REGISTRATION REPORT
Part A

Risk Management

Product code: **Mospilan SG**

Active Substance: **200 g/kg Acetamiprid**

COUNTRY: Germany

Central Zone
Zonal Rapporteur Member State: Germany

NATIONAL ASSESSMENT

Applicant: **Nisso Chemical Europe GmbH**

Date: **20/06/2013**

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PART A – Risk Management

This document describes the acceptable use conditions required for applied **label extension** of Mospilan SG containing 200 g/kg acetamiprid as active substance in Germany. The approval number of the previously registered use is 005655-00/00. The label extension has the number 005655-00/16.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B sections 1, 2, 4, 5 and 6 as well as national addendum B sections 5 and 6 for Germany.

The information, data and assessments provided in Registration Report, Parts B include assessment of further data or information as required at national registration by the EU review. It also includes assessment of data and information relating to Mospilan SG where that data has not been considered in the EU review. Otherwise assessments for the safe use of Mospilan SG