynchus mykiss	BANJO FORTE	96 h, static	LC_{50} = 0.7*	Ref. IIIA 10.2.2.1/01: Böttcher, M., Wydra, V. (2009)	75276
Daphnia magna	BANJO FORTE	48 h, static	EC_{50} = 0.482*	Ref. IIIA 10.2.2.2/01: Kuhl, R., Wydra, V. (2009)	75275

Pseudokirchneriella subcapitata	BANJO FORTE	72 h, static	E_rC_{50} = 1.090 E_bC_{50} = 0.444	Ref. IIIA 10.2.2.3/01: Kley, A., Wydra, V. (2009)	75050

* Endpoint differing from LoEP / New study submitted

6.5.1 Justification for new endpoints

New studies conducted with the preparation BANJO FORTE as well as with the fluazinam-metabolites HYPA and G-504 have been made available with the dossier of the applicant (for background see general introduction to chapter 6); in addition, more sensitive endpoints than those reported in the list of endpoints of fluazinam (EFSA Scientific Report (2008) 137, 1-82) as available in the data base of the zRMS have been included (however, no summaries are provided in Appendix 2).

6.5.2 Toxicity to exposure ratios for aquatic species (MIIIA 10.2.1)

The evaluation of the risk for aquatic and sediment-dwelling organisms was performed in accordance with the recommendations of the "Guidance Document on Aquatic Ecotoxicology", as provided by the Commission Services (SANCO/3268/2001 rev.4 (final), 17 October 2002).

As the formulation BANJO FORTE does contain two active substances, their joint effects have to be considered in risk assessment. Therefore the recommendations made in chapter 10.3 of the EFSA-PPR-OPINION "Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters" (EFSA Journal 2013;11(7):3290) are followed. In a first step, the results of the toxicity studies available for BANJO FORTE (L/EC_{50}-values recalculated to mg ∑ a.s./L, taking the density (1.176) of the formulation into account) are compared to respective calculated L/EC_{50} making use of the concentration addition model (CA model) as suggested by EFSA Journal 2013;11(7):3290. Important to note that potential contributions of the other constituents of the formulation are not considered here, i.e. it is assumed that only the active substances determine the toxicity of BANJO FORTE. The CA-formula is denoted as:

$$L/EC_{50}(mix) = \left(\sum_i \frac{X(a.s._i)}{L/EC_{50}(a.s._i)} \right)^{-1}$$

where:

X(a.s. *i*)= fraction of active substance (i) in the mixture expressed (here: 0.5 for both fluazinam and dimethomorph)

L/EC_{50}(a.s. *i*) = acute toxicity value for active substance (*i*)

Table 6.5-4: Mixture toxicity analysis for BANJO FORTE endpoints

Species	**Calculated mixture toxicity (CA-prediction)** **[mg ∑a.s. /L]**	**Measured mixture toxicity (BANJO FORTE)** **[mg ∑a.s./L]**	**MDR (model deviation ratio) = calculated mixtox/measured mixtox**	**Interpretation according EFSA Journal 2013;11(7):3290**
Oncorhynchus mykiss	LC_{50} = 0.07	LC_{50} = 0.251	0.28	CA approximately holds for the mixture (i.e. within 0.2 -5)
Daphnia magna	EC_{50} = 0.325	EC_{50} = 0.173	1.88	CA approximately holds for the mixture (i.e. within 0.2 -5)
Pseudokirchneriella subcapitata	E_bC_{50} = 0.073	E_bC_{50} = 0.159	0.46	CA approximately holds for the mixture (i.e. within 0.2 -5)

The results of the mixture toxicity analysis presented in the table above do not point at a relevant more-than-additive mixture toxicity of the two active substances and do not indicate a relevant contribution by other formulation constituents to the experimentally determined BANJO FORTE toxicity, respectively. Furthermore, this analysis reveals that fluazinam does clearly drive the acute toxicity of BANJO FORTE towards fish, daphnia and algae: For all three endpoints considered, the largest part of the sum of toxic units (here: > 90 %) comes from the contribution of fluazinam and thus, according EFSA Journal 2013;11(7):3290: "a sufficient protection level might be achieved by simply basing the RA on the toxicity data for that single driver". As the above analysis is based on acute toxicity endpoints, a further comparison of the relevant chronic endpoints available for fluazinam and dimethomorph provides support for this approach: fluazinam is 19, 8 and 656 times more toxic towards fish, daphnia and chironomids than dimethomorph. Finally, the difference between both active substances in terms of RAC (regulatory acceptable concentration) is obvious:

- The RAC for fluazinam calculates as 0.000258 mg/L from the SSD-HC_5 (0.00129 mg/L) determined for a number of EC_{10}-values available for aquatic invertebrates considering an adjusted assessment factor of 5. This RAC is also protective for fish (NOEC = 0.0029 mg/L, assessment factor 10) and algae (E_bC_{50} = 0.0366 mg/L, assessment factor 10).
- The RAC for dimethomorph calculates as 0.0056 mg/L from the lowest endpoint for fish (NOEC = 0.056 mg/L, assessment factor 10).

In conclusion, the risk assessment for aquatic organisms is based on endpoints related to the individual active substances without further quantitative mixture risk assessment.

The relevant global maximum FOCUS Step 1, 2 and 3 PEC_{SW} for risk assessments covering the proposed use pattern and the resulting TER values are presented in the following table. For details regarding PEC-calculations refer to Part B Section 5 Chapter 5.6 Core Assessment.

6.5.2.1 Toxicity to exposure ratio for the active substances

In the following table the TER values for each FOCUS scenario for each organisms group are given.

Table 6.5-4: Aquatic organisms: PEC_{sw} for fluazinam and relevant ecotoxicological endpoints for each organism' group.

Scenario **FOCUS**	**PEC_{SW} global max** **[µg/L]**	**Fish acute** ***O. mykiss*** **LC_{50}** 36 **[µg/L]**	**Fish prolonged** ***O. mykiss*** **NOEC** 2.9 **[µg/L]**	**Invertebrates acute** ***SSD (from EC_{10}-values)*** **HC_5** 1.29 **[µg/L]**	**Invertebrates prolonged** ***D. magna*** **NOEC** 12.5 **[µg/L]**	**Algae** ***P. subcapitata*** **E_bC_{50}** 36.6 **[µg/L]**	**Sed. dweller prolonged** ***C. riparius*** **NOEC** 6.25 **[µg/L]**					
Step 1												
	15.15	**2.4**	**0.2**	**0.1**	**0.8**	**2.4**	**0.4**					
Step 2												
N.Europe	1.84	**19.6**	**1.6**	**0.7**	**6.8**	19.9	**3.4**					
S.Europe	1.85	**19.5**	**1.6**	**0.7**	**6.8**	19.8	**3.4**					
Step 3												
D3/ditch	0.992	**36.3**	**2.9**	**1.3**	12.6	36.9	**6.3**					
D4/pond	0.0389	925.4	74.6	33.2	321.3	940.9	160.7					
D4/stream	0.774	**46.5**	**3.7**	**1.7**	16.1	47.3	**8.1**					
D6/ditch	0.976	**36.9**	**3**	**1.3**	12.8	37.5	**6.4**					
R1/pond	0.0389	925.4	74.6	33.2	321.3	940.9	160.7					
R1/stream	0.687	**52.4**	**4.2**	**1.9**	18.2	53.3	**9.1**					

R2/stream	0.91	**39.6**	**3.2**	**1.4**	13.7	40.2	**6.9**					
R3/stream	0.969	**37.2**	**3**	**1.3**	12.9	37.8	**6.4**					
Step 4 (including risk mitigation measures: 90% nozzle reduction and buffer width 20 m)												
D3/ditch	0.00856	4206	339	151	1460	4276	730					
D4/pond	0.00157	22930	1847	822	7962	23312	3981					
D4/stream	0.00864	4167	336	149	1447	4236	723					
D6/ditch	0.00842	4276	344	153	1485	4347	742					
R1/pond	0.00157	22930	1847	822	7962	23312	3981					
R1/stream	0.00855	4211	339	151	1462	4281	731					
R2/stream	0.0102	3529	284	126	1225	3588	613					
R3/stream	0.0108	4206	339	151	1460	4276	730					
TER criterion		100	10	5	10	10	10					

TER values shown in bold fall below the relevant trigger.

Table 6.5-5: Aquatic organisms: PEC_{sw} for dimethomorph and relevant ecotoxicological endpoints for each organism' group.

Scenario	**PEC_{SW} global max**	**Fish acute**	**Fish prolonged**	**Invertebrates acute**	**Invertebrates prolonged**	**Algae**	**Sed. dweller prolonged**					
		O. mykiss	***O. mykiss***	***D.magna***	***D. magna***	***P. subcapitata***	***C. riparius***					
FOCUS		**LC_{50}**	**NOEC**	**EC_{50}**	**NOEC**	**E_bC_{50}**	**NOEC**					
		6200	56	10600	100	24400	4100					
	[µg/L]	**[µg/L]**	**[µg/L]**	**[µg/L]**	**[µg/L]**	**[µg/L]**	**[µg/L]**					

Step 1												
	173.17	35.8	**0.32**	61.2	**0.58**	141	23.7					
Step 2												
N.Europe	15.05	412	**3.7**	704.3	**6.6**	1621.3	272.4					
S.Europe	28.2	219.9	**2**	375.9	**3.5**	865.2	145.4					
Step 3												
D3/ditch	1.046	5927.3	53.5	10133.8	95.6	23327	3919.7					
D4/pond	0.96	6458.3	58.3	11041.7	104.2	25416.7	4270.8					
D4/stream	1.302	4761.9	43	8141.3	76.8	18740.4	3149					
D6/ditch	1.029	6025.3	54.4	10301.3	97.2	23712.3	3984.5					
R1/pond	0.487	12731	115	21765.9	205.3	50102.7	8418.9					
R1/stream	5.521	1123	10.1	1919.9	18.1	4419.5	742.6					
R2/stream	2.638	2350.3	21.2	4018.2	37.9	9249.4	1554.2					
R3/stream	7.478	829.1	**7.5**	1417.5	13.4	3262.9	548.3					
TER criterion		100	10	10	10	10	10					

TER values shown in bold fall below the relevant trigger.

Even when refining exposure, the relevant TER-triggers are not met for the FOCUS Step 3 scenarios and thus, safe use of BANJO FORTE according to GAP can only be show by further consideration of risk mitigation measures at member state level. However, specific risk mitigation requirements for the protection of surface waters for Germany (zRMS) do identify a safe use of BANJO FORTE; the respective risk assessment is provided in the Section 6 of the National Addendum.

6.5.2.2 Risk assessment for the product, valid for run-off and not run-off endangered areas (based on drift only)

Refer to the reasoning provided in the introduction to chapter 6.5.2.

6.5.2.3 Consideration of metabolites

The toxicity data available for the active substance fluazinam and the metabolites HYPA, AMPA and G-504 (which were considered potentially of concern in aquatic systems) as presented in Table 5.5-1 do indicate a lower toxicity of the metabolites towards fish, daphnia and algae if compared with the parent fluazinam. Concurrently, relevant PECsw values for these metabolites do not exceed the predicted concentrations calculated for the parent compound. Thus, either way (from both the toxicity and exposure point of view), it is reasonably concluded that TER values are significantly higher compared to the active substances and that the risk for aquatic organisms arising from these metabolites is covered by the parent compound. Consequently, separate TER calculations for these metabolites are not presented.

6.5.2.4 Accumulation in aquatic organisms

Dimethomorph

As stated in the EFSA Scientific Report (2006) 82 for dimethomorph, the $\log K_{OW}$ for the second active ingredient contained in BANJO FORTE was determined at 2.73 (Z-isomer). This value is below the relevant trigger of 3 and thus, a low potential for bioaccumulation is indicated and no deterministic risk assessments by calculating TER values have to be conducted.

Fluazinam and its metabolites

Based on a $\log K_{OW}$ of 4.03 for fluazinam, a potential for bioconcentration may be expected according to SANCO/3268/2001 (relevant threshold: $\log K_{OW} > 3$). In the bioconcentration study summarised in the Draft Assessment Report for fluazinam, bioconcentration factors for whole fish of 960 (pyridyl label) and 1090 (phenyl label) were determined (EU agreed endpoint cited in the EFSA Scientific Report (2008) 137 for fluazinam). Furthermore, less than 95 % depuration was observed after 14 days. On this account, a chronic risk assessment for fish based on full life cycle data (FLC) was conducted in Chapter 6.5.2.1 resulting in an acceptable chronic risk for fish.

In addition, the risk to fish-eating birds and mammals was assessed for fluazinam as well as its metabolites AMPA-fluazinam and G-504 (in view of a $\log K_{OW} > 3$). TERLT calculations resulted in values exceeding the relevant trigger of 5 indicating an acceptable risk for fish-eating terrestrial vertebrates (see chapters 6.2.25 and 6.3.2.5).

Furthermore, a potential of HYPA (minor metabolite in surface water) for bioconcentration is not indicated due to an experimentally determined $logK_{OW}$ of 1.5 at pH 7 (Ref. IIIA 2.15/02: Mollandin, G., 2010) that is below the threshold of 3.

In conclusion, the risks arising from bioaccumulation of the compounds of concern in aquatic organism are considered to be low.

6.5.3 Overall conclusions

Based on the calculated concentrations of fluazinam and dimethomorph in surface water (PEC_{SW} FOCUS Step 3), the calculated TER values for the acute and long-term risk resulting from an exposure of aquatic organisms to fluazinam and dimethomorph according to the GAP of the formulation BANJO FORTE achieve the acceptability criteria (TER ≥ 100 and TER ≥ 10 and the adapted 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 aquatic organisms due to the intended use of BANJO FORTE in potatoes according to the label.

6.6 Effects on bees (MIIIA 10.4, KPC 10.3.1)

Effects on honey bees for Banjo forte have not been evaluated as part of the EU review of fluazinam or dimethomorph. Therefore all relevant data and assessments are provided here and are considered adequate.

Toxicity

Table 6.6-1 presents the results of laboratory bee toxicity studies with the formulation. Further details regarding the tests with the formulation are provided in section 10.4.2. For the sake of completeness the table also presents results of laboratory bee toxicity studies with the active substance.

Table 6.6-1: Results of laboratory bee toxicity studies

Test substance	Exposure route	LD_{50}	Reference
Banjo forte	oral 48 h	> 222.8 µg product/bee	Schmitzer, S. (2008) Project no. 42129035
	contact 48 h	> 200 µg product/bee	
dimethomorph tech.	oral 48 h	> 32.4 µg a.s./bee *	peer review of dimethomorph (2006) EFSA Scientific Report 82
	contact 48 h	> 102 µg a.s./bee *	
fluazinam	oral 48 h	> 100 µg a.s./bee *	peer review of fluazinam

tech.	contact 48 h	> 200 µg a.s./bee *	(2008) EFSA Scientific Report 137

* EU agreed endpoint

Exposure

The recommended use pattern for Banjo forte includes application in potatoes at a maximum application rate of up to 1 L product/ha. This maximum single application rate is equivalent to 1156 g product/ha.

Bees may be exposed to Banjo forte 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

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)). Bulletin OEPP/EPPO Bulletin 33: 141-145) were calculated as follows:

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

Table 6.6-2 Hazard quotients for honeybees

Test substance	Max. single application rate [g product/ha]	Exposure route	LD_{50} [µg product/bee]	Hazard quotient (HQ)	HQ trigger
Banjo forte	1156	oral	> 222.8 µg	< 5.1	50
		contact	> 200 µg	< 5.7	

* Application rate calculated considering a density of 1.156 g/mL for Banjo forte.

Risk assessment

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

Overall conclusion:
It is concluded that Banjo forte will not adversely affect bees or bee colonies when used as recommended.

6.7 Effects on arthropods other than bees (MIIIA 10.5, KPC 10.3.2)

Table 6.7-1: Toxicity of the product BANJO FORTE to non-target arthropods

Species	Substance	Exposure System	Results	Reference	Internal code
Typhlodromus pyri	BANJO FORTE	2.4 L prod./ha (limit test), bean leaves (fresh-dried abd 7-day aged-residue test), 2-D	LR_{50} (fresh) = 2.4 L* ER_{50} (fresh) not determined LR_{50} (7d aged) > 2.4 L ER_{50} (7 d aged) > 2.4 L	Ref. IIIA 10.5.2/02: Moll, M. (2008)	75090
Aphidius rhopalosiphi	BANJO FORTE	2.4 L/ha (limit test), bean leaves (fresh-dried residues), 3-D	LR_{50}/ER_{50} > 2.4 L/ha*	Ref. IIIA 10.5.2/01: Moll, M. (2008)	75059
Chrysoperla carnea	BANJO FORTE	BANJO FORTE, 2.7 L prod./ha (limit test), bean leaves (fresh-dried residue test), 2-D	LR_{50}/ER_{50} > 2.7 L/ha*	Ref. IIIA 10.5.2/03: Moll, M. (2009)	75251
Poecilus cupreus	BANJO FORTE	3.2 L prod./ha (limit test), natural soil (overspray test)	LR_{50}/ER_{50} > 3.2 L/ha*	Ref. IIIA 10.5.2/04: Schmitzer, S. (2008)	75053

* Endpoint differing from LoEP / New study submitted

6.7.1 Justification for new endpoints

New studies with the preparation BANJO FORTE have been made available with the dossier of the applicant.

6.7.2 Risk assessment

The evaluation of the risk for non-target arthropods was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002), and in consideration of the recommendations of the guidance document ESCORT 2.

6.7.2.1 Risk assessment for in-field exposure

Exposure

The in-field exposure, given as predicted environmental rates, PER, for non-target arthropods resulting from the intended uses of BANJO FORTE 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:

$$PER_{in-field} = \text{Application rate (g a.s. or L prod./ha)} \times \text{MAF}$$

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.

Table 6.7-2: Predicted in-field environmental rates (PER)

Intended use	Exposure	Single appl. rate [L/ha]	MAF	$PER_{in-field}$ [L/ha]
Potatoes	In-field	1 L/ha	2.7	2.7

MAF: Multiple application factor; f_{drift}: Drift factor; f_{veg}: Vegetation distribution factor; PER: Predicted environmental rates

Tier 1 risk assessment for in-field exposure

The risk for non-target arthropods exposed in-field to BANJO FORTE was assessed by calculating the hazard quotient (HQ = exposure/toxicity) as the ratio of the predicted environmental rate (PER) and the lowest lethal rate (LR_{50}) estimated in standard toxicity tests with non-target arthropods according to the formula:

$$\text{In field HQ} = \frac{\text{In - field PER}}{LR_{50}}$$

The resulting HQ in-field values for the standard species are presented in the following table.

Table 6.7-3: HQ values for non-target arthropods (Tier-1) for in-field exposure

Intended use	Species	L/ER_{50}	Exposure	PER	HQ

[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.

		[L/ha]		**[L/ha]**	
Potatoes	*T. pyri*	2.4 (fresh dried residues) > 2.4 (7 d aged residues)	in-field	2.7	1.125 (fresh dried residues) < 1.125 (7 d aged residues)

PER: Predicted environmental rates ; HQ: Hazard quotient

The risk for non-target arthropods exposed in-field to BANJO FORTE was assessed by comparing the environmental rate ($PER_{in\text{-}field}$) to the lowest lethal or effective (reproduction) rate (L/ER_{50}) estimated in toxicity tests with non-target arthropods. With regard to extended laboratory tests and semi-field tests, lethal and sublethal effects of less than 50 % are considered acceptable, provided that the tests covered the appropriate field rate. Although the limit test rate of 2.4 L/ha as applied in the studies conducted with *A. rhopalosiphi* and *T. pyri* did not cover the full $PER_{in\text{-}field}$, the study results (for details see Appendix 2) do not indicate effects in clear excess of the 50 % acceptability criterion relevant for in-field effects: corrected mortality of 2.6 % and 28.9 % (7 day aged residues) for *A. rhopalosiphi* and *T. pyri*, respectively) or reproduction (-0.8 % and 1.2 % (7 day aged residues) for *A. rhopalosiphi* and *T. pyri*, respectively) were observed. It can thus be reasonably assumed that even after exposure at the $PER_{in\text{-}field}$ (2.7 L prod./ha), no unacceptable in-field effects (i.e. > 50 %) would be observed from the intended use of BANJO FORTE according to the GAP.

6.7.2.2 Risk assessment for off-field exposure

Exposure

Exposure of non-target arthropods living in off-field areas to BANJO FORTE 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:

$$Off-field\ PER = \frac{Maximum\,in-field\ PER\ x \left(drift\ percentile \Big/ 100 \right)}{vegetation\,distribution\ factor\ (vdf)}$$

where:

vdf = vegetation distribution factor used in combination with test results derived from 2-dimensional exposure set-ups

To account for interception and dilution by three-dimensional vegetation in off-crop areas, a vegetation distribution or dilution factor (vdf, see above) is incorporated into the equation when calculating off-field exposure in conjunction with toxicity endpoints derived from two-dimensional studies (e.g. glass plate or leaf discs). A dilution factor of 10 is recommended by the Guidance Document, but has been questioned.

[2] BBA (Biologische Bundesanstalt für Land- und Forstwirtschaft) (2000): Abdrifteckwerte für Flächen- und Raumkulturen sowie für den gewerblichen Gemüse-, Zierpflanzen- und Beerenobstanbau. Bundesanzeiger 100, 26. Mai 2000, Köln, pp. 9879.

The risk assessment procedure here considers a dilution factor of 5 more appropriated. For endpoints resulting from 3-dimensional studies, i.e. where spray treatment is applied onto whole plants, the dilution factor is not considered.

Fluazinam has a vapour pressure of > 10^{-4} Pa and is therefore classified as semi-volatile. Hence, deposition following volatilization has to be considered. A refined exposure assessment including deposition following volatilization is presented in the National Addendum.

When assessing the risk to non-target arthropods based on the endpoint for BANJO FORTE obtained from the *T. pyri* study, a vegetation distribution factor has to be considered (study conducted in 2D-design).

Table 6.7-4: Predicted off-field environmental rates (PER) for BANJO FORTE

Intended use	**Exposure**	**Single appl. rate [L/ha]**	**MAF**	**Drift scenario**	**f_{drift}**	**f_{veg}**	**$PER_{off-field}$ [L/ha]**
Potatoes	Off-field	1.0	2.7	arable crops, 74th percentile	1.85 % (at 1 m)	5	0.01 (at 1 m)

MAF: Multiple application factor; f_{drift}: Drift factor; f_{veg}: Vegetation distribution factor; PER: Predicted environmental rates

Tier 1 risk assessment for off-field exposure

In order to assess the risk of BANJO FORTE to non-target arthropods in off-field areas, the predicted environmental rate in the off-field 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.

Additionally to the HQ-approach, the assessment of the risk to non-target arthropods due to an exposure to BANJO FORTE 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 results of the risk assessment are summarized in the following table.

Table 6.7-5: HQ and TER values for non-target arthropods (Tier-1) for off-field exposure

Intended use	Species	L/ER_{50} [L/ha]	Exposure	$PER_{off\text{-}field}$ [L/ha]	$PER_{off\text{-}field}$ x correction factor [L/ha]	HQ	TER
Potatoes	*T. pyri*	≥ 2.4 L/ha	off-field	0.01 (at 1 m)	0.05 (at 1 m)	< 0.02	≥ 240

PER: Predicted environmental rates ; HQ: Hazard quotient; TER: Toxicity to exposure ratio

The calculated HQ-value indicates that effects of BANJO FORTE if applied according to the GAP of 50 % or more are clearly not to be expected; the risk is considered acceptable. In analogy, the TER off-field value by far does exceed the relevant acceptability criterion (5) and thus, indicating an acceptable risk, too.

6.7.2.3 Risk mitigation measures

No risk mitigation needed.

6.7.3 Overall conclusions

In-field

Based on the calculated rates of BANJO FORTE in in-field areas, the calculated HQ and TER values describing the risk resulting from an exposure of non-target arthropods BANJO FORTE according to the GAP of the formulation BANJO FORTE achieve the acceptability criteria of less than 50% effects 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 BANJO FORTE in potatoes according to the label.

Off-field

Based on the calculated rates of BANJO FORTE in off-field areas, the calculated HQ and TER values describing the risk resulting from an exposure of non-target arthropods to BANJO FORTE if applied according to the GAP of the formulation BANJO FORTE achieve the acceptability criteria of less than 50% effects at calculated drift rates resp. 5 (Higher tier), 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 BANJO FORTE in potatoes according to the label.

6.8 Effects on non-target soil meso- and macrofauna (MIIIA 10.6, KPC 10.4, KPC 10.4.1, KPC 10.4.2)

Table 6.8-1: EU agreed endpoints and new endpoints for earthworms and other soil macro- and mesofauna

Species	Substance	Exposure System	Results	Reference	Internal code
Eisenia fetida	Fluazinam	acute, 14 d	LC_{50corr} [mg/kg $soil_{dw}$] >500**	Edwards,P.J.;Coulson,J.M. 1985 RJ0409B	26628
Eisenia fetida	Dimethomorph	acute, 14 d	LC_{50corr} [mg/kg $soil_{dw}$] > 500**	Winkelmann, G. 2006 #107091	75443
Eisenia fetida	BANJO FORTE	acute, 14 d	LC_{50} [mg/kg $soil_{dw}$] > 1000*	Ref. IIIA 10.6.2/01: Lührs, U. (2008) R-23930, 42138021	75296
Eisenia fetida	HYPA	acute, 14 d	LC_{50} [mg/kg $soil_{dw}$] > 1000#	Lührs, U. (2000) Report-No. 8691021	54067
Eisenia fetida	Dimethomorph	chronic, 56 d	$NOEC_{corr}$ [mg/kg $soil_{dw}$] = 60**	EU agreed endpoint: EFSA Scientific Report (2006) 82	38588
Eisenia fetida	HYPA	chronic, 56 d	NOEC [mg/kg $soil_{dw}$] = 15#*	Kromme, K. 2009 113FZI ! 081117CM Study submitted with dossier to ZA6897 (“CHA 5810”)	72686
Eisenia fetida	BANJO FORTE	chronic, 56 d	NOEC [mg/kg $soil_{dw}$] = 92.22 (recalculated from 20.7 L product/ha)	Ref. IIIA 10.6.3/01: Witte, B. (2009) R-25549, 42148022	75297
Folsomia candida	HYPA	chronic, 28 d	NOEC [mg/kg $soil_{dw}$] = 6.08#	Lührs, U. 2007 32887016	75624
Folsomia candida	BANJO FORTE	chronic, 28 d	NOEC [mg/kg $soil_{dw}$] = 16*	Ref. IIIA 10.6.6/01: Lührs, U. (2008) R-23932, 42144016	75094
Hypoaspis aculeifer	BANJO FORTE	chronic, 14 d	NOEC [mg/kg $soil_{dw}$] = 250*	Ref. IIIA 10.6.6/02: Lührs, U. (2009)	75254

**Corrected value derived by dividing the endpoint by a factor of 2 in accordance with the EPPO earthworm scheme 2002 (for substances with a log K_{ow} > 2 and 10% peat in the study).

#since the log K_{OW} of HYPA is below 2 (i.e. 1.5 at pH 7; Ref. IIIA 2.15/02: Mollandin, G., 2010), the endpoint for risk assessments was not adjusted

* Endpoint differing from LoEP / New study submitted

6.8.1 Justification for new endpoints

New studies with the preparation BANJO FORTE have been made available with the dossier of the applicant; additionally, the relevant endpoint for effects on reproduction in earthworms of the fluazinam-soil-metabolite HYPA available in the data base of the zRMS was included.

6.8.2 Toxicity exposure ratios for earthworms and other soil macro- and mesofauna, TER_A and TER_{LT} (MIIIA 10.6.1)

The evaluation of the risk for earthworms and other soil macro-organisms was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

For the calculations of predicted environmental concentrations in soils (PEC soil), reference is made to the environmental fate section (Part B, Core Assessment, Section 5, Chapter 5.5) of this submission.

Most relevant for a Tier-1 risk assessment are the toxicity data generated with the product BANJO FORTE since these do cover potential joint effects of the two active substances fluazinam and dimethomorph as well as of further formulation constituents. As from the available data there is no indication that the product BANJO FORTE is more toxic towards soil-organism than the active substances themselves (at least regarding acute toxicity towards earthworms, a respective conclusion regarding chronic toxicity is hampered by the lack of toxicity data for fluazinam) it can be reasonably assumed that the outcome of the risk assessment based on the product data does cover the individual as well as joint risk of both active substances. The risk of the persistent soil metabolite of fluazinam, HYPA, is assessed additionally.

The acute risk for earthworms and other non-target soil macro- and mesofauna resulting from an exposure to BANJO FORTE as well as the major soil degradation product HYPA was assessed by comparing the maximum PEC_{SOIL} with the 14-day LC_{50} value to generate acute TER values. The TER_A was calculated as follows:

$$TER_A = \frac{LC_{50}\ (mg/kg)}{PEC_{soil}\ (mg/kg)}$$

The chronic risk for earthworms, other non-target soil macro- and mesofauna and organic matter breakdown resulting from an exposure to BANJO FORTE as well as the major soil degradation product HYPA was assessed by comparing the maximum PEC_{SOIL} with the NOEC value to generate chronic TER values. The TER_{LT} was calculated as follows:

$$TER_{LT} = \frac{NOEC\ (mg/kg)}{PEC_{soil}\ (mg/kg)}$$

The results of the risk assessment are summarized in the following table.

Table 6.8-2: TER values for earthworms and other soil macro- and mesofauna (Tier-1), potatoes 4 x 1.0 L prod./ha (corresponding to 200 g fluazinam and 200 g dimethomorph/ha), 7 d interval

Species	Test item	Time scale	Endpoint [mg/kg soil dw]	Max. PEC_{SOIL} [mg/kg soil dw]	TER
Eisenia fetida	BANJO FORTE	acute	> 1000	1.657	> 603
	HYPA	acute	> 1000	0.038	> 26316
	BANJO FORTE	chronic	92.22	1.657	56
	HYPA	chronic	15	0.038	395
Folsomia candida	BANJO FORTE	chronic	16	1.657	9.6
	HYPA	chronic	6.08	0.038	160
Hypoaspis aculeifer	BANJO FORTE	chronic	250	1.657	151

TER values shown in bold fall below the relevant trigger.

6.8.3 Higher tier risk assessment

Not relevant.

6.8.4 Overall conclusions

Based on the predicted concentrations of BANJO FORTE and of the fluazinam-metabolite HYPA in soils, the TER values describing the acute and long-term risk for earthworms and other non-target soil organisms following exposure to BANJO FORTE and HYPA, respectively, according to the GAP of the formulation BANJO FORTE achieve the acceptability criteria TER ≥ 10 resp. TER ≥ 5 according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for soil organisms due to the intended use of BANJO FORTE in potatoes according to the label.

6.9 Effects on soil microbial activity (MIIIA 10.7, KPC 10.5)

Table 6.9-1: EU agreed endpoints and new endpoints for soil microorganisms

Substance	Test design	Results	Source	Internal code
BANJO FORTE	N-/C-transformation	No detrimental effects (E < ±25 % of the control) on N-transformation (42 d) and C-mineralisation (28 d) up to 10.0 L prod./ha corresponding to 15.68 mg prod./kg soil d.w.*	Ref. IIIA 10.7.1/01: Feil, N. (2009)	-/-
HYPA	N-/C-transformation	No detrimental effects (E < ±25 % of the control) on N-	EU agreed endpoint:	-/-

		transformation (28 d) and C-mineralisation (28 d) up to 0.38 mg/kg $soil_{dw}$	EFSA Scientific Report (2008) 137	

* Endpoint differing from LoEP / New study submitted

6.9.1 Justification for new endpoints

A new study conducted with the preparation BANJO FORTE has been made available with the dossier of the applicant.

6.9.2 Risk assessment

The evaluation of the risk to soil micro-organism was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

Please refer to the above chapter 6.8 for the predicted environmental concentrations in soil (PEC_{SOIL}) of BANJO FORTE and the fluazinam-metabolite HYPA.

The results of the risk assessment are summarized in the following table.

Table 6.9-2: Risk assessment for effects on soil micro-organisms

Test substance	**Test concentration (adverse effects < 25%)** **[mg /kg]**	**PEC_{SOIL}** **[mg/kg]**	**Risk acceptable** **[yes/no]**
BANJO FORTE	15.68	1.657	yes
HYPA	0.38	0.038	yes

6.9.3 Overall conclusions

Based on the predicted concentrations of BANJO FORTE and of the fluazinam-metabolite HYPA in soils, the risk to soil microbial processes following exposure to BANJO FORTE / the fluazinam-metabolite HYPA according to the GAP of the formulation BANJO FORTE is considered to be acceptable according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2.

6.10 Effects on non-target plants (MIIIA 10.8, KPC 10.6)

6.10.1 Effects on non-target terrestrial plants (MIIIA 10.8.1)

Table 6.10-1: EU-agreed endpoints and new endpoints for non-target terrestrial plants

Species	**Substance**	**Exposure System**	**Results**	**Reference**	**Internal code**

6 species (oilseed rape, soybean, sugar beet, carrot, oat and onion)	BANJO FORTE	Vegetative vigour 21 d	ER_{50} > 1 L/ha (all species)	Ref. IIIA 10.8.1.2/01: Bützler, R., Mollandin, G. (2009)	75289

* Endpoint differing from LoEP / New study submitted

6.10.2 Justification for new endpoints

A new study conducted with the preparation BANJO FORTE has been made available with the dossier of the applicant.

6.10.2.1 Risk assessment

The risk assessment is based on the "Guidance Document on Terrestrial Ecotoxicology", (SANCO/10329/2002 rev.2 final, 2002). It is restricted to off-field situations, as non-target plants are non-crop plants located outside the treated area. Spray drift from the treated areas may lead to residues of a product in off-crop areas.

Exposure

Effects on non-target plants are of concern in the off-field environment, where they may be exposed to spray drift. The amount of spray drift reaching off-crop habitats is calculated using the 90th percentile estimates derived by the BBA (2000) from the spray-drift predictions of Ganzelmeier & Rautmann (2000). Any dilution over the 3-dimensional vegetation surface is accounted for in the study design. Therefore, in contrast to the assessment of risks to arthropods from standard laboratory tests, no vegetation distribution factor is considered here.

$PER_{off\text{-}field}$= Maximum $PER_{in\text{-}field}$ (including MAF) x %drift

Fluazinam has a vapour pressure of 10^{-4} Pa and is therefore classified as semi-volatile. Hence, deposition following volatilization has to be considered. A refined exposure assessment including deposition following volatilization is presented /in the National Addendum.

For calculation of $PER_{in\text{-}field}$, please refer to 6.7.2.1.

Table 6.10-2: Predicted off-field environmental rates (PER) for BANJO FORTE

Intended use	Exposure	Single appl. rate [L/ha]	MAF	Drift scenario	f_{drift}	$PER_{off\text{-}field}$ [L/ha]
Potatoes	Off-field	1.0	2.7	arable crops, 74th percentile	1.85 % (at 1 m)	0.05

MAF: Multiple application factor; f_{drift}: Drift factor; PER: Predicted environmental rates

Tier 1 assessment

The assessment of the risk to non-target arthropods due to an exposure to BANJO FORTE is performed on basis of the calculation of toxicity-exposure ratios (TER values) according the following formula:

$$TER = \frac{ER50\,(L\ product/ha)}{Off-field\ PER\,(L\ product/ha)}$$

The results of the risk assessment are summarized in the following table.

Table 6.10-3: Risk assessment for non-target terrestrial plants exposed to BANJJO FORTE for potatoes

Intended use	**ER_{50} [L/ha]**	**$PER_{off-field}$ [L/ha]**	**TER**
Potatoes	>1.0	0.05	20

Risk mitigation measures

No risk mitigation needed.

6.10.2.2 Higher tier risk assessment (quantitative risk assessment)

Not relevant.

6.10.2.3 Overall conclusions

Based on the predicted rates of BANJO FORTE in off-field areas, the TER values describing the risk for non-target plants following exposure to BANJO FORTE according to the GAP 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. The results of the assessment indicate an acceptable risk for non-target terrestrial plants due to the intended use of BANJO FORTE in potatoes according to the label.

6.11 Effects on other terrestrial organisms (flora and fauna) (KPC 10.7)

6.12 Monitoring data (KPC 10.8)

6.13 Available preliminary data (IIIA 10.9)

6.14 Other/special studies (IIIA 10.10)

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 number (OECD-Format)	Author(s)	Year	Title Testing Facility Report No GLP or GEP status (where relevant) Published or not	Data Protection Claimed yes/no	Owner*	Relied on Y/N/add
KIIIA1 10.1.6/01	[redacted]	2008	Avian acute oral toxicity study of MCW-853 SC LPT, Hamburg, Germany Report no. 23317; Sponsor no. R-24358 GLP / GEP Unpublished	yes	MCW	Y
KIIIA1 10.2.2.1/01	[redacted]	2009	Acute toxicity of MCW-853 SC to rainbow trout (*Oncorhynchus mykiss*) in a 96-hour flow through test IBACON GmbH, Rossdorf, Germany Report no. 42126230; Sponsor no. R-23923 GLP / GEP Unpublished	yes	MCW	Y
KIIIA1 10.2.2.1/02	[redacted]	2009	Acute toxicity of MCW-853 SC to Zebrafish (*Danio rerio*) in a 96-hour flow through test IBACON GmbH, Rossdorf, Germany Report no. 42146230; Sponsor no. R-23924 GLP / GEP Unpublished	yes	MCW	add
KIIIA1 10.2.2.1/03	[redacted]	2010	Acute Toxicity of HYPA to Rainbow trout (*Oncorhynchus mykiss*) in a 96-hour Static Test IBACON GmbH, Rossdorf, Germany Report no. 48365230, Sponsor no.: R-26738 GLP / GEP Unpublished	yes	MCW	add
KIIIA1 10.2.2.1/04	[redacted]	2011	Acute Toxicity of G-504 to Rainbow trout (*Oncorhynchus mykiss*) in a 96-hour Static Test IBACON GmbH, Rossdorf, Germany Report no. 63083230, Sponsor no.: R-28033 GLP / GEP Unpublished	yes	MCW	Y

Annex point/ reference number (OECD-Format)	Author(s)	Year	Title Testing Facility Report No GLP or GEP status (where relevant) Published or not	Data Protection Claimed yes/no	Owner*	Relied on Y/N/add
KIIIA1 10.2.2.2/01	Kuhl, R., Wydra, V.	2009	Acute toxicity of MCW-853 SC to *Daphnia magna* in a static 48-hour immobilisation test IBACON GmbH, Rossdorf, Germany Report no. 42125220; Sponsor no. R-23922 GLP / GEP Unpublished	yes	MCW	Y
KIIIA1 10.2.2.2/02	Böttcher, M., Deierling, T.	2010	Acute Toxicity of HYPA to *Daphnia magna* in a Static 48-hour Immobilisation Test IBACON GmbH Report no. 48364220, Sponsor no.: R-26737 GLP / GEP Unpublished	yes	MCW	add
KIIIA1 10.2.2.2/03	Kuhl, R., Wydra, V.	2011	Acute Toxicity of G-504 to *Daphnia magna* in a Static 48-hour Immobilisation Test IBACON GmbH Report no. 63082220, Sponsor no.: R-28032 GLP / GEP Unpublished	yes	MCW	Y
KIIIA1 10.2.2.3/01	Kley, A., Wydra, V.	2009	Toxicity of MCW-853 SC to *Desmodesmus subspicatus* in an algal growth inhibition test IBACON GmbH, Rossdorf, Germany Report no. 42127210, Sponsor no. R-23921 GLP / GEP Unpublished	yes	MCW	Y
KIIIA1 10.2.2.3/02	Böttcher, M., Deierling, T.	2010	Revised Final Report No.1 (2nd Original) - Toxicity of HYPA to *Pseudokirchneriella subcapitata* in an Algal Growth Inhibition Test IBACON GmbH Report no. 48363210, Sponsor no.: R-26736 GLP / GEP Unpublished	yes	MCW	Y

Annex point/ reference number (OECD-Format)	Author(s)	Year	Title Testing Facility Report No GLP or GEP status (where relevant) Published or not	Data Protection Claimed yes/no	Owner*	Relied on Y/N/add
KIIIA1 10.2.2.3/03	Kuhl, R., Wydra, V.	2011	Toxicity of G-504 to *Pseudokirchneriella subcapitata* in an Algal Growth Inhibition Test IBACON GmbH Report no. 63081210, Sponsor no.: R-28031 GLP / GEP Unpublished	yes	MCW	Y
KIIIA1 10.3/01	Barfknecht, R.	2003	Attractiveness of Potato Fields for Herbivorous Mammals and Birds, Field Monitoring in Nordrhein-Westfalen, Germany Bayer CropScience AG, Monheim, Germany E 307 2310-6 GLP / GEP Unpublished	yes	BCS	add
KIIIA1 10.4.2/01	Schmitzer, S.	2008	Effects of MCW-853 SC (Acute Contact and Oral) on Honey Bees (*Apis mellifera* L.) in the Laboratory IBACON GmbH, Rossdorf, Germany Report no. 42129035; Sponsor no.: R-23925 GLP / GEP Unpublished	yes	MCW	(JKI)
KIIIA1 10.5.2/01	Moll, M.	2008	Effects of MCW-853 SC on the Parasitoid *Aphidius rhopalosiphi* IBACON GmbH, Rossdorf, Germany Report no. 4213303; Sponsor no. R-23927 GLP / GEP Unpublished	yes	MCW	Y
KIIIA1 10.5.2/02	Moll, M.	2008	Effects of MCW-853 SC on the predatory mite *Typhlodromus pyri* extended laboratory study, aged residue test IBACON GmbH, Rossdorf, Germany Report no. 42134060, Sponsor no. R-23928 GLP / GEP Unpublished	yes	MCW	Y
KIIIA1 10.5.2/03	Moll, M.	2009	Effects of MCW-853 SC on the Lacewing *Chrysoperla carnea* IBACON GmbH, Rossdorf, Germany Report no. 42147047; Sponsor no. R-25548 GLP / GEP Unpublished	yes	MCW	Y

Annex point/ reference number (OECD-Format)	Author(s)	Year	Title Testing Facility Report No GLP or GEP status (where relevant) Published or not	Data Protection Claimed yes/no	Owner*	Relied on Y/N/add
KIIIA1 10.5.2/04	Schmitzer, S.	2008	Effects of MCW-853 SC on the Carabid Beetle *Poecilus cupreus* L. IBACON GmbH, Rossdorf, Germany Report no. 42130007; Sponsor no. R-23926 GLP / GEP Unpublished	yes	MCW	Y
KIIIA1 10.6.2/01	Lührs, U.	2008	Acute Toxicity (14 Days) of MCW-853 SC to the Earthworm *Eisenia fetida* in Artificial Soil with 5% Peat IBACON GmbH, Rossdorf, Germany Report no. 42138021; Sponsor no. R-23930 GLP / GEP Unpublished	yes	MCW	Y
KIIIA1 10.6.3/01	Witte, B.	2009	Effects of MCW-853 SC on Reproduction and Growth of Earthworms *Eisenia fetida* in Artificial Soil with 5% Peat IBACON GmbH, Rossdorf, Germany Report no. 42148022; Sponsor no. R-25549 GLP / GEP Unpublished	yes	MCW	Y
KIIIA1 10.6.6/01	Lührs, U.	2008	Effects of MCW-853 SC on Reproduction of the Collembola *Folsomia candida* in Artificial Soil with 5% Peat IBACON GmbH, Rossdorf, Germany Report no. 42144016; Sponsor no. R-23932 GLP / GEP Unpublished	yes	MCW	Y
KIIIA1 10.6.6/02	Lührs, U.	2009	Effects of MCW-853 SC on Reproduction of the predatory mite *Hypoaspis aculeifer* in artificial soil with 5 % peat IBACON GmbH, Rossdorf, Germany Report no. 50881089; Sponsor no. R-25550 GLP / GEP Unpublished	yes	MCW	Y

Annex point/ reference number (OECD-Format)	Author(s)	Year	Title Testing Facility Report No GLP or GEP status (where relevant) Published or not	Data Protection Claimed yes/no	Owner*	Relied on Y/N/add
KIIIA1 10.6.6/03	Schulz, L.	2009	Field study to evaluate the effects of MCW 465 500 SC (500 g/L Fluazinam) on micro-arthropods under grassland conditions BioChem agrar, Machern, Germany Makhteshim Chemical Works Ltd. Israel Report no. 08 10 48 008 F GLP / GEP Unpublished	yes	MCW	add
KIIIA1 10.6.7/01	Lührs, U.	2009	Effects of MCW 465 500 SC on the breakdown of organic matter in litter bags in the field IBACON GmbH, Rossdorf, Germany Makhteshim Chemical Works Ltd. Israel Report no. 42253081, Sponsor report no. R-24106 GLP / GEP Unpublished	yes	MCW	add
KIIIA1 10.7.1/01	Feil, N.	2009	Effects of MCW-853 SC on the Activity of the Soil Microflora in the Laboratory IBACON GmbH, Rossdorf, Germany Report no. 42149080; Sponsor no. R-25551 GLP / GEP Unpublished	yes	MCW	Y
KIIIA1 10.8.1.2/01	Bützler, R., Mollandin, G.	2009	Effects of MCW-853 SC on Terrestrial (Non-Target) Plants: Vegetative Vigour Test IBACON GmbH, Rossdorf, Germany Report no. 42140087; Sponsor no. R-25552 GLP / GEP Unpublished	yes	MCW	Y

* The study owner (sponsor) of the studies is Makhteshim Chemical Works Ltd. or ADAMA Deutschland, both members of Makhteshim Agan Industries (MAI).

Table A 2: List of data submitted for other authorization procedures and used in support of the evaluation of the current product

MIII A 10.2 (Excerpt from table 6.5-1; it has to be stressed that the dossier submitted by the applicant formally addressed all standard data requirements, the studies listed below revealed more sensitive species/endpoints as available in the UBA database but have been submitted with the dossiers to other applications than BANJO FORTE).

Species	**Substance**	**Exposure System**	**Results** **[mg/L]**	**Reference**	**Internal code**
Oncorhynchus mykiss	Fluazinam	96 h, flow-through	LC_{50} = 0.036*	[redacted] 1992 5099-91-0422-TX-002 Submitted with dossier to ZA4092	53577
Oncorhynchus mykiss	HYPA	96 h, static	LC_{50} = 2.09*	[redacted] 16.01.2009 C09083 Submitted with dossier to ZA?(lacking ICS-entry)	72684
Danio rerio	AMPA	96 h, static	LC_{50} > 0.089	[redacted] 21.10.1997 662512 Submitted with dossier to ZA4092	53585
Oncorhynchus mykiss	G-504	96 h, static	LC_{50} > 100*	[redacted] C09061 Submitted with dossier to ZA6897	77206
Daphnia magna	Fluazinam	48 h, static	EC_{50} = 0.165*	Noack, M. 2006 R-20525 ! DAI106911 Submitted with dossier to ZA?(lacking ICS-entry)	72857
SSD Invertebrates (based on EC_{10})	Fluazinam	96 h, static	HC_5 = 0.00129	Arts, G.H.P. et al. 15.03.2004 072003 Submitted with dossier to ZA4092	55116
Daphnia magna	HYPA	48 h, static	EC_{50} = 0.876*	Peither, A. 2009	72562

				C09072!103FZI Submitted with dossier to ZA6897	
Daphnia magna	AMPA	48 h, static	EC_{50} > 0.260	Hertl, J. 24.10.1997 662490 Submitted with dossier to ZA4092	53971
Pseudo-kirchneriella subcapitata	Fluazinam	72 h, static	E_rC_{50} > 0.0705* E_bC_{50} = 0.0366	Scheerbaum, D. 2006 R-20524 ! SPO106911 Submitted with dossier to ZA?(lacking ICS-entry)	72889
Pseudo-kirchneriella subcapitata	AMPA	72 h, static	E_rC_{50} = 0.334* E_bC_{50} = 0.14	Pupp, A., Wydra, V. 2008 R-23886 ! 39392210 Submitted with dossier to ZA?(lacking ICS-entry)	72891
Lemna gibba	Fluazinam	7 d, semi-static	E_rC_{50} = 0.069*	Boeri, R. L. and Ward, T. J. 2001 2129-SK Submitted with dossier to ZA4092	53593
Lemna gibba	HYPA	7 d, semi-static	E_rC_{50} > 69.1*	Boeri, R. L., Ward, T. J. 18.06.2001 2129-SK ! 013022 Submitted with dossier to ZA7411	79670

MIII A 10.6 (Excerpt from table 6.8-1; it has to be stressed that the dossier submitted by the applicant formally addressed all standard data requirements, ther studies listed below revealed more sensitive species/endpoints as available in the UBA database but have been from submitted with the dossiers to other applications than BANJO FORTE).

Species	**Substance**	**Exposure System**	**Results**	**Reference**	**Internal code**
Eisenia fetida	HYPA	chronic, 56 d	NOEC [mg/kg $soil_{dw}$] = 15#*	Kromme, K. 2009 113FZI ! 081117CM Study submitted with dossier to ZA6897 (“CHA 5810”)	72686

Appendix 2 Detailed evaluation of the new studies

IIIA 10.1 Effects on birds

IIIA 10.1.3 Baits: Concentration of active substance in bait in mg/kg

IIIA 10.1.4 Pellets, granules, prills or treated seed

IIIA 10.1.4.1 Amount of active substance in or on each item

IIIA 10.1.4.2 Proportion of active substance LD_{50} per 100 items and per gram of items

IIIA 10.1.5 Size and shape of pellet, granule or prill

IIIA 10.1.6 Acute toxicity of the formulation

Report:	KIIIA1 10.1.6/01, [redacted] 2008
Title:	Avian acute oral toxicity study of MCW-853 SC - Japanese quail
Testing facility:	LPT Laboratory of Pharmacology and Toxicology GmbH & Co. KG, Hamburg, Germany
Document No:	23317, sponsor report no.: R-24358
Guidelines:	SETAC Guideline Document (1995), EPA OPPTS 850.2100 (1996). Deviations: none
GLP	Yes (certified laboratory)
Comments of zRMS:	**Acceptable. Used in evaluation.**

Executive summary

A group of three female Japanese quails (*Coturnix coturnix japonica*) was exposed to MCW-853 SC applied as a single oral dose of 2000 mg prod./kg bw. A control group receiving tap water was run concurrently. The animals were observed for 14 days. Observations included mortality, regurgitation, signs of toxicity, abnormal behaviour, food consumption and body weight. Body weight was determined within 24 hours of dosing and weekly after administration. Food consumption was recorded for the periods 1 - 3 days, 4 - 7 days and 8 - 14. All animals were sacrificed, dissected and inspected macroscopically.

No mortality was observed during the test duration and thus, The LD_{50} was estimated to be above the applied dose of 2000 mg prod./kg bw. Furthermore, no behavioural changes and no abnormal clinical signs were observed in both the control and the test item group, and no adverse influence on body weight development and food consumption could be determined.

I. Materials and methods

A. Materials

1. Test material: MCW-853 SC
   Description: white to light pink, liquid
   Lot/Batch no.: 242-060708-01
   Active ingredient content: dimethomorph: 201 g/L
   fluazinam: 196 g/L
   Stability of the test compound: expiry date: July 07, 2010

2. Control: tap water
   Toxic reference: none

3. Test organisms -
   Species: *Coturnix coturnix japonica* (Japanese quail)
   Age at study initiation: 42 days
   Body weight at study initiation: 199 - 219 g
   Feeding: commercial diet, served as standard diet; feeding was discontinued approx. 16 hours before test item administration
   Acclimatization period: 14 days
   No. of birds: 3 females per group

4. Test units -
   Housing: 1 animal per pen with a surface area of 500 cm^3 per bird

5. Test conditions -
   Room temperature: 20 - 25 °C
   Relative humidity: 40 - 80 %
   Illumination: by artificial light (about 150 lux) for 8 hours daily
   Ventilation: not stated

6. Test duration: 14 days

B. Study design and method

1. In life dates: August 08 to 22, 2008

2. Test procedure:

A group of three female Japanese quails (*Coturnix coturnix japonica*) was exposed to MCW-853 SC applied as a single oral dose of 2000 mg prod./kg bw. A control group receiving tap water was run concurrently. The animals were observed for 14 days.

3. Observations:

Observations included mortality, regurgitation, signs of toxicity, abnormal behaviour, food consumption and body weight. Body weight was determined within 24 hours of dosing and weekly after administration. Food consumption was recorded for the periods 1 - 3 days, 4 - 7 days and 8 - 14. All animals were sacrificed, dissected and inspected macroscopically.

4. Statistics:

A well-defined LD_{50} could not be statistically determined since no mortality occurred at the limit test dose of 2000 mg prod./kg bw.

II. Results and discussion

A. Mortality

No mortality was observed in the control and the test item group. Therefore, the LD_{50} was estimated to be above 2000 mg test item/kg bw.

B. Body weight changes

No significant differences in body weight development between the test item group and the control group were observed. Body weight changes within the test duration are summarised in the table below.

Table 10- 1: Mean body weights of Japanese quails during the test period

Group	Test day		
	0	9	15
Weight control group [g]	201.0	222.7 (+10.8 %)	219.3 (+9.1 %)
Weight test item group [g]	217.8	250.3 (+14.9 %)	240.5 (+10.4 %)

( ): Body weight gain (%) compared to the initial body weights

C. Food consumption

No influence was noted in mean food consumption of birds in the test item group compared with those in the control group during the study period. Food consumption within the test duration is summarised in the table below.

Table 10- 2: Mean food consumption per quail and day during the test period

Group	Test period [d]		
	1 - 3	4 - 7	8 - 14
Mean food consumption per animal and day in the control group [g]	30.1	23.5	21.3
Mean food consumption per animal and day in the test item group [g]	36.6	38.5	40.0

D. Other observations

No changes of behaviour or other signs of toxicity were observed at the dose level of 2000 mg prod./kg bw, and no pathological findings were noted at necropsy.

E. Deficiencies

In the control group, mortality did not exceed 10 % during the test period. Thus, the test is considered valid without restrictions.

III. Conclusions

In the framework of a 14-day single-dose oral toxicity test, the test item MCW-853 SC was applied at a limit test dose of 2000 mg/kg bw to a group of 3 female Japanese quails (*Coturnix coturnix japonica*). A control group receiving tap water was run concurrently. No mortality was observed during the test duration and thus, The LD_{50} was estimated to be above the applied dose of 2000 mg prod./kg bw. Furthermore, no behavioural changes and no abnormal clinical signs were observed in both the control and the test item group, and no adverse influence on body weight development and food consumption could be determined. A summary of the relevant endpoint is given below.

Study comments: IIIA 10.1.6/01	Test system: Test method: Test item: Test conc.: GLP: Validity:	Japanese quail, acute oral toxicity test, 14 days SETAC Guideline Document (1995), EPA OPPTS 850.2100 (1996) MCW-853 SC (nominal a.s. content: 200 g dimethomorph/L, 200 g fluazinam/L) 2000 mg prod./kg bw (limit test) Yes Considered valid without restrictions
Agreed endpoint/s: IIIA 10.1.6/01	LD_{50} (14 d)	> 2000 mg prod./kg bw

IIIA 10.1.7 Supervised cage or field trials

IIIA 10.1.8 Acceptance of bait, granules or treated seeds (palatability testing)

IIIA 10.2 Effects on aquatic organisms

IIIA 10.2.2 Acute toxicity (aquatic) of the preparation

IIIA 10.2.2.1 Fish acute toxicity LC_{50}, freshwater, cold-water species

Report:	**KIIIA1 10.2.2.1/01, [redacted]. (2009)**
Title:	Acute toxicity of MCW-853 SC to rainbow trout (*Oncorhynchus mykiss*) in a 96-hour flow through test
Testing facility:	IBACON GmbH, Rossdorf, Germany
Document No:	42126230, sponsor report no.: R-23923
Guidelines:	Directive 92/69/ EC C.1 (1992). OECD 203 (1992). Deviation: none
GLP	**Yes (certified laboratory)**

Comments zRMS:	**Acceptable. Used in evaluation.**

Executive summary

Groups of 7 rainbow trout were exposed for 96 hours to nominal test concentrations of 0.1, 0.2, 0.5, 1.1 and 2.3 mg MCW-853 SC/L SC under flow-through conditions. A control group exposed to reconstituted water without test item was run concurrently. The fish were observed for symptoms of intoxication and mortality after 2, 24, 48, 72 and 96 hours.

Under the conditions of this study, the LC_{50} was established at 0.7 mg prod./ha. Furthermore, no adverse sublethal effects were observed at and below a nominal test concentration of 0.5 mg prod./L. Thus, the NOEC (0 - 96 h) was directly deduced from this observation.

I. Materials and methods

A. Materials

1. Test material: MCW-853 SC
   Description: orange, liquid
   Lot/Batch no.: 175-191107-02
   Active ingredient content: dimethomorph: 211 g/L (certified)
   fluazinam: 211 g/L (certified)
   Stability of test compound: date of expiry: November 22, 2009

2. Control: reconstituted water without test item
   Solvent/vehicle: none
   Toxic reference: none

3. Test organisms -
   Species: Rainbow trout (*Oncorhynchus mykiss*)
   Age: juvenile
   Mean body length: 3.83 ± 0.24 cm
   Mean body weight: 0.66 ± 0.18 g
   Source: Forellenzuchtbetrieb Wagenhausen, Bad Saulgau, Germany
   Acclimatisation period: not stated
   No of fish: 7 fish per replicate per group, 6 groups (5 test item rates and 1 control)
   Feeding during test: none

4. Test units and exposure -
   Type and size: 15 L glass aquaria with 13.9 L test medium
   Test procedure: flow-through
   Exposure time: 96 hours

5. Test conditions -
   Test medium: reconstituted water
   pH value: 7.2 - 7.8
   Environmental conditions -
   Water temperature: 13 - 14 °C
   Aeration: gentle aeration was provided
   Photoperiod: 16 hours light/ 8 hours dark

Light intensity: 520 - 980 lux
Dissolved oxygen: 89.8 - 98.5 % of air saturation value

B. Study design and method

1. In life dates: July 30 to August 04, 2009

2. Test method:

Groups of 7 fish were exposed for 96 hours under flow-through conditions to nominal test concentrations of:

- 0.1, 0.2, 0.5, 1.1 and 2.3 mg prod./L

A control was implemented with reconstituted water without test substance or other additives. The fish were observed for symptoms of intoxication and mortality after 2, 24, 48, 72 and 96 hours. Water temperature, pH-values and dissolved oxygen concentrations were measured at the beginning of the test and every 24 hours. Also the behaviour of the test item in all test concentrations was determined once every day during the test.

3. Analysis of test item concentrations:

Analytical verification of the active ingredient Fluazinam was performed at test start and test end by means of HPLC.

4. Statistics

LC_0 (96 h) and LC_{100} (96 h), which lead to 0 and 100 % mortality, as well as the NOEC, which represents the highest tested concentration without lethal or other effects, were determined directly from the test results. LC_{50}-values were calculated by probit analysis.

II. Results and discussion

A. Analytical data

1. Method validation

The analytical system gave a linear response over the whole range of prepared standards. Linearity (r^2) of the calibration curves was 0.9997 for fluazinam and 0.9999 for dimethomorph. Accuracy (RR) and precision (RSD) were determined for eight replicates of a fortified concentration of 0.2 and 2.0 mg prod./L and resulted in mean recovery rates of 91 % (mean RSD = 9 %) for fluazinam and 101 % (mean RSD = 9 %) for dimethomorph (required: RR = 70 - 110 %, RSD ≤ 20 %). The limit of quantification was 0.2 mg test item/L for fluazinam and dimethomorph.

2. Analytical verification of the active substance

The concentrations of fluazinam and dimethomorph were determined at test start and test end. The concentrations measured for dimethomorph were within a range of 99 - 135 % of nominal concentrations. Particularly the correct dosing was demonstrated for 0.5 and 1.1 mg prod./L, but the test medium of 2.3 mg prod./L was overdosed. Since this treatment level was above the LC_{100} of 1.1 mg prod/L, this does not influence the integrity of the study. For fluazinam, the recovery rates were in the range 44 - 82 % of the nominal mean values. This might be caused by precipitation. However, since the correct dosing of the test item could be demonstrated by measurement of dimethomorph, this

was considered not to influence the integrity of the study, and endpoints are related to nominal concentrations of the test item.

B. Mortality

No lethal effects were observed at and below a nominal test item concentration of 0.5 mg/L. Therefore the LC_0 (96 h) was determined at 0.5 mg prod./L. Data concerning mortality during the test duration are summarised in the table below.

Table 10- 3: Cumulative mortality [number of fish] of rainbow trout during the test period

Nominal concentrations [mg prod./L]	Test duration [h]				
	2	24	48	72	96
control	0	0	0	0	0
0.1	0	0	0	0	0
0.2	0	0	0	0	0
0.5	0	0	0	0	0
1.1	0	7	7	7	7
2.3	0	7	7	7	7

C. Toxicological symptoms

Above a test concentration of 0.5 mg prod./L all fish showed strong ventilation just after the introduction into the test aquaria. After two hours in the test concentration of 1.1 mg/L, tumbling, apathy and fish lying on the side or back were observed. At concentrations of 2.3 mg/L additionally dark coloured fish occurred after two hours. In both test concentrations all fish were dead after 24 hours. Therefore the NOEC and LOEC (0-96 h) were determined at 0.5 mg prod./L and 1.1 mg prod./L, respectively.

D. Deficiencies

No fish in the control died during the test (required: < 10 %), and the dissolved oxygen concentration was above the air saturation value of 60 % throughout the test. Thus, the test was considered to be valid without restrictions.

III. Conclusions

In a 96-hour acute toxicity test, groups of rainbow trout (*Oncorhynchus mykiss*) were exposed to MCW-853 SC (a.s. content: 211 g fluazinam/L, 211 g dimethomorph/L) applied at concentrations ranged from 0.1 to 2.3 mg prod./L under flow-through conditions. A control group exposed to dilution water without test item was run concurrently. Under the conditions of this study, the LC_{50} was established at 0.7 mg prod./L. Furthermore, no adverse sublethal effects were observed at and below a nominal test concentration of 0.5 mg prod./L. Thus, the NOEC (0 - 96 h) was directly deduced from this observation. The relevant endpoints defined by mortality and intoxication symptoms observed in fish are summarised in the table below:

Study comments: IIIA 10.2.2.1/01	Test system:	*Oncorhynchus mykiss*, acute toxicity test (flow-through), 96 h
	Test method:	Directive 92/69/ EC C.1 (1992). OECD 203 (1992)
	Test item:	MCW-853 SC (nominal a.s. content: 200 g fluazinam/L, 200 g dimethomorph/L)

	Test conc.: 0.1, 0.2, 0.5, 1.1 and 2.3 mg prod./L (nominal) GLP: Yes Validity: Considered valid without restrictions
Agreed endpoint/s: IIIA 10.2.2.1/01	LC_{50} (96 h) = 0.7 mg prod./L (nominal)

Report:	KIIIA1 10.2.2.1/02, [redacted]., 2009
Title:	Acute toxicity of MCW-853 SC to zebrafish (*Danio rerio*) in a 96-hour flow through test
Testing facility:	IBACON GmbH, Rossdorf Germany
Document No:	42146230, sponsor report no.: R-23924
Guidelines:	Directive 92/69/ EC C.1 (1992), OECD 203 (1992). Deviations: none
GLP	Yes (certified laboratory)
Comments zRMS:	**Acceptable. Additional information.**

Executive summary

7 zebrafish per group were exposed to nominal test concentrations of 0.20, 0.44, 0.97, 2.13 and 4.69 mg/L MCW-853 SC for 96 hours under flow-through conditions. A control group exposed to reconstituted water without test item was run concurrently. The fish were observed for symptoms of intoxication and mortality after approximately 2, 24, 48, 72 and 96 hours.

Under the conditions of this study, LC_{50} (96 h) and NOEC (0 - 96 h) were determined at nominal concentrations of 0.76 mg prod./L and 0.44 mg prod./L, respectively.

I. Materials and methods

A. Materials

A. Materials

1. Test material: MCW-853 SC
   Description: orange, liquid
   Lot/Batch no.: 175-191107-02
   Active ingredient content: dimethomorph: 211 g/L (certified)
   fluazinam: 211 g/L (certified)
   Stability of test compound: date of expiry: November 22, 2009

2. Control: reconstituted water without test item
   Solvent/vehicle: none
   Toxic reference: none

3. Test organisms -
   Species: Zebrafish (*Danio rerio*)

Age:	juvenile
Mean body length:	2.75 cm ± 0.16 cm
Mean body weight:	0.14 ± 0.3 g
Source:	Aquarium Glaser, Rodgau, Germany
Acclimatisation period:	not stated
No of fish:	7 fish per group, 6 groups (5 test item rates and 1 control)
Feeding during test:	none

4. Test units and exposure -

Type and size:	15 L glass aquaria with 13.9 L test item
Test procedure:	flow-through
Exposure time:	96 hours

5. Test conditions -

Test medium:	reconstituted water
pH value:	7.3 - 7.9
Environmental conditions -	
Water temperature:	25 - 26 °C
Aeration:	gentle aeration was provided
Photoperiod:	16 hours light/8 hours dark
Light intensity:	410 - 1200 lux
Dissolved oxygen:	88 - 100 % of air saturation value

B. Study design and method

1. In life dates: September 22 to September 26, 2008

2. Main test:

Groups of 7 fish were exposed for 96 hours under flow-through conditions to nominal test concentrations of:

- 0.20, 0.44, 0.97, 2.13 and 4.69 mg prod./L

A control was implemented with reconstituted water without test substance or other additives. The fish were observed for symptoms of intoxication and mortality after approximately 2, 24, 48, 72 and 96 hours. Water temperature, pH-values and dissolved oxygen concentrations were measured at the beginning of the test and every 24 hours.

3. Analysis of test item concentrations:

Analytical verification of the active ingredient fluazinam and dimethomorph was performed at test start and test end by means of HPLC.

4. Statistics

LC_0 (96 h) and LC_{100} (96 h), which lead to 0 and 100 % mortality, as well as the NOEC, which represents the highest tested concentration without lethal or other effects, were determined directly from the test results. LC_{50}-values were calculated by probit analysis.

II. Results and discussion

A. Analytical data

1. Method validation

The analytical system gave a linear response over the whole range of prepared standards. Linearity (r^2) of the calibration curves was 0.9991 for fluazinam and 0.9998 for dimethomorph. Accuracy (RR) and precision (RSD) were determined for replicates of fortified concentrations of 0.2, 0.5 and 5 mg prod./L and resulted in recovery rates of 109 % (n = 8; mean RSD = 15 %) for fluazinam and 108 % (n = 11; mean RSD = 14 %) for dimethomorph (required: RR = 70 - 110 %, RSD ≤ 20 %). The limit of quantification was set to 0.5 mg test item/L for fluazinam and 0.2 mg test item/L for dimethomorph.

2. Analytical verification of the active substance

The concentrations of fluazinam and dimethomorph were determined at test start and test end by means of HPLC. The concentrations measured for dimethomorph were within a range of 84 - 98 % of nominal concentrations. For fluazinam, the analytical values ranged from 66 to 155 % of the nominal concentrations. For the test concentrations of 0.44 - 4.69 mg prod./L, the reduced recovery rates might be caused by precipitation. However, since a formulation was tested and correct dosing could be demonstrated by analysis of dimethomorph, all reported results are related to nominal concentrations of the test item.

B. Mortality

No lethal effects were observed in the control group as well as at and below a nominal test concentration of 0.44 mg prod./L. Therefore the LC_0 (96 h) was determined at 0.44 mg prod./L. Data concerning mortality during the test duration are summarised in the table below.

Table 10- 4: Cumulative mortality [number of fish] of zebrafish during the test period

Nominal concentration [mg prod./L]	Test duration [h]				
	2	24	48	72	96
Control	0	0	0	0	0
0.20	0	0	0	0	0
0.44	0	0	0	0	0
0.97	0	4	5	6	6
2.13	4	7	7	7	7
4.69	5	7	7	7	7

C. Toxicological symptoms

No signs of intoxication occurred up to and including a test concentration 0.44 mg prod./L. Above an exposure level of 0.44 mg prod./L, symptoms observed were some fish lying on their side or back.

D. Deficiencies

No fish in the control died during the test (required: < 10 %), and the dissolved oxygen concentration was above the air saturation value of 60 % throughout the test. Thus, the test was considered to be valid without restrictions.

III. Conclusions

In a 96-hour acute toxicity test, groups of zebrafish (*Danio rerio*) were exposed to MCW-853 SC (a.s. content: 211 g fluazinam/L and 211 g dimethomorph/L) applied at concentrations ranged from 0.2 to 4.69 mg prod./L under flow-through conditions. A control group exposed to reconstituted water without test item was run concurrently. Under the conditions of this study, the LC_{50} was established at 0.76 mg prod./L. Furthermore, no adverse sublethal effects were observed at and below a nominal test concentration of 0.44 mg prod./L. Thus, the NOEC (0 - 96 h) was directly deduced from this observation. The relevant endpoints defined by mortality and intoxication symptoms observed in fish are summarised in the table below:

Study comments: IIIA 10.2.2.1/02	Test system: *Danio rerio*, acute toxicity test (flow-through), 96 h Test method: Directive 92/69/ EC C.1 (1992), OECD 203 (1992) Test item: MCW-853 SC (nominal a.s. content: 200 g fluazinam/L, 200 g dimethomorph/L) Test conc.: 0.20, 0.44, 0.97, 2.13 and 4.69 mg prod./L (nominal) GLP: Yes Validity: Considered valid without restrictions
Agreed endpoint/s: IIIA 10.2.2.1/02	LC_{50} (96 h) = 0.76 mg prod./L (nominal)

Acute toxicity data on metabolites, considered relevant for the risk assessment

Additionally, since Annex I inclusion acute fish toxicity tests with HYPA (minor metabolite of fluazinam in aquatic systems, but major metabolite in soil) and G-504 have been conducted which are summarised in the following.

Report:	KIIIA1 10.2.2.1/03, [redacted] 2010
Annex II point:	IIA 8.2.1.3
Title:	Acute Toxicity of HYPA to Rainbow trout (*Oncorhynchus mykiss*) in a 96-hour Static Test
Testing facility:	IBACON GmbH
Document No:	48365230, Sponsor no.: R-26738
Guidelines:	OECD 203 (1992) Deviations: none
GLP	Yes (certified laboratory)
Comments zRMS:	**Acceptable. Additional information.**

Executive summary

7 rainbow trout per group were exposed to nominal test concentrations of 0.85, 1.9, 4.1, 9.1 and 20 mg test item/L for 96 hours under static conditions. A control group exposed to dilution water without test item was run concurrently. The fish were observed for symptoms of intoxication and mortality after approximately 2, 24, 48, 72 and 96 hours.

Analytical verification of test item concentration was performed at test start and test end via HPLC. The concentrations of HYPA were determined at test start and test end by means of HPLC. The recovery rates

were within the range of 80 - 120 %, i.e. 97 - 100 %. Therefore, LC-values are given as nominal test item concentrations.

Under the conditions of this study, no mortality was observed at and below a nominal test item concentration of 1.9 mg test item/L. Therefore the LC_0 (96 h) was determined at 1.9 mg test item/L. The LC_{50} (96 h) were determined at a nominal concentration of 3.1 mg test item/L.

I. Materials and methods

A. Materials

1. Test material: HYPA
   Description: light-yellow, solid
   Lot/Batch no.: 381-194-00
   Purity: 93.06 %
   Stability of test compound: date of expiry: July 28, 2011

2. Control: reconstituted water without test item
   Solvent: none
   Toxic reference: none

3. Test organisms -
   Species: Rainbow trout (*Oncorhynchus mykiss*)
   Age: juveniles
   Mean body length: 5.21 cm
   Mean body weight: 1.29 g
   Source: Forellenzuchtbetrieb Roth, Eichenzell-Döllbach, Germany
   Acclimatisation period: 12 days
   No of fish: 7 fish per replicate, 1 replicate per test concentration and control
   Feeding during test: none

4. Test units and exposure -
   Type and size: glass aquaria with 12 L test volume
   Test procedure: static
   Exposure time: 96 hours

5. Test conditions -
   Test medium: deionised water
   Water hardness: 250 mg $CaCO_3$/L
   pH value: 7.8 - 7.9
   Environmental conditions -
   Water temperature: 14 - 16 °C
   Aeration: gentle aeration was provided
   Photoperiod: 16 h light : 8 h dark
   Light intensity: 470 - 1010 lux
   Dissolved oxygen: 96 - 106 % of air saturation value

B. Study design and method

1. In life dates: April 19 to 23, 2010

2. Range finding test:

A preliminary range finding test was performed to define the test concentrations for the main test.

3. Main test:

Groups of 7 fish were exposed for 96 hours under static conditions to nominal test concentrations of:

- 0.85, 1.9, 4.1, 9.1 and 20 mg test item/L

A control was implemented with test medium without test substance or other additives. The fish were observed for symptoms of intoxication and mortality after approximately 2, 24, 48, 72 and 96 hours. Water temperature, pH-values and dissolved oxygen concentrations were measured at the beginning of the test and every 24 hours.

4. Analysis of test item concentrations:

Analytical verification of the test substance HYPA was performed at test start and test end by means of HPLC.

5. Statistics

The LC_{50} at the observation times was calculated by Probit analysis. The NOEC, the LOEC, the LC_0 and the LC_{100} were determined directly from the raw data.

II. Results and discussion

A. Analytical data

1. Method validation

The analytical system gave a linear response over the whole range of prepared standards. Linearity (r^2) of the calibration curves was 0.9999. Accuracy (RR) and precision (RSD) were determined resulted in mean recovery in the fortified samples of 99 % (n = 10, mean RSD = 4 %) for HYPA (required: RR = 70 - 110 %, RSD ≤ 20 %). The limit of quantification was set to 0.75 mg test item/L.

2. Analytical verification of the active substance

The concentrations of HYPA were determined at test start and test end by means of HPLC. The recovery rates were within the range of 80 - 120 %, i.e. 97 - 100 %. Therefore, LC-values are given as nominal test item concentrations.

B. Mortality

No mortality was observed at and below a nominal test item concentration of 1.9 mg test item/L. Therefore the LC_0 (96 h) was determined at 1.9 mg test item/L. Data concerning mortality during the test duration are summarised in the table below.

Table 10- 5: Cumulative mortality of rainbow trout during the test period

Nominal concentration [mg test item/L]	Test duration [h]				
	2	24	48	72	96
Control	0/7	0/7	0/7	0/7	0/7
0.85	0/7	0/7	0/7	0/7	0/7
1.9	0/7	0/7	0/7	0/7	0/7
4.1	0/7	4/7	4/7	6/7	6/7
9.1	1/7	7/7	7/7	7/7	7/7
20	7/7	7/7	7/7	7/7	7/7

C. Toxicological symptoms

At 0.85 mg test item/L one fish showed strong ventilation and extended gills after 72 h. At 9.1 mg/L tumbling, strong ventilation and mainly swimming at the water surface and on the bottom were observed at 2 hours. At 4.1 mg/L six fish showed strong ventilation after 2 h and after 24 h three fish displayed extended gills and swimming at the water surface. After 72 h one fish showed strong ventilation and extended gills until the end of the test. Therefore the 96-hour NOEC was determined at 1.9 mg test item/L.

D. Deficiencies

The validity criteria were fulfilled without any restictions: No fish in the control died during the test and the dissolved oxygen concentration was above the air saturation value of 60 % throughout the test. Furthermore, the concentrations of HYPA were satisfactorily maintained between 94 and 103 % of nominal values. Therefore, LC-values are given as nominal test item concentrations.

III. Conclusions

In a 96-hour acute toxicity test, groups of rainbow trout (*Oncorhynchus mykiss*) were exposed to HYPA under static conditions. A control group exposed to dilution water without test item was run concurrently. No mortality was observed at and below a nominal test concentration of 1.9 mg test item/L. The NOEC (96 h), which represents the highest tested concentration without any significant toxicological effects compared to the control, was determined at a nominal test concentration of 1.9 mg test item. The relevant endpoints defined by mortality observed in fish are summarised in the table below:

Study comments: IIIA 10.2.2.1/03	Test system: *Oncorhynchus mykiss*, acute toxicity test (static), 96 h Test method: OECD 203 (1992) Test item: HYPA (purity: 93.06 %) Test conc.: 0.85, 1.9, 4.1, 9.1 and 20 mg test item/L GLP: Yes Validity: Considered valid without restrictions
Agreed endpoint/s: IIIA 10.2.2.1/03	LC_{50} (96 h) = 3.1 mg test item/L (nominal)

Report:	KIIIA1 10.2.2.1/04, [redacted] 2011
Annex II point:	IIA 8.2.1.3
Title:	Acute Toxicity of G-504 to Rainbow trout (*Oncorhynchus mykiss*) in a 96-hour Static Test
Testing facility:	IBACON GmbH
Document No:	63083230, Sponsor no.: R-28033
Guidelines:	OECD 203 (1992) Deviations: none
GLP	Yes (certified laboratory)
Comments zRMS	**Acceptable. Used in evaluation.**

Executive summary

7 rainbow trout per group were exposed to nominal test concentrations of 6.69, 13.3, 26.5, 50.5 and 103 mg G-504/L for 96 hours under static conditions. A control group exposed to dilution water without test item was run concurrently. The fish were observed for symptoms of intoxication and mortality after approximately 2, 24, 48, 72 and 96 hours.

Analytical verification of test item concentration was performed at test start and test end via HPLC-UV. The mean recovery rates were 105 % and 104 % of nominal test concentrations at test start and test end, respectively. Since a filtrate and its dilutions were tested, all results relate to mean measured concentrations.

Under the conditions of this study, no mortality was observed at any of the tested concentrations and in the control group. Therefore, the LC_{50} (96 h) was determined above the highest test concentration of 103 mg test item/L. Furthermore, no fish showed any sublethal effects during the exposure time.

I. Materials and methods

A. Materials

1. Test material: G-504
   Description: solid, yellow
   Lot/Batch no.: EPP / RH 693.14
   Purity: 98.5 % (certified)
   Stability of test compound: date of expiry: January 17, 2012

2. Control: reconstituted water without test item
   Solvent/Vehicle: none
   Toxic reference: none

3. Test organisms -

Species:	Rainbow trout (*Oncorhynchus mykiss*)
Age:	juveniles
Mean body length:	4.84 cm
Mean body weight:	1.02 g
Source:	Forellenzuchtbetrieb Störk, Bad Saulgau, Germany
Acclimatisation period:	12 days
No of fish:	7 fish per replicate, 1 replicate per test concentration and control
Feeding during test:	none

4. Test units and exposure -

Type and size:	glass aquaria with 12 L test volume
Test procedure:	static
Exposure time:	96 hours

5. Test conditions -

Test medium:	deionised water
pH value:	7.6 - 8.0
Water temperature:	14 °C
Aeration:	gentle aeration was provided
Photoperiod:	16 h light : 8 h dark
Light intensity:	500 - 980 lux
Dissolved oxygen:	85 - 98 % of air saturation value

B. Study design and method

1. In life dates: January 30 to February 04, 2011

2. Test design:

Groups of 7 fish were exposed for 96 hours under static conditions to mean measured test concentrations of:

- 6.69, 13.3, 26.5, 50.5 and 103 mg test item/L

A control was implemented with test medium without test substance or other additives. The fish were observed for symptoms of intoxication and mortality after approximately 2, 24, 48, 72 and 96 hours. Water temperature, pH-values and dissolved oxygen concentrations were measured at the beginning of the test and every 24 hours.

3. Analysis of test item concentrations:

Analytical verification of the test substance G-504 was performed at test start and test end by means of HPLC-UV.

4. Statistics

A well-defined LC_{50} was not determinable in view of effects below 50 % at the highest test concentration. The NOEC, the LOEC and the LC_0 were determined directly from the raw data.

II. Results and discussion

A. Analytical data

1. Method validation

The analytical system gave a linear response over the whole range of prepared standards. Linearity (r^2) of the calibration curves was 0.9999. Accuracy (RR) and precision (RSD) were determined resulted in mean recovery in the fortified samples of 101 % (n = 12, mean RSD = 2 %) for G-504 (required: RR = 70 - 110 %, RSD ≤ 20 %). The limit of quantification was set to 4.0 mg test item/L.

2. Analytical verification of the active substance

The concentrations of G-504 were determined at test start and test end by means of HPLC-UV. The mean recovery rates were 105 % and 104 % of nominal test concentrations at test start and test end, respectively. Since a filtrate and its dilutions were tested, all results relate to mean measured concentrations.

B. Mortality

No mortality was observed at any of the tested concentrations and in the control group. Therefore, the LC_{50} (96 h) was determined above the highest test concentration of 103 mg test item/L. Data concerning mortality during the test duration are summarised in the table below.

Table 10- 6: Cumulative mortality of rainbow trout during the test period

Mean measured concentration [mg test item/L]	Test duration [h]				
	2	24	48	72	96
Control	0/7	0/7	0/7	0/7	0/7
6.69	0/7	0/7	0/7	0/7	0/7
13.3	0/7	0/7	0/7	0/7	0/7
26.5	0/7	0/7	0/7	0/7	0/7
50.5	0/7	0/7	0/7	0/7	0/7
103	0/7	0/7	0/7	0/7	0/7

C. Toxicological symptoms

In the control and in all test concentrations, all fish survived until the end of the study and showed no sublethal effects during the exposure time. Therefore, the 96-hour NOEC was determined at the highest test concentration of 103 mg test item/L.

D. Deficiencies

No fish in the control died during the test and the dissolved oxygen concentration was above the air saturation value of 60 % throughout the test. Thus, the validity criteria given by the underlying guideline were fulfilled and the study is considered valid without restrictions.

III. Conclusions

In a 96-hour acute toxicity test, groups of rainbow trout (*Oncorhynchus mykiss*) were exposed to G-504 under static conditions. A control group exposed to dilution water without test item was run concurrently. Under the conditions of this study, no mortality was observed at any of the tested concentrations and in the control group. Therefore, the LC_{50} (96 h) was determined above the highest test concentration of 103 mg test item/L. Furthermore, no fish showed any sublethal effects during the exposure time. The relevant endpoints defined by mortality observed in fish are summarised in the table below:

Study comments: IIIA 10.2.2.1/04	Test system: *Oncorhynchus mykiss*, acute toxicity test (static), 96 h Test method: OECD 203 (1992) Test item: G-504 (purity: 98.5 %) Test conc.: 6.69, 13.3, 26.5, 50.5 and 103 mg test item/L (mean measured) GLP: Yes Validity: Considered valid without restrictions
Agreed endpoint/s: IIIA 10.2.2.1/04	LC_{50} (96 h) > 103 mg test item/L (mean measured)

IIIA 10.2.2.2 Acute toxicity (24 & 48 h) for Daphnia preferably Daphnia magna

Report:	**KIIIA1 10.2.2.2/01, Kuhl, R. & Wydra V., 2009**
Title:	Acute toxicity of MCW-853 SC to *Daphnia magna* in a static 48-hour immobilisation test
Testing facility:	IBACON GmbH, Rossdorf, Germany
Document No:	42125220, sponsor report no.: R-23922
Guidelines:	OECD 202 (2004); Directive 92/69/EC Method C.2 L 383A/172 (1992) Deviations: none
GLP	**Yes (certified laboratory)**
Comments zRMS	**Acceptable. Used in evaluation.**

Executive summary

Groups of 20 daphnids were exposed to test concentrations of 0.09, 0.19, 0.41, 0.91 and 2.0 mg prod./L of MCW-853 SC (active ingredient content: 211 g fluazinam/L and 211 g dimethomorph/L) for 48 hours under static conditions. A control group exposed to reconstituted water without test item was run concurrently. The invertebrates were observed for immobilisation after 24 and 48 hours of exposure.

Analytical verification of test item concentrations was performed at test start and test end via HPLC. Measured concentrations of fluazinam were in the range of 77 - 110 %, and dimethomorph was found at 110 % of the nominal concentrations.

Under the conditions of this study, the EC_{50} (48 h), which leads to 50 % immobilisation was calculated to be 0.482 mg prod./L.

I. Materials and methods

A. Materials

1. Test material: MCW-853 SC
   Description: orange, liquid
   Lot/Batch no.: 175-191107-02
   Active ingredient content: dimethomorph: 211 g/L (certified)
   fluazinam: 211 g/L (certified)
   Stability of test compound: date of expiry: November 22, 2009

2. Control: reconstituted water without test item
   Solvent/vehicle: none
   Toxic reference: separate test performed with potassium dichromate

3. Test organisms -
   Species: female *Daphnia magna*, clone 5
   Age: 6.75 - 22.5 hours old
   Source: bred in-house
   Acclimatisation: 6.75 h
   Feeding: not stated
   No of *Daphnia*: 20 animals/group, 6 groups (5 for the test item, 1 for the control), groups divided into 4 replicates of 5 animals

4. Test units and exposure -
   Type and size: 100 mL glass beakers with 80 mL test medium, covered with a lid
   Test procedure: static
   Exposure time: 48 hours

5. Test conditions -
   Test medium: reconstituted water acc. to EC method C.2 (92/69/EC)
   Water temperature: 20 - 21 °C
   pH value: 7.6 - 7.9
   Environmental conditions -
   Photoperiod: 16 hours light/8 hours dark
   Light intensity: 280 - 370 lux
   Dissolved oxygen: 8.5 - 9.0 mg/L

B. Study design and method

1. In life dates: September 23 to 25, 2008

2. Main test:

Groups of 20 daphnids were exposed for 48 hours under static conditions to test concentrations of:

- 0.09, 0.19, 0.41, 0.91 and 2.0 mg prod./L

A control with test medium without test substance was run concurrently. The invertebrates were observed for immobilisation after 24 and 48 hours of exposure. The pH-values, dissolved oxygen and water temperature concentrations were measured in the test media of all test concentrations and the control. Additionally the temperature was measured at test end in one control beaker.

3. Analysis of test item concentrations:

Analytical verification of the test item concentrations was performed at test start and test end. The concentrations of fluazinam and dimethomorph were determined by means of HPLC.

4. Statistics

EC_{100}-, LOEC- and NOEC-values after 48 h were deduced directly from the raw data. EC_{50}-value after 24 h and 48 h were calculated by moving average computations.

II. Results and discussion

A. Analytical data

1. Method validation

The analytical system gave a linear response over the whole range of prepared standards. Linearity (r^2) of the calibration curves was 0.9998 for fluazinam and dimethomorph. Accuracy (RR) and precision (RSD) were determined for replicates of fortified concentrations of 0.09, 0.2 and 2.0 mg prod./L and resulted in recovery rates of 84 % (n = 12; mean RSD = 7 %) for fluazinam and 105 % (n = 12; mean RSD = 4 %) for dimethomorph (required: RR = 70 - 110 %, RSD ≤ 20 %). The limit of quantification was set to 0.09 mg test item/L for fluazinam and dimethomorph.

2. Analytical verification of the active substance

Mean recovery rates of dimethomorph were determined at 110 % (at test start and end) of the nominal concentrations. Measured concentrations of fluazinam were in the range of 110 % at test start to 77 % at test end. Since a formulation was tested and correct dosing could be demonstrated by analysis of dimethomorph, all reported results are related to nominal concentrations of the test item.

B. Immobilisation

No immobilisation was observed after 48 h in the control group as well as at and below a nominal test item concentration of 0.19 mg prod./L. At the test concentration of 0.41 mg prod./L, six animals were immobile (30 %), whereas 20 animals were immobile at the concentrations of 0.91 and 2.0 mg/L. Immobilisation data during the test duration are summarised in the table below.

Table 10- 7: Mean immobilisation (%) of daphnids during the test period

Nominal concentration [mg prod./L]	Mean immobilisation [%]	
	24 h	48 h
Control	0	0
0.09	0	0
0.19	0	0
0.41	0	30
0.91	85	100
2.0	90	100

C. Deficiencies

No daphnids in the control group were immobilised after 48 hours of exposure. The dissolved oxygen concentration was > 3 mg/L throughout the test, and the pH was maintained within 1 unit of variation. Furthermore, the EC_{50} (24 h) for the reference substance, determined in a separate test, was 1.214 mg/L (required: 0.6 - 2.1 mg/L). Thus, the test was considered to be valid without restrictions.

III. Conclusions

In a 48-hour acute toxicity test, groups of *Daphnia magna* were exposed to MCW-853 SC (active ingredient content: 211 g fluazinam/L and 211 g dimethomorph/L) applied at concentrations ranged from 0.09 to 2.0 mg prod./L under static conditions. A control group exposed to dilution water without test item was run concurrently. No immobilisation after 48 h was observed at and below a nominal test item concentration of 0.19 mg prod./L. The LC_{50} (48 h) was determined at 0.482 mg prod./L. The following endpoints based on nominal concentrations of BANJO FORTE were established:

Study comments: IIIA 10.2.2.2/01	Test system: *Daphnia magna*, acute immobilisation test (static), 48 h Test method: OECD 202 (2004); Directive 92/69/EC Method C.2 L 383A/172 (1992) Test item: MCW-853 SC (nominal a.s. content: 200 g fluazinam/L, 200 g dimethomorph/L) Test conc.: 0.09, 0.19, 0.41, 0.91 and 2.0 mg prod./L (nominal) GLP: Yes Validity: Considered valid without restrictions
Agreed endpoint/s: IIIA 10.2.2.2/01	EC_{50} (24 h) = 0.721 mg prod./L (nominal) EC_{50} (48 h) = 0.482 mg prod./L (nominal)

Acute toxicity data on metabolites, considered relevant for the risk assessment

Additionally, since Annex I inclusion acute immobilisation tests with HYPA (minor metabolite of fluazinam in aquatic systems, but major metabolite in soil) and G-504 have been conducted which are summarised in the following.

Report:	KIIIA1 10.2.2.2/02, [redacted], 2010
Annex II point:	IIA 8.3.1.1
Title:	Acute Toxicity of HYPA to *Daphnia magna* in a Static 48-hour Immobilisation Test
Testing facility:	IBACON GmbH
Document No:	48364220, Sponsor no.: R-26737
Guidelines:	OECD 202 (2004) Deviations: none
GLP	Yes (certified laboratory)
Comments zRMS	**Acceptable. Additional information.**

Executive summary

Groups of 20 daphnids (divided into 4 groups of 5 animals) were exposed to five test concentrations (1.0, 2.2, 4.8, 11 and 23 mg test item/L) of HYPA (major metabolite of fluazinam in soil) for 48 hours under static conditions. A control group exposed to dilution water without test item was run concurrently. The invertebrates were observed for immobilisation after 24 and 48 hours of exposure.

Analytical verification of test item concentrations was performed at test start and test end via HPLC. At the start of the test 93 % of the nominal test concentration was found (average of all test concentrations). After 48 hours test duration, 92 % of the nominal value was determined (average of all test concentrations). Therefore, all effect levels are given as nominal test item concentrations.

Under the conditions of this study, EC_{50} (48 h), which leads to 50 % immobilisation, and NOEC (48 h), which represents the highest tested concentration without significant effects on immobilisation compared to the control group, were determined at nominal concentrations of 1.824 mg test item/L and 1.0 mg test item/L, respectively.

I. Materials and methods

A. Materials

1. Test material: HYPA
   Description: light-yellow, solid
   Lot/Batch no.: 381-194-00
   Purity: 93.06 %
   Stability of test compound: date of expiry: July 28, 2011

2. Control: reconstituted water without test item
   Solvent: none
   Toxic reference: potassium dichromate

3. Test organisms -
   Species: *Daphnia magna* (Straus), clone 5
   Age: 6.5 - 22.5 hours old
   Source: bred in-house
   Acclimatisation: not necessary, since the test was performed in the same medium as the culturing
   Feeding: none (during the study)
   No of *Daphnia*: 20 animals/group divided into 4 groups of 5 animals

4. Test units and exposure -
   Type and size: 100 mL glass beakers with 80 mL test medium
   Test procedure: static
   Exposure time: 48 hours

5. Test conditions -
   Test medium: deionised water
   Water hardness: 250 mg $CaCO_3$/L
   pH value: 7.7 - 7.9
   Environmental conditions -
   Temperature: 21 °C
   Photoperiod: 16 h light : 8 h dark
   Light intensity: 900 - 1080 lux
   Dissolved oxygen: 8.4 - 8.6 mg/L

B. Study design and method

1. In life dates: July 28 to 30, 2010

2. Range finding test:

A preliminary range finding test was performed to define the test concentrations for the main test.

3. Main test:

Groups of 20 daphnids (divided into 4 groups of 5 animals) were exposed for 48 hours under static conditions to nominal test concentrations of:

- 1.0, 2.2, 4.8, 11 and 23 mg test item/L

A control with test medium without test substance was run concurrently. The invertebrates were observed for immobilisation after 24 and 48 hours of exposure. At test start and end the pH-values and the dissolved oxygen concentrations were determined in the test media of all test concentrations and the control. The water temperature was measured in the test media of all test concentrations and the control at test start and at the end of the test.

4. Analysis of test item concentrations:

Analytical verification of the test item concentration was performed at test start and test end. The concentrations of HYPA were determined by means of HPLC.

5. Statistics

The 24-hour and 48-hour EC50 and the 95 % confidence limits were calculated by Probit analysis. The NOEC and LOEC after 24 and 48 hours were determined directly from the raw data.

II. Results and discussion

A. Analytical data

1. Method validation

The analytical system gave a linear response over the whole range of prepared standards. Linearity (r^2) of the calibration curves was at least 0.9998. Accuracy (RR) and precision (RSD) were determined resulted in mean recovery in the fortified samples of 91 % (n = 14, mean RSD = 1 %) for HYPA (required: RR = 70 - 110 %, RSD ≤ 20 %). The limit of quantification was set to 1.0 mg test item/L.

2. Analytical verification of the active substance

The concentrations of HYPA were determined at test start and test end by means of HPLC. At the start of the test 93 % of the nominal test concentration was found (average of all test concentrations). After 48 hours test duration, 92 % of the nominal value was determined (average of all test concentrations). Therefore, all effect levels are given as nominal test item concentrations.

B. Immobilisation

No immobilisation after 48 h was observed at a nominal test item concentration of 1.0 mg test item/L. Therefore the NOEC (48 h) was determined at 1.0 mg test item/L. Immobilisation data during the test duration are summarised in the table below.

Table 10-8: Mean immobilisation (%) of daphnids during the test period

Nominal concentration [mg test item/L]	**Mean immobilisation [%]**	
	24 h	**48 h**
Control	0	0
1.0	0	0
2.2	65	95
4.8	80	100
11	95	100
23	95	100

C. Deficiencies

No daphnids in the control group were immobilised after 48 hours of exposure and no control daphnids were trapped on the surface of the water. The EC_{50} (24 h) for the reference substance was within the range of 1.0 - 2.5 mg/L (i.e. 1.59 mg/L derived from the most recent separate test). The dissolved oxygen concentration was > 3 mg/L (i.e. ≥ 7.8 mg/L) throughout the test, and the pH was maintained within 1 unit of variation. Furthermore, the test concentration was verified by analytical measurements to be within 80 - 120 % of nominal. Thus, the test was considered to be valid without restrictions.

III. Conclusions

In a 48-hour acute toxicity test, groups of *Daphnia magna* were exposed to HYPA under static conditions. A control group exposed to dilution water without test item was run concurrently. No immobilisation after 48 h was observed at a nominal test item concentration of 1.0 mg test item/L. Therefore the NOEC (48 h) was determined at 1.0 mg prod./L. The EC_{50} (48 h) was determined at 1.824 mg test item/L. The results of the study are summarised below:

Study comments: IIIA 10.2.2.2/02	Test system: *Daphnia magna*, acute immobilisation test (static), 48 h Test method: OECD 202 (2004) Test item: HYPA (purity: 93.06 %) Test conc.: 1.0, 2.2, 4.8, 11 and 23 mg test item/L (nominal) GLP: Yes Validity: Considered valid without restrictions
Agreed endpoint/s: IIIA 10.2.2.2/02	EC_{50} (24 h) = 2.512 test item/L (nominal) EC_{50} (48 h) = 1.824 test item/L (nominal)

Report:	KIIIA1 10.2.2.2/03, [redacted]., 2011
Annex II point:	IIA 8.3.1.1
Title:	Acute Toxicity of G-504 to *Daphnia magna* in a Static 48-hour Immobilisation Test
Testing facility:	IBACON GmbH

Document No:	63082220, Sponsor no.: R-28032
Guidelines:	OECD 202 (2004) Deviations: none
GLP	Yes (certified laboratory)
Comments zRMS	**Acceptable. Used in evaluation.**

Executive summary

Groups of 20 daphnids (divided into 4 groups of 5 animals) were exposed to five test concentrations (6.18, 12.5, 24.5, 49 and 98 mg test item/L) of G-504 for 48 hours under static conditions. A control group exposed to dilution water without test item was run concurrently. The invertebrates were observed for immobilisation after 24 and 48 hours of exposure.

The concentrations of G-504 were determined at test start and test end by means of HPLC-UV. The mean recovery rates were 97 % and 100 % of nominal test concentrations at test start and test end, respectively. Since a filtrate and its dilutions were tested, all results relate to mean measured concentrations.

Under the conditions of this study, no immobilisation was observed at any of the tested concentrations and in the control group. Therefore, the EC_{50} (48 h) was determined above the highest test concentration of 98 mg test item/L.

I. Materials and methods

A. Materials

1. Test material: G-504
   Description: solid, yellow
   Lot/Batch no.: EPP / RH 693.14
   Purity: 98.5 % (certified)
   Stability of test compound: date of expiry: January 17, 2012

2. Control: reconstituted water without test item
   Solvent/Vehicle: none
   Toxic reference: separate test performed with potassium dichromate

3. Test organisms -
   Species: *Daphnia magna* (Straus), clone 5
   Age: 6.5 - 23 hours old
   Source: bred in-house
   Acclimatisation: not necessary, since the test was performed in the same medium as the culturing
   Feeding: none (during the study)
   No of *Daphnia*: 20 animals/group divided into 4 groups of 5 animals

4. Test units and exposure -
   Type and size: 100 mL glass beakers with 60 mL test medium
   Test procedure: static
   Exposure time: 48 hours

5. Test conditions -

Test medium:	deionised water
pH value:	7.2 - 7.9
Water temperature:	19 - 21 °C
Aeration:	gentle aeration was provided
Photoperiod:	16 h light : 8 h dark
Light intensity:	700 - 880 lux
Dissolved oxygen:	5.6 - 8.8 mg/L

B. Study design and method

1. In life dates: February 01 to 04, 2011

2. Test design:

Groups of 20 daphnids (divided into 4 groups of 5 animals) were exposed for 48 hours under static conditions to mean measured test concentrations of:

- 6.18, 12.5, 24.5, 49 and 98 mg test item/L

A control with test medium without test substance was run concurrently. The invertebrates were observed for immobilisation after 24 and 48 hours of exposure. At test start and end the pH-values and the dissolved oxygen concentrations were determined in the test media of all test concentrations and the control. The water temperature was measured in the test media of all test concentrations and the control at test start and at the end of the test.

3. Analysis of test item concentrations:

Analytical verification of the test substance G-504 was performed at test start and test end by means of HPLC-UV.

4. Statistics

A well-defined EC_{50} was not determinable in view of effects below 50 % at the highest test concentration. The NOEC and LOEC were determined directly from the raw data.

II. Results and discussion

A. Analytical data

1. Method validation

The analytical system gave a linear response over the whole range of prepared standards. Linearity (r^2) of the calibration curves was 0.9999. Accuracy (RR) and precision (RSD) were determined resulted in mean recovery in the fortified samples of 100 % (n = 12, mean RSD = 2 %) for G-504 (required: RR = 70 - 110 %, RSD ≤ 20 %). The limit of quantification was set to 4.0 mg test item/L.

2. Analytical verification of the active substance

The concentrations of G-504 were determined at test start and test end by means of HPLC-UV. The mean recovery rates were 97 % and 100 % of nominal test concentrations at test start and test end, respectively. Since a filtrate and its dilutions were tested, all results relate to mean measured concentrations.

B. Immobilisation

No immobilisation was observed at any of the tested concentrations and in the control group. Therefore, the EC_{50} (48 h) was determined above the highest test concentration of 98 mg test item/L. Data concerning immobilisation during the test duration are summarised in the table below.

Table 10- 9: Mean immobilisation (%) of daphnids during the test period

Mean measured concentration [mg test item/L]	**Mean immobilisation [%]**	
	24 h	**48 h**
Control	0	0
6.19	0	0
12.5	0	0
24.5	0	0
49	0	0
98	0	0

C. Deficiencies

No daphnids in the control group were immobilised after 48 hours of exposure and no control daphnids were trapped on the surface of the water. The EC_{50} (24 h) for the reference substance was within the range of 1.0 - 2.5 mg/L (i.e. 1.63 mg/L derived from the most recent separate test). The dissolved oxygen concentration was > 3 mg/L (i.e. ≥ 5.6 mg/L) throughout the test, and the pH was maintained within 1 unit of variation. Thus, the test was considered to be valid without restrictions.

III. Conclusions

In a 48-hour acute toxicity test, groups of *Daphnia magna* were exposed to G-504 under static conditions. A control group exposed to dilution water without test item was run concurrently. No immobilisation was observed at any of the tested concentrations and in the control group. Therefore, the EC_{50} (48 h) was determined above the highest test concentration of 98 mg test item/L. The results of the study are summarised below:

Study comments: IIIA 10.2.2.2/03	Test system: *Daphnia magna*, acute immobilisation test (static), 48 h Test method: OECD 202 (2004) Test item: G-504 (purity: 98.5 %) Test conc.: 6.18, 12.5, 24.5, 49 and 98 mg test item/L (mean measured) GLP: Yes Validity: Considered valid without restrictions
Agreed endpoint/s: IIIA 10.2.2.2/03	EC_{50} (24 h) > 98 test item/L (mean measured) EC_{50} (48 h) > 98 test item/L (mean measured)

IIIA 10.2.2.3 Effects on algal growth and growth rate

Report:	**KIIIA1 10.2.2.3/01, [redacted] 2009**
Title:	Toxiciy of MCW-853 SC to *Desmodesmus subspicatus* in an algal growth inhibition test
Testing facility:	IBACON GmbH, Rossdorf, Germany
Document No:	42127210, sponsor report no.: R-23921
Guidelines:	OECD 201 (2006). Deviations: none
GLP	**Yes (certified laboratory)**
Comments zRMS	**Acceptable. Used in evaluation.**

Executive summary

A growth inhibition test was performed with the unicellular freshwater green alga *Desmodesmus subspicatus*. Three replicates with a initial cell concentration of approximately 5 x 10^3 cells/mL test medium were exposed to MCW-853 SC (active ingredient content: 211 g fluazinam/L and 211 g dimethomorph) applied at nominal concentrations of 1.0, 0.32, 0.10, 0.032, 0.010, 0.0032 and 0.0010 mg prod./L for 72 hours under static conditions. A control with 6 replicates exposed to reconstituted water without the test item was run concurrently. Cell density was measured by spectrophotometrical measurements at test start and after 24, 48 and 72 hours of exposure.

Analytical verification of all test concentrations was performed at test start and test end. Measured concentrations were in the range of 102 - 105 % of nominal for dimethomorph and 52 - 92 % for fluazinam.

Under the conditions of this study, E_rC_{50} (72 h) was 1.09 mg prod./L and the E_bC_{50} (72 h) was 0.444 mg prod./L, both values based on nominal test concentrations.

I. Materials and methods

A. Materials

1. Test material: MCW-853 SC
   Description: orange, liquid
   Lot/Batch no.: 175-191107-02
   Active ingredient content: dimethomorph: 211 g/L (certified)
   fluazinam: 211 g/L (certified)
   Stability of test compound: date of expiry: November 22, 2009

2. Control: reconstituted water without test item
   Solvent/vehicle: none
   Toxic reference: separate test performed with potassium dichromate

3. Test organisms -

Species:	*Desmodesmus subspicatus* (chodat) Hegewald et Schmidt, Strain no. 86.81 SAG
Source:	cultivated in-house (Origin: Sammlung von Algenkulturen, Universität Göttingen, Germany)
Initial cell concentration:	approximately 5 x 10^3 cells/mL
Replicates:	8 treatment groups (7 test item rates and 1 control), 3 replicates per test concentrations, six replicates for the control

4. Test units and exposure -

Type and size:	50 mL Erlenmeyer flasks with 50 mL test medium
Test procedure:	static
Exposure time:	72 hours

5. Test conditions -

Test medium:	reconstituted water
Environmental conditions -	
Water temperature:	23 - 24 °C
Photoperiod:	continuous illumination
Light intensity:	6900 - 8230 Lux
pH value:	8.0 (test start), 9.0 - 10.0 (test end)

B. Study design and method

1. In life dates: November 04, 2008 - July 03, 2009

2. Main test:

Three replicates per test concentration, each with initially 5 x 10^3 cells/mL test medium, were exposed for 72 hours under static conditions at nominal test concentrations of:

- 1.0, 0.32, 0.10, 0.032, 0.010, 0.0032 and 0.0010 mg prod./L

A control was implemented with test medium without test substance. Cell density was measured by spectrophotometrical measurements after 24, 48 and 72 hours of exposure. The pH-values were measured at test start and -end in all test item concentrations.

3. Analysis of test item concentrations:

Analytical verification of the test item concentrations was performed at test start and test end. The concentrations of fluazinam and dimethomorph were determined by means of HPLC.

4. Statistics

The E_bC_{50}- and E_rC_{50}-values after 72 h, as well as their 95 % confidence limits, were calculated by probit analysis. The NOEC and LOEC were determined by testing significant differences compared to the control values using the Bonferroni t-test.

II. Results and discussion

A. Analytical data

1. Method validation

The analytical system gave a linear response over the whole range of prepared standards. Linearity (r^2) of the calibration curves was 0.9901 for fluazinam and 0.9980 for dimethomorph. Accuracy (RR) and precision (RSD) were determined for replicates of fortified concentrations of 0.1, 0.3 and 1.0 mg prod./L and resulted in recovery rates of 87 % (n = 8; mean RSD = 15 %) for fluazinam and 106 % (n = 12; mean RSD = 11 %) for dimethomorph (required: RR = 70 - 110 %, RSD ≤ 20 %). The limit of quantification was set to 0.3 mg test item/L for fluazinam and 0.1 mg test item/L for dimethomorph.

2. Analytical verification of the active substances

Mean recovery rates of dimethomorph were 105 % at test start and 102 % at test end. Fluazinam was detected at mean concentrations of 92 % (of nominal) at test start and 52 % at test end. Since a formulation was tested and correct dosing could be demonstrated by analysis of dimethomorph, all reported results are related to nominal concentrations of the test item.

B. Growth inhibition

Mean cell densities and inhibition of growth rate and biomass are presented in the table below.

Table 10- 10: Cell densities, biomass and rate related inhibition of *Desmodesmus subspicatus* after 72 hours

Nominal concentration [mg prod./L]	Mean cell density [10^4 cells/mL]			Inhibition after 72 h [%]	
	24 h	48 h	72 h	growth rate	biomass
1.0	0.747	1.187	8.724	45.9	91.5
0.32	2.595	20.044	69.547	6.5	29.0
0.10	3.093	27.082	93.066	0.9	4.8
0.032	3.475	26.173	91.395	1.3	6.5
0.010	3.064	29.164	98.844	-0.2	-1.1
0.0032	3.387	26.760	92.685	1.1	5.2
0.0010	3.445	26.291	97.495	0.0	0.3
Control	3.064	26.217	97.744	-	-

C Other observations

In a microscopic examination the shape of the algal cell was examined after 72 h. No obvious affection of the shape at nominal test concentrations of 1.0 mg prod./L was detected.

D. Deficiencies

The cell concentration in the control had increased by a factor of more than 16 within the three days of the study (i.e. 195-fold). The coefficient of variation of the sectional growth rates in the control cultures did not exceed 35 % (i.e. 24 %), and the coefficient of variation of the average growth between the control replicates did not exceed 7 % (i.e. 0.8 %). Thus, the validity criteria were fulfilled and the test was considered to be valid without restrictions.

III. Conclusions

In a 72-hour growth inhibition test, *Desmodesmus subspicatus* was exposed to MCW-853 SC (active ingredient content: 211 g fluazinam/L and 211 g dimethomorph/L) under static conditions. A control group exposed to reconstituted water without test item was run concurrently. Effect concentrations of growth rate (E_rC) and biomass (E_bC) after 72 h were calculated by probit analysis. The effects of MCW-853 SC on algal growth after 72 hours of exposure based on nominal test concentrations were as follows:

Study comments: IIIA 10.2.2.3/01	Test system: *Desmodesmus subspicatus*, growth inhibition (static), 72 h Test method: OECD 201 (2006) Test item: MCW-853 SC (nominal a.s. content: 200 g fluazinam/L, 200 g dimethomorph/L) Test conc.: 1.0, 0.32, 0.10, 0.032, 0.010, 0.0032and 0.0010 mg prod./L (nominal) GLP: Yes Validity: Considered valid without restrictions
Agreed endpoint/s: IIIA 10.2.2.3/01	E_rC_{50} (72 h) = 1.09 mg prod./L (nominal) E_bC_{50} (72 h) = 0.444 mg prod./L (nominal)

Toxicity data on metabolites, considered relevant for the risk assessment

Additionally, since Annex I inclusion algal growth inhibition tests with HYPA (minor metabolite of fluazinam in aquatic systems, but major metabolite in soil) and G-504 have been conducted which are summarised in the following.

Report:	KIIIA1 10.2.2.3/02, Böttcher, M., Deierling, T., 2010
Annex II point:	IIA 8.4
Title:	Revised Final Report No.1 (2nd Original) - Toxicity of HYPA to *Pseudokirchneriella subcapitata* in an Algal Growth Inhibition Test
Testing facility:	IBACON GmbH
Document No:	48363210, Sponsor no.: R-26736
Guidelines:	OECD 201 (2006) Deviations: none
GLP	Yes (certified laboratory)
Comments zRMS	**Acceptable. Used in evaluation.**

Executive summary

A growth inhibition test was performed with the unicellular freshwater green alga *Pseudokirchneriella subcapitata*. Three replicates with a initial cell concentration of approximately 5000 cells/mL test medium were exposed to HYPA (major metabolite of fluazinam in soil) at nominal concentrations of 0.034, 0.17, 0.84, 4.2 and 21 mg test item/L for 72 hours under static conditions. A control with 6 replicates exposed to water without the test item was run concurrently. Cell density was measured via spectrophotometrical measurement at test start and after 24, 48 and 72 hours of exposure. The inhibition of algae growth was determined from the growth rate and yield over a period of 72 h.

Analytical verification of all test concentrations was performed at test start and test end. At the start of the test 97 % of the nominal test concentrations were found (average of all test concentrations). After 72 hours test duration, 53 % of the nominal value was determined (average of all test concentrations). Therefore, all effect levels are given as mean measured test item concentrations.

Under the conditions of this study, the E_rC_{50} (72 h) was determined at 26.47 mg test item/L and the E_yC_{50} (72 h) was determined at 7.81 mg test item/L, both values based on mean measured test concentrations.

I. Materials and methods

A. Materials

1. Test material: HYPA
   Description: light-yellow, solid
   Lot/Batch no.: 381-194-00
   Purity: 93.06 %
   Stability of test compound: date of expiry: July 28, 2011

2. Control: reconstituted water
   Solvent: none
   Toxic reference: separate test performed with potassium dichromate

3. Test organisms -
   Species: Pseudokirchneriella subcapitata, Strain No. 61.81 SAG
   Source: cultivated in-house (Origin: Sammlung von Algenkulturen, Universität Göttingen, Germany)
   Initial cell concentration: approximately 5000 cells/mL
   Replicates: 3 replicates per test concentration, 6 replicates in the control

4. Test units and exposure -
   Type and size: 50 mL Erlenmeyer flasks with 50 mL test medium
   Test procedure: static
   Exposure time: 72 hours

5. Test conditions -
   Test medium: reconstituted water (according to test guideline)
   Environmental conditions -
   Room temperature: 23 °C
   Photoperiod: continuous illumination
   Light intensity: 6420 - 7480 lux
   pH value: 8.0 (test start), 9.4 - 10.0 (test end)

B. Study design and method

1. In life dates: April 27 to 30, 2010

2. Range finding test:

A preliminary range finding test was performed to define the test concentrations for the main test.

3. Main test:

Three replicates per test concentration, each with initially 5000 cells/mL test medium, were exposed for 72 hours under static conditions at nominal test concentrations of:

- 0.034, 0.17, 0.84, 4.2 and 21 mg test item/L

A control was implemented with test medium without test substance. Cell density was measured via spectrophotometrical measurement at test start and after 24, 48 and 72 hours of exposure. The inhibition of algae growth was determined from the growth rate and yield over a period of 72 h.

4. Analysis of test item concentrations:

Analytical verification of the test item concentration was performed at test start and test end. The concentrations of HYPA were determined by means of HPLC.

5. Statistics

Based on the calculated cell densities, the 72-hour E_rC_{50} and the 72-hour E_yC_{50}, the corresponding EC_{10} values and where possible their 95 %-confidence limits were calculated by Probit analysis. For the determination of the 72-hour LOEC and the 72-hour NOEC, the calculated growth rates and yields at each test concentrations were tested for significant differences compared to the control values by the Bonferroni-Welch t-test (growth rate) and the Williams t-test (yield), respectively.

II. Results and discussion

A. Analytical data

1. Method validation

The analytical system gave a linear response over the whole range of prepared standards. Linearity (r^2) of the calibration curves was at least 0.9979. Accuracy (RR) and precision (RSD) were determined resulted in mean recovery in the fortified samples of 96 % (n = 28, mean RSD = 5 %) for HYPA (required: RR = 70 - 110 %, RSD ≤ 20 %). The limit of quantification was set to 0.05 mg test item/L.

2. Analytical verification of the active substance

At the start of the test 97 % of the nominal test concentrations were found (average of all test concentrations). After 72 hours test duration, 53 % of the nominal value was determined (average of all test concentrations). Therefore, all effect levels are given as mean measured test item concentrations.

B. Growth inhibition

Mean cell densities and inhibition of growth rate and yield are presented in the table below.

Table 10- 11: Cell densities, biomass and rate related inhibition of *Pseudokirchneriella subcapitata* after 72 hours

Nominal concentration [mg test item/L]	Mean cell density [cells × 10^4/mL]			Inhibition after 0 - 72 h [%]	
	24 h	48 h	72 h	growth rate	yield
Control	3.632	24.166	80.552	-	-
0.034	3.425	23.473	83.146	-0.6	-3.2
0.17	3.573	24.240	82.232	-0.4	-2.1
0.84	4.929	26.363	81.348	-0.2	-1.0
4.2	3.425	22.117	70.911	2.5*	12.0*
21	0.826	6.963	11.533	38.3*	86.2*

* mean value significantly different from the control (tested with Williams t-test, α = 0.05, one-sided)

C. Deficiencies

The cell concentration in the control had increased by a factor of more than 16 within the three days of the study (i.e. 161-fold). The Coefficent of Variation (CV) of sectional (daily) growth rates in control cultures was 26 % (required: ≤ 35 %) and the CV of average growth between control replicates was 1.1 % (required: ≤ 7 %). Thus, the validity criteria were fulfilled and the test was considered to be valid without restrictions.

III. Conclusions

In a 72-hour growth inhibition test, *Pseudokirchneriella subcapitata* was exposed to HYPA under static conditions. A control group exposed to dilution water without test item was run concurrently. Effect concentrations of growth rate (E_rC) and yield (E_yC) after 72 h were calculated by Probit analysis. The effects of HYPA on algal growth after 72 hours of exposure based on mean measured test concentrations were as follows:

Study comments: IIIA 10.2.2.3/02	Test system: *Pseudokirchneriella subcapitata*, growth inhibition (static), 72 h Test method: OECD 201 (2006) Test item: HYPA (purity: 93.06 %) Test conc.: 0.034, 0.17, 0.84, 4.2 and 21 mg test item/L (nominal) GLP: Yes Validity: Considered valid without restrictions
Agreed endpoint/s: IIIA 10.2.2.3/02	E_rC_{50} (72 h) = 26.47 mg test item/L (mean measured) E_yC_{50} (72 h) = 7.81 mg test item/L (mean measured)

Report:	KIIIA1 10.2.2.3/03, Kuhl, R., Wydra, V., 2011
Annex II point:	IIA 8.4
Title:	Toxicity of G-504 to *Pseudokirchneriella subcapitata* in an Algal Growth Inhibition Test
Testing facility:	IBACON GmbH
Document No:	63081210, Sponsor no.: R-28031
Guidelines:	OECD 201 (2006) Deviations: none
GLP	Yes (certified laboratory)
Comments zRMS	**Acceptable. Used in evalutation.**

Executive summary

A growth inhibition test was performed with the unicellular freshwater green alga *Pseudokirchneriella subcapitata*. Three replicates with an initial cell concentration of approximately 5000 cells/mL test medium were exposed to G-504 at nominal concentrations of 0.16, 0.50, 1.58, 5.0, 15.8 and 50 mg test item/L for 72 hours under static conditions. A control with 6 replicates exposed to water without the test item was run concurrently. Cell density was measured via spectrophotometrical measurement at test start and after 24, 48 and 72 hours of exposure. The inhibition of algae growth was determined from the growth rate and yield over a period of 72 h.

The concentrations of G-504 were determined at test start and test end by means of HPLC-UV. The mean recovery rates were 108 % and 104 % of nominal test concentrations at test start and test end, respectively. Therefore, all reported results refer to nominal concentrations.

Under the conditions of this study, the E_rC_{50} (72 h) was determined at > 50 mg test item/L and the E_yC_{50} (72 h) was determined at 20 mg test item/L, both values based on nominal test concentrations.

I. Materials and methods

A. Materials

1. Test material: G-504
   Description: solid, yellow
   Lot/Batch no.: EPP / RH 693.14
   Purity: 98.5 % (certified)
   Stability of test compound: date of expiry: January 17, 2012

2. Control: reconstituted water
   Solvent: none
   Toxic reference: separate test performed with potassium dichromate

3. Test organisms -
   Species: *Pseudokirchneriella subcapitata*, Strain No. 61.81 SAG
   Source: cultivated in-house (Origin: Sammlung von Algenkulturen, Universität Göttingen, Germany)
   Initial cell concentration: approximately 5000 cells/mL

Replicates:	3 replicates per test concentration, 6 replicates in the control

4. Test units and exposure -

Type and size:	50 mL Erlenmeyer flasks with 50 mL test medium
Test procedure:	static
Exposure time:	72 hours

5. Test conditions -

Test medium:	reconstituted water
Water temperature:	23 °C
Photoperiod:	continuous illumination
Light intensity:	6250 - 6850 lux
pH value:	8.0 (test start), 8.4 - 9.6 (test end)

B. Study design and method

1. In life dates: January 31 to February 03, 2011

2. Test design:

Three replicates per test concentration, each with initially 5000 cells/mL test medium, were exposed for 72 hours under static conditions at nominal test concentrations of:

- 0.16, 0.50, 1.58, 5.0, 15.8 and 50 mg test item/L

A control was implemented with test medium without test substance. Cell density was measured via spectrophotometrical measurement at test start and after 24, 48 and 72 hours of exposure. The inhibition of algae growth was determined from the growth rate and yield over a period of 72 h.

3. Analysis of test item concentrations:

Analytical verification of the test substance G-504 was performed at test start and test end by means of HPLC-UV.

4. Statistics

Based on the calculated cell densities, the 72-hour E_rC_{50} and the 72-hour E_yC_{50}, the corresponding EC_{10} values and where possible their 95 %-confidence limits were calculated by Probit analysis. For the determination of the 72-hour LOEC and the 72-hour NOEC, the calculated growth rates and yields at each test concentrations were tested for significant differences compared to the control values by the Williams t-test.

II. Results and discussion

A. Analytical data

1. Method validation

The analytical system gave a linear response over the whole range of prepared standards. Linearity (r^2) of the calibration curves was 0.9999. Accuracy (RR) and precision (RSD) were determined resulted in mean recovery in the fortified samples of 104 % (n = 12, mean RSD = 3 %) for G-504 (required: RR = 70 - 110 %, RSD ≤ 20 %). The limit of quantification was set to 1.0 mg test item/L.

2. Analytical verification of the active substance

The concentrations of G-504 were determined at test start and test end by means of HPLC-UV. The mean recovery rates were 108 % and 104 % of nominal test concentrations at test start and test end, respectively. Therefore, all reported results refer to nominal concentrations.

B. Growth inhibition

Mean cell densities and inhibition of growth rate and yield are presented in the table below.

Table 10- 12: Cell densities, biomass and rate related inhibition of *Pseudokirchneriella subcapitata* after 72 hours

Nominal concentration [mg test item/L]	Mean cell density [cells × 10000/mL]			Inhibition after 0 - 72 h [%]	
	24 h	48 h	72 h	growth rate	yield
Control	4.751	18.971	67.069	-	-
0.16	4.972	19.209	66.644	0.1	0.6
0.5	5.890	19.515	66.576	0.1	0.7
1.58	4.021	17.918	65.828	0.4	1.9
5.0	5.278	10.069	57.300	3.2*	14.7*
15.8	3.273	5.210	43.674	8.8*	35.1*
50	2.424	3.205	9.661	39.5*	86.2*

* mean value significantly different from the control (tested with Williams t-test, $\alpha = 0.05$, one-sided)

C. Deficiencies

The cell concentration in the control had increased by a factor of more than 16 within the three days of the study (i.e. 134-fold). The Coefficent of Variation (CV) of sectional (daily) growth rates in control cultures was 33.3 % (required: ≤ 35 %) and the CV of average growth between control replicates was 1.1 % (required: ≤ 7 %). Thus, the validity criteria were fulfilled and the test was considered to be valid without restrictions.

III. Conclusions

In a 72-hour growth inhibition test, *Pseudokirchneriella subcapitata* was exposed to G-504 under static conditions. A control group exposed to dilution water without test item was run concurrently. Effect concentrations of growth rate (E_rC) and yield (E_yC) after 72 h were calculated by Probit analysis. The effects of G-504 on algal growth after 72 hours of exposure based on nominal test concentrations were as follows:

Study comments: IIIA 10.2.2.3/03	Test system: *Pseudokirchneriella subcapitata*, growth inhibition (static), 72 h Test method: OECD 201 (2006) Test item: G-504 (purity: 98.5 %) Test conc.: 0.16, 0.50, 1.58, 5.0, 15.8 and 50 mg test item/L (nominal) GLP: Yes Validity: Considered valid without restrictions
Agreed endpoint/s: IIIA 10.2.2.3/03	E_rC_{50} (72 h) > 50 mg test item/L (nominal) E_yC_{50} (72 h) = 20 mg test item/L (nominal)

IA 10.2.2.4 Marine or estuarine organisms acute toxicity LC_{50}/EC_{50}

IIIA 10.2.2.5 Marine sediment invertebrates, acute toxicity LC_{50}/EC_{50}

IIIA 10.2.3 Microcosm or mesocosm study

IIIA 10.2.4 Residue data in fish (long-term)

IIIA 10.2.5 Chronic fish toxicity data

IIIA 10.2.5.1 Chronic toxicity (28 day exposure) to juvenile fish.
Analytical data on concentrations in the test media

IIIA 10.2.5.2 Fish early life stage toxicity test.
Analytical data on concentrations in the test media

IIIA 10.2.5.3 Fish life cycle test.
Analytical data on concentrations in the test media

IIIA 10.2.6 Chronic toxicity to aquatic invertebrates

IIIA 10.2.6.1 Chronic toxicity in Daphnia magna (21-day).
Analytical data on concentrations in the test media

IIIA 10.2.6.2 Chronic toxicity for a representative species of aquatic insects.
Analytical data on concentrations in the test media

IIIA 10.2.6.3 Chronic toxicity for a representative species of aquatic gastropod molluscs.
Analytical data on concentrations in the test media

IIIA 10.2.7 Accumulation in aquatic non-target organisms.
Analytical data on concentrations in the test media

IIIA 10.3.2.1 Acute oral toxicity of the preparation

IIIA 10.3.2.2 Acceptance of bait, granules or treated seeds by terrestrial vertebrates (palatability test)

IIIA 10.3.3 Supervised cage or field trials or other appropriate studies

Report:	**KIIIA1 10.3/01, Barfknecht, R., 2003**
Title:	Attractiveness of Potato Fields for Herbivorous Mammals and Birds, Field Monitoring in Nordrhein-Westfalen, Germany
Testing facility:	Bayer CropScience AG, Institute for Ecotoxicology, Monheim, Germany
Document No:	Laboratory Project ID E 307 2310-6
Guidelines:	Pesticides and Wildlife - Field Testings: Recommendations of an international workshop on terrestrial field testing of pesticides, attached to Pesticide Effects on Terrestrial Wildlife, Somerville & Walker (ed.), Taylor & Francis, London 1990
GLP	**Yes (certified laboratory)**
Comments zRMS	**Acceptable. Used in evaluation.**

Executive summary

This generic field study was performed to evaluate which mammals and birds occur in potato fields and which of them are herbivorous. 4 potato fields (2.5 - 10.4 ha) in the vicinity of Rommerskirchen (Nordrhein-Westfalen, Germany), were chosen as study sites. This area is a typical region for the cultivation of potatoes in Germany. The composition of vegetation and the availability of food for herbivorous animals were assessed on randomly assigned plots within and in the vicinities of the study fields. To determine bird activities and abundance on potato fields, two times during the whole daylight period all fields were observed: every hour each field was surrounded by an ornithologist and every bird in the field was recorded (species, number, behaviour). Additionally three times within the study period a bird census was carried out at each study field and its vicinity, in order to get a list of species and their relative abundance in potato growing areas and surrounding habitats. Small mammals were monitored using life traps and marking animals with radio collars. 12 animals with radio collars were monitored for 24 hrs via radio telemetry to obtain information about habitat use and the portion of time spent within potato fields.

VEGETATION MONITORING			
Total coverage of soil (in brackets: coverage of soil of other plat species, yielding fruits or seeds) (% of soil covered, mean)	on potato fields	potato plants	89.0 %
		other species	1.7 % (0.2 %)
	surrounding habitats	potato plants	0.0 %
		other species	80.8 % (24.1 %)

BIRD MONITORING		
Bird diversity (number of species observed on the fields, in the surroundings or flying over the fields during all study activities)	potato fields	21 species (thereof 18 spp. only sporadically or singular)
	surroundings	59 species (thereof 11 spp. only flying over)
Relative abundance of birds in potato fields and surrounding habitats (percentage of observations after 12 counts on 4 fields)	potato fields	3 %
	surroundings	97 %
Absolute abundance of birds in potato fields (mean of 128 counts during the whole daylight period on 4 fields, standardized on 1 ha)	0.63 individuals per ha	
Main species on the fields	Blackbird, Woodpigeon, Yellow wagtail	
Observations of feeding behavior of birds on potato fields (in summary 7 observations of feeding behavior on potato fields were made)	item	number of observations
	insects	6
	earthworms	1
	potato plants	0

MAMMAL MONITORING		
Mammal species observed on potato fields		Roe deer (*Capreolus capreolus*)
		Brown hare (*Lepus europaeus*)
		Fox (*Vulpes vulpes*)
		Stoat (*Mustela ermine*)
		Wood mouse (*Apodemus sylvaticus*)
		Common vole (*Microtus arvalis*)
		Pine vole (*Microtus subterraneus*)
Small mammal species Caught and radio tracked in or around potato fields. Mean value for th portion of time each species spent in potato fields (sd)	species	portion of time
	Wood mouse (n=4)	0.52 (0.36)
	Common vole (n=2)	0.14 (0.20)
	Bank vole (n=4)	0 (0)

Potato fields are intensively cultivated areas. The test fields were covered by plants to ninety percent approximately. Only a small proportion of the plants were weeds while the majority were cultivated potatoes. The vegetation in the surroundings completely consisted of plants, others than potatoes, with about 25 % yielding fruits and seeds. The abundance and diversity of birds on the potato fields were very low, compared to the surrounding habitats. Main species on the fields were the Yellow Wagtail, the Blackbird and the Wood Pigeon and in much lower abundance the Pheasant, the Skylark, the Dunnock and the Magpie. 5 other species were observed only once. Seven different species of mammals were observed on the potato fields. Foxes, stoats, roe deer, hares and rabbits were present on the fields, information about feeding behaviour of these species could not be gained in the frame of this study. Three species of small mammals were radio tracked. The bank vole was not found on potato fields at all. Common voles spent only a small portion of time on potato fields. Wood mice spent about half of their time on the fields. Their pattern of movements inside potato fields indicates that they are more likely to feed on rare food items like weed seeds or invertebrates than on the abundant potato plants. This would be compliance with data from literature.

Study comments: IIIA 10.3/01	Test system: Generic *field monitoring study (birds and mammals)* Test method: according to: Pesticides and Wildlife - Field Testings: Recommendations of an international workshop on terrestrial field testing of pesticides, attached to Pesticide Effects on Terrestrial Wildlife, Somerville & Walker (ed.), Taylor & Francis, London 1990 Test rates: generic GLP: Yes Validity: Considered valid without restrictions
Agreed endpoint/s: IIIA 10.3/01	The average time of wood mouse spent in potato fields was determined as 52 %, while the maximum value observed for one animal was 83% (of the other three individuals, one spent no (0) and two 62 % of their time in the potato fields). In view of the rather narrow database (i.e. only 4 individuals studied), the consideration of the average value is not supported. Instead, the maximum PT value as observed will be taken into the DDD calculation. This more cautious interpretation of this potato field study results is generally in line with an opinion of the EFSA scientific panel on methamidophos (The EFSA Journal (2004) 144, 1-50), however, the conclusion there was even more restrictive since the acute risk assessment was concerned.

MIIIA 10.4 Effects on bees

IIIA 10.4.2 Acute toxicity of the preparation to bees

The following bee acute toxicity study performed on Banjo forte (MCW-853 SC) is provided in support of the assessment and has been previously evaluated for the initial registration of Banjo forte. Since no major deviations from the guideline were reported which could have influenced the results of the study only a brief summary and the endpoints are presented below.

Report:	**KIIIA1 10.4.2.1/01** Schmitzer, S. (2008) Effects of MCW-853 SC (acute contact and oral) on honey bees (*Apis mellifera* L.) in the laboratory. IBACON GmbH, Rossdorf, Germany, Project 42129035
Document No:	R-23925
Guidelines:	OECD 213 and 214
GLP	Yes

Materials and Methods

In a test under laboratory conditions MCW-853 SC was offered to worker honey bees (*Apis mellifera* L.) in oral and contact route. Treatments with the test substance, the control and the reference item (dimethoate) were carried out in five replicates containing 10 bees each.

Test species:	Worker honey bees *Apis mellifera*
Test substance:	MCW-853 SC (Banjo forte) dimethomorph: 211 g/L (certified) fluazinam: 211 g/L (certified)
Control:	oral: 50 % aqueous sugar solution in tap water contact: tap water with 0.5 % Adhäsit (wetting agent: 100 g/L Marlopon)
Toxic standard:	Perfekthion EC (400 g dimethoate/L) oral: 0.05, 0.08, 0.15, 0.30 µg a.s./bee contact: 0.10, 0.15, 0.20, 0.30 µg a.s./bee dissolved in tap water + 0.5 % Adhäsit
Doses:	oral (MCW-853 SC sucrose solution): 200 µg product/bee contact (MCW-853 SC dissolved in tap water + 0.5 % Adhäsit): 200 µg product/bee
Bees per dose:	10
Replicates:	5

Oral toxicity study:
In a limit test, five replicates of 10 bees were fed with a sugar/water solution containing MCW-853 SC. The tested concentration was 200 µg product/bee. An untreated sugar/water solution was used as water control. Dimethoate was used as toxic standard. The test was conducted at darkness and a temperature of

25 °C and humidity between 45 and 73%. 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 MCW-853 SC dissolved in tap water + 0.5 % Adhäsit, administered topically in a small droplet (5µL) to the thorax of each bee. The tested concentration was 200 µg product/bee. A group of bees treated with an equivalent volume of tap water with 0.5 % Adhäsit was used as water control. Dimethoate solved in tap water with 0.5 % Adhäsit was used as toxic standard. The test was conducted at darkness and a temperature of 25 °C and humidity between 45 and 73%. Biological observations, including mortality and behavioural changes were recorded at 4, 24 and 48 hours after application.

Findings

Oral toxicity:
No behavioural abnormalities were observed at the nominal test concentration and in the sugar solution control.
Mortality data are summarised in the table below.

Table 10.4.2-1: Cumulative mortality after oral application of MCW-853 SC.

	Nominal test concentration [µg prod./bee]	**Measured test concentration [µg prod./bee]**	**Sum mortality [%]**		
			4 h	**24 h**	**48 h**
Control	0	0	0	0	0
Test substance	200	222.8	0	0	0
Toxic reference	0.30	0.32	6	90	96
	0.15	0.17	0	78	88
	0.08	0.08	0	18	36
	0.05	0.06	0	6	10

Contact toxicity:
No behavioural abnormalities were observed at the nominal test concentration and the water control.
Mortality data are summarised in the table below.

Table 10.4.2-2: Cumulative mortality after contact exposure to MCW-853 SC.

	Nominal test concentration [µg a.s./bee]	Sum mean mortality [%]		
		4 h	24 h	48 h
Water control	0	0	0	0
Test substance	200	0	0	0
Toxic reference	0.30	0	94	94
	0.20	0	74	90
	0.10	0	26	40
	0.05	0	4	12

Conclusions

The mortality rate in the control was below 10 % at the end of the test (i.e. 0 % in oral mode, and 0 % in contact mode). Contact LD_{50} of the toxic reference was in the range of 0.10 - 0.30 µg a.s./bee (i.e. 0.17 µg a.s./bee) and for the oral mode within the demanded range of 0.10 - 0.35 µg a.s./bee (i.e. 0.14 µg a.s./bee). Thus, the study is considered to be valid with restrictions.

Under the conditions of this study, the acute oral LD_{50} after 48 h was > 222.8 µg product/bee, based on actual ingestion of the test item. The acute contact LD_{50} after 48 h was determined at > 200 µg product/bee, based on the nominal test concentration.

IIIA 10.4.2.1 Acute oral toxicity

Refer to IIIA 10.4.2.

IIIA 10.4.2.2 Acute contact toxicity

Refer to IIIA 10.4.2.

IIIA 10.4.3 Effects on bees of residues on crops

Not required.

IIIA 10.4.4 Cage tests

Not required.

IIIA 10.4.5 Field tests

Not required.

IIIA 10.4.6 Investigation of special effects

Not required.

IIIA 10.4.6.1 Larval toxicity

Not required since the test item is not an IGR.

IIIA 10.4.6.2 Long residual effects

Not required.

IIIA 10.4.6.3 Disorienting effects on bees

Not required.

IIIA 10.4.7 Tunnel testing to investigate effects of feeding on contaminated honey dew or flowers

Not required.

MIIIA 10.5 Effects on arthropods other than bees

IIIA 10.5.1 Effects on sensitive species already tested, using artificial substrate

IIIA 10.5.2 Effects on non-target terrestrial arthropods in extended laboratory tests

Report:	**KIIIA1 10.5.2/01, Moll, M., 2008**
Title:	Effects of MCW-853 SC on the parasitoid *Aphidius rhopalosiphi,* extended laboratory study
Testing facility:	IBACON GmbH, Rossdorf, Germany
Document No:	4213303, sponsor report no. R-23927
Guidelines:	Mead-Briggs et al. (2002) Deviations: none
GLP	**Yes (certified laboratory)**
Comments zRMS	**Acceptable. Used in evaluation.**

Executive summary

Groups of 40 wasps of the species *Aphidius rhopalosiphi* (4 replicates/group, 10 wasps/replicate) were exposed to MCW-853 SC (active ingredient content: 211 g fluazinam/L and 211 g dimethomorph/L) after spray application on bean leaves (2.4 L prod./ha in 400 L tap water /ha) to determine the effects of the test item on vitality and reproduction rate. A control exposed to tap water without test item was run concurrently. Mortality and behaviour of the wasps was recorded after 2, 24 and 48 hours. Surviving females of the mortality test were used for a following reproduction test. Because there were no significant effects of MCW-853 SC on survival and reproduction of *Aphidius rhopalosiphi*, it was not necessary to perform further testing with aged residues.

No effects on mortality or reproduction exceeding 50 % could be observed compared to the control group. Thus, the LR_{50}/ER_{50} can be established above the highest test rate of 2.4 L prod./ha.

I. Materials and methods

A. Materials

1. Test material: MCW-853 SC
   Description: orange, liquid
   Lot/Batch no.: 175-191107-02
   Active ingredient content: dimethomorph: 211 g/L (certified)
   fluazinam: 211 g/L (certified)
   Stability of test compound: date of expiry: November 22, 2009
   Density: 1.18 g/mL

2. Control: tap water
   Solvent/vehicle: none
   Toxic reference: Perfekthion EC , a.s. content: 395.9 g dimethoate/L

3. Test organisms -
   Species: *Aphidius rhopalosiphi* (Hym.: Aphidiidae)
   Age: < 48 h
   Source: Katz Biotech AG, Baruth,Germany

Acclimatisation:	approx. 1 - 2 days under test conditions in hatching chambers
Feeding:	Acclimatisation period: cotton plug moistened with a 10 % fructose solution (5 g fructose in 50 g deionised water) Exposure period: the bean leaves, with the dry spray residues for exposure, were lightly sprayed with the sugar solution (*ad libitum*) and left to dry. Three hours after introduction of the parasitoids into the test unit, additional food was given in small test tubes, which were connected with the exposure units.
No. of wasps:	4 replicates each with 10 adults (7 females, 3 males)

4. Environmental conditions -

Temperature:	18 - 22 °C
Relative humidity:	64 - 86 % (acclimatisation and exposure period) 60 % (post-exposure period)
Photoperiod:	16 h light / 8 h dark
Light intensity:	500 - 800 lux (acclimatisation and exposure period) 1200 - 1400 lux (parasitisation period) 11600 - 14000 lux (post-parasitisation period)

5. Test substrate: bean leaves

6. Test duration: mortality test: 48 h
reproduction test: 11 d

B. Study design and method

1. In life dates: August 20 to September 02, 2008

2. Description of test procedures:

Application rates of the test item were

- 2.4 L prod./ha diluted in tap water equivalent to 400 L/ha

Perfekthion EC was used as reference item at a rate of:

- 50 mL prod./ha diluted in tap water equivalent to 400 L/ha

A control was implemented with tap water with an application volume equivalent to 400 L/ha without the test item.

Mortality test: The wasps were exposed to freshly dried residues on leaves from field-treated bean plants for 48 h.
Reproduction test: After 48 h the females were removed from the test containers and their reproductive capacity was assessed by confining them individually over untreated barley plants infested with the host cereal aphids *Phopalosiphum padi*. After 24 hours the adult females were removed and the aphid-infested plants left for another 10 days. After this time period, the number of aphid mummies that had developed where assessed. The mummies were counted after these 10 days.

3. Observations:

Mortality and behaviour of the wasps were recorded after 2, 24 and 48 hours in mortality tests; the reproduction rate was determined on day 13 after the start of the tests.

4. Statistics:

Mortality was corrected according to Abbott (1925) and Schneider-Orelli (1947). Its significance was analysed using the Fisher Exact Test. Settling data were tested for normal distribution and homogeneity of variance using the Kolmogoroff-Smirnov-Test and the Cochran-Test. The mean mummy production per female was used to calculate the parasitisation efficiency. Reproduction data were tested for normal distribution using the Kolmogoroff-Smirnov-Test and the Bartlett-Test. Homogenous variances was analysed with the Student-t-Test.

II. Results and discussion

A. Mortality

The control mortality was 2.5 %. No statistically significant differences compared to control could be observed in the test item group. The corrected mortality of the test item group was 2.6 %. Mortality data after 48 h are summarised in the table below.

Table 10-13: Mortality of *Aphidius rhopalosiphi* 48 h after test start

Test item concentration [L prod./ha]	**mortality and behavioural abnormalities [%] after 48 h**			
	alive	**affected**	**moribund**	**dead**
Control	97.5	0	0	2.5
2.4	95.0	0	0	5.0
Reference item	0	0	0	100

B. Reproduction

In the control, parasitisation rate was at mean 19.8 mummies per female. No statistically significant differences compared to control could be observed in the test item group. The data are given in the following table.

Table 10- 14: Reproduction of *Aphidius rhopalosiphi*

Test item concentration [L prod./ha]	**Parasitisation rate [Mean no. of mummies per female]**	**Reduction of parasitisation efficiency [%]**
Control	19.8	-
2.4	19.9	- 0.8

C. Deficiencies

Control mortality was 2.5 % (required: < 10 %) and reference mortality was 100 % (required: > 50 %). In the reproduction test, the females in the control produced 19.8 mummies/female on average and only one parasitoid produced no mummies (required: > 5.0 mummies/female and not more than 2 replicates without any mummy). Thus, the validity criteria were fulfilled and the test was considered to be valid without restrictions.

III. Conclusions

In a 48-hour mortality test and a following reproduction test, groups of *Aphidius rhopalosiphi* were exposed to MCW-853 SC (active ingredient content: 211 g fluazinam/L and 211 g dimethomorph/L) after a single spray application on bean leaves. Control replicates exposed to tap water without the test item were run concurrently. No effects on mortality or reproduction exceeding 50 % could be observed compared to the control group. Thus, the LR_{50}/ER_{50} can be established above the highest test rate of 2.4 L prod./ha. Because there were no (statistically) significant effects of MCW-853 SC on survival and reproduction of *Aphidius rhopalosiphi*, it was not necessary to perform further testing with aged residues. Relevant data on mortality and reproduction are summarised below:

Study comments: IIIA 10.5.2/01	Test system: *Aphidius rhopalosiphi*, extended lab test using bean leaves Test method: Mead-Biggs et al. (2002) Test item: MCW-853 SC (nominal a.s. content: 200 g fluazinam/L, 200 g dimethomorph/L) Test rates: 2.4 L prod./ha (limit test) GLP: Yes Validity: Considered valid without restrictions
Agreed endpoint/s: IIIA 10.5.2/01	$Mortality_{corr}$ = 2.6 % Reduction in reproduction = -0.8 %

Report:	**KIIIA1 10.5.2/02, Moll, M., 2008**
Title:	Effects of MCW-853 SC on the predatory mite *Typhlodromus pyri*, extended laboratory study - Aged residue test
Testing facility:	IBACON GmbH, Rossdorf, Germany
Document No:	42134060, sponsor report no.: R-23928
Guidelines:	Blümel et al. (2000); Oomen (1988) Deviations: none
GLP	**Yes (certified laboratory)**
Comments zRMS	**Acceptable. Used in evaluation.**

Executive summary

In a 7-day mortality test, 100 predatory mites (10 replicates/group, 10 mites/replicate) were exposed to fresh residues of MCW-853 SC (active ingredient content: 211 g fluazinam/L and 211 g dimethomorph/L) applied on bean leaves at a single rate of 2.4 L prod./ha (1st bioassay). A control and a reference item group (10 replicates, 10 mites/replicate) were run concurrently. Mortality of the mites was recorded on day 2 and 7 after application. Since the control mortality exceeded the relevant validity threshold of 20 %, an equal designed 2nd bioassay was started 7 days after application of the test item. Surviving mites of the mortality test in the 2nd bioassay were used for a following 7-day reproduction test.

In the 2nd bioassay (aged residue part), no effects on mortality or reproduction exceeding 50 % could be observed when compared to the control group. Thus, the LR_{50}/ER_{50} can be established above the highest test rate of 2.4 L prod./ha.

I. Materials and methods

A. Materials

1. Test material: MCW-853 SC
   Description: orange, liquid
   Lot/Batch no.: 175-191107-02
   Active ingredient content: dimethomorph: 211 g/L (certified)
   fluazinam: 211 g/L (certified)
   Stability of test compound: date of expiry: November 22, 2009
   Density: 1.15 - 1.21 g/mL

2. Control: 400 L tap water
   Solvent/vehicle: none
   Toxic reference: Perfekthion, a.s. content: 395.9 g dimethoate/L

3. Test organisms -
   Species: *Typhlodromus pyri* (Acari: Phytoseiidae)
   Age: protonymphs, max. 24 h old at the beginning of test mode 1
   Source: Katz Biotech AG, Baruth, Germany
   Adaption: egg were kept under test conditions
   Feeding: mixture of pine (*Pinus nigra*) and birch (*Betula sp.*) pollen *ad libidum* at test start and on each assessment day
   No. of mites: mortality test (test mode 1):
   1st bioassay: 3 groups (1 test item, 1 control, 1 reference item), 10 replicates, each containing 10 mites
   2nd bioassay: 2 groups (1 test item, 1 control), 10 replicates, each containing 10 mites
   reproduction test (test mode 2): surviving mites of test mode 1 (control and test item)

4. Environmental conditions -
   Temperature: 25 - 26 °C
   Relative humidity: 60 - 81 %
   Photoperiod: 16 h light/8 h dark
   Light intensity: 220 - 540 lux

5. Test substrate: bean leaves

6. Test duration: mortality test (test mode 1): 7 d
reproduction test (test mode 2): further 7 d

B. Study design and method

1. In life dates: August 20 to September 10, 2008

2. Description of test procedures:

The test item was applied via spraying at a limit test rate of:

- 2.4 L prod./ha diluted in 400 L tap water

and Perfekthion was used as reference item at a rate of:

- 50 mL prod./ha in a final volume of 400 L/ha

A control was implemented with tap water with an application volume equivalent to 400 L/ha without the test item.

Mortality test (test mode 1): In the 1st bioassay, the predatory mites were exposed to residues freshly dried on field-treated bean leaves. Discs of those leaves were placed with its treated side upwards on a wet cotton wool in a petri dish. A band of insect trap coating was applied around the leaves to avoid the escape of the mites. Since the control mortality exceeded the relevant validity threshold of 20 %, an equal designed 2nd bioassay was started 7 days after application of the test item.
Reproduction test (test mode 2): After test mode 1 of the 2nd bioassay, a reproduction test was performed. For this purpose, the sex of surviving mites was determined and eggs laid during test mode 1 of the 2nd bioassay were removed from the test arena and not counted. After further 7 days, the number of eggs laid and live and dead juvenile stages per female was counted and removed.

3. Observations:

Mortality, vitality and number of escaped mites were observed on day 2 and 7 of test mode 1. Reproduction rate of surviving mites was deduced from the number of offspring, consisting of eggs and larvae, produced during test mode 2.

4. Statistics:

Mortality data were analysed for significance with the Fisher exact test. The Kolmogoroff-Smirnov-test and the Cochran-test (both $\alpha = 0.05$) were used to test the reproduction for normal distribution and homogeneity of variance. The student-t-test for homogeneous variances was used for a one-sided pair wise comparison ($\alpha = 0.05$)

II. Results and discussion

A. Mortality

In the 1st bioassay (test start on the day of application) control mortality was above the validity threshold of 20 % (i.e. 36 %). Therefore, a 2nd bioassay was conducted using aged residues of MCW-853 SC. In both bioassays, corrected mortality in the treatment group exposed to 2.4 L prod./ha was below 50 %. Mortality data are summarised in the table below.

Table 10- 15: Mortality of predatory mites [%] after 7 days of exposure to fresh and aged residues of MCW-853 SC

Group, test rate	1st bioassay		2nd bioassay	
	Mean mortality# [%]	Corrected mortality# [%]	Mean mortality# [%]	Corrected mortality# [%]
Control group	36.0	-	17.0	-
Test item group, 2.4 L prod./ha	66.0*	46.9	41.0	28.9
Reference item, 50 mL prod./ha	82.0*	71.9	-	-

dead and escaped mites
* statistically significant different according to Fisher exact test, α = 0.05

B. Reproduction

No statistically significant reduction of reproduction (i.e. 1.2 %) could be observed in the treatment group when compared to the control. Reproduction data are summarised in the table below.

Table 10- 16: Reproduction of female mites during the 7 day egg laying period (test mode 2 of the 2nd bioassay)

Group, test rate	Reproduction [eggs/female]	Effect on reproduction [%]
Control group	4.32	-
Test item group, 2.4 L prod./ha	4.27	1.2

C. Deficiencies

The mean mortality of control in test mode 1 of the 2nd bioassay was 17 % (required: ≤ 20 %) and corrected mortality of reference item treatment was 71.9 % (required: 50 - 100 %). Furthermore, mean number of offspring per control female was 4.32 (required: ≥ 4). Thus, the validity criteria according to Blümel *et al.* (2000) were fulfilled for the 2nd bioassay of test mode 1 and test mode 2 and this part of the test was considered to be valid without restrictions.

III. Conclusions

In a 7-day acute toxicity test and in a following 7-day reproduction test, the predatory mite *Typhlodromus pyri* was exposed to aged residues of MCW-853 SC applied on bean leaves at a single rate of 2.4 L prod./ha. A control group exposed to tap water without test item was run concurrently. In the 2nd bioassay (aged residue part), no effects on mortality or reproduction exceeding 50 % could be observed when compared to the control group. Thus, the LR_{50}/ER_{50} can be established above the highest test rate of 2.4 L prod./ha. Relevant data on mortality and reproduction are summarised below:

Study comments: IIIA 10.5.2/02	Test system: *Typhlodromus pyri*, extended lab test using bean leaves (aged residue test) Test method: Blümel et al. (2000), Oomen (1988) Test item: MCW-853 SC (nominal a.s. content: 200 g fluazinam/L, 200 g dimethomorph/L) Test rates: 2.4 L prod./ha (limit test) GLP: Yes Validity: Formally, the 1st bioassay (exposure to fresh dried residues is not valid since the average control mortality of 36% exceeded the relevant validity criterion (20 %). However, in view of the rather narrow failure of the validity criterion and taking the results of the 2nd bioassay (exposure to 7-day aged residues) into account, it is reasonably assumed that the correct LR_{50} (exposure to fresh dried residues) does not fall well above the limit dose tested and thus the LR_{50} (fresh dried residues) is defined as 2.4 L/ha.
Agreed endpoint/s: IIIA 10.5.2/02	1st bioassay (exposed to fresh residues): $Mortality_{corr}$ = 46.9 % LR_{50} = 2.4 L prod./ha (weight-of-evidence derived LR_{50} taking the results of the 1st and 2nd bioassay into account) 2nd bioassay (exposed to aged residues): $Mortality_{corr}$ = 28.9 % Reduction in reproduction = 1.2 % LR_{50}/ER_{50} > 2.4 L prod./ha

Report:	**KIIIA1 10.5.2/03, Moll, M., 2009**
Title:	Effects of MCW-853 SC on the Lacewing *Chrysoperla carnea* under extended laboratory conditions
Testing facility:	IBACON GmbH, Rossdorf, Germany
Document No:	42147047, sponsor report no.: R-25548
Guidelines:	Vogt et al. (2000) Deviations: none
GLP	**Yes (certified laboratory)**
Comments zRMS	**Acceptable. Used in evaluation.**

Executive summary

In a mortality and reproduction test 40 green lacewings (*Chrysoperla carnea*) were exposed to MCW-853 SC (active ingredient content: 211 g fluazinam/L and 211 g dimethomorph/L) directly after spray application on bean leaves. A control exposed to deionised water without test item and a test with a reference item were run concurrently. Mortality of the green lacewings larvae and number of pupae was recorded at least 3 times a week and mortality of the adults was checked regularly. Surviving adults were used for a following 7-day reproduction test with 2 replicates for the test item and the control.

Under the conditions of this study, no statistically significant lethal and sublethal were observed in the test item group. Since the effects were below 50 % when compared to the control the LR_{50}/ER_{50} can be established above the highest test rate of 2.7 L prod./ha.

I. Materials and methods

A. Materials

1. Test material: MCW-853 SC
   Description: orange, liquid
   Lot/Batch no.: 175-191107-02
   Active ingredient content: dimethomorph: 211 g/L (certified)
   fluazinam: 211 g/L (certified
   Stability of test compound: date of expiry: November 22, 2009
   Density: 1.176 g/mL

2. Control: deionised water
   Solvent/vehicle: none
   Toxic reference: Perfekthion, a.s. content: 422.4 g dimethoate/L

3. Test organisms -
   Species: *Chrysoperla carnea* (Neuroptera, Chrysopidae)
   Age: larvae, 2 days old at the beginning of test mode 1
   Source: Katz Biotech AG, Baruth, Germany
   Acclimatisation: not stated
   Feeding: Larvae: UV-sterilised *Sitotraga cerealella* eggs *ad libitum*;
   Adults: artificial diet: (15 ml condensed milk, 1 egg, 1 egg yolk, 20 g fructose, 30 g honey, 30 g brewer yeast, 50 wheat germ and 45 mL deionised water) *ad libitum*.
   No. of lacewings: Exposure period (test mode 1): 3 groups with 40 replicates with each one larva
   Oviposition period (test mode 2): 2 reproduction units per treatment group (considered as 1 replicate), max 37 adults per replicate

4. Environmental conditions -
   Temperature: 23 - 25 °C
   Relative humidity: 63 - 80 %
   Photoperiod: 16 h light / 8 hours dark
   Light intensity: 1390 - 1550 lux

5. Test substrate: bean leaves

6. Test duration: Exposure period (test mode 1): 14 - 19 d
   Oviposition period (test mode 2): further 7 d

B. Study design and method

1. In life dates: May 13 to June 23, 2009

2. Description of test procedures:

The test item was applied at a limit rate of:

- 2.7 L prod./ha with an amount of 200 L/ha

and Perfekthion was used as reference item at a rate of:

- 100 mL prod./ha in a final volume of 200 L/ha

A control was implemented with deionised water with an application volume equivalent to 200 L/ha without the test item.

Exposure period (test mode 1): Bean plants were cut into discs and treated on their upper surface with a laboratory sprayer. The freshly dried leaf-discs were placed with its treated side upward on a wet cotton wool pad in a petri dish. Escaping of the larvae was prevented by a cylinder with Fluon on the walls around the leaf.
Oviposition period (test mode 2): Adult and unaffected lacewings from test mode 1 were put in a cylinder with a cotton gause for egg-laying. Hatched larvae were removed daily for a fertility assessment. 6 - 7 days after the last larvae had hatched, the remaining eggs were determined as unhatched.

3. Observations:

Mortality of the larvae as well as the number of developed pupae was determined at least 3 times a week after test start. The number of adults was checked regularly. The number of eggs was counted after a 24 hour egg-laying period and 2 checks were done within one week thereafter. The number of larvae was determined after hatching of all larvae.

4. Statistics:

Mortality data were analysed for significance using Fisher exact test. The mortality was corrected according to Abbott, (1925) and Schneider-Orelli (1947).

II. Results and discussion

A. Mortality

Control mortality was 7.5 % and concurrently, no treatment related mortality could be observed in the treatment group exposed to a test rate of 2.7 L prod./ha indicated by corrected mortality of 10.8 %. Relevant data are summarised in the table below.

Table 10- 17: Mortality of green lacewings after termination of test mode 1

Test item concentration [L prod./ha]	Mean mortality [%]	Corrected mortality [%]
Control	7.5	-
2.7	17.5	10.8
Reference item	95.0*	94.6

* statistically significant different according to Fisher Exact test with α = 0.05

B. Reproduction

Since the eggs per female were > 15 no effect of fecundity was observed at the test item concentration of 2.7 L prod./ha. The larval hatching rate being below 70 % indicates a slight effect of the test item on fertility which is below 50 % compared to the control. Reproduction data are summarised in the table below.

Table 10- 18: Reproduction of green lacewings exposed to MCW-853 SC at test mode 2

Test item concentration [L prod./ha]	Eggs per female and day	Larval hatching rate [%]
Control	22.2	87.6
2.7	22.5	62.0

C. Deficiencies

The mean mortality of the control was 7.5 % (required: ≤ 20 %). The mean mortality of reference item treatment was 94.6 % (required: 50 - 100 %). Furthermore, mean number of eggs produced per female in the control was 22.2 (required: ≥ 15), and mean hatching rate was 87.6 % (required ≥ 70 %) at each assessment day. Thus, the validity criteria were fulfilled and the test was considered to be valid without restrictions.

III. Conclusions

In a mortality test and in a following 7-day reproduction test, the green lacewing *Chrysoperla carnea* was exposed to MCW-853 SC applied on bean leaves at a single rate of 2.7 L prod./ha.. A control group exposed to deionised water without test item was run concurrently. Under the conditions of this study, no statistically significant lethal and sublethal were observed in the test item group. Furthermore, since the effects were below 50 % when compared to the control the LR_{50}/ER_{50} can be established above the highest test rate of 2.7 L prod./ha. Relevant data on effects of MCW-853 SC on *Chrysoperla carnea* were determined as follows:

Study comments: IIIA 10.5.2/03	Test system: *Chrysoperla carnea*, extended lab test using bean leaves Test method: Vogt et al. (2000) Test item: MCW-853 SC (nominal a.s. content: 200 g fluazinam/L, 200 g diemthomorph/L) Test rates: 2.7 L prod./ha (limit test) GLP: Yes Validity: Considered valid without restrictions
Agreed endpoint/s: IIIA 10.5.2/03	$Mortality_{corr}$ = 10.8 %

Report:	**KIIIA1 10.5.2/04, Schmitzer, S., 2008**
Title:	Effects of MCW-853 SC on the carabid beetle *Poecilus cupreus* L.- Extended laboratory study
Testing facility:	IBACON GmbH, Rossdorf, Germany
Document No:	42130007, sponsor report no.: R-23926
Guidelines:	Heimbach et al. (2000) Deviations: none
GLP	**Yes (certified laboratory)**
Comments zRMS	**Acceptable. Used in evaluation.**

Executive summary

An extended laboratory test was performed to assess the effects on mortality, behaviour and food intake of the ground beetle *Poecilus cupreus* when exposed to MCW-853 SC (a.s. content: 211 g fluazinam/L and 211 g dimethomorph/L). The test item was applied once onto the uncovered test containers including the beetles at a limit rate of 3.2 L prod./ha. A control group exposed to deonised water without test item was run concurrently. Mortality, damage and abnormal behaviour of the beetles were recorded after 2 h after application and on day 1, 2, 4, 7, 10 and 14 of the test period. In addition, the feeding rate was determined on day 2, 4, 7, 10 and 14.

Under the conditions of this study no treatment related effects on mortality, behaviour and food intake could be observed when compared to the control. In conclusion, the LR_{50}/ER_{50} can be established above the highest test rate of 3.2 L prod./ha.

I. Materials and methods

A. Materials

1. Test material: MCW-853 SC
   Description: orange, liquid
   Lot/Batch no.: 175-191107-02
   Active ingredient content: dimethomorph: 211 g/L (certified)
   fluazinam: 211 g/L (certified)
   Stability of test compound: date of expiry: November 22, 2009
   Density: 1.18 g/mL

2. Control: deionised water
   Solvent/vehicle: none
   Toxic reference: Perfekthion EC, a.s. content: 400 g dimethoate/L (nominal)

3. Test organisms -
   Species: *Poecilus cupreus* L. (Coleoptera, Carabidae)
   Age: 6 weeks at test start
   Source: Bio-Test Labor GmbH, Sagerheide, Germany
   Acclimatisation: 4 days before test start under test conditions
   Feeding: 1 pupae of the fly species *Calliphora spec.* per living beetle, offered on test days 0, 1, 2 4, 7 and 10
   No. of ground beetles: 5 replicates, each with 3 females and 3 males

4. Environmental conditions -
   Temperature: 18 - 22 °C
   Relative humidity: 68 - 89 %
   Photoperiod: 16 h light / 8 hours dark
   Light intensity: 830 - 1470 lux

5. Test substrate: natural soil; Lufa 2.1 soil
   Soil type: sand (according to DIN)
   Batch no.: Sp 2.10708
   C-content: 0.81 %
   pH: 5.1
   Water content: 33.2 of WHC (g/100 g dw)

6. Test duration: 14 days

B. Study design and method

1. In life dates: June 30 to July 14, 2008

2. Description of test procedures:

The test item was applied onto the uncovered test containers including the beetles at a limit rate of

- 3.2 L prod./ha with a water amount of 400 L/ha

and Perfekthion EC was used as reference item at rates of

- 1.2 L prod. in a final volume of 400 L/ha

A control was implemented with deionised water with an application volume equivalent to 400 L/ha without the test item.

3. Observations:

Mortality, damage and abnormal behaviour of the beetles were recorded after 2 h after application and on day 1, 2, 4, 7, 10 and 14 of the test period. In addition, the feeding rate was determined on day 2, 4, 7, 10 and 14.

4. Statistics:

Not necessary due to the results.

II. Results and discussion

A. Mortality

No mortality in the treatment group as well as in the control group could be observed as outlined in the table below.

Table 10- 19: Mortality of *Poecilus cupreus* after 14 days of exposure to MCW-853 SC

Test item concentration [L prod./ha]	**Mean mortality [%]**
Control	0
3.2	0
Reference item	100

B. Feeding rate

No statistically or biologically significant effects on the feeding rate could be observed when compared to the control. Data on feeding rates are summarised in the table below.

Table 10- 20: Feeding rate of the beetles during the test period

Test item concentration [L prod./ha]	**Mean feeding rate [consumed pupae/living beetle]**		
	days 0 - 7	**days 7 - 14**	**days 0 - 14**
Control	1.0	0.7	1.7
3.2	1.2	0.5	1.7

C. Deficiencies

Mortality in the control was 0 % after 2 weeks (required: ≤ 6.7 %), and mortality in the reference item group was 100 % (required: 65 ± 35 %). Thus, the validity criteria according to Heimbach *et al.* (2000) were fulfilled and the test was considered to be valid without restrictions.

III. Conclusions

In a 14-day extended laboratory test, effects of MCW-853 SC on mortality, behaviour and feeding rate of the ground beetle *Poecilus cupreus* were assessed. The test item was applied once onto the uncovered test containers including the beetles at a limit rate of 3.2 L prod./ha. A control group exposed to deionised water without test item was run concurrently. Under the conditions of this study no treatment related effects on mortality, behaviour and food intake could be observed when compared to the control. In conclusion, the LR_{50}/ER_{50} can be established above the highest test rate of 3.2 L prod./ha. Relevant data for the effects of MCW-853 SC on *Poecilus cupreus* were determined as follows:

Study comments: IIIA 10.5.2/04	Test system: *Poecilus cupreus*, extended lab test using soil Test method: Heimbach et al. (2000) Test item: MCW-853 SC (nominal a.s. content: 200 g fluazinam/L, 200 g dimethomorph/L) Test rates: 3.2 L prod./ha (limit test) GLP: Yes Validity: Considered valid without restrictions
Agreed endpoint/s: IIIA 10.5.2/04	$Mortality_{corr}$ = 0 % Effects on feeding rate = 0 %

IIIA 10.5.3 Effects on non-target terrestrial arthropods in semi-field tests

IIIA 10.5.4 Field tests on arthropods species

IIIA 10.6 Effects on earthworms and other soil macro-organisms

IIIA 10.6.2 Acute toxicity to earthworms

Report:	**KIIIA1 10.6.2/01, Lührs, U., 2008**
Title:	Acute toxicity (14 Days) of MCW-853 SC to the Earthworm *Eisenia fetida* in Artificial Soil with 5 % peat
Testing facility:	IBACON GmbH, Rossdorf, Germany
Document No:	42138021, sponsor report no.: R-23930
Guidelines:	OECD 207 (1984), ISO 11268-1 (1993). Deviations: Only 5 % peat was taken for the artificial soil instead of 10 %. This was done according to OECD (222) and EPPO (2003). These deviations were considered to have no impact on the quality or integrity of the study.
GLP	**Yes (certified laboratory)**
Comments of zRMS	**Acceptable. Used in evaluation.**

Executive summary

Groups of 40 earthworms (10 worms per replicate, 4 replicates per group) were exposed for 14 days to MCW-865 SC incorporated into artificial soil (peat content: 5 %) at concentrations in a range of 62.5 - 1000 mg prod./kg soil dry weight. Mortality, body weight changes and toxicological signs were recorded.

LC_{50} was not determinable since no mortality was observed during the test period. The NOEC, which represents the highest tested concentration without significant effects on mortality, body weight loss and behaviour was determined at 62.5 mg/kg soil dry weight.

I. Materials and methods

A. Materials

1. Test material: MCW-853 SC

Description:	orange, liquid
Lot/Batch no.:	175-191107-02
Active ingredient content:	dimethomorph: 211 g/L (certified) fluazinam: 211 g/L (certified)
Stability of test compound:	expiry date: November 22, 2009
Density:	1.15 - 1.21 g/mL

2. Control: artificial soil, moistened with deionised water
   Solvent/vehicle: none
   Toxic reference: 2-Chloracetamide, separated test most recent

3. Test organisms -
   Taxonomic group: earthworms (Annelida: Oligochaeta)
   Species: *Eisenia fetida*
   Age: adult (11 - 12 month old), with clitellum
   Body weight: 300 - 600 mg
   Source: own breeding
   Feeding: none (during test)
   Acclimatisation: 1 day, in artificial soil under test conditions
   No. of worms: 40 per group (10 worms per replicate, 4 replicates per group)

4. Test units -
   Test vessels: normal glass bottling jars (1 L), loosely covered by glass-lids to enable exchange of air
   Filling: 500 g soil (dry weight)

5. Test conditions -
   Test substrate: artificial soil
   Composition: 74.8 % quartz sand, 20 % kaolinite clay, 5 % sphagnum peat (reduced content), 0.2 % calcium carbonate (for pH adjustment)
   pH value: 6.0 ± 0.5
   Soil moisture: Test start: 54.1 - 57.4 % of max. WHC
   Test end: 52.1 - 54.1 % of max. WHC
   Environmental conditions -
   Temperature: Exposure: 18 - 21 °C
   Photoperiod: continuous
   Light intensity: 480 - 770 lux

6. Test duration: 14 days

B. Study design and method

1. In life dates: July 11 to August 05, 2008

2. Range-finding test:

In the preliminary test, the test substance was mixed in the basic substrate in the following concentrations: 10, 100, 300, 600 and 1000 mg/kg substrate (dry weight).

3. Main test:

Forty earthworms per group (10 worms per replicate, 4 replicates per group) were exposed for 14 days to MCW-853 SC incorporated into artificial soil with a peat content of 5 % at concentrations of

- 62.5, 125, 250, 500 and 1000 mg prod./kg soil dry weight

Control replicates with untreated soil were run concurrently. The earthworms were weighted and placed onto the surface of the artificial soil after application.

4. Observations:

Mortality, behaviour and morphological changes were observed on day 7 and 14 after application. Mean body weights were determined at test start and test end.

5. Statistics:

To test for normal distribution and homogeneity the Kolmogoroff-Smirnov and Cochrans's test (both with $\alpha = 0.5$) were conducted. Dunnett's test was used for determination of statistically significant differences in mortality and body weights compared to the control. LC_{50} was not determinable by statistical analysis since no mortality was observed. The NOEC was determined directly from the test results.

II. Results and discussion

A. Mortality

No mortality was observed within the test period. Therefore, the LC_{50} was estimated to be above the highest concentration of 1000 mg prod./kg soil dry weight. Mortality data are summarised in the table below.

Table 10- 21: Earthworms mortality after 7 and 14 days of exposure

Test concentration [mg/kg dry soil]	Mean mortality [%]	
	day 7	day 14
Control	0	0
62.5	0	0
125	0	0
250	0	0
500	0	0
1000	0	0

B. Body weight changes

At the test item concentrations of 62.5 mg/kg dry soil, the weight loss of the earthworms was not significantly different compared to the control. In contrast, a statistically significant decrease of body weight was observed at concentrations of 125 mg prod./kg soil and higher. However, the decrease was ≤ 20 % indicating no biologically significance according to DIN ISO 11268-1. Body weight changes during the test period are given in the table below.

Table 10- 22: Body weight changes of earthworms after 14 days of exposure

Test concentration [mg/kg dry soil]	Mean body weight [mg/worm] day 0	day 14	Body weight loss* [%]
Control	412.0	396.4	3.8
62.5	394.5	362.2	8.2
125	402.4	360.0	10.5**
250	400.0	341.6	14.6**
500	392.3	326.6	16.8**
1000	379.6	307.4	19.0**

*** loss of ≤ 20 % biologically not significant according to DIN ISO 11268-1 (1997)**

** statistically significant different according to Dunnett`s method

C. Other observations

During the test duration of 14 days, no pathological or abnormal behavioural symptoms could be observed in the control group as well as in the test item groups.

D. Deficiencies

Mean mortality in the control group was 0 % (required: ≤ 10 %), and the mean loss of biomass in the control group was 3.8 % (required: ≤ 20 %) at the end of the test. Thus, the validity criteria were fulfilled and the test was considered to be valid without restrictions.

III. Conclusions

In a 14-day acute toxicity test, earthworms (*Eisenia fetida* ssp.) were exposed to MCW-853 SC applied to artificial soil (peat content: 5 %) at concentrations of 62.5 -1000 mg prod./kg soil d.w. The LC_{50} was estimated to be above the highest concentration of 1000 mg test item/kg soil dry weight, since no significant effects on mortality were observed at the end of the test. At and below a test concentration of 62.5 mg/kg soil d.w., no biologically significant effects on body weight changes could be observed. In according to this, the NOEC were established at 62.5 mg/kg soil dw. A summary of relevant data is given below.

Study comments: IIIA 10.6.2/01	Test system:	*Eisenia fetida*, acute toxicity test, 14 d, substrate: soil (5 % peat)
	Test method:	OECD 207 (1984), ISO 11268-1 (1993)
	Test item:	MCW-853 SC (nominal a.s. content: 200 g fluazinam/L, 200 g dimethomorph/L)
	Test conc.:	62.5, 125, 250, 500 and 1000 mg prod./kg $soil_{dw}$, incorporated into artificial soil
	GLP:	Yes
	Validity:	Considered valid without restrictions
Agreed endpoint/s: IIIA 10.6.2/01	LC_{50} > 1000 mg prod./kg $soil_{dw}$	

IIIA 10.6.3 Sublethal effects on earthworms

Report:	KIIIA1 10.6.3/01, Witte, B., 2009
Title:	Effects of MCW-853 SC on reproduction and growth of earthworms *Eisenia fetida* in artificial soil with 5 % peat
Testing facility:	IBACON GmbH, Rossdorf, Germany
Document No:	42148022, sponsor no.: R-25549
Guidelines:	OECD 222 (204), ISO 11268-2 (1998) Deviations: none
GLP	Yes (certified laboratory)
Comments of zRMS	**Acceptable. Used in evaluation.**

Executive summary

Groups of 40 earthworms (10 worms per replicate, 4 replicates per group) were exposed for 28 days to MCW-853 SC sprayed onto artificial soil (peat content: 5 %) at rates in a range of 8.3 - 20.7 L prod./ha. Mortality, behavioural and morphological changes were assessed after 28 days of exposure and the adult earthworms were removed. The body weights of the adult earthworms were determined on day 0 and day 28. The number of juveniles was determined at test end on day 56.

Under the conditions of this test, no mortality and no significant effects on body weight changes and reproduction were observed compared to the control. Thus, the NOEC for sublethal effects was established at the highest test rate of 20.7 L prod./ha.

I. Materials and methods

A. Materials

1. Test material: MCW-853 SC
   Description: orange, liquid
   Lot/Batch no.: 175-191107-02
   Active ingredient content: dimethomorph: 211 g/L (certified)
   fluazinam: 211 g/L (certified)
   Stability of test compound: date of expiry: November 22, 2009
   Density: 1.176 g/cm³

2. Control: artificial soil, moistened with deionised water
   Solvent/vehicle: none
   Toxic reference: Luxan Carbendazim 500 FC

3. Test organisms -
   Taxonomic group: earthworms (Annelida: Oligochaeta)
   Species: *Eisenia fetida* ssp. *andrei*
   Age: adult (8 - 9 months old), with clitellum
   Body weight: 328 - 600 mg
   Source: own breeding
   Acclimatisation: 1 day in artificial soil under test conditions
   Feeding: 10 g cattle manure/kg soil dw was mixed into the soil of each plastic box before test start and 5 g/container was scattered on the soil surface at day 1. The next four weeks 5 g food was added onto the surface once a week, when the food of the precious week had almost been consumed. Four weeks after application the food was

	mixed by hand into the substrate following removal of the adult worms.
No. of worms:	10 worms/replicate, 4 replicates/test item group and 8 replicates/control group

4. Test units -

Type and size:	plastic boxes (18.3 × 13.6 × 6.0 cm), transparent and perforated lids
Filling:	500 g soil (dry weight)

5. Test conditions -

Test substrate:	artificial soil according to OECD 222, with reduced organic matter content
Composition:	74.8 % quartz sand, 20 % kaolin clay, 5 % sphagnum peat, ca. 0.2 % calcium carbonate (for pH adjustment)
Environmental conditions -	
Temperature:	18 - 20 °C
Photoperiod:	16 h light / 8 h dark
Light intensity:	410 - 690 lux
pH value:	5.7 - 5.9
Soil moisture:	50.0 - 61.6 67.3 % of max. WHC

6. Test duration: 56 days

B. Study design and method

1. In life dates: April 28 to June 26, 2009

2. Description of test procedures:

The test item was dissolved in deionised water and sprayed onto the soil surface (using laboratory-spraying equipment) at application rates of:

- 8.3, 10.0, 12.0, 14.4, 17.3 and 20.7 L prod./ha

Application was done after the earthworms had been introduced and had burrowed into the soil. A control and reference group exposed to deionised water without test item and Luxan Carbendazim 500 FC as toxic reference, respectively, were run concurrently. The adult earthworms were removed on day 28 and the test medium including cocoons laid during the first 28 days was incubated for further four weeks.

3. Observations:

Mortality, behavioural and morphological changes were assessed after 28 days of exposure. The body weights of the adult earthworms were determined on day 0 and day 28. The number of juveniles was determined at test end on day 56.

4. Statistics:

Significance of body weight changes and reproduction compared to the control was assessed using Dunnett's exact test. Distribution and homogeneity of variance were tested with the Kolmogoroff-Smirnov test and the Cochran test. Well-defined LC_{50}/EC_{50} values were not determinable in view of a lack of relevant effects (exceeding 50 %) on mortality and reproduction. The NOEC was directly deduced from the test results.

II. Results and discussion

A. Mortality, behavioural and morphological changes

No mortality was observed in the control as well as in the treatment groups. Furthermore, earthworms in the control and all test item groups showed no obvious pathological symptoms or behavioural abnormalities. Mortality data are summarised in the table below.

Table 10- 23: Earthworms mortality after 28 days of exposure

Test rate [L prod./ha]	Mean mortality after 28 days of exposure [%]
Control	0
8.3	0
10.0	0
12.0	0
14.4	0
17.3	0
20.7	0

B. Body weight changes

An increase of body weights during the 28 days of exposure was observed for the control and all test item groups indicating no statistically significant differences when compared to the control. The results are summarised in the table below.

Table 10- 24: Body weight gain of earthworms after 28 days of exposure

Test rate [L prod./ha]	Mean body weight gain	
	[mg]	[%]
Control	130	29.1
8.3	173	38.8
10.0	136	30.2
12.0	156	34.8
14.4	152	34.0
17.3	166	37.3
20.7	131	29.5

C. Reproduction

No statistically significant effects on reproduction (mean number of juveniles) compared to the control was observed within the range of tested rates. Reproduction data after 8 weeks of exposure are summarised in the table below.

Table 10- 25: Reproduction rate of earthworms after 56 days

Test rate [L prod./ha]	Number of juveniles	
	Mean	% of control
Control	333	-
8.3	301	90.4
10.0	351	105.6
12.0	315	94.8
14.4	288	86.5
17.3	293	88.1
20.7	307	92.3

D. Deficiencies

In the control, adult mortality was 0 % over the initial 4 weeks of the test (required: ≤ 10), and the number of juveniles per control replicate at test end was in the range from 228 to 448 (required: ≥ 30) with a coefficient of variation of 22 % (required: ≤ 30 %). Furthermore, the EC_{50} for the toxic reference item was calculated at 1.59 mg carbendazim/kg soil dw indicating that the sensitivity of the worms was consistent with the level proposed by OECD 222. Thus, the validity criteria were fulfilled and the test was considered to be valid without restrictions.

III. Conclusions

In a 56-day reproduction test, groups of earthworms (*Eisenia fetida* ssp. *andrei*) were exposed to MCW-853 SC (a.s. content: 211 g fluazinam/L and 211 g dimethomorph/L) sprayed onto artificial soil (peat content: 5 %) at rates in a range of 8.3 - 20.7 L prod./ha. Under the conditions of this test, no mortality and no significant effects on body weight changes and reproduction were observed compared to the control. Thus, the NOEC for sublethal effects was established at the highest test rate of 20.7 L prod./ha. A summary of relevant data is given below.

Study comments: IIIA 10.6.3/01	Test system: *Eisenia fetida*, reproduction test, 56 d, substrate: soil (5 % peat) Test method: OECD 222 (204), ISO 11268-2 (1998) Test item: MCW-853 SC (nominal a.s. content: 200 g fluazinam/L, 200 g dimethomorph/L) Test rates: 8.3, 10.0, 12.0, 14.4, 17.3 and 20.7 L prod./ha, sprayed onto the soil surface GLP: Yes Validity: Considered valid without restrictions
Agreed endpoint/s: IIIA 10.6.3/01	NOEL = 20.7 L prod./ha. (Additional note by zRMS: Recalculating the NOEC of 20.7 L prod./ha by taking the density of the formulation (1.176), the surface-area of each test chamber sprayed (189.75 cm^2) and the weight of the test soil in each test chamber (500 g d.w.) into account yields a NOEC of 92.22 mg prod./kg d.w.).

IIIA 10.6.4 Field tests (effects on earthworms)

IIIA 10.6.5 Residue content of earthworms

IIIA 10.6.6 Effects of other soil non-target macro-organisms

Report:	KIIIA1 10.6.6/01, Lührs, U., 2008
Title:	Effects of MCW-853 SC on the reproduction of the collembola *Folsomia candida* in artificial soil with 5 % peat
Testing facility:	IBACON GmbH, Rossdorf, Germany
Document No:	42144016, sponsor report no. R-23932
Guidelines:	ISO 11267 (1999) Deviations: none
GLP	Yes (certified laboratory)
Comments of zRMS:	**Acceptable. Used in evaluation.**

Executive Summary

Fifty springtails (*Folsomia candida*) per group (10 organisms per replicate, 5 replicates per group) were exposed for 28 days to MCW-853 SC (211 g fluazinam/L and 211 g dimethomorph/L) incorporated into artificial soil (peat content: 5 %) at concentrations of 4.0, 8.0, 16.0, 32.0, and 64.0 mg prod./kg soil (dry weight). After 28 days of exposure, the number and behaviour of living adults and the number of juveniles were assessed.

Under the conditions of this study, the LC_{50} was estimated above the highest test concentration of 64 mg prod./kg soil dry weight. No effects on reproduction were observed up to and including 16 mg prod./kg soil. Thus, the NOEC was established at this test concentration. The EC_{50} (reproduction) was determined by Probit analysis at 33.3 mg prod./kg soil dry weight.

I. Materials and methods

A. Materials

1. Test Material: MCW-853 SC
   Description: orange liquid
   Lot/Batch no.: 175-191107-02
   Active ingredient content: dimethomorph: 211 g/L (certified)
   fluazinam: 211 g/L (certified)
   Stability of test compound: date of expiry: November 22, 2009
   Density: 1.176 g/cm^3

2. Control: untreated soil (and moistened with deionised water)
   Solvent/vehicle: none
   Toxic reference: Betosip (a.s. phenmedipham, 157 g/L, nominal), effects of the reference item were investigated in a separate study (most recent)

3. Test organisms -
   Taxonomic group: Collembola (commonly known as springtails)

Species:	*Folsomia candida*
Age:	juvenile, 10 - 12 days old
Source:	bred in-house
Feeding:	approx. 2 mg of dry yeast at the beginning of the test and on day 14
No. of organisms:	50 per group (10 springtail per replicate, 5 replicates per group)

4. Test units -

Type and size:	glass vessel, diameter: 5 cm, volume 100 mL, closed tightly to avoid water evaporation
Filling:	30 g ± 1.5 g fresh weight of artificial soil

5. Test conditions -

Test substrate:	artificial soil according to OECD 222, with reduced organic matter content
Composition:	5 % sphagnum peat, 20 % kaolin clay, 74.8 % fine quartz sand, approx. 0.2 % calcium carbonate (for pH adjustment, pH 6.0 ± 0.5)
pH value:	test start: 6.1 - 6.2 test end: 5.5 - 5.7
Soil moisture:	test start: 53.2 - 54.7 % of the max. WHC test end: 49.4 - 43.0 % of the max. WHC max. water holding capacity (WHC): 41 %
Environmental conditions -	
Temperature:	18 - 22°C
Photoperiod:	16 hours light/ 8 hours dark
Light intensity:	470 - 570 lux
Ventilation:	twice a week by opening the lids for a short period

6. Test duration: 28 days

B. Study design and method

1. In life dates: July 07 to August 05, 2008

2. Description of test procedures:

The test item was dissolved in deionised water and incorporated into artificial soil by mixing to final concentrations of:

- 4, 8, 16, 32, and 64 mg prod./kg soil (dry weight)

Control replicates with untreated soil were run concurrently. The springtails were placed onto the surface of the test soil after application of the test item via incorporation into the soil.

3. Observations:

After 28 days of exposure, the number of living adults (missing springtails were recorded as dead as it is assumed that missing Collembola have died and degraded during the test period), and the number of juveniles were assessed. Surviving Collembola were observed for any abnormal behaviour or conditions at day 28.

4. Statistics

Mortality data were statistically analysed by Fisher´s exact test and reproduction distribution and homogeneity of variance with Kolmogoroff-Smirvon test and Cochran test. Further statistical evaluation was performed with the Dunnett´s test method. The EC_{50}-value was calculated by Probit analysis and the NOEC was directly deduced from the test results.

II. Results and discussion

A. Mortality

Mortality in the range of 12 to 16 % (mean) was observed in the test item groups, which was statistically not significantly different compared to the control. In the control group, 6 % of the Collembola died within 28 days of exposure. The results for the control and test item treatments are summarised in the table below.

Table 10- 26: Mortality of adult Collembola after 28 days of exposure to MCW-853 SC

Test concentration [mg prod./kg dry soil]	**Mean mortality [%]**	**significance (+/-)**
Control	6	
4.0	12	-
8.0	14	-
16.0	16	-
32.0	14	-
64.0	16	-

+ significantly different from control (Fisher`s exact test, $\alpha < 0.05$)

B. Reproduction and behavioural changes

Reproduction of the collembolans exposed to MCW-853 SC was not statistically significantly different compared to the control up to and including the test concentration of 16 mg prod./kg soil dry weight. At the concentration of 32 and 64 mg prod./kg soil dry weight a statistically significantly reduced number of juveniles was found. Furthermore, no behavioural abnormalities were observed in any of the treatment groups. The mean number of juveniles in the control and test item treatments is presented in the table below.

Table 10- 27: Reproduction of Collembola after 28 days of exposure to MCW-853 SC

Test concentration [mg prod./kg dry soil]	Mean number of juveniles	Reproduction [% of control]
Control	709	-
4.0	638	90
8.0	653	92
16.0	656	93
32.0	391*	55
64.0	33*	5

* significantly different compared to control (Dunnett test, $\alpha = 0.05$)

C. Deficiencies

In the control, adult mortality was 6 % over the initial 4 weeks of the test (required: ≤ 20), and the number of juveniles per control replicate at test end was in the range from 608 to 772 (required: ≥ 100) with a coefficient of variation of 9.9 % (required: ≤ 30 %). Furthermore, the EC_{50} (reproduction) for the toxic reference item was calculated to be 127 mg Betosip/kg soil dry weight indicating the sensitivity of the test system. Thus, the validity criteria were fulfilled and the test was considered to be valid without restrictions.

III. Conclusions

In a 28-day reproduction toxicity test, *Folsomia candida* were exposed to MCW-853 SC (a.s. content: 211 g fluazinam/L and 211 g dimethomorph/L) in artificial soil. The test item was incorporated into artificial soil (5 % peat) at concentrations between 4.0 and 64.0 mg prod./kg soil dry weight prior to introduction of the springtails. Under the conditions of this study, the LC_{50} was estimated above the highest test concentration of 64 mg prod./kg soil dry weight. No effects on reproduction were observed up to and including 16 mg prod./kg soil. Thus, the NOEC was established at this test concentration. The EC_{50} (reproduction) was determined by Probit analysis at 33.3 mg prod./kg soil dry weight. Relevant endpoints established for the test item are summarised below:

Study comments: IIIA 10.6.6/01	Test system: *Folsomia candida*, reproduction test, 28 days, substrate: artificial soil with 5 % peat Test method: ISO 11267 (1999) Test item: MCW-853 SC (nominal a.s. content: 200 g fluazinam/L, 200 g dimetomorph/L) Test conc.: 4.0, 8.0, 16.0, 32.0, and 64.0 mg prod./kg dry soil, incorporated into artificial soil GLP: Yes Validity: Considered valid without restrictions
Agreed endpoint/s: IIIA 10.6.6/01	NOEC = 16 mg prod./kg $soil_{dw}$

Report:	KIIIA1 10.6.6/02, Lührs, U., 2009
Title:	Effects of MCW-853 SC on the reproduction of the predatory mite *Hypoaspis aculeifer* in artificial soil with 5 % peat
Testing facility:	IBACON GmbH, Rossdorf, Germany
Document No:	50881089, sponsor report no. R-25550
Guidelines:	OECD 226 (2008) Deviations: none
GLP	Yes (certified laboratory)
Comments of zRMS:	**Acceptable. Used in evaluation.**

Executive Summary

Fifty predatory mites (*Hypoaspis aculeifer*) per test item group (10 organisms per replicate, 5 replicates per group) were exposed for 14 days to MCW-853 SC (211 g fluazinam/L and 211 g dimethomorph/L) incorporated into artificial soil (peat content: 5 %) at concentrations of 62.5, 125, 250, 500 and 1000 mg prod./kg soil (dry weight). After 14 days of exposure, the number of living adults and the number of juveniles were assessed.

Under the conditions of this study, no statistically significant effects on reproduction (compared to the control) were observed up to and including a test concentration of 250 mg prod./kg soil. Thus, the NOEC for reproduction was established at this test concentration. A well-defined EC_{50} for reproduction was not determinable due to a lack of effects on reproduction exceeding 50 %.

I. Materials and methods

A. Materials

1. Test Material: MCW-853 SC
   Description: orange liquid
   Lot/Batch no.: 175-191107-02
   Active ingredient content: dimethomorph: 211 g/L (certified)
   fluazinam: 211 g/L (certified)
   Stability of test compound: date of expiry: November 22, 2009
   Density: 1.176 g/cm^3

2. Control: untreated soil (and moistened with deionised water)
   Solvent/vehicle: none
   Toxic reference: Dimethoate (422.4 g a.s./L), effects of the reference item were investigated in a separate study (most recent)

3. Test organisms -
   Taxonomic group: Preadatory mites (Acari: Gamasida)
   Species: *Hypoaspis aculeifer*
   Age: adult females, aprrox. 12 days old after reaching the adult stage
   Source: Öre-Bioprotect GmbH, Raisdorf, Germany; provided by Katz Biotech AG, Baruth, Germany
   Feeding: cheese mite (Tyrophagus putrescentiae cultured by IBACON) offered ad libitum after introduction of the test organisms and on day 2, 5, 7, 9 and 12
   No. of organisms: 50 per treatment group (10 mites/replicate, 5 replicates/group), 80 in the control group (10 mites/replicate, 8 replicates/control)

4. Test units -
   Type and size: glass containers, diameter: 5 cm, volume 100 mL, closed tightly to avoid water evaporation
   Filling: 20 g ± 1.0 g dry weight of artificial soil

5. Test conditions -

Test substrate:	artificial soil according to OECD 222, with reduced organic matter content
Composition:	5 % sphagnum peat, 20 % kaolin clay, 74.8 % fine quartz sand, approx. 0.2 % calcium carbonate (for pH adjustment, pH 6.0 ± 0.5)
pH value:	5.5
Soil moisture:	test start: 41.9 - 47.0 % of the max. WHC test end: 40.0 - 46.2 % of the max. WHC max. water holding capacity (WHC): 39 %
Environmental conditions -	
Temperature:	18 - 21 °C
Photoperiod:	16 hours light/ 8 hours dark
Light intensity:	580 - 800 lux

6. Test duration: 14 days

B. Study design and method

1. In life dates: August 12 to September 02, 2009

2. Description of test procedures:

The test item was dissolved in deionised water and incorporated into artificial soil by mixing to final concentrations of:

- 62.5, 125, 250, 500 and 1000 mg prod./kg soil (dry weight)

Control replicates with untreated soil were run concurrently. The mites were placed onto the surface of the test soil after application of the test item via incorporation into the soil.

3. Observations:

After 14 days of exposure, the number of living adults (missing mites were recorded as dead) and the number of juveniles were assessed.

4. Statistics

Mortality data were statistically analysed by Fisher´s exact test and reproduction distribution and homogeneity of variance with Shapiro-Wilk's test and Levene's test. Further statistical evaluation was performed using Dunnett´s test method. The NOEC was directly deduced from the test results.

II. Results and discussion

A. Mortality

In the test item groups, mortality ranged from 3 to 15 % (mean) which was statistically not significantly different compared to the control. In the control group, 5 % of the mites died within 14 days of exposure. The results for the control and test item treatments are summarised in the table below.

Table 10- 28: Mortality of adult mites after 14 days of exposure to MCW-853 SC

Test concentration [mg prod./kg dry soil]	**Mean mortality [%]**	**significance (+/-)**
Control	5	
62.5	3	-
125	5	-
250	3	-
500	15	-
1000	5	-

+ significantly different from control (Fisher`s exact test, $\alpha < 0.05$)

B. Reproduction

Reproduction of the mites exposed to MCW-853 SC was not statistically significantly different compared to the control up to and including the test concentration of 250 mg prod./kg soil dry weight. In contrast, a statistically significantly reduced number of juveniles was observed at the concentration of 500 and 1000 mg prod./kg soil dry weight. The mean number of juveniles in the control and test item treatments is presented in the table below.

Table 10- 29: Reproduction of mites after 14 days of exposure to MCW-853 SC

Test concentration [mg prod./kg dry soil]	**Mean number of juveniles**	**Reproduction [% of control]**
Control	183	-
62.5	166	90
125	169	92
250	163	89
500	115*	63
1000	100*	55

* significantly different compared to control (Dunnett's test, $\alpha = 0.05$)

C. Deficiencies

In the control, adult mortality was 5 % over the 2 weeks of exposure (required: ≤ 20), and the number of juveniles per control replicate at test end was in the range from 129 to 286 (required: ≥ 50) with a coefficient of variation of 29.8 % (required: ≤ 30 %). Furthermore, the EC_{50} (reproduction) for the toxic reference item was calculated to be 2.84 mg a.s./kg soil dry weight indicating the sensitivity of the test system. Thus, the validity criteria were fulfilled and the test was considered to be valid without restrictions.

III. Conclusions

In a 14-day reproduction toxicity test, the predatory mite *Hypoaspis aculeifer* were exposed to MCW-853 SC (a.s. content: 211 g fluazinam/L and 211 g dimethomorph/L) in artificial soil. The test item was incorporated into artificial soil (5 % peat) at concentrations ranging from 62.5 to 1000 mg prod./kg soil dry weight. Under the conditions of this study, no statistically significant effects on reproduction (compared to the control) were observed up to and including a test concentration of 250 mg prod./kg soil. Thus, the NOEC for reproduction was established at this test concentration. A well-defined EC_{50} for reproduction was not determinable due to a lack of effects on reproduction exceeding 50 %. A summary of relevant endpoints is given below.

Study comments: IIIA 10.6.6/02	Test system: *Hypoaspis aculeifer*, reproduction test, 14 days, substrate: artificial soil with 5 % peat Test method: OECD 226 (2008) Test item: MCW-853 SC (nominal a.s. content: 200 g fluazinam/L, 200 g dimethomorph/L) Test conc.: 62.5, 125, 250, 500 and 1000 mg prod./kg dry soil, incorporated into artificial soil GLP: Yes Validity: Considered valid without restrictions
Agreed endpoint/s: IIIA 10.6.6/02	NOEC = 250 mg prod./kg $soil_{dw}$

Report:	KIIIA1 10.6.6/03, Schulz, L., 2009
Title:	Field study to evaluate the effects of MCW 456 500 SC (500 g/L Fluazinam) on micro-arthropods under grassland conditions
Testing facility:	BioChem agrar GmbH, Gerichshain, Germany
Document No:	08 10 48 008 F
Guidelines:	ISO 23611-2 (2006) Deviations: none
GLP	Yes (certified laboratory)
Comment by zRMS:	**Additional information. Not considered in evaluation.**

Executive summary

Soil arthropod populations (mites and collembolans) were exposed for approximately 11 months (duration from 1st application to last sampling) to MCW 465 500 SC sprayed onto grassland with a medium loam sand soil at rates of 8× 0.4 L prod./ha, 8× 0.8 L prod./ha and 8× 1.6 L prod./ha. Methamidophos was applied to the plots as toxic reference item at 12 L prod./ha and regular tap water was applied as a control. Total number of mites and collembolans, and community structure (order/family composition) were observed during the test duration. The arthropods were sampled on five dates: 1 day before 1st application (pre-sampling), approx. 3 weeks after 1st application (1st sampling), approx. 2 months after last application (2nd sampling), approx. 5 months after last application (3rd sampling) and approx. 10 months after last application (4th sampling).

Under the conditions of the test, no statistically significant effects (compared to the control) on the total number of mites were observed up to and including an application rate of 8× 0.8 L prod./ha, whereas no statistically significant effects on the total number of collembolans were observed within the range of tested rates. In conclusion, MCW 465 500 SC will not cause any long-term adverse impact on mite and collembolan populations under field conditions.

I. Materials and methods

A. Materials

1. Test material: MCW 465 500 SC
   Description: yellowish liquid
   Lot/Batch no.: 20113149
   Active ingredient content: 509 g/L Fluazinam (analysed)
   Density: 1.2665 g/mL
   Stability of test compound: expiry date: March 21, 2010

2. Control: site treated with tap water without test item
   Toxic reference: Methamidophos (a.s. content: 605 g/L Methamidophos)

3. Test organisms: soil arthropods (mites and collembols) naturally occurring on grassland in Northern Germany:
   Mite orders: *Gamasina*, *Oribatida*, *Prostigmata*, *Acaridida*, *Mesostigmata*
   Collembolan families: *Entomobryidae*, *Hypogastruridae*, *Isotomidae*, *Onychiuridae*, *Sminthuridae*, *Tomoceridae*, *Tullbergiidae*
   Age: variable based on natural climatic and environmental conditions

4. Test site -
   Location: Sommerfeld, Saxony, Eastern Germany
   Description: permanent grassland
   Site history: cultural practices performed during 2005 till 2007 followed by usual agricultural practice for grassland. No fertilisers or pesticides were applied

5. Soil -
   Type: medium loam sand
   pH value: 5.6 (average)
   Total organic carbon: 1.98 % dry matter (average)
   Soil moisture: 32.32 % w/w of max. WHC in A-horizon (average)

6. Test duration: last sampling: approximately 12 months after 1st application

B. Study design and method

1. In life dates: May 28, 2008 (pre-treatment population sampling) to May 13, 2009 (last population sampling)

2. Description of test procedures:

The test item was applied at the following rates:

- 8× 0.4 L prod./ha, 8× 0.8 L prod./ha and 8× 1.6 L prod./ha

Methamidophos (a.s. content: 605 g/L Methamidophos) was applied to the plots as toxic reference item at 12 L prod./ha (1st application, untreated at all other applications). Regular tap water was applied as a control (1st application, untreated at all other applications). An application volume of 600 L/ha of water was used for all applications.

The applications were conducted with a calibrated plot sprayer (PL 1, agrotop GmbH, Obertraubling) with Lechler DG Teejet 8004 VS nozzles. In an annual technical validation the sprayer was calibrated to deliver a target spray solution with a maximum deviation in the cross distribution of ± 10 %.

The experiment was a randomised block design with four replicates. Each plot measured 10 m × 10 m (central plot area: 6 m × 6 m, surrounded by a 2 m wide edge strip). The samples were taken exclusively from the central area of the plots, so that the sampling area was surrounded by a 2 m wide edge strip, which was also treated.

3. Observations:

Soil arthropods were sampled on the following dates:

- pre-sampling on May 28, 2008: 1 day before 1st application
- 1st sampling on June 16, 2008: approx. 3 weeks after 1st application
- 2nd sampling on September 01, 2008: approx. 2 months after last application
- 3rd sampling on December 16, 2008: approx. 5 months after last application
- 4th sampling on May 13, 2009: approx. 10 months after last application

Specimens (soil cores) were randomly taken exclusively from the central plot area using stainless tubes. For extraction of the micro-arthropods from the soil a MacFadyen high-gradient extractor was used.

Total number of mites and collembolans, and community structure (order/family composition) were observed during the test duration.

4. Statistics:

Effects of the test item were analysed using Outlier test after Dixon & Hartley (for dominant orders/families), Tukey-Kramer Test (pre-sampling) and two two-sided Dunnett-test/Welch-test (post-application samplings). In contrast, post-application data for the reference item was analysed using Student-t-test instead of Dunnett-test.

II. Results and discussion

A. Community structure

As outlined in the table below, the mite community included 5 orders: *Prostigmata* > *Oribatida* > *Gamasina* > *Acaridida* > *Mesostigmata*. The orders *Prostigmata*, *Oribatida* and *Gamasina* were identified as dominant mite orders with mean distributions per m² of 42.6 %, 31.6 % and 17.9 %, respectively. Overall 7 collembolan families could be determined: *Isotomidae* > *Entomobryidae* > *Sminthuridae* > *Onychiuridae* > *Hypogastruridae* > *Tomoceridae* > *Tullbergiidae*. In this context, the dominant collembolan families were *Entomobryidae* (on average 36.8 %) and *Isotomidae* (on average 51.1 %).

Table 10- 30: Order distribution of mites at pre-sampling

Mite order	**Order distribution of mites at pre-sampling [%]**					**Mean per m² [%]**
	Control	**Test item - 8× 0.4 L/ha**	**Test item - 8× 0.8 L/ha**	**Test item - 8× 1.6 L/ha**	**Reference item**	
Gamasina	19.0	16.9	17.3	15.8	20.5	17.9
Oribatida	29.5	22.1	34.2	35.2	37.0	31.6
Prostigmata	41.6	40.2	35.4	48.8	46.8	42.6
Acaridida	9.8	6.6	5.2	8.4	7.1	7.4
Mesostigmata	0.7	0.4	0.5	0.7	0.4	0.5

Table 10- 31: Family distribution of collembolans at pre-sampling

Collembolan family	**Family distribution of collembolans at pre-sampling [%]**					**Mean per m² [%]**
	Control	**Test item - 8× 0.4 L/ha**	**Test item - 8× 0.8 L/ha**	**Test item - 8× 1.6 L/ha**	**Reference item**	
Entomobryidae	28.9	32.0	35.5	43.5	44.2	36.8
Hypogastruridae	1.0	1.4	0.3	1.4	1.4	1.1
Isotomidae	49.1	43.9	42.8	57.8	62.0	51.1
Onychiuridae	3.1	2.8	0.3	1.0	0.7	1.6
Sminthuridae	3.8	11.8	10.8	10.4	7.7	8.9
Tomoceridae	0.7	0.0	0.3	0.3	0.0	0.3
Tullbergiidae	0.0	0.7	0.0	0.0	0.0	0.1

B. Total number of soil arthropods

In the course of the study, no statistically significant effects (compared to the control) on the total number of mites were observed up to and including an application rate of 8× 0.8 L prod./ha, whereas no statistically significant effects on the total number of collembolans were observed within the range of tested rates. The results are presented in the tables below.

Table 10- 32: Total number of mites

Treatment	Total no. of mites [individuals per m² (% of control)]				
	Pre-sampling	1st sampling	2nd sampling	3rd sampling	4th sampling
Control	18016 (100.0 %)	16488 (100.0 %)	30993 (100.0 %)	32850 (100.0 %)	50282 (100.0 %)
Test item - 8× 0.4 L/ha	15406 (85.5 %)	12075 (73.0 %)	20839 (67.4 %)	30611 (93.2 %)	48022 (95.5 %)
Test item - 8× 0.8 L/ha	16552 (91.9 %)	14610 (88.6 %)	28849 (93.3 %)	39248 (119.5 %)	43407 (86.3 %)
Test item - 8× 1.6 L/ha	19481 (108.1 %)	11141 (67.8 %)	32637 (105.5 %)	69169* (210.6 %)	48351 (96.2 %)

* statistically significant at 5 % significance levels according to Dunnett-test (two-sided)

Table 10- 33: Total number of collembolans

Treatment	Total no. of collembols [individuals per m² (% of control)]				
	Pre-sampling	1st sampling	2nd sampling	3rd sampling	4th sampling
Control	7926 (100.0 %)	20563 (100.0 %)	13210 (100.0 %)	26070 (100.0 %)	29571 (100.0 %)
Test item - 8× 0.4 L/ha	8467 (106.8 %)	14833 (72.1 %)	11120 (84.2 %)	22993 (88.2 %)	23173 (78.4 %)
Test item - 8× 0.8 L/ha	8244 (104.0 %)	13698 (66.1 %)	12382 (93.7 %)	21040 (80.7 %)	23364 (79.0 %)
Test item - 8× 1.6 L/ha	10472 (132.1 %)	20022 (97.4 %)	11979 (90.7 %)	29433 (112.9 %)	22823 (77.2 %)

* statistically significant at 5 % significance levels according to Dunnett-test (two-sided)

Total numbers were also determined considering the most dominant taxa of mites and collembolans. Mites of the order *Oribatida* were not statistically significantly affected by any of the test item application regimes tested up to an application rate of 8× 1.6 L prod./ha in the course of the study. Statistically significant effects on the total numbers of mites of the order *Gamasina* were only determined at the highest test rate of 8× 1.6 L prod./ha (at 4th sampling). At an application rate of 8× 0.8 L prod./ha, mites of the order *Prostigmata* were affected approx. 3 weeks after the 1st application (1st sampling) with an statistically significant increase in total number of about 57 % (compared to the control). However, at the end of the study, ten months after the last application (4th sampling), the total number were 88.3 % of the control indicating no statistically significant difference.

For the collembolan family *Entomobryidae*, no statistically significant effects on total numbers of collembolans were observed within the range of tested application rates. In contrast, collembolans of the family *Isotomidae* were temporarily (only at 2nd sampling) statistically reduced by about 52 and 67 % at application rates of 8× 0.8 and 8× 1.6 L prod./ha, respectively. However, at the end of the test (10 months after last application) the total numbers of were not statistically significant reduced for these both application regimes clearly indicating the potential of recovery. The results are summarised in tabular format below.

Table 10- 34: Total number of mites, subdivided into the three dominant mite orders (i.e. *Gamasina*, *Oribatida*, *Prostigmata*)

Treatment	**Total no. of mites [individuals per m² (% of control)]**				
	Pre-sampling	**1st sampling**	**2nd sampling**	**3rd sampling**	**4th sampling**
Gamasina					
Control	3406 (100.0 %)	3470 (100.0 %)	6303 (100.0 %)	7480 (100.0 %)	14037 (100.0 %)
Test item - 8× 0.4 L/ha	3024 (88.8 %)	2483 (71.6 %)	5093 (80.8 %)	4870 (65.1 %)	11873 (84.6 %)
Test item - 8× 0.8 L/ha	3088 (90.7 %)	2737 (78.9 %)	7417 (117.7 %)	5157 (68.9 %)	11332 (80.7 %)
Test item - 8× 1.6 L/ha	2833 (83.2 %)	2546 (73.4 %)	6430 (102.0 %)	7257 (97.0 %)	10281* (73.2 %)
Oribatida					
Control	5284 (100.0 %)	8785 (100.0 %)	16319 (100.0 %)	18303 (100.0 %)	17136 (100.0 %)
Test item - 8× 0.4 L/ha	3947 (74.7 %)	5316 (60.5 %)	10536 (64.6 %)	19120 (104.5 %)	21401 (124.9 %)
Test item - 8× 0.8 L/ha	6112 (115.7 %)	6780 (77.2 %)	13910 (85.2 %)	26834 (146.6 %)	16828 (98.2 %)
Test item - 8× 1.6 L/ha	6303 (119.3 %)	5857 (66.7 %)	18876 (115.7 %)	53158 (290.4 %)	21592 (126.0 %)
Prostigmata					
Control	7448 (100.0 %)	2642 (100.0 %)	4393 (100.0 %)	3756 (100.0 %)	12902 (100.0 %)
Test item - 8× 0.4 L/ha	7194 (96.6 %)	2939 (111.2 %)	2663 (60.6 %)	4106 (109.3 %)	10738 (83.2 %)
Test item - 8× 0.8 L/ha	6334 (85.0 %)	4138* (156.6 %)	4276 (97.3 %)	4647 (123.7 %)	11395 (88.3 %)
Test item - 8× 1.6 L/ha	8722 (117.1 %)	2005 (75.9 %)	4467 (101.7 %)	5093 (135.6 %)	9889 (76.6 %)

* statistically significant at 5 % significance levels according to Dunnett-test (two-sided)

Table 10- 35: Total number of collembolans, subdivided into the two dominant collembolan families (i.e. *Entomobryidae*, *Isotomidae*)

Treatment	**Total no. of collembolans [individuals per m² (% of control)]**				
	Pre-sampling	**1st sampling**	**2nd sampling**	**3rd sampling**	**4th sampling**
Entomobryidae					
Control	2642 (100.0 %)	4361 (100.0 %)	4647 (100.0 %)	15534 (100.0 %)	13401 (100.0 %)
Test item - 8× 0.4 L/ha	2928 (110.8 %)	3342 (76.6 %)	4149 (89.3 %)	12446 (80.1 %)	10854 (81.0 %)
Test item - 8× 0.8 L/ha	3247 (122.9 %)	3894 (89.3 %)	7958 (171.3 %)	15343 (98.8 %)	12032 (89.8 %)
Test item - 8× 1.6 L/ha	3979 (150.6 %)	6907 (158.4 %)	8350 (179.7 %)	19162 (123.4 %)	10759 (80.3 %)
Isotomidae					
Control	4488 (100.0 %)	9899 (100.0 %)	6239 (100.0 %)	5507 (100.0 %)	11491 (100.0 %)
Test item - 8× 0.4 L/ha	4011 (89.4 %)	5157 (52.1 %)	5443 (87.2 %)	7077 (128.5 %)	10218 (88.9 %)
Test item - 8× 0.8 L/ha	3915 (87.2 %)	5284 (53.4 %)	2992* (48.0 %)	4265 (77.4 %)	9581 (83.4 %)
Test item - 8× 1.6 L/ha	5284 (117.7 %)	4838 (48.9 %)	2069* (33.2 %)	6769 (122.9 %)	8435 (73.4 %)

* statistically significant at 5 % significance levels according to Dunnett-test (two-sided)

C. Deficiencies

Total number of soil arthropods determined at pre-sampling was considered sufficiently high. Furthermore, the reference item showed clear effects on mites and collembolans abundance. Furthermore, the abundances of the mites of the orders *Gamasina*, *Oribatida* and *Prostigmata* as well as the abundances of the collembolan families *Isotomidae* and *Entomobryidae* were statistically affected by the reference item, indicating a sensitive and valid test system.

III. Conclusions

Within the framework of this field study, soil arthropod populations (mites and collembolans) were exposed to MCW 465 500 SC (a.s. content: 500 g Fluazinam/L) at rates of 8× 0.4 L prod./ha, 8× 0.8 L prod./ha and 8× 1.6 L prod./ha applied via spray treatment. The test site was permanent grassland with a medium loam sand soil. In the course of the study, no statistically significant effects (compared to the control) on the total number of mites were observed up to and including an application rate of 8× 0.8 L prod./ha, whereas no statistically significant effects on the total number of collembolans were observed within the range of tested rates. Furthermore, total numbers were also determined considering the most dominant taxa of mites and collembolans resulting in no long-term adverse effects on the total numbers for mites of the orders *Oribatida* and *Prostigmata* as well as for collembolan of the families *Entomobryidae* and *Isotomidae*. At the test end (10 months after last application), statistically significant effects on the total numbers were only determined for mites of the order *Gamasina* exposed to the highest test rate of 8× 1.6 L prod./ha. In conclusion, MCW 465 500 SC will not cause any long-term adverse impacts on mite and collembolan populations under field conditions.

Study comments: IIIA 10.6.6/03	Test system: Soil arthropod field study, 12 months Test method: ISO 23611-2 (2006) Test item: MCW 465 500 SC (active ingredient content: 500 g fluazinam/L) Test rates: 8× 0.4, 8× 0.8 and 8× 1.6 L prod./ha GLP: Yes Validity: Considered valid without restrictions
Agreed endpoint/s: IIIA 10.6.6/03	No statistically significant adverse long-term effects up to and including a test rate of 8× 0.8 L prod./ha

IIIA 10.6.7 Effects on organic matter breakdown

Report:	KIIIA1 10.6.7/01, Lührs, U., 2009
Title:	Effects of MCW 465 500 SC on the Breakdown of Organic Matter in Litter Bags in the Field
Testing facility:	IBACON GmbH, Rossdorf, Germany
Document No:	42253081, Sponsor no. R-24106
Guidelines:	Breakdown of organic matter in litter bags developed during the EPFES workshop, Lisbon, April 2003) and OECD Series on testing and assessment No. 56, 2006: Guidance document on the breakdown of organic matter in litter bags. Deviations: none
GLP	Yes (certified laboratory)
Comments by zRMS	**Additional information. Not used in evaluation.**

Executive Summary

The effects of Fluazinam (formulated as MCW 465 500 SC) on the organic matter breakdown were investigated using enclosed litter bags. The test item was applied on 2 occasions on a field sown with summer barley (*Djamila*). On the day of the first application the test item was incorporated into the soil with a rotary harrow up to a depth of 10 cm at a concentration of 200 g a.s./ha, corresponding to 400 mL MCW 465 500 SC/ha (similar to the calculated long term plateau concentration). At the same time, summer barley seed (variety ´*Djamila*´) was drilled to a depth of approx. 3 cm. 10 days later (and taking into account a crop interception of 50%), a second application at 3200 mL MCW 465 500 SC/ha (corresponding to the annual application rate) was performed. Litter bags filled with 4.0 ± 0.1 g dried wheat straw were buried horizontally at a depth of approx. 5 cm in the soil 7 days after the first application (three days before the second application). The litter bags were sampled 33 days, 88 days, 182 days and 333 days after application to calculate the mean % decomposition (mass loss of organic matter) for each treatment replicate.

In this study, effects exceeding the EPFES trigger of 10 % deviation from the control were only observed at the first two samplings (33 and 88 days of exposure). At the two following sampling dates (182 and 333 days of exposure) the deviation from the control mass loss was less than 10 %. The values were not statistically significant at any sampling date. After 333 days of exposure, mass loss in the litter bags from the untreated control pots was 64.1 % while in the MCW 465 500 SC pots mass loss was 65.4 %. Thus, MCW 465 500 SC is considered to have no detrimental effects on breakdown of organic matter in the field up to an annual rate of 3200 mL/ha even after reaching a plateau concentration of 400 mL/ha.

I. Materials and methods

A. Materials

1. Test Material: MCW 465 500 SC
   Description: yellow-brown liquid
   Lot/Batch no.: 20113149
   Active ingredient content: 500 g/L Fluazinam nominal, 517 g/L analysed
   Stability of test compound: date of expiry: March 21, 2010
   Density: 1.2529 g/mL

2. Control: tap water
   Solvent for treatment solutions: tap water
   Toxic reference: none

3. Test conditions -
   Test soil:
   - Type: Silty loam
   - Sand content: 18.5 - 18.6 %
   - Silt content: 66.3 - 68.1 %
   - Clay: 13.3 - 15.2 %
   - Organic carbon content: 1.12 - 1.24 %
   - pH: 7.2 - 7.6
   - Moisture: 49.2 % of max WHC

Test site:	Arable land, Municipality: D-64380 Rossdorf, Germany District authority: Darmstadt-Dieburg
Treatment:	2007/2008: intercrop: white mustard Fertilisation: pig manure: July 07, 2007, 150 dt/ha cow slurry: September 01, 2007, 8.1 m³/ha horse manure: December 21, 2007, 125 dt/ha 2006/2007: crop: winter barley Fertilisation: Alzon 37: March 03, 2007, 2.0 dt/ha April 16, 2007, 1.8 dt/ha plant protection: September 05, 2006: 5.0 L/ha Clinic (360 g/L glyphosat),October 10, 2007: 0.6 kg/ha Herold (200 g/kg diflufenican, 400 g/kg flufenacet), April 18, 2007: 0.8 L/ha Stratego (125 g/L propiconazole, 187.5 g/L Trifloxystrobin), 0.5 L/ha Moddus (222 g/L Trinexapac) 2005/2006: crop: winter wheat Fertilisation: ammonium sulphate: September 23, 2005, 0.1 dt/ha pig manure: February 13, 2006, 9.0 m³/ha Alzon 37: February 27, 2006, 2.5 dt/ha May 06, 2006, 2.0 dt/ha plant protection: September 23, 2005: 5.0 L/ha Clinic (360 g/L glyphosat) April 08, 2006: 0.5 L/ha CCC 720 (558 g/L chlormequat) 0.06 kg/ha Lexus Class (154 g/kg Flupyrsulfuron, 310 g/kg Carfentrazone) June 16, 2006: 0.15 L/ha Fury 10 EW (100 g/L α-cyprmethrin) 1.25 L/ha Input (300 g/L Spiroxamine, 160 g/L Prothioconazole) During the experimental period no fertiliser and no additional pesticide treatments were applied.
No. and size of plots:	plots of 6 m × 5 m each with 3 m distance between the plots and at least 5 m distance to the field edges.
No. of plots	6 plots (replicates) per treatment and control group

4. Test units -

Type and size:	Litter bags made from curtain material (100 % polyester) with a mesh size of 5 mm with a size of approx. 10 cm x 20 cm
Filling:	4.0 ± 0.1 g dried (12 h, 35 °C) wheat straw
No. of litter bags:	40 bags per plot (32 for scheduled samples plus 8 as reserve, bag size: 10 × 20 cm, filled with 4.0 ± 0.1 g dried wheat straw,

5. Sampling dates: 33 days, 88 days, 182 days and 333 days after application

B. Study design and method

1. In life dates: June 18, 2008 to April 14, 2009 (experimental dates)

2. Description of test procedures:

The test item was applied on 2 occasions. On the day of the first application the test item was incorporated into the soil with a rotary harrow up to a depth of 10 cm at a concentration similar to the calculated long term plateau concentration of:

- 400 mL MCW 465 500 SC/ha, corresponding to 200 g a.s./ha or 501 g prod./ha

At the same time, summer barley seed (variety *´Djamila´*) was drilled to a depth of approx. 3 cm. After the introduction of the litter bags into the plots (day 7), the second application (day 10) was sprayed at a rate equal to the annual application of:

- 3200 mL MCW 465 500 SC/ha, corresponding to 1600 g a.s./ha and taking into account a crop interception of 50 %

A control only treated with tap water was run concurrently. The litter bags were sampled 33 days, 88 days, 182 days and 333 days after application. At each sampling date the bags were dried for 12 h at 35 °C and following this, the straw was dry sieved and manually sorted to remove roots, soil particles, earthworms etc. For the calculation of the % mass loss of organic matter the dry weight of the straw and the ash-free dry weight (AFDW, combusted 30 min at 600°C) were determined. 10 reference samples, each 4.0 ± 0.1 g were combusted to determine the AFDW at the start of the study.

3. Analytical verification of the test item:

The application concentration was analysed by quantification of Fluazinam in 9 soil cores taken from each treated plot, by means of liquid-chromatography with MS/MS detection. The soil samples were taken on the day of the first application and on the day of the second application.

4. Statistics:

Normal distribution was checked using the Kolmogoroff-Smirnov test, the Cochran test was used to check the homogeneity of variance. A two-tailed Student`s t-test was used to determine significant differences between the control and the treatment groups (software ToxRat Pro 2.09).

II. Results and discussion

A. Analytical data

1. Method validation

The analytical system gave a linear response over the whole range of prepared standards. Linearity (r^2) of the calibration curve was ≥ 0.9995. Accuracy (RR) and precision (RSD) were determined for fortified samples ranging from 29 to 2500 µg test item/kg soil, and resulted in recovery rates of 82 - 99 % (RSD = 8 %) for Fluazinam (required: RR = 70 - 110 %, RSD ≤ 20 %). The limit of quantification was set to 12 µg a.s./kg soil.

2. Analytical verification of the active substance

The mean recovery rate of active ingredient in the soil specimens taken after the first application was 51 % of the nominal value. The mean recovery rate after the second application was 54 % of the nominal value. The results of the chemical analysis confirm that the initial exposure concentration of MCW 465 500 SC in the soil of the treated plots were within the recommended range of the nominal values (50 to 150 % according to EPFES, 2003) after the 2nd application.

B. Decomposition of organic matter

The decomposition in the test item treated group ranged between 102.0 % (at the fourth sampling after 333 days of exposure and 126.2 % (at the first sampling after 33 days of exposure) compared to the control. Statistical analysis revealed no significance between the mass loss for the control and the test item groups at any sampling date. The results are summarised in the table below.

Table 10- 36: Mass loss (%) in the litter bags and effect compared to the control

Group	**Mean weight loss at each sampling date [%]**			
	33 days after appl. June 18, 2008	**88 days after appl. August 12, 2008**	**182 days after appl. November 14, 2008**	**333 days after appl. April 14, 2009**
Control group	13.0	31.8	55.8	64.1
Treatment group	16.4	36.9	57.4	65.4
Effect compared to the control [%]	126.2	116.0	102.9	102.0

C. Deficiencies

The decomposition in the control group was 64.1 % at the end of the experimental phase (required: ≥ 60 %). The coefficient of variation of mass loss in the control should not exceed 40 % (i.e. 10.4 - 17.5 %). Thus, the validity criteria of the underlying draft guideline were fulfilled and the study is considered to be valid without restrictions.

III. Conclusions

The effects of Fluazinam (formulated as MCW 465 500 SC) on the organic matter breakdown were investigated in enclosed litter bags at a concentration of 200 g a.s./ha (corresponding to the long term plateau concentration of Fluazinam in soil) followed by a second application of 1600 g a.s./ha (corresponding to the annual application of Fluazinam). Effects on decomposition of organic matter were as follows: Mass loss in the test item group was higher than in the control and deviated more than 10 % from the control values at the two first samplings up to 88 days exposure. At the two following sampling dates (182 and 333 days of exposure) the deviation from the control mass loss was less than 10 %. The values were not statistically significant at any sampling date. It was therefore concluded that MCW 465 500 SC will not cause any long-term adverse impacts on organic matter decomposition under field conditions.

Study comments: IIIA 10.6.7/01	Test system: Litter bag test, 333 d Test method: Breakdown of organic matter in litter bags developed during the EPFES workshop, Lisbon, April 2003) and OECD Series on testing and assessment No. 56, 2006: Guidance document on the breakdown of organic matter in litter bags Test item: MCW 465 500 SC (active ingredient content: 500 g fluazinam/L) Test rates: 200 + 1600 g a.s./ha GLP: Yes Validity: Not assessed in detail by zRMS (as only additional information).
Agreed endpoint/s: IIIA 10.6.7/01	No statistically significant adverse long-term effects up to and including a test rate of 200 + 1600 g a.s./ha

IIIA 10.7 Effects on soil microbial activity

IIIA 10.7.1 Laboratory test to investigate impact on soil microbial activity

Report:	KIIIA1 10.7.1/01, Feil, N., 2009
Title:	Effects of MCW-853 SC on the activity of the soil microflora in the laboratory
Testing facility:	IBACON GmbH, Rossdorf, Germany
Document No:	42149080, sponsor report no.: R-25551
Guidelines:	OECD 216/217 (2000) Deviations: none
GLP	Yes (certified laboratory)
Comments by zRMS	**Acceptable. Used in evaluation.**

Executive summary

The effects of MCW-853 SC on the activity of soil micro-organisms with regard to carbon (soil respiration) and nitrogen transformation (nitrate production) were investigated in loamy sand over a test duration of 28 (C-test)/42 days (N-test). The test item was mixed into the soil at rates of 4.0 and 10.0 L prod./ha (corresponding to 6.27 and 15.68 mg prod./kg $soil_{dw}$ or 4.704 and 11.76 kg prod./ha). Control replicates with untreated soils were run concurrently. In the carbon transformation test the respiration rate was determined by calculation the O_2 consumption of the soil microflora. Nitrogen concentrations were measured on day 0, 7, 14, 28 and 42 by means of photometric analysis.

In consideration of this study, MCW-853 SC is not expected to lead to any adverse long-term effects (> 25 %) on carbon and nitrogen turnover in soil, even at concentrations 10 times higher than the single application rate.

I. Materials and methods

A. Materials

1.	Test material:	MCW-853 SC
	Description:	orange, liquid
	Lot/Batch no.:	175-191107-02
	Active ingredient content:	dimethomorph: 211 g/L (certified) fluazinam: 211 g/L (certified)
	Stability of test compound:	expiry date: November 22, 2009
	Density:	1.176 g/cm^3
2.	Control:	soil treated with deionised water
	Toxic reference:	Sodium chloride, effects of the reference item were investigated in a separate study (most recent)
3.	Test substrate:	field fresh sampled
	Type:	loamy sand
	Sand content:	61.70 %
	pH-value:	7.0
	Organic carbon content:	1.22 %
	Soil moisture:	Carbon transformation test: 45.6 - 52.2 % of max. WHC Nitrogen transformation test: 47.7 - 50.4 % of max. WHC
	Replicates:	3 replicates
4.	Test units -	
	Type and size:	1 L plastic boxes with perforated tops
	Filling:	Carbon transformation test: 750 - 1000 g soil dry weight Nitrogen transformation test: 250 - 500 g soil dry weight
5.	Test conditions -	
	Temperature:	20 - 22 °C
	Photoperiod:	dark
6.	Test duration:	Carbon transformation: 28 days Nitrogen transformation: 42 days

B. Study design and method

1. In life dates : May 12 to July 03, 2009

2. Description of test procedures:

The test item was mixed into the soil at rates of:

- 6.27 and 15.68 mg prod./kg soil$_{dw}$ corresponding to 4.704 and 11.76 kg prod./ha or 4 and 10 L prod./ha

Afterwards, the soil was mixed in order to ensure a homogeneous distribution of the test item. Water was added to the soil to a water content of approximately 48.4 - 48.5 % of max. WHC. A control treated with water only was run concurrently. Additionally for the nitrogen transformation test, the soil was enriched with lucerne meal (0.5 % of dry weight). A toxic reference substance (Sodium chloride) was tested in a separate study at a concentration of:

- 16 g prod./kg soil$_{dw}$

3. Sampling:

Samples from the soil carbon transformation test were taken on day 0, 7, 14 and 28 after application. In the nitrogen transformation test, sampling was conducted on day 0, 7, 14, 28 and 42.

4. Description of analytical procedures:

In the carbon transformation test the respiration rate was determined by calculation the O_2 consumption of the soil microflora. Nitrogen concentrations were measured on day 0, 7, 14, 28 and 42 by means of photometric analysis.

5. Statistics:

Mean values, standard deviations and coefficients of variation were calculated for each assessment date and treatment group. Normality and homogeneity of variances were assessed with the R/S-Test and Cochrans's test (α =0.05). Pair-wise comparisons of treated and control values were performed according to the student-t-test and the Welch-t-test (α =0.05).

II. Results and discussion

A. Carbon transformation

No long-term effects (< ±25 % deviation compared to the control after day 28) on the carbon transformation expressed as soil respiration could be observed. Effects on carbon transformation are summarised in the table below.

Table 10- 37: Effects on carbon transformation

Days after application	Control	4.0 L prod./ha (6.27 mg prod./kg $soil_{dw}$)		10.0 L prod./ha (15.68 mg prod./kg $soil_{dw}$)	
	Respiration rate [mg CO_2/kg soil dw/h]	Respiration rate [mg CO_2/kg soil dw/h]	Deviation from control [%]	Respiration rate [mg CO_2/kg soil dw/h]	Deviation from control [%]
0	13.828	15.301*	10.65	15.080*	9.05
7	13.662	12.394*	-9.28	10.974*	-19.68
14	11.951	9.852*	-17.56	8.492*	-28.94
28	12.121	10.454*	-13.75	9.588*	-20.90

* statistically significant different from control (student-t-test & Welch-t-test, α = 0.05

B. Nitrogen transformation

No long-term effects (< ±25 % deviation compared to the control after day 42) on the nitrogen transformation could be observed. Effects on nitrogen transformation are summarised in the table below.

Table 10- 38: Effects on nitrogen transformation

Days after application	Control		4.0 L prod./ha (6.27 mg prod./kg $soil_{dw}$)			10 L prod./ha (15.68 mg prod./kg $soil_{dw}$)		
	Mineral-N [mg N/kg soil dw]	NO_3 [mg N/kg soil dw]	Mineral-N [mg N/kg soil dw]	NO_3 [mg N/kg soil dw]	Deviation of NO_3[1] [%]	Mineral-N [mg N/kg soil dw]	NO_3 [mg N/kg soil dw]	Deviation of NO_3[1] [%]
0	20.386	12.938	19.944*	13.098	1.24	19.594*	13.051	0.87
7	8.407	5.975	15.908*	13.104*	119.31	19.300*	16.539*	176.80
14	15.889	14.312	25.768*	23.703*	65.62	26.260*	24.003*	67.71
28	36.362	34.601	44.478*	42.672*	23.33	44.799*	42.959*	24.16
42	46.542	45.202	52.539*	51.184*	13.23	53.739*	52.312*	15.73

* statistically significant different from control (student-t-test & Welch-t-test, α = 0.05)
[1] compared to the control

C. Deficiencies

The variation (CV) between replicate control samples concerning soil respiration and nitrate production was 0.86 - 5.96 % and 0.52 - 11.26 %, respectively (required: ≤ ± 15 %). Furthermore, at the concentration of 16 g prod/kg $soil_{dw}$, the toxic standard Sodium chloride caused effects on soil respiration of 47.48 % and on nitrate production of 98.67 % at day 28 after application (required: > 25 %), demonstrating the sensitivity of the test system. Thus, the validity criteria according to OECD 216/217 (2000) are fulfilled and the study is considered to be valid without restrictions.

III. Conclusions

In a 28-day carbon- and a 42-day nitrogen transformation test, the effects of MCW-853 SC on the activity of soil micro-organisms were investigated in a loamy sand at application rates of 4.0 and 10.0 L prod./ha (corresponding to 6.27 and 15.68 mg prod./kg $soil_{dw}$ or 4.704 and 11.76 kg prod./ha). A control with untreated soil as test substrate was run concurrently. Under the conditions of this test, no irreversible long-term influence on carbon and nitrogen transformation in soils (i.e. effects < ±25 %) could be observed up to and including the highest test rate of 10.0 L prod./ha. Thus, the NOEL can be established at this rate as outlined in the table below.

Study comments: IIIA 10.7.1/01	Test system:	N-/C-transformation test, 28/42 d, substrate: loamy sand soil
	Test method:	OECD 216/217 (2000)
	Test item:	MCW-853 SC (nominal a.s. content: 200 g fluazinam/L, 200 g dimethomorph/L)
	Test rates:	4.0 and 10.0 L prod./ha
	GLP:	Yes
	Validity:	Considered valid without restrictions

Agreed endpoint/s: IIIA 10.7.1/01	NOEL* = 10.0 L prod./ha (corresponding to 15.68 mg prod./kg $soil_{dw}$)

* defined as highest test rate resulting in effects < ±25 % when compared to the control

IIIA 10.7.2 Further laboratory, glasshouse of field testing to investigate impact on soil microbial activity

III 10.8 Effects on non-target plants

III 10.8.1 Effects on non-target terrestrial plants

IIIA 10.8.1.1 Seed germination

IIIA 10.8.1.2 Vegetative vigour

Report:	**KIIIA1 10.8.1.2/01, Bützler, R., Mollandin, G., 2009**
Title:	Effects of MCW-853 SC on terrestrial (non-target) plants: Vegetative vigour test
Testing facility:	IBACON GmbH, Rossdorf, Germany
Document No:	42140087, sponsor report no.: R-25552
Guidelines:	**OECD 227 (2006)** **Deviations: none**
GLP	**Yes (certified laboratory)**
Comments zRMS	**Acceptable. Used in evaluation.**

Executive summary

The effects of MCW-853 SC (a.s. content: 211 g fluazinam/L, 211 g dimethomorph/L) on non-target plants were recorded in a vegetative vigour test with 6 representative species, i.e. oilseed rape, soybean, sugar beet, carrot, oat and onion. The test item was sprayed onto the plants at the 2 - 4 leaf stage in a volume of 400 L/ha at a limit rate of 1.0 L prod./ha. Visual phytotoxicity was assessed weekly on day 7, 14 and 21, mortality, fresh weight and growth stages were recorded at test termination on day 21 after application.

Under the conditions of the test, no significant visual phytotoxicity including mortality and no significant inhibitory effects on fresh weight and growth could be observed. Thus, the NOER was set to 1.0 L prod./ha and the ER_{50}/LOER was established above the tested limit rate of 1.0 L prod./ha.

I. Materials and methods

A. Materials

1. Test material: MCW-853 SC

Description:	orange, liquid
Lot/Batch no.:	175-191107-02
Active ingredient content:	dimethomorph: 211 g/L (certified) fluazinam: 211 g/L (certified)
Stability of test compound:	expiry date: November 22, 2009

2. Control: tap water
   Solvent/vehicle: none
   Toxic reference: none

3. Test organisms -
   Dicotyledonous species: Sugar beet (*Beta vulgaris*, Chenopodiaceae)
   Soybean (*Glycine max*, Fabaceae)
   Oilseed rape (*Brassica napus*, Brassicaceae)
   Carrot (*Daucus carota*, Apiaceae)
   Monocotyledonous species: Oat (*Avena sativa*, Poaceae)
   Onion (*Allium cepa*, Liliaceae)

   Growth stage at treatment: 2 - 4 leaf stage, BBCH 14
   No. of plants: 6 - 10 pots (= replicates) containing 2 - 5 plants for each group

4. Test units -
   Type and size: commercial plastic flower pots, 12 - 14 cm diameter in a growth camber

5. Test medium: certified LUFA soil No. 2.3
   Soil type: sandy loam (USDA)
   Grain size: ≤ 20 mm
   Carbon content: 0.98 ± 0.05 %
   pH-value: 6.4 ± 0.6

6. Test conditions -
   Temperature: 19 - 26.3 °C
   Photoperiod: 16 h
   Light intensity: 5670 - 15800 lux
   Relative humidity: 57.3 - 72.4 %
   Watering: Bottom watering of the test containers

7. Test duration: 21 days

B. Study design and method

1. In life dates: May 29 to June 19, 2009

2. Description of test procedures:

The seeds of the tested plant species were sown in flower pots. At 2 - 4 leaf growth stage (BBCH 14), the test item was sprayed onto the plant`s foliage once at a limit rate of:

- 1.0 L prod./ha in 400 L water/ha

A control group treated with tap water (400 L/ha) was run concurrently.

3. Verification of application rates:

Analytical verification of the active ingredients fluazinam and dimethomorph was performed at test start by means of HPLC-UV-method.

4. Observations:

Visual phytotoxicity was assessed weekly on day 7, 14 and 21. Mortality, fresh weight and growth stages were recorded at test termination on day 21 after application.

5. Statistics

ER_{50}-values were statistically not determinable since no effects could be observed, which leads to 50 % growth inhibition. Fresh weight data were tested for normal distribution and homogeneity of variance using the Kolmogoroff-Smirnov-Test and the Cochran-test (α = 0.05). Normal distributed and homogeneous data were compared with the Student-t-test, and otherwise with the Welch-t-test.

II. Results and discussion

A. Analytical data

1. Method validation

The analytical system gave a linear response over the whole range of prepared standards. Linearity (r^2) of the calibration curves was at least 0.9998. Accuracy (RR) and precision (RSD) were determined for five replicates of fortified concentrations of 300 (LOQ) and 3000 mg test item/L (10× LOQ) and resulted in recovery rates of 89 - 99 % (n = 10, mean RSD = 4.0 %) for fluazinam and 100 - 106 % (n = 10, mean RSD = 2.0 %) for dimethomorph (required: RR = 70 - 110 %, RSD ≤ 20 %). In the blank validation samples response was lower than 30 % of LOQ (required: ≤ 30 % of LOQ). The limit of detection was set to 2.7 mg fluazinam/L and 8.3 mg dimethomorph/L.

2. Analytical verification of the active substance

The concentrations of fluazinam and dimethomorph were determined at test start by means of HPLC-UV-method. The measured concentrations were 93 % and 101 % of the nominal value determined for fluazinam and dimethomorph, respectively.

B. Effects on plant growth

Under the conditions of the test, no statistical significant or inhibitory effects on biomass production and growth could be observed as outlined in the tables below.

Table 10- 39: Mean fresh weight of terrestrial plants after 21 days of exposure

Test rate [L prod./ha]	**Mean fresh weight [g]**											
	Rape	Inhib. (%)	Soy bean	Inhib. (%)	Sugar beet	Inhib. (%)	Carrot	Inhib. (%)	Oat	Inhib. (%)	Onion	Inhib. (%)
Control	30.259	-	17.411	-	21.958	-	19.073	-	37.856	-	13.226	-
1.0	30.077	-0.6	18.033	3.6	23.462	6.8	19.407	1.8	40.687	7.5	10.921	-17.4

Inhib.: Inhibition compared to the control

Table 10- 40: Growth stages at study initiation and 21 days after application (DAA)

Test rate [L prod./ha]	BBCH stages											
	Rape		Soybean		Sugar beet		Carrot		Oat		Onion	
	0 DAA	21 DAA	0 DAA	21 DAA	0 DAA	21 DAA	0 DAA	21 DAA	0 DAA	21 DAA	0 DAA	21 DAA
Control	12	16	12	23-24	12	14-15	13-14	16-17	13	34	12-13	14-15
1.0	12	16	12	23-24	12	14-15	13-14	16-17	13	34	12-13	14-15

C. Other observations

Very slight phytotoxic effects were observed for *Glycine max* (i.e. 0.4 %, chlorosis and necrosis), *Beta vulgaris* (0.4 %, necrosis and growth reduction), *Daucus carota* (0.2 %, necrosis) and *Allium cepa* (1.2 %, growth reduction and abnormal growth of the leaves).

D. Deficiencies

Plants in the control group exhibited no visible phytotoxic effects. No mortality could be observed in the control group (required: mean plant survival of at least 90 %). Thus, the validity criteria according to OECD 227 (2006) were fulfilled and the test was considered to be valid without restrictions.

III. Conclusions

Effects of MCW-853 SC (a.s. content: 211 g fluazinam/L and 211 g dimethomorph/L) on non-target plants were recorded in a vegetative vigour test with 6 representative species, i.e. oilseed rape, soybean, sugar beet, carrot, oat and onion. MCW-853 SC was sprayed onto the plants at the 2 - 4 leaf stage in a volume of 400 L/ha at a limit rate of 1.0 L prod./ha. Under the conditions of the test, no significant visual phytotoxicity including mortality and no significant inhibitory effects on fresh weight and growth could be observed. Thus, the NOER was set to 1.0 L prod./ha and the ER_{50}/LOER was established above the tested limit rate of 1.0 L prod./ha. A summary of the results in tabular format is given below.

Study comments: IIIA 10.8.1.2/01	Test system:	Vegetative vigour test (6 plant species), 21 d
	Test method:	OECD 227 (2006)
	Test item:	MCW-853 SC (nominal a.s. content: 200 g fluazinam/L, 200 g dimethomorph)
	Test rates:	1.0 L prod./ha (limit test)
	GLP:	Yes
	Validity:	Considered valid without restrictions
Agreed endpoint/s: IIIA 10.8.1.2/01	Lowest ER_{50} > 1.0 L prod./ha	

IIIA 10.8.1.3 Seedling emergence

IIIA 10.8.1.4 Terrestrial field testing

MIII 10.8.2 Effects on non-target aquatic plants

IIIA 10.8.2.1 Aquatic plant growth – Lemna

IIIA 10.8.2.2 Aquatic field testing

DRAFT REGISTRATION REPORT
Part B

Section 6: Ecotoxicological studies
Detailed summary of the risk assessment

Product code: **BANJO forte/MCW 853**

Active Substance: **Fluazinam 200 g/L**
Dimethomorph 200 g/L

Central Zone
Zonal Rapporteur Member State: Germany

NATIONAL ADDENDUM

Applicant: **ADAMA Deutschland**

Date: **April 2015**

Table of Contents

Sec 6 ECOTOXICOLOGICAL STUDIES (MIIIA 10)

A full risk assessment according to Uniform Principles for the plant protection product BANJO FORTE in its intended uses in potatoes is documented in detail in the core assessment of the plant protection product BANJO FORTE dated from February 2014 performed by zRMS Germany.

This document comprises specific risk assessment for some annex points for authorization of the plant protection product BANJO FORTE in Germany according to the uses listed in Appendix 2.

General information on the formulation BANJO FORTE can be found in Table 5.1-1of Section 5 of the National addendum Germany.

6.1 Proposed use pattern and considered metabolites

6.1.1 Grouping of intended uses for risk assessment

Full details of the proposed use pattern of the formulation BANJO FORTE that will be assessed are presented in Appendix 1. The intended uses in Germany are covered by the core assessment performed by zRMS Germany.

6.1.2 Consideration of metabolites

Please refer to the core assessment.

6.2 Effects on birds (MIIIA 10.1, KPC 10.1, KPC 10.1.1)

Please refer to the core assessment.

Consequences for authorization:

None

6.3 Effects on Terrestrial Vertebrates Other Than Birds (MIIIA 10.3, KPC 10.1, KPC 10.1.2)

Please refer to the core assessment.

Consequences for authorization:

none

6.4 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KPC 10.1.3)

Please refer to the core assessment.

Consequences for authorization:

none

6.5 Effects on aquatic organisms (MIIIA 10.2, KPC 10.2, KPC 10.2.1)

6.5.1 Overview

Results of aquatic risk assessment for the intended for uses of BANJO FORTE in potatoes based on FOCUS Surface Water PEC values is presented in the Core assessment, Part B, Section 6, chapter 6.5

For authorization in Germany, exposure assessment of surface water considers the two routes of entry (i) spraydrift and volatilisation with subsequent deposition and (ii) run-off, drainage separately in order to allow risk mitigation measures separately for each entry route. Hence, aquatic risk assessment differs from those in the core assessment.

The risk assessment for aquatic organism for authorization of BANJO FORTE is outlined in the following chapters.

6.5.2 Toxicity

Please refer to the core assessment.

6.5.3 Justification for new endpoints

Please refer to the core assessment.

6.5.4 Toxicity to exposure ratios for aquatic species (MIIIA 10.2.1)

The evaluation of the risk for aquatic and sediment-dwelling organisms was performed in accordance with the recommendations of the "Guidance Document on Aquatic Ecotoxicology", as provided by the Commission Services (SANCO/3268/2001 rev.4 (final), 17 October 2002). Additionally, the recommendations made in chapter 10.3 of the EFSA-PPR-OPINION "Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters" (EFSA Journal 2013;11(7):3290) regarding mixture risk assessment are followed in the core assessment (see chapter 6.5.2.). In conclusion, the risk assessment for aquatic organisms is based on endpoints related to the individual active substances without further quantitative mixture risk assessment. The relevant endpoints for the TER-calculations of the two active substances are as follows:

- **Fluazinam**: SSD-HC_5 (0.00129 mg/L) determined for a number of EC_{10}-values available for aquatic invertebrates considering an adjusted assessment factor of 5.
- **Dimethomorph:** NOEC for fish (ELS) 0.056 mg/L, standard assessment factor of 10

6.5.4.1 TER values for the entry into surface water via spraydrift and deposition following volatilization

The calculation of concentrations in surface water is based on spray drift data by Rautmann and Ganzelmeier. Fluazinam has a vapour pressure of > 10^{-4} Pa and is therefore classified as semi-volatile. Hence, deposition following volatilization has to be considered. Hence, deposition following volatilization has been considered. The input parameters for fluazinam and dimethomorph are given in Section 5 National Addendum.

Table 6.5-1: Risk assessment for fluazinam for aquatic organisms for the entry route via spray-drift and deposition following volatilization under the implementation of different risk mitigation measures

Compound:	fluazinam							
Crop/Application rate:	Potatoes, 200 g ai/ha (1.0 L product/ha) (single application as worst case)							
Growth stage and season	BBCH 31-91							
Intended use:	00-001							
DT_{50} water (SFO):	3 d							
PEC-selection:	PECinitial							
Drift-Percentile:	agriculture (90th percentile), 80 % interception by crop plants (relevant figure for volatilization)							
Buffer zone	**Entry via spraydrift**		**Entry via deposition following volatilization**		**PECsw; conventional and drift reducing technique**			
					0% conv.	**50% red.**	**75% red.**	**90% red.**
[m]	**[%]**	**[g/ha]**	**[%]**	**[µg/L]**	**[µg /L]**			
0	100.00	66.67			66.67	33.33	16.67	6.67
1	2.770	1.847	0.095	0.064	1.910	0.99	0.53	0.25
5	0.570	0.380	0.052	0.035	0.415	0.22	0.13	0.07
10	0.290	0.193	0.026	0.017	0.211	0.11	0.07	0.04
15	0.200	0.133	0.017	0.012	0.145	0.08	0.04	0.02
20	0.150	0.100	0.017	0.012	0.112	0.06	0.04	0.02
Relevant toxicity endpoint: SSD-HC_5 (Invertebrates) = 1.2 µg a.i./L Relevant TER: 5								
Buffer zone [m]					**TER**			
0					-/-	-/-	-/-	-/-
1					**0,63**	**1,21**	**2,26**	**4,80**
5					**2,89**	5,45	9,23	17
10					5,69	11	17	30
15					8,28	15	30	60
20					10,71	20	30	60
Risk mitigation measures	NW 605/606							

PEC: predicted environmenral concentration; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger.

Table 6.5-2: Risk assessment for dimethomorph for aquatic organisms for the entry route via spraydrift and deposition following volatilization under the implementation of different risk mitigation measures

Compound:	dimethomorph							
Crop/Application rate:	potaoes, 200 g ai/ha (1.0 L product/ha) (cumulative application rate as worst case)							
Growth stage and season	BBCH 31-91							
Intended use:	00-001							
DT_{50} water (SFO):	19 d							
PEC-selection:	PECinitial							
Drift-Percentile:	agriculture (90th percentile)							
Buffer zone	**Entry via spraydrift**		**Entry via deposition following volatilization**		**PECsw; conventional and drift reducing technique**			
					0% conv.	**50% red.**	**75% red.**	**90% red.**
[m]	**[%]**	**[g/ha]**	**[%]**	**[µg/L]**	**[µg /L]**			
0	100.00	66.67			66.67	33.33	16.67	6.67
1	2.770	1.847			1.974	1.05	0.59	0.31
5	0.570	0.380			0.482	0.29	0.20	0.14
10	0.290	0.193			0.271	0.17	0.13	0.10
15	0.200	0.133			0.193	0.13	0.09	0.07
20	0.150	0.100			0.145	0.10	0.07	0.06
Relevant toxicity endpoint: NOEC (O. mykiss, ELS) = 56 µg a.i./L Relevant TER: 10								
Buffer zone [m]					**TER**			
0					-/-	-/-	-/-	-/-
1					30	60	121	303
5					147	294	589	1473
10					289	579	1158	2896
15					420	840	1680	4200
20					560	1120	2240	5600
Risk mitigation measures	-/-							

PEC: predicted environmenral concentration; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger.

6.5.4.2 TER values for the entry into surface water via run-off and drainage

The concentration of the active substance fluazinam and dimethomorph in adjacent ditch due to surface runoff and drainage is calculated using the model EXPOSIT 3.0. The input parameters for fluazinam and dimethomorph for exposure modelling with EXPOSIT 3.0 are given in the German National Addendum Section 5.

Table 6.5-3: Risk assessment for fluazinam for aquatic organisms for the entry route via run-off and drainage under the implementation of different risk mitigation measures

Compound:	fluazinam
Application rate:	4 x 200 g ai/ha (worst case), minimum interval 7 days

Intended use	00-001 (potatoes)	
Relevant toxicity endpoint:	SSD-HC_5 (Invertebrates) = 1.2 µg a.i./L	
Relevant TER:	5	
Run-off		
Buffer zone	**PEC**	**TER**
[m]	**[µg/L]**	
0	0.09	14
5	0.08	16
10	0.07	19
20	0.05	27
Drainage		
Time of application	**PEC**	**TER**
	[µg/L]	
Autumn/winter/early spring	Not relevant (since application only in early spring)	-/-
Spring/summer	0.03	49
Risk mitigation measures	-/-	

PEC: predicted environmenral concentration; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger.

Table 6.5-4: Risk assessment for dimethomorph for aquatic organisms for the entry route via run-off and drainage under the implementation of different risk mitigation measures

Compound:	dimethomorph	
Application rate:	4 x 200 g ai/ha (worst case), minimum interval 7 days	
Intended use	00-001 (potatoes)	
Relevant toxicity endpoint:	NOEC (O. Mykiss, ELS) = 56 µg a.i./L	
Relevant TER:	10	
Run-off		
Buffer zone	**PEC**	**TER**
[m]	**[µg/L]**	
0	1.58	35
5	1.37	41
10	1.17	48
20	0.82	68
Drainage		
Time of application	**PEC**	**TER**

	[µg/L]	
Autumn/winter/early spring	Not relevant (since application only in early spring)	-/-
Spring/summer	0.57	98
Risk mitigation measures	-/-	

PEC: predicted environmenral concentration; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger.

6.5.4.3 Consideration of Metabolites

Please refer to the core assessment, chapter 6.5.2.3.

6.5.5 Overall conclusions

Based on the calculated concentrations of the active substances fluazinam and dimethomorph in surface water (EVA 2.1, EXPOSIT 3.0) considering risk mitigation measures applicable in Germany (spray-drift reducing nozzles and no-spray/run-off buffer zones), the calculated TER values for the acute and long-term risk resulting from an exposure of aquatic organisms to fluazinam and dimethomorph according to the GAP of the formulation BANJO FORTE achieve the (modified) acceptability criteria TER ≥ 5 (fluazinam) and TER ≥ 10 (dimethomorph), 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 aquatic organisms due to the intended use of BANJO FORTE in potatoes according to the label.

Consequences for authorization:

For the authorization of the plant protection product BANJO FORTE following labeling and conditions of use are mandatory:

Required Labelling

NW 262	Fluazinam *Pseudokirchneriella subcapitata* NOEC < 0.0.0366 mg/L (as E_bC_{50} = 0.0366 mg/L)
NW 264	Fluazinam NOEC = 0.0125 mg/L (*D. magna*) and NOEC = 0.0029 mg/L (*P. promelas*) Dimethomorph NOEC = 0.100 mg/L (*D. magna*) and NOEC = 0.056 mg/L (*O.mykiss*)
NW 265	Fluazinam *Lemna gibba* NOErC = 0.0359

Conditions for use

BANJO FORTE	NW 468
use No. 00-001	NW 605/606 (conv. – 10 m; 50 % red. – 5 m; 75 % red. – 5 m; 90 % red. – 5 m)

6.6 Effects on bees (MIIIA 10.4, KPC 10.3.1)

Please refer to the core assessment.

6.7 Effects on arthropods other than bees (MIIIA 10.5, KPC 10.3.2)

Please refer to the core assessment.

6.7.1 Toxicity

Please refer to the core assessment.

6.7.2 Justification for new endpoints

Please refer to the core assessment.

6.7.3 Risk assessment

Fluazinam has a vapour pressure of > 10^{-4} Pa and is therefore classified as semi-volatile. Hence, deposition following volatilization has to be considered in the risk assessment conducted for Germany. The input parameters for fluazinam are given in Section 5. According to the windtunnel study conducted for this active substance (Staffa 2012; refer to Part B Section 5 National Addendum, Chapter 5.6.1), the amount of fluazinam that adds to spray-drift input is 0.11 % of the fluazinam application rate (i.e. 0.22 g) at 1 m distance from the field edge. In view of the comfortable exceedance (TER ≥ 240) of the TER-trigger (5) calculated for the formulation BANJO FORTE as documented in the core assessment in chapter 6.7.2.2, it becomes evident that the expected exposure of non-target arthropods including the exposure pathway volatilization and deposition for the active substance fluazinam would only marginally change the overall outcome of the assessment. Concluding, a quantitative assessment is not necessary, the risk is considered acceptable.

6.7.4 Conclusion

Based on the calculated rates of BANJO FORTE in off-field areas, the calculated TER values describing the risk resulting from an exposure of non-target arthropods to BANJO FORTE according to the GAP of the formulation BANJO FORTE achieve the acceptability criteria of 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 non-target arthropods due to the intended use of BANJO FORTE in potatoes according to the label.

Consequences for authorization:

None

6.8 Effects on non-target soil meso- and macrofauna (MIIIA 10.6, KPC 10.4, KPC 10.4.1, KPC 10.4.2)

Please refer to the core assessment.

6.8.1 Justification for new endpoints

Please refer to the core assessment.

6.8.2 Toxicity exposure ratios for earthworms and other soil macro- and mesofauna, TER_A and TER_{LT} (MIIIA 10.6.1)

For the calculations of predicted environmental concentrations in soils (PEC soil), reference is made to the environmental fate section (Part B, Section 5, National Addendum, Table 5.5-2) of this submission. As documented there, the German exposure assessment yields PEC_{act}-values that do exceed the respective numbers given in the core assessment by maximum a factor of 5 (reflecting the difference in soil depth considered as relevant in the EU assessment and German assessment, respectively). Consequently, the TER-values calculated for the formulation BANJO FORTE and the fluazinam-metabolite HYPA in the core assessment to assess the risk towards earthworms (*E.fetida*) and soil-arthropods (*F.candida*) (Table 6.8-2) would calculate at maximum 5-times lower if the German PEC-values are considered instead. Still, this calculation would indicate an exceedance of the relevant TER-trigger (10 for acute and 5 for long-term effects) and thus an acceptable acute and chronic risk for all endpoints except one: The Tier-1 TER-value calculated on the basis of the soil-arthropod endpoint available for the formulation BANJO FORTE (*F. candida*, NOEC = 16 mg/kg soil dw) and the German PEC_{act} (8.273mg/kg dw) is 1.9 and thus falls below the trigger (5), requiring a refined risk assessment.

6.8.3 Higher tier risk assessment

No data on the toxicity of the technical active substances fluazinam and dimethomorph towards *F. candida* are available, what is why respective data available for mono-formulations are considered here:

- The EFSA Scientific Report (2008) 137 for fluazinam reports a $NOEC_{corr}$ < 0.785 mg a.s./kg d.w.soil from a *Folsomia*-study conducted with the formulation "Fluazinam 500 SC" (internal study code 72789, initially submitted with dossier ZA 6899). In this study, already at the lowest concentration tested (3.13 mg Fluazinam 500 SC/mg kg dw corresponding to 1.57 mg a.s./kg dw) a statistically increased (22 %) mortality was observed, followed by concentration-dependent increase of both mortality and inhibition of reproduction at the higher test rates.
- The EFSA Scientific Report (2006) 82 for dimethomorph does not contain *Folsomia*-endpoints, but the UBA-database does report on a respective study meanwhile made available for the EU-representative formulation "FORUM" (synonym "BAS 550 02 F, 150 g/L dimethomorph, internal code 66120, initially submitted with dossier ZA4315). The overall NOEC (mortality and reproduction) of this study was determined as 500 mg prod./kg dw (corresponding to 75 mg a.s./kg dw), however no statistically significant effects have been observed up to the highest concentration tested.

Comparing these mono-formulation results it becomes obvious that fluazinam is clearly dominating the toxicity observed for BANJO FORTE towards *F. candida* (as the product-NOEC of 16 mg/kg soil dw is corresponding to about 3.2 mg a.s./kg for each of the two active substances).

For the purpose of a higher-tier risk assessment regarding the long-term effects of fluazinam, the applicant submitted a soil arthropod field study (see Core assessment, Appendix 2, Ref. IIIA 10.6.6/03: Schulz, L; 2009, internal study code 72808, initially submitted to ZA6899) and a litter bag test (see Core assessment, Appendix 2, Ref. IIIA 10.6.7/01: Lührs, U.; 2009), both conducted with the solo-formulation "BANJO" (synonym MCW 465 500 SC; content: 500 g fluazinam/L).

In the soil arthropod field study, mite and collembolan populations were exposed for approximately 11 months (duration from 1st application to last sampling) to MCW 465 500 SC at rates of 8× 0.4 L prod./ha, 8× 0.8 L prod./ha and 8× 1.6 L prod./ha (corresponding to 8× 200 g fluazinam/ha, 8× 400 g fluazinam/ha and 8× 800 g fluazinam/ha) applied via spray treatment. The test site was permanent grassland with a medium loam sand soil. Total number of mites and collembolans, and community structure (order/family composition) were observed during 3 times post-application (i.e. up to approximately 10 months after last application). At the end of the study, no statistically significant adverse effects (compared to the control) on the total number of mites and springtails were observed up to and including the high test rates of 8× 400 g fluazinam/ha and 8× 800 g fluazinam/ha, both clearly covering the intended application scenario, i.e. 4× 200 g fluazinam/ha for treatment of potato with BANJO FORTE. Furthermore, total numbers were also determined considering the most dominant taxa of mites and collembolans resulting in no long-term adverse effects on the total numbers for mites of the orders Oribatida and Prostigmata as well as for collembolan of the families Entomobryidae and Isotomidae. At test end (10 months after the last application), statistically significant adverse effects on the total numbers were only determined for mites of the order Gamasina exposed to the highest test rate of 8× 1.6 L prod./ha with a total number of 73.2 % compared to the control. However, although statistically significant, this deviation is within the range of natural biological variation under field conditions. No statistically significant effects on Gamasina were found at 8× 200 g fluazinam/ha and 8× 400 g fluazinam/ha and the total number of individuals of 84.6 % and 80.7 % of the control in these treatments indicate a lack of any adverse effects. In conclusion, MCW 465 500 SC will not cause any statistically significant adverse long-term effects on soil arthropod populations up to and including a test rate of 8× 400 g fluazinam/ha (3200 g fluazinam/ha in total) that covers the annual application rate of 4× 200 g fluazinam/ha (800 g fluazinam/ha in total) for treatment of potato with BANJO FORTE. Further, biologically relevant long-term effects were not observed even at tested rates up to and including 8× 800 g fluazinam/ha.

In the litterbag-study, the effects of MCW 465 500 SC on the organic matter breakdown were investigated using enclosed litter bags. The test item was applied on 2 occasions on a field sown with summer barley (Djamila). On the day of the first application, the test item was incorporated into the soil with a rotary harrow up to a depth of 10 cm at a concentration of 200 g a.s./ha, corresponding to 400 mL prod./ha (= 0.13 mg a.s./kg soildw). At the same time, summer barley seed (variety ´Djamila´) was drilled to a depth of approx. 3 cm. 10 days later (and taking into account a crop interception of 50 %), a second application at 1600 g a.s./ha, corresponding to 3200 mL prod./ha (= 1.07 mg a.s./kg soildw) was performed. Litter bags filled with 4.0 ± 0.1 g dried wheat straw were buried horizontally at a depth of approx. 5 cm in the soil 7 days after the first application (three days before the second application). The litter bags were sampled 33

days, 88 days, 182 days and 333 days after application to calculate the mean % decomposition (mass loss of organic matter) for each treatment replicate.In this study, effects exceeding the EPFES trigger of 10 % deviation from the control were only observed at the first two samplings (33 and 88 days of exposure). At the two following sampling dates (182 and 333 days of exposure) the deviation from the control mass loss was less than 10 %. The values were not statistically significant at any sampling date. After 333 days of exposure, mass loss in the litter bags from the untreated control pots was 64.1 % while in the MCW 465 500 SC pots mass loss was 65.4 %. Thus, MCW 465 500 SC is considered to have no detrimental effects on breakdown of organic matter in the field up to a rate of 1600 g fluazinam/ha even after reaching a plateau concentration of 200 g fluazinam/ha and thus, covering the annual application rate of 4× 200 g fluazinam/ha (800 g fluazinam/ha in total) for treatment of potato with BANJO FORTE.

Considering the results of the soil-arthropod field study and litterbag-study conducted with the mono-formulation “BANJO” (MCW 465 500 SC) containing the active substance fluazinam which does obviously dominate the toxicity of BANJO FORTE it can be reasonably concluded that the risk to soil-arthropods from the intended use of BANJO FORTE in potatoes is acceptable.

6.8.4 Overall conclusions

Based on the predicted concentrations of BANJO FORTE in soils, the TER values describing the acute and long-term risk for earthworms and other non-target soil organisms following exposure to the active substances fluazinam and dimethomorph, the metabolite HYPA and the formulation BANJO FORTE according to the GAP of the formulation BANJO FORTE achieve the acceptability criteria TER ≥ 10 resp. TER ≥ 5 according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. The results of the Tier1- and refined risk assessment indicate an acceptable risk for soil organisms due to the intended use of BANJO FORTE in potatoes according to the label.

Consequences for authorization:

none

6.9 Effects on soil microbial activity (MIIIA 10.7, KPC 10.5)

Please refer to the core assessment.

6.9.1 Justification for new endpoints

Please refer to the core assessment.

6.9.2 Risk assessment

The evaluation of the risk for soil micro-organisms was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

Please refer to for the predicted environmental concentrations in soil (PEC_{SOIL}) of the fluazinam-metabolite HYPA and the formulation BANJO FORTE as provided in Table 5.5-2 of Section 5 National Addendum.

The results of the risk assessment are summarized in the following table.

Table 6.9-1: Risk assessment for effects on soil micro-organisms

Test substance	**Test concentration (adverse effects < 25%)** **[mg/kg]**	**PEC_{SOIL}** **[mg/kg]**	**Risk acceptable** **[yes/no]**
BANJO FORTE	15.68	8.273	yes
HYPA	0.38	0.1871	yes

6.9.3 Overall conclusions

Based on the predicted concentrations of the fluazinam-metabolite HYPA as well as the formulation BANJO FORTE in soils, the risk to soil microbial processes following exposure to both the metabolite and the formulation according to the GAP of the formulation BANJO FORTE is considered to be acceptable acceptable according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2.

Consequences for authorization:

none

6.10 Effects on non-target plants (MIIIA 10.8, KPC 10.6)

6.10.1 Effects on non-target terrestrial plants (MIIIA 10.8.1)

Please refer to the core assessment.

6.10.2 Toxicity

Please refer to the core assessment.

6.10.3 Justification for new endpoints

Please refer to the core assessment.

6.10.4 Risk assessment

Fluazinam has a vapour pressure of > 10^{-4} Pa and is therefore classified as semi-volatile. Hence, deposition following volatilization has to be considered in the risk assessment conducted for Germany. The input parameters for fluazinam are given in Section 5. According to the windtunnel study conducted for this active substance (Staffa 2012; refer to Part B Section 5 National Addendum, Chapter 5.6.1), the amount of

fluazinam that adds to spray-drift input is 0.11 % of the fluazinam application rate (i.e. 0.22 g) at 1 m distance from the field edge. In view of the comfortable exceedance (TER = 20) of the TER-trigger (5) calculated for the formulation BANJO FORTE as documented in the core assessment in chapter 6.10.2.1 of the Core Assessment, it becomes evident that the expected exposure of non-target plants including the exposure pathway volatilization and deposition for the active substance fluazinam would only marginally change the overall outcome of the assessment. Concluding, a quantitative assessment is not necessary, the risk is considered acceptable.

6.10.5 Conclusion

Based on the predicted rates of BANJO FORTE in off-field areas, the TER values describing the risk for non-target plants following exposure to BANJO FORTE according to the GAP of the formulation BANJO FORTE achieve acceptability criteria TER ≥ 10 resp. ≥ 5 according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for non-target terrestrial plants due to the intended use of BANJO FORTE in potatoes according to the label.

Consequences for authorization:

None

Appendix 1 Table of Intended Uses in Germany (according to BVL 08.07.2013)

PPP (product name/code) BANJO FORTE

Formulation type: **SC**

active substance 1 fluazinam

Conc. of as 1: 200 g /L

active substance 2 dimethomorph

Conc. of as 2: 200 g/L

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**			**Application rate**			**PHI** (days)	**Remarks:** e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
00-001	DE	Potatoes	F	Late blight (Phytophthora infestans) PHYTIN	Foliar spraying	Summer applications BBCH 31-91	a) 4 b) 4	a) 1.0 L/ha b) 4.0 L/ha	a) as1 : 0.2 kg/ha as2: 0.2 kg/ha b) as1 : 0.8 kg/ha as2 : 0.8 kg/ha	300-600	7	

REGISTRATION REPORT

Part B

Section 7: Efficacy Data and Information

Detailed Summary

Product Code: BANJO forte/MCW 853

Reg. No.: ZV1 027012-00/00

Active Substance:

Dimethomorph 200 g/L, Fluazinam 200 g/L

Central Zone

Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Feinchemie Schwebda GmbH

Date: April 2015

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IIIA1 6 Efficacy Data and Information on the Plant Protection Product

The present draft Registration Report (dRR) is prepared to support the registration of the fungicide BANJO forte containing the active ingredients fluazinam and dimethomorph for *Phytophthora infestans* control in potato in the central registration zone (Zone B).
BANJO forte is formulated as suspension concentrate (SC) and contains 200 g/L of fluazinam and 200 g/L of dimethomorph. Both actives were added to the list of approved active substances contained in Commission Implementing Regulation (EU) No 540/2011.

The application is provided as a national application only for Germany. Germany as zRMS belongs to the central registration zone (zone B). Other countries (cMS) are not involved in the registration procedure (Tab. 6.0-1). According to EPPO standard PP1/241 (zones of comparable climate in the EPPO region) Germany is part of the maritime EPPO zone.

Table 6.0-1: Zonal rapporteur member state (zRMS) and concerned member states (cMS).

zRMS	Germany	DE
cMS	-	-

Recent registration situation/history of the PPP

The formulation MAC 94530 F is sold under the commercial names BANJO forte and others in several countries of the central zone. BANJO forte was approved in Germany in 2012. The test compound is not yet registered in other EU-Member States.

Information on the active ingredients (Uptake and mode of action)

The active ingredient fluazinam is a compound from the group of the uncouplers of oxidative phosphorylation in the respiration metabolic pathway, described in the chemical class of 2,6 dinitroanilines (FRAC classification C5).
The active ingredient fluazinam belongs to the group of phenylpyridylamine. The mechanism of action of fluazinam is due to the disruption of oxidative phosphorylation. Thus, the breathability of the fungal pathogens and thus the spore germination and development prevented. The risk of formation of resistant strains is thus low.
Fluazinam is characterized by a good activity against fungi of the genus *Phytophthora*, *Botrytis*, *Sclerotinia* and *Alternaria*.
Fluazinam has a preventive effect. Due to the non-systemic action (contact fungicide) is not already existing fight infection. The spread of the infection but is stopped reliably. Fluazinam also protects the tuber from infection. Produced spores are killed.

Dimethomorph possesses translaminar-systemic, curative and antisporulant attributes which may ensure prolonged efficacy of treatments after infection.
Dimethomorph inhibits cell wall biosynthesis and assembly. There are indications that all stages in the development cycles of *Phytophthora infestans* except zoosporogenesis, zoospore discharge and motility are inhibited. Sporangiophore and oospore formation are particularly sensitive to the compound. Dimethomorph exhibits its fungicidal activity by alternating fungal cell wall formation. This specific mode of action is associated with good efficacy at low dose rates under field conditions.
Dimethomorph uptake is rapid and the substance is translocated acropetally. The biochemical mode of action of CAA fungicides (including DMM) is still speculative. Potential targets are phospholipid biosynthesis and cell wall deposition. Most likely, the target site for CAA fungicides is membrane-bound at the interface between plasma lemma and cell wall.

Information on crops and pests

Phytophthora infestans

Late blight caused by the oomycete pathogen *Phytophthora infestans* (Mont.) de Bary is the most important potato disease worldwide due to rapid asexual reproduction of spores under conducive weather conditions.
Phytophthora infestans is heterothallic with two known mating types, A1 and A2. The A2 mating type of *P. infestans* was detected in several countries in Europe in the 1980s and is now found almost everywhere. Interaction between hyphae of opposite mating type induces the formation of antheridia and oogonia which may associate and fuse to form an oospore. Oospores in addition to spores and infected tubers constitute an additional source of inoculum. Fields with oospores will remain infested between crops as oospores can survive in the soil for years. The sexual process of oospore formation also allows increased genetic recombination.

Late blight of potato is an extremely damaging disease, which can destroy the foliage and reduce tuber yields in consequence. At a later stage, if sporulating *P. infestans* is present in the foliage during rain showers sporangia are washed down into the soil and can infect the new tubers. Infected tubers are a main source of (primary) inoculum for late blight epidemics the following year.
When a regional clonal reproducing population of *P. infestans* is being displaced by more aggressive late blight strains, the speed of the epidemic will increase. The development cycle and temperature tolerance of the fungus has changed thoroughly the last 10 years. While former population's required 100 - 120 hrs. to complete a cycle, the new ones take only 48 - 72 hrs. and the fungus can grow at high temperatures such as 28° C even. The general resurgence of late blight in Europe is linked to fungicide resistance.

Phytophthora infects leaves, stems and tubers of the potato plant throughout the growing season. The first symptom of the disease is a white mycelia under the leaves. In humidity conditions late blight develops very intensively and infected leaves are browning and rotting. Dry and hot air temperature during growing season stops development of late blight but the disease returns quickly during rainy weather. At harvest and later on in storage infested tubers show the typical browning and rotting for which the disease is feared for.

Table 6.0-2: Classification of crop and pest in the rapporteur member state (zRMS)

Crop/pest	EPPO-Code	Classification	
		major	minor
Potato/*Phytophthora infestans*	SOLTU/PHYTIN	DE	-

Information on the intended uses (2013-07-09)

Use No.	**027012-00/00-001**
Field of use	Agriculture (field crops)
Crop(s)/object(s)	potato (SOLTU)
Pest(s)/target(s)	late blight of potato (*Phytophthora infestans*) (PHYTIN)
Area of application	Outdoors
Timing of application	In case of danger of infection and/or after warning service appeal
Max. number of treatments for the use	4
Max. number of treatments per crop or season	4
Interval between treatments	7 to 10 days
Application method/kind of treatment	Spraying

Application rate(s) in amount of water to be used	1 L/ha in 300 to 600 l water/ha

IIIA1 6.1 Efficacy data

IIIA1 6.1.1 Preliminary range-finding tests

Preliminary field tests to assess the biological activity of BANJO forte in the intended use were not conducted by the applicant. The absence of such tests is justified with already available knowledge concerning the active substances in the formulated product on their known application rates for a sufficient control of *Phytophthora infestans* in potato.

The applicant demonstrated the necessity of the combination of two different active ingredients in their unique properties combining the translaminar-systemic activity of dimethomorph with the protectant activity of fluazinam. This combination is an alternative to mancozeb containing products. In Germany dimethomorph was registered in combination with mancozeb (ACROBAT), fluazinam was marketed originally as single compound (SHIRLAN).

IIIA1 6.1.2 Minimum effective dose tests

The minimum effective dose rate of BANJO forte was tested between 2006 to 2008 in a total of 18 efficacy trials in potatoes against *Phytophthora infestans* with doses of 0.5 or 0.6, 0.8 and 1.0 L product/ha. The trials were conducted in Germany, Denmark, The Netherlands and Czech Republic.
The tested rates reflect the proposed label rate and 50% or 60% and 80% of the maximum recommended rate of BANJO forte. In 12 trials the minimum effective dose were tested against tuber rot (late blight) at 0.4 - 0.6, 0.8 and 1.0 L/ha, assessed at harvest and in storage.

Material and methods are described in IIIA1 6.1.3.

On average, the minimum dose rate of 0.4-0.8 L/ha showed lower efficacy on *Phytophthora infestans* compared to the intended rate of 1.0 L/ha. The intended dose rate resulted in 73% control, the minimum rate with 0.8 L/ha reached 43% and the dose rate of 0.4-0.6 L/ha reached 65%. Untreated had a mean infestation level of 88% (Table 6.1.2-1).

Table 6.1.2-1: Minimum effective dose tests of BANJO forte against potato late blight at dose rates of 0.4 - 0.6, 0.8 and 1.0 L/ha. Foliar assessments.

Value	**Efficacy main assessment – Foliar infection**						
	N	**BBCH**	**U (%) Infested**	**Efficacy (%)**			
				BANJO forte			**Standard**
				0.4-0.6 L/ha	**0.8 L/ha**	**1.0 L/ha**	*
Mean	18	86	88	47	65	73	70
Min		69	50	0	25	41	25
Max		95	100	90	98	99	99

* Standards: Acrobat Plus WG, Acrobat WG, Acrobat (dimethomorph/mancozeb) 2.0 kg/ha, Altima 500 SC (fluazinam) 0.4 L/ha

Results of tuber rot control show also a dose response however at a low level of control. The 1.0 L/ha dose rate of the test compound achieved 62% control, the dose rate 0.8 L/ha 48%, while the minimum dose rate of 0.4 / 0.6 L/ha reached only 38%. Untreated had a mean of infested tubers of 7.7% (Table 6.1.2-2).

Table 6.1.2-2: Minimum effective dose BANJO forte against tuber rot (late blight) at 0.4 - 0.6, 0.8 and 1.0 L/ha, assessed at harvest and in storage.

Percentage of infested tubers and efficacy against tuber rot									
n	**U (%) Infest. tubers**	**BANJO FORTE**						**Standards**	
		0.4-0.6 L/ha		**0.8 L/ha**		**1.0 L/ha**		*****	
		Inf. (%)	**Eff. (%)**	**Inf. (%)**	**Eff. (%)**	**Inf. (%)**	**Eff. (%)**	**Inf. (%)**	**Eff. (%)**
12	7.7 0.3 - 30	7.3	40 (0 - 100)	4.2	53 (0 - 100)	2.4	65 (0 - 100)	3.4	60 (0 - 100)

* Standards: Acrobat Plus WG, Acrobat WG, Acrobat (dimethomorph/mancozeb) 2.0 kg/ha, Altima 500 SC (fluazinam) 0.4 L/ha

IIIA1 6.1.3 Efficacy tests

The efficacy was tested between 2006 and 2008 in a total of 18 efficacy trials in potatoes against *Phytophthora infestans*. The trials were conducted in Germany, Denmark, The Netherlands and Czech Republic. The efficacy of the test compound is classified as control of *Phytophthora infestans* on leaves and stems of potatoes and as control of tuber rot. The results of the efficacy trials are summarized in table 6.1.3-1, 6.1.3-2 and 6.1.3-3.

Material and methods

• No. of trials, year of trials, Country	(6), 2008 (6), Germany; (4), 2006 (1), 2007 (3), Denmark; (4), 2006 (2), 2007 (2), Czech Republic; (4), 2008 (4), The Netherlands
• Testing facility, replicates	Official (7), Contractor (11), 4 replicates each

• Testing facility / trial location	Official	DE	LWK Nordrhein-Westfalen, PD Bonn
			LWK Nordrhein-Westfalen, PD Münster
			Weihenstephan TUM, Freising
	Contractor	DE	Agrartest, Aarbergen-Panrod
			AGROPLAN, Goch-Nierswalde
			BioChem agrar GmbH, Machern
	Official	DK	University of Aarhus, Research Centre Flakkebjerg, Slagelse

Contractor	NL	Research Company for Plant Protection „De Bredelaar“ B.V., Elst
	CZ	ZS Trutnov, Trutnov
	CZ	Zemservis, zk. Stanice Domaninek s.r.o.
	CZ	ZS Vaclav Marecek, Krasne Üdoli

Guidelines and experimental design

• GEP and guidelines	GEP yes, EPPO standards PP 1/2, PP 1/135, PP 1/152, PP 1/181
• Developmental code	BBCH
• Design, size of plots	Randomized block design, 21 – 37.5 m²

Crop Species, cultivars and standard products

• Trials per crop species	Potato (11)
• Cultivars	Bintje, Belana, Marabel, Maxilla, Bacara, Dianella, Folva, Oleva, Milva, Producent, Rozara
• Standard product, dose	Acrobat Plus WG 2.0 kg/ha (dimethomorph/mancozeb), Acrobat WG 2.0 kg/ha (dimethomorph/mancozeb), Acrobat 2.0 kg/ha (dimethomorph/mancozeb); CZ (4): Altima 500 SC 0.4 L/ha (fluazinam)
• Additional fungicides	Desiccant application: Reglone + Shirlan 2.5 + 0.3 L/ha in trial 01

Assessment Survey

• Frequency and time of assessments	Foliage and stems: Before applications and 1 - 2 weeks after last application, on average 9. Tubers: 3, at harvest, after 2 and 8 weeks storage
• Assessments of efficacy	Foliage: Main assessment at BBCH 86 (range 69 – 95) 9 days (range 6 - 14) after 8 applications. Stem (4 trials): Main assessment at BBCH 89 (range 79 – 95) 8 days (range 6 - 9) after 9 applications. Tubers: At harvest, after 2 and 8 weeks storage
Type of assessments	Foliage and stems: Estimate of infestation intensity in treated and untreated plots (%). Tubers: Weighting [kg] or counting [n] of infested tubers, share %

The effectiveness of the fungicide against foliar infection of potato late blight was demonstrated in 18 trials. In the mean of the results the disease level in the untreated control was 88%. The efficacy of the test product amounted to 73% and that of the standards to 70% (Table 6.1.3-1).

Table 6.1.3-1: Efficacy of BANJO forte against Potato late blight at dose rates of 1.0 L/ha. Main foliar assessment.

Value	**Efficacy - main assessment of foliar infection**				
	n	**BBCH**	**U [%] Infested**	**Efficacy (%)**	
				BANJO forte	**Standards**
				1.0 L/ha	*

Mean	18	86	88	73	70
Min		69	50	41	25
Max		95	100	99	99

* Standards: Acrobat Plus WG, Acrobat WG, Acrobat (dimethomorph/mancozeb) 2.0 kg/ha, Altima 500 SC (fluazinam) 0.4 L/ha

The effectiveness of the fungicide against stem infection of potato late blight was demonstrated in 4 trials. In the mean of the results the disease level in the untreated control was 93%. The efficacy of the test product amounted to 82% and that of the standard (Acrobat Pus WG) to 80% (Table 6.1.3-2).

Table 6.1.3-2: Efficacy of BANJO forte against Potato late blight stem infection at 1.0 L/ha.

Value	**Efficacy main assessment - stem infection**				
	n	**BBCH**	**U [%] Infestation of stems**	**Efficacy [%] of BANJO forte**	**Efficacy [%] of Standard Acrobat Plus WG**
				1.0 L/ha	**2.0 kg/ha**
Mean	4	89	93	82	80
Min		79	75	66	62
Max		95	100	99	99

Tuber rot was assessed at harvest in 6 trials, CZ (2) and NL (4), at storage in 11 trials (range 4 – 18 weeks). The efficacy of BANJO forte against tuber rot at harvest was 81% and 70% of the standards (Table 6.1.3-3). After storage the efficacy was 47% of BANJO forte and 49% of the standards.

Table 6.1.3-3: Efficacy of BANJO forte against tuber rot caused by late blight at 1.0 L/ha.

Value	**Share infested tubers and Efficacy at harvest and 8 weeks storage**						
	Date	**n**	**U [%] Infested tubers**	**MAC 94530 F 1.0 L/ha**		**Standards***	
				Infested [%]	**Efficacy [%]**	**Infested [%]**	**Efficacy [%]**
Mean	Harvest	6	**8.0** (0.3-25)	1.6	**81** (61-100)	3.3	**70** (1-100)
	Storage	11	**3.7** (0.2-12)	2.0	**47** (0-100)	2.1	**49** (0-100)

* Standards: Acrobat Plus WG, Acrobat WG, Acrobat (dimethomorph/mancozeb) 2.0 kg/ha, Altima 500 SC (fluazinam) 0.4 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

The starch content was measured in 7 potato samples from efficacy trials 2006 and 2007 in Denmark and Czech Republic. The mean starch content of the potatoes of the test substance plot at 1.0 L/ha was 111% (range 90 - 129) in relation to the untreated control. The standards (Acrobat (dimethomorph/mancozeb) and Altima 500 (fluazinam)) resulted in 111% too (range 96 - 129) (Table 6.1.4-1).

Table 6.1.4-1: Effect of 1.0 L/ha BANJO forte on starch content [%]. Efficacy trials in EU-countries 2006 and 2007

Country	Starch content	Untreated	BANJO forte [L/ha] b)			Standard Acrobat / Altima 500 [kg, L/ha]	Number of trials
			0.6	0.8	1.0	2.0 / 0.4	
DK	[%]	15.0	17.4	17.5	18.1	17.9	3
	[% rel.]	100	116	117	121	120	
CZ	[%]	12.6	12.4	12.9	12.9	13.1	4
	[% rel.]	100	99	103	103	104	
Mean	**[%]**	**13.6**	**14.5**	**14.9**	**15.1**	**15.2**	**7**
	[% rel.]	**100**	**107**	**110**	**111**	**111**	

IIIA1 6.1.4.2 Effects on the processing procedure

The possible effect of BANJO forte on the processing procedure was assessed in 7 trials covering the years 2006-2008 in Germany and Czech Republic. The cooking and gustatory quality i.e. colour, consistency, structure mealiness, deficiency of taste and moisture of potatoes treated with the test product did not result in any differences compared to the untreated control and the reference standards Shirlan, Altima 500 SC and Acrobat Plus WG.

IIIA1 6.1.4.3 Effects on the yield of treated plants and plant products

18 trials were carried out to evaluate the yield level of plants treated with BANJO forte for the control of *Phytophthora infestans* in potatoes. All trials were conducted according to GEP and followed the appropriate EPPO standards by official or officially recognised testing organisations. Trials were conducted between 2006 and 2008 in Germany, Denmark, the Netherlands and Czech Republic representing the maritime and north-east EPPO climatic zones.

Material and methods

The test product was applied at different rates in the trials carried out in potatoes against *Phytophthora infestans*. In the effectiveness trials the standard dose of 1.0 L/ha was tested whereas in the minimum dose tests rates of 0.4, 0.5, 0.6, 0.8 and 1.0 L/ha were applied and the double dose of 2.0 L/ha was tested in the selectivity trials. The results were compared to the untreated control and the standard products Altima at 0.4 L/ha (4 trials) and Acrobat at 2.0 kg/ha (14 trials).

Assessed characteristics:	(i)	Tuber yield in dt/ha	(18 trials)
	(ii)	Tuber grading into three size classes: < 35 mm, 35 - 55 mm and > 55 mm diameter	(6 trials, DE)
	(iii)	Tuber grading into two size classes: Under size (< 35 mm), over size (> 55 mm)	(4 trials, CZ)
	(iv)	Tuber grading into three size classes:	(4 trials, NL)

< 35 mm, 35 - 50 mm and > 50 mm diameter

Method: According to the EPPO standard PP 1/135(3):
(i) Yield was harvested and weighed per plot and re-calculated to dt/ha.
(ii)-(iv) Yield was sorted according to above stated criteria and each class was weighed separately.

Annotation to material and methods: *Tuber size classes were determined as follows: In trial no 11 - 14 of CZ: Under size (< 35 mm), over size (> 55 mm). In trial no 15 – 18 of NL: < 35 mm, 35 - 50 mm, > 50 mm. For trials of DK no determination of tuber grade was determined.

The grad “marketable ware“ is summarized: > 35 mm diameter.

18 of the efficacy trials include the evaluation of potato yield. The yield increase is given in dt/ha and in percentage of untreated control. In the efficacy trials the treatment against *P. infestans* showed a yield effect of 172% compared to untreated control. The standard reached an efficacy of 169% compared to the untreated control (Table 6.1.4.3-1).

Table 6.1.4.3-1: Mean yield level [dt/ha] of all efficacy trials carried out in Germany and other EU-countries, 2006 to 2008

Value	Yield	U a)	T 1.0 b)	S c)	T-U d)	S-U e)	T-S f)	S*	n g)
Mean	[dt/ha]	317	504	497	187	180	7	-	18
	[% rel.]	100	172	169					

a) U = Untreated.
b) T = Test product BANJO forte.
c) S = Standard product.
d) Yield-difference T to U.
e) Yield-difference S to U.
f) Yield-difference T to S.
g) n = number of trials.
S* = Acrobat 2.0 kg/ha (14 trials), Altima 0.4 L/ha (4).

In the four Czech trials the higher dose rate of 2 L/ha BANJO forte is not reflected by higher yields. The intended dose rate yielded 132% of untreated, the dose rate of 2 L/ha yielded 120% (Table 6.1.4.3-2).

Table 6.1.4.3-2: Effect of double dose rate BANJO forte at 2.0 L/ha on yield level. CZ 2006 to 2007

Value	Yield	U a)	T [L/ha] b)		S [L/ha] c)	n d)
			1.0	2.0	0.4	
Mean	[dt/ha]	279	360	329	320	4
	(% rel.)	100	132	120	114	

a) U = Untreated.
b) T = Test product BANJO forte.
c) S = Standard product Altima 500 SC.
d) n = number of trials.

In 14 of the efficacy trials include the evaluation of marketable ware. 6 trials were conducted in Germany in 2008, 4 in Czech Republic in 2006-2008 and 4 in the Netherlands in 2006-2008. The share of the marketable tuber size of > 35 mm in diameter of the test product was 97% (range 95 - 99) and that of the standard was also 97% (range 95 - 99) in Germany. Of the control plot only 89% (range 82 – 98) of the yield was marketable (Table 6.1.4.3-3). In the mean of the results the share of marketable tuber size of > 35 mm in diameter of the test product was 92 % and that of the standards were also 92 % in EU-countries (Tab. 6.1.4.3-4).

Table 6.1.4.3-3: Effect of 1.0 L/ha MAC 94530 F on Tuber grade and marketable ware [%]. Efficacy trials in Germany 2008

Value	Share e)	U a)	T b)	S c)	n d)
Mean	[%]	89	97	97	6

a) U = Untreated.
b) T = Test product.
c) S = Standard product = Acrobat Plus WG 2 kg/ha
d) n = number of trials.
e) Share marketable ware in %.

Table 6.1.4.3-4: Effect of 1.0 L/ha MAC 94530 F on Tuber grade marketable ware [share %]. Efficacy trials in EU-countries 2006 to 2008

Country	Share e)	U a)	T b)	S c)	S [L, kg/ha]	N d)
CZ	[%] [% rel.]	88 100	89 101	89 101	Altima 500 SC 0.4 L/ha	4
NL	[%] [% rel.]	91 100	95 105	95 105	Acrobat 2.0 kg/ha	4
Mean	[%] [% rel.]	89 100	92 103	92 103	Standards	8

a) U = Untreated.
b) T = Test product.
c) S = Standard product.
d) n = number of trials.
e) Share marketable ware in %.

IIIA1 6.2 Adverse effects

IIIA1 6.2.1 Phytotoxicity to host crop

In all 18 trials, no phytotoxicity occurred after treatment with the registered dose rate of 1.0 L/ha BANJO forte. Since no phytotoxicity occurred at normal dose rate in efficacy testing it can be assumed that crop safety is given. However, in addition it was shown in 4 trials with the double dose of 2.0 L/ha BANJO forte that there are no indications for a limited crop safety. No varietal sensitivity was observed either within the range of 9 potato varieties.

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)

The toxicity of BANJO forte on beneficial organisms has been investigated by carrying out tests under extended laboratory conditions on *Aphidius rhopalosiphi*, *Chrysoperla carnea, Poecilus cupreus* and *Typhlodromus pyri.* The results are shown in Table 6.2.4-1 to Table 6.2.4-4.
On the basis of these results slightly effects (25% to 50%) are expected for populations of *Chrysoperla carnea,* when BANJO forte is applied according to the recommended use pattern, i.e. 4 applications of 1.25 L/ha to potatoes. The recommended 4 applications of BANJO forte are not harmful for populations of *Aphidius rhopalosiphi* and *Poecilus cupreus*. However, *Aphidius rhopalosiphi* is not a relevant antagonist for the proposed crop.
The effects of BANJO forte on the predatory mite *Typhlodromus pyri* cannot be evaluated finally (first part of the test is not valid).

Table 6.2.4-1: Effects of BANJO forte on *Aphidius rhopalosiphi* (exposed stage: male and female) in an extended laboratory test (substrate: leaves from field-treated bean plants)

Application rate [L/ha]	Corrected mortality [%]	Effect on parasitisation rate [%]	Reference
2.4	2.6	-0.8	Moll, M., 2008 Project 42133003

Table 6.2.4-2: Effects of BANJO forte on *Chrysoperla carnea* (exposed stage: larva) in an extended laboratory test (substrate: maize leaves)

Application rate [L/ha]	Corrected mortality [%]	Effect on fertility [%]	Reference
2.7	10.8	28.3	Moll, M., 2009 Project 42147047

Table 6.2.4-3: Effects of BANJO forte on *Poecilus cupreus* (exposed stage: female and male) in an extended laboratory test (substrate: Lufa 2.1)

Application rate [L/ha]	Corrected mortality [%]	Effect on feeding rate [%]	Reference
3.2	0	0	Schmitzer, S., 2008 Project 42130007

Table 6.2.4-4: Effects of BANJO forte on *Typhlodromus pyri* (exposed stage: protonymph) in an aged residue test (substrate: leaves from field-treated bean plants)

Application rate [L/ha]	Corrected mortality [%]	Effect on reproduction [%]	Reference
2.4	0 days after application		Moll, M., 2008 Project 42134060
	46.9*	-	
	7 days after application		
	28.9	1.2	

*Mortality in the control > 20%, therefore validity criterion was not fulfilled.

Conclusions
BANJO forte is classified as not harmful for populations of *Poecilus cupreus*.
BANJO forte is classified as slightly harmful for populations of *Chrysoperla carnea*.

Adverse effects on soil quality indicators (e. g. microorganisms, earthworms) are considered in Section 6 Ecotoxicological Studies in the Registration Report.

IIIA1 6.2.5 Adverse effects on parts of plant used for propagating purposes

No specific trials were set up to record adverse effects on parts of plant used for propagating purposes. According to the applicant no effects on the germination or vigour of potatoes used for propagation were reported.

IIIA1 6.2.6 Impact on succeeding crops

No analysis according to EPPO standard PP1/207 was submitted but the applicant supposed that the moderate values of the DT_{50} of dimethomorph and fluazinam in soil together with the lack of phytotoxicity indicate that at dose rates applied for registration no risk for succeeding crops is given.

IIIA1 6.2.7 Impact on other plants including adjacent crops

The impact on adjacent crops was described in sensitivity studies and non-target plant studies (Annex IIIA, Section 6). The product was tested for effects on the vegetative vigour of six plant species from 6 plant families (oilseed rape, soybean, sugar beet, carrot, oat and onion) in a limit test (non-target plants test). No phytotoxic effects and plant mortality was recorded during the study period except for soybean with very slight phytotoxic effects of 1 % after treatment with 0.8 L/ha BANJO forte. The most sensitive species with regard to fresh weight were oilseed rape and oat with a NOER (No Observed Effect Rate) of <800 mL/ha (effect of 14.2 % in rape and 9.0 % in oat) (Table 6.2.7-1). All other test plant species showed a NOER value of 800 mL/ha. No mortality was observed for any species tested.
The applicant assumed that at possible drift rates resulting from normal dose rates of 1.0 L/ha no effect is to be expected on neighbouring arable crops.
Therefore there is no risk for adjacent crops to get injured irreversively by drift of BANJO forte applied at the intended use rate of 1.0 L/ha.

Table 6.2.7-1: Effects on Fresh Weight. Test compound: BANJO forte 0.8 L/ha

Test plant	Fresh weight			
	[g]		[%]*	Significance
	C	T	T	
Oilseed Rape	35.524	30.483	-14.19	s.
Soybean	18.452	16.819	-8.85	n.s.
Sugar beet	32.155	34.760	8.10	n.s.
Carrot	15.098	15.378	1.86	n.s.
Oat	48.110	43.797	-8.97	s.
Onion	10.532	10.728	1.86	n.s.

C = control. *Negative values = indicate reduction compared to control. DAA = days after application. s. = significant, n.s. = not significant.

A maximum amount of 74 ml/ha test product reaches neighbouring plants at 1 m distance of the treated potatoes for four applications (Table 6.2.7-2). At 5 m distance the maximum dose rate amounts to only 15.2 ml/ha (0.38 % x 1.0 L/ha x 4 applications). However as calculated before, the accumulated drift rate of 0.74 ml/ha for four treatments at 1 m distance is > 10-fold below the dose rate applied in the Limit Test. Therefore no risk exists for neighbouring plants.

Table 6.2.7-2: Potential drift values of BANJO forte applied according to the GAP use

Crop	Number of applications	Application rate [L/ha]	Crop growth stage BBCH	Drift [%]*	Max. amount reaching neighbouring plants at one meter distance ml/ha
Potato	4	1.0	Before or at infestation	1.85	74

* The basic drift value is 1.85% (90th percentile, per application for multiple uses in field crops at 1 m distance) according to the Ganzelmeier table. Since 4 applications are applied for registration, the maximum dose reaching the ground or neighbouring plants at 1 m distance can be calculated as 4 x 18.5 ml/ha = 74 ml/ha.

IIIA1 6.2.8 Possible development of resistance or cross-resistance

Agronomic risk

The agronomic risk of resistance is characterised by the following parameters:

- The timing of treatments against late blight is based mainly on simulation and predictive models. Therefore treatments are oriented on actual needs and unnecessary treatments which may increase selection pressure on resistance, are to be avoided.
- The number of treatments applied for registration of BANJO forte is limited to four. Again this limits selection pressure and the risk of resistance development.
- The product contains dimethomorph and fluazinam which only bear a low risk of resistance. No evidence of resistance against the target organism is given from both the actives.

Thus, the agronomic risk of BANJO forte is classified as a “medium risk of resistance”.

Management of resistance

- The unrestricted use pattern for controlling *Phytophthora infestans* is 4 applications of BANJO forte per year and crop.
- As shown above the risk of the active ingredients and the agronomic risk of resistance development are considered to be low, respectively medium. The use pattern does not require restrictions with regard to the number of applications applied for (4).
- Due to the medium risk classification no risk modifiers are required for BANJO forte. However “good agricultural practise” is recommended in order to minimise the risk and to delay the possible development of resistance.
- The strategies recommended for the management of resistance in potatoes include the use of protectant (contact) fungicides, which are less prone to resistance development. The use of BANJO forte being a co formulation of the translaminar-systemic dimethomorph and the protectant fluazinam is a strategy that reduces the probability of developing resistant strains. By preventing a fungal population building up to an infestation, a protectant fungicide is acting on a smaller number of pathogens than a curative fungicide that is attacking a larger population with a greater genetic diversity. Therefore, the mixture reduces the chances of resistant individuals to survive, and being selected by the removal of other competing strains.

The risk of development of resistance to the target organism was analysed following EPPO standard PP 1/213. The evaluation of the resistant risk factors indicates a low to medium agronomic risk for the use of BANJO forte. The use of the test product includes the possibility for alternating the active ingredients and the active principle in potato late blight control. The selection and resistance pressure on other compounds can be reduced.

Basing on the resistance results the order WW764 is to award: In order to prevent resistance, alternate with other products from different active substance groups.

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

IIIA1 6.6 Summary and assessment of data according to points 6.1 to 6.5

BANJO forte, based on dimethomorph and fluazinam, has been developed for the control of Late Blight of potato caused by *Phytophothora infestans*.
The biological assessment is based on field trials conducted in Czech Republic, The Netherlands, Denmark and Germany to prove efficacy and selectivity of BANJO forte.

Efficacy
To evaluate the efficacy of BANJO forte 18 field tests were carried out in the years 2006 to 2008 at a dose rate of 1.0 L/ha. Infestation incidence (percentage of stems/leaves and tubers infested) served as test parameters. In conclusion, in all parameters an adequate efficacy could be achieved.

Dose justification (minimum effective dose rate trials)
The dose rate of 1.0 L/ha represents the limit of efficacy and should not be reduced as results of 18 minimum dose rate tests confirm.

Effects on the quality and quantity of yield of treated plants or plant products
BANJO forte had no relevant adverse effects on quality and quantity of yield. The test compound shows a slight positive yield effect compared to untreated.

Phytotoxicity

In efficacy trials at 1 to 2 L/ha phytotoxicity (chloroses, necroses, thinning or stunting) was not reported.

Risk of resistance
The evaluation indicates a medium inherent and agronomic risk of resistance development for BANJO forte in potato. Basing on the resistance results the order WW764 is to award: In order to prevent resistance, alternate with other products from different active substance groups.

Adverse effects
No unacceptable effects on beneficial organism, on plants or plant products used for propagation and on other plants including neighbouring crops were reported in the trials and are not to be expected.

Adverse effects on beneficial organisms (other than bees)
BANJO forte is classified as slightly harmful for populations of *Chrysoperla carnea* but as not harmful for populations of *Poecilus cupreus*.

IIIA1 6.7 List of test facilities including the corresponding certificates

Testing facility	Country [1]	Address	Number of trials
Pflanzenschutzdienst der Landwirtschaftskammer Nordrhein-Westfalen, Dienststelle Bonn	DE	xxx	1
Pflanzenschutzdienst der Landwirtschaftskammer Nordrhein-Westfalen, Dienststelle Münster	DE	xxx	1
Lehrstuhl für Phytopathologie Wissenschaftszentrum Weihenstephan TUM	DE	xxx	1
Agrartest GmbH	DE	xxx	1
AGROPLAN Auftragsinstitut für Pflanzenschutz und Pflanzenproduktion	DE	xxx	1
BioChem agrar GmbH	DE	xxx	1
University of Aarhus Faculty of Agricultural Science,	DK	xxx	4
ZS Trutnov	CZ	xxx	2
Zemservis, zk. Stanice Domaninek s.r.o.	CZ	xxx	1
ZS Vaclav Marecek	CZ	xxx	1
Research Company for Plant Protection „De Bredelaar“ B.V.	NL	xxx	4
Landesanstalt für Pflanzenbau Forchheim Außenstelle Saatbauamt Donaueschingen	DE	xxx	Processing test 5
Agro nord – Kürzinger GbR Kartoffelforschung, Phytodiagnostik, Feldversuchswesen, Pflanzenschutz	DE	xxx	Glasshouse test 1
Institut für Biologische Analytik und Consulting IBACON GmbH	DE	xxx	NTP-test 1

)[1] DE = Germany; DK = Denmark

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

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
MIIIA1 Sec 6	Fein-chemie Schwebda GmbH	Draft Registration Report - Part B - BANJO forte - DE - Section 6 – Ecotoxicology - Core assessment	2013	313816
MIIIA1 Sec 7	Fein-chemie Schwebda GmbH	Draft Registration Report - Part B - BANJO forte - DE - Section 7 – Efficacy Data and Information - Core assessment	2013	313818
MIIIA1 Sec 6	Fein-chemie Schwebda GmbH	Draft Registration Report - Part B - BANJO forte - DE - Section 6 – Ecotoxicology - Core assessment	2013	313828
MIIIA1 Sec 7	Fein-chemie Schwebda GmbH	Draft Registration Report - Part B - BANJO forte - DE - Section 7 – Efficacy Data and Information - Core assessment	2013	313830
KIIIA1 6.1.3	Zickart, U.	Efficacy of MAC 94530F on Phytophthora infestans in potatoes	2008	FCS08-2231b-E03 313884
KIIIA1 6.1.4.3	Zickart, U.	Efficacy of MAC 94530F on Phytophthora infestans in potatoes	2008	FCS08-2231b-E03 313886
KIIIA1 6.2.1	Zickart, U.	Efficacy of MAC 94530F on Phytophthora infestans in potatoes	2008	FCS08-2231b-E03 313888

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 6.1.2	Nielsen, B.J.	Efficacy of MCW 853 against potato late blight (Phytophthora infestans) in potato. Results from field trials 2006	2007	06577-1 313890
KIIIA1 6.1.3	Nielsen, B.J.	Efficacy of MCW 853 against potato late blight (Phytophthora infestans) in potato. Results from field trials 2006	2007	06577-1 313892
KIIIA1 6.1.4.3	Nielsen, B.J.	Efficacy of MCW 853 against potato late blight (Phytophthora infestans) in potato. Results from field trials 2006	2007	06577-1 313894
KIIIA1 6.2.1	Nielsen, B.J.	Efficacy of MCW 853 against potato late blight (Phytophthora infestans) in potato. Results from field trials 2006	2007	06577-1 313896
KIIIA1 6.1.2	Nielsen, B.J.	Efficacy of MCW 853 against potato late blight (Phytophthora infestans) in potato. Results from field trials 2007	2007	07568-1 313898
KIIIA1 6.1.3	Nielsen, B.J.	Efficacy of MCW 853 against potato late blight (Phytophthora infestans) in potato. Results from field trials 2007	2007	07568-1 313900
KIIIA1 6.1.4.3	Nielsen, B.J.	Efficacy of MCW 853 against potato late blight (Phytophthora infestans) in potato. Results from field trials 2007	2007	07568-1 313902
KIIIA1 6.2.1	Nielsen, B.J.	Efficacy of MCW 853 against potato late blight (Phytophthora infestans) in potato. Results from field trials 2007	2007	07568-1 313904
KIIIA1 6.1.2	Nielsen, B.J.	Efficacy of MCW 853 against potato late blight (Phytophthora infestans) in potato. Results from field trials 2007	2007	07568-2 313906
KIIIA1 6.1.3	Nielsen, B.J.	Efficacy of MCW 853 against potato late blight (Phytophthora infestans) in potato. Results from field trials 2007	2007	07568-2 313908

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 6.1.4.3	Nielsen, B.J.	Efficacy of MCW 853 against potato late blight (Phytophthora infestans) in potato. Results from field trials 2007	2007	07568-2 313911
KIIIA1 6.2.1	Nielsen, B.J.	Efficacy of MCW 853 against potato late blight (Phytophthora infestans) in potato. Results from field trials 2007	2007	07568-2 313913
KIIIA1 6.1.2	Nielsen, B.J.	Efficacy of MCW 853 against potato late blight (Phytophthora infestans) in potato. Results from field trials 2007	2007	07568-3 313915
KIIIA1 6.1.3	Nielsen, B.J.	Efficacy of MCW 853 against potato late blight (Phytophthora infestans) in potato. Results from field trials 2007	2007	07568-3 313917
KIIIA1 6.1.4.3	Nielsen, B.J.	Efficacy of MCW 853 against potato late blight (Phytophthora infestans) in potato. Results from field trials 2007	2007	07568-3 313919
KIIIA1 6.2.1	Nielsen, B.J.	Efficacy of MCW 853 against potato late blight (Phytophthora infestans) in potato. Results from field trials 2007	2007	07568-3 313921
KIIIA1 6.1.2	Subr. J.	Trial report of Plant Protection Products	2007	EZ-FLM+DMM-06-119-01 313923
KIIIA1 6.1.3	Subr. J.	Trial report of Plant Protection Products	2007	EZ-FLM+DMM-06-119-01 313925

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 6.1.4.3	Subr. J.	Trial report of Plant Protection Products	2007	EZ-FLM+DMM-06-119-01 313927
KIIIA1 6.2.1	Subr. J.	Trial report of Plant Protection Products	2007	EZ-FLM+DMM-06-119-01 313929
KIIIA1 6.1.2	Jana, F.	Trial report of Plant Protection Products	2007	EZ-FLM+DMM-06-119-02 313931
KIIIA1 6.1.3	Jana, F.	Trial report of Plant Protection Products	2007	EZ-FLM+DMM-06-119-02 313933
KIIIA1 6.1.4.3	Jana, F.	Trial report of Plant Protection Products	2007	EZ-FLM+DMM-06-119-02 313935
KIIIA1 6.2.1	Jana, F.	Trial report of Plant Protection Products	2007	EZ-FLM+DMM-06-119-02 313938

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 6.1.2	Subr. J.	Trial report of Plant Protection Products	2007	EZ-flo-07-20-01 313940
KIIIA1 6.1.3	Subr. J.	Trial report of Plant Protection Products	2007	EZ-flo-07-20-01 313943
KIIIA1 6.1.4.3	Subr. J.	Trial report of Plant Protection Products	2007	EZ-flo-07-20-01 313945
KIIIA1 6.2.1	Subr. J.	Trial report of Plant Protection Products	2007	EZ-flo-07-20-01 313947
KIIIA1 6.1.2	Frantisek, S.	Trial report of Plant Protection Products	2007	EZ-flo-07-20-02 313950
KIIIA1 6.1.3	Frantisek, S.	Trial report of Plant Protection Products	2007	EZ-flo-07-20-02 313952
KIIIA1 6.1.4.3	Frantisek, S.	Trial report of Plant Protection Products	2007	EZ-flo-07-20-02 313954
KIIIA1 6.2.1	Frantisek, S.	Trial report of Plant Protection Products	2007	EZ-flo-07-20-02 313956

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 6.1.2	van Tilbourg, F.W.G.	Control of Phytophthora infestans in ware potatoes 2008 - The Netherlands	2009	F-08-2107-1 313958
KIIIA1 6.1.3	van Tilbourg, F.W.G.	Control of Phytophthora infestans in ware potatoes 2008 - The Netherlands	2009	F-08-2107-1 313960
KIIIA1 6.2.1	van Tilbourg, F.W.G.	Control of Phytophthora infestans in ware potatoes 2008 - The Netherlands	2009	F-08-2107-1 313962
KIIIA1 6.1.2	van Tilbourg, F.W.G.	Control of Phytophthora infestans in ware potatoes 2008 - The Netherlands	2009	F-08-2107-2 313964
KIIIA1 6.1.3	van Tilbourg, F.W.G.	Control of Phytophthora infestans in ware potatoes 2008 - The Netherlands	2009	F-08-2107-2 313966
KIIIA1 6.2.1	van Tilbourg, F.W.G.	Control of Phytophthora infestans in ware potatoes 2008 - The Netherlands	2009	F-08-2107-2 313968
KIIIA1 6.1.2	van Tilbourg, F.W.G.	Control of Phytophthora infestans in ware potatoes 2008 - The Netherlands	2009	F-08-2107-3 313970
KIIIA1 6.1.3	van Tilbourg, F.W.G.	Control of Phytophthora infestans in ware potatoes 2008 - The Netherlands	2009	F-08-2107-3 313972

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 6.2.1	van Tilbourg, F.W.G.	Control of Phytophthora infestans in ware potatoes 2008 - The Netherlands	2009	F-08-2107-3 313974
KIIIA1 6.1.2	van Tilbourg, F.W.G.	Control of Phytophthora infestans in ware potatoes 2008 - The Netherlands	2009	F-08-2107-4 313976
KIIIA1 6.1.3	van Tilbourg, F.W.G.	Control of Phytophthora infestans in ware potatoes 2008 - The Netherlands	2009	F-08-2107-4 313978
KIIIA1 6.2.1	van Tilbourg, F.W.G.	Control of Phytophthora infestans in ware potatoes 2008 - The Netherlands	2009	F-08-2107-4 313980
KIIIA1 6.1.3	Strub, O., Knewitz, H., Koch, H.	Untersuchungen zur Belagsbildung von Pflanzenschutzmitteln bei Kartoffeln und getreide	2008	313982
KIIIA1 6.1.4.2	Kürzinger	Fungicide trial - Potatoes 2007	2007	FCS07-2051c-E01 313984
KIIIA1 6.1.4.2	Rohr, J.	Efficacy of different contact-fungicides against Phythophora infentans (PHYTIN) in potato	2008	FCS07-2051c-E02 313986
KIIIA1 6.1.4.2	Zickart, U.	Efficacy of different fungicides on Phythophora infentans in potato	2007	07 1047 516 313988

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 6	Kürzinger, W.	Kraut- und Braunfäule - Bekämpfung notwendig	2007	313990
KIIIA1 6	Albert, G.	Protektiv gegen Krautfäule	2007	313992
KIIIA1 6	Brendler, F., Kürzinger, W., Scheid, L., Zellner, M.	Pflanzenschutz-Rückblick 2007 aus West,- ost., nord- und süddeutscher Sicht	2007	313994
KIIIA1 6	Brendler, F., Kürzinger, W., Scheid, L., Zellner, M.	Pflanzenschutz-Rückblick 2008 aus west,- ost., nord- und süddeutscher Sicht	2008	313996
KIIIA1 6	Albert, G., Curtze, J., Drandarevski, C.A.	Dimethomorph (CME 151), a novel curative fungicide	1988	313998
KIIIA1 6	Anema, B.P., Bouwman, J.J., Komyoji, T., Suzuki, K.	Fluazinam: a novel fungicide for against Phytophthora infestans in potatoes	1992	314000
KIIIA1 6	Albert, G., Thomas, A., Guehne, M.	Fungicidal activity of Dimethomorph on different stages in the life cycle of Phytophthora infestans and Plasmopara viticola	1991	314002
KIIIA1 6	Gisi, U., Sierotzki, H.	Fungicide mode of action and resistance in downy mildrew	2008	314004

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 6.1.1	Bützler, R., Meinerling, M.	Effects of MCW-853 SC on terrestrial (non-Target) Plants: Vegetative vigour test	2008	0FC0001 6565 ! R-23935!42 141087 314006
KIIIA1 6.1.2	Disse-mond	Amtliche Zulassungsprüfung Phytophthora - Kartoffeln 2008	2008	FCS08-2231a-E01 314008
KIIIA1 6.1.3	Disse-mond	Amtliche Zulassungsprüfung Phytophthora - Kartoffeln 2008	2008	FCS08-2231a-E01 314010
KIIIA1 6.1.4.3	Disse-mond	Amtliche Zulassungsprüfung Phytophthora - Kartoffeln 2008	2008	FCS08-2231a-E01 314012
KIIIA1 6.2.1	Disse-mond	Amtliche Zulassungsprüfung Phytophthora - Kartoffeln 2008	2008	FCS08-2231a-E01 314014
KIIIA1 6.1.2	Benker, M.	Amtliche Zulassungsprüfung Phytophthora infes-tans an Kartoffeln	2008	FCS08-2231a-E03 314016
KIIIA1 6.1.3	Benker, M.	Amtliche Zulassungsprüfung Phytophthora infes-tans an Kartoffeln	2008	FCS08-2231a-E03 314018

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 6.1.4.3	Benker, M.	Amtliche Zulassungsprüfung Phytophthora infestans an Kartoffeln	2008	FCS08-2231a-E03 314019
KIIIA1 6.2.1	Benker, M.	Amtliche Zulassungsprüfung Phytophthora infestans an Kartoffeln	2008	FCS08-2231a-E03 314021
KIIIA1 6.1.2	Hausladen, H.	Determination of the efficacy of different products on Phytophthora infestans in solanum tuberosum	2008	2231a 314023
KIIIA1 6.1.3	Hausladen, H.	Determination of the efficacy of different products on Phytophthora infestans in solanum tuberosum	2008	2231a 314025
KIIIA1 6.1.4.3	Hausladen, H.	Determination of the efficacy of different products on Phytophthora infestans in solanum tuberosum	2008	2231a 314027
KIIIA1 6.2.1	Hausladen, H.	Determination of the efficacy of different products on Phytophthora infestans in solanum tuberosum	2008	2231a 314029
KIIIA1 6.1.2	Rohr, J.	Efficacy of MAC 94530F against Phytophthora infestans in potatoes	2008	FCS08-2231b-E01 314031
KIIIA1 6.1.3	Rohr, J.	Efficacy of MAC 94530F against Phytophthora infestans in potatoes	2008	FCS08-2231b-E01 314033

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 6.1.4.3	Rohr, J.	Efficacy of MAC 94530F against Phytophthora infestans in potatoes	2008	FCS08-2231b-E01 314035
KIIIA1 6.2.1	Rohr, J.	Efficacy of MAC 94530F against Phytophthora infestans in potatoes	2008	FCS08-2231b-E01 314037
KIIIA1 6.1.2	Mass-mann, K.-W.	Efficacy of MAC 94530F against potato late blight (Phytophthora infestans) in potatoes	2008	FCS08-2231b-E02 314039
KIIIA1 6.1.3	Mass-mann, K.-W.	Efficacy of MAC 94530F against potato late blight (Phytophthora infestans) in potatoes	2008	FCS08-2231b-E02 314041
KIIIA1 6.1.4.3	Mass-mann, K.-W.	Efficacy of MAC 94530F against potato late blight (Phytophthora infestans) in potatoes	2008	FCS08-2231b-E02 314043
KIIIA1 6.2.1	Mass-mann, K.-W.	Efficacy of MAC 94530F against potato late blight (Phytophthora infestans) in potatoes	2008	FCS08-2231b-E02 314045
KIIIA1 6.1.2	Zickart, U.	Efficacy of MAC 94530F on Phytophthora in-festans in potatoes	2008	FCS08-2231b-E03 314047

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 6.1.4.3	van Tilbourg, F.W.G.	Control of Phytophthora infestans in ware potatoes 2008 - The Netherlands	2009	F-08-2107-1 314049
KIIIA1 6.1.4.3	van Tilbourg, F.W.G.	Control of Phytophthora infestans in ware potatoes 2008 - The Netherlands	2009	F-08-2107-2 314051
KIIIA1 6.1.4.3	van Tilbourg, F.W.G.	Control of Phytophthora infestans in ware potatoes 2008 - The Netherlands	2009	F-08-2107-3 314054
KIIIA1 6.1.4.3	van Tilbourg, F.W.G.	Control of Phytophthora infestans in ware potatoes 2008 - The Netherlands	2009	F-08-2107-4 314056
KIIIA1 6.2.8	Kürzinger, W.	Kraut- und Braunfäule - Bekämpfung notwendig	2007	314058
KIIIA1 6.2.8	Hausladen, H.	Ist der Erreger der Krautfäule Phytophthora infestans noch kontrollierbar?	2008	314060
KIIIA1 6.2.8	Grünwald, N.J., Sturbaum, A.K., Montes, E.G., Serrano, E.G.,	Selection for Fungicide resistance within a growing season in field populations of Phythophthora infestans at the Center of Origin	2006	314062
KIIIA1 6.5	Kürzinger, W.	Kurative Leistung nach künstlicher Inokulation	2007	314064

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 6.1.4.1	Nielsen, B.J.	Efficacy of MCW 853 against potato late blight (Phytophthora infestans) in potato. Results from field trials 2007	2007	07568-3 314066
KIIIA1 6.1.4.1	Subr. J.	Trial report of Plant Protection Products	2007	EZ-FLM+DMM-06-119-01 314068
KIIIA1 6.1.4.1	Jana, F.	Trial report of Plant Protection Products	2007	EZ-FLM+DMM-06-119-02 314070
KIIIA1 6.1.4.1	Subr. J.	Trial report of Plant Protection Products	2007	EZ-flo-07-20-01 314072
KIIIA1 6.1.4.1	Nielsen, B.J.	Efficacy of MCW 853 against potato late blight (Phytophthora infestans) in potato. Results from field trials 2007	2007	07568-2 314074
KIIIA1 6.1.4.1	Nielsen, B.J.	Efficacy of MCW 853 against potato late blight (Phytophthora infestans) in potato. Results from field trials 2006	2007	06577-1 314076
KIIIA1 6.1.4.1	Zickart, U.	Efficacy of MAC 94530F on Phytophthora infestans in potatoes	2008	FCS08-2231b-E03 314078
KIIIA1 6.1.4.1	Massmann, K.-W.	Efficacy of MAC 94530F against potato late blight (Phytophthora infestans) in potatoes	2008	FCS08-2231b-E02 314080

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 6.1.4.2	Jana, F.	Trial report of Plant Protection Products	2007	EZ-FLM+DMM-06-119-02 314082
KIIIA1 6.1.4.2	Frantisek, S.	Trial report of Plant Protection Products	2007	EZ-flo-07-20-02 314084
KIIIA1 6.1.4.1	Frantisek, S.	Trial report of Plant Protection Products	2007	EZ-flo-07-20-02 314086
KIIIA1 3.9	Anony-mous	Banjo Forte (MAC 94530 F) - Fungizid zur Bekämpfung von Kraut- und Knollenfäule (Phytophythora infestans) in Kartoffeln	2010	314088
KIIA 8.8.1.1	Bruhnke, C.	MCW 465 500 SC, acute effects on adults of Aphidius rhopalosiphi (Hym.: Aphidiidae)	2007	R-20618 ! IWA107664 314100
KIIIA1 10.5.2	Moll, M.	Effects of MCW-853 SC on the Parasitoid Aphidius rhopalosiphi, extended laboratory study - aged residue test -	2008	R-23927 ! 42133003 314139
KIIIA1 10.5.2	Moll, M.	Effects of MCW-853 SC on the predatory mite Typhlodrolus pyri extended laboratory study, aged residue test	2008	R-23928 ! 42134060 314141
KIIIA1 10.5.2	Moll, M.	Effects of MCW-853 SC on the Lacewing Chrysoperla carnea under extended laboratory conditions	2009	R-25548 ! 42147047 314143

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 10.5.2	Schmitzer, S.	Effects of MCW-853 SC on the Carabid Beetle Poecilus cupreus L. - extended laboratory study	2008	R-23926 ! 42130007 314145

Appendix 2: GAP table

GAP rev. (1), date: 2013-05-13

PPP (product name/code)	**BANJO FORTE**	**Formulation type:**	**SC**
active substance 1	**fluazinam**	**Conc. of as 1:**	**200 g/L**
active substance 2	**dimethomorph**	**Conc. of as 2:**	**200 g/L**
Applicant:	**Feinchemie Schwebda 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: develop-mental stages of the pest or pest group)	**Application**			**Application rate**			**PHI** (days)	**Remarks:**
					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		e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
001	DE	Potatoes SOLTU	F	Late blight *(Phytophthora in-festans)* PHYTIN	spraying	in case of danger of infection and/or after warning service appeal (BBCH 31 – 91)	a) 4 b) 4 (7 - 10 days)	a) 1.0 L/ha b) 4.0 L/ha	a) as1 : 0.2 kg/ha as2: 0.2 kg/ha b) as1 : 0.8 kg/ha as2 : 0.8 kg/ha	300 - 600	7	

Remarks: (a) In case of group of crops the Codex classification should be used

(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench

(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and sucking insects, soil born insects, foliar fungi
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) Use CIPAC/FAO Codes where appropriate
(f) All abbreviations used must be explained
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants
(i) g/kg or g/l
(j) Growth stage at last treatment
(k) PHI = Pre-harvest interval
(l) Remarks may include: Extent of use/economic importance/restrictions (e.g. feeding, grazing)/minimal intervals between applications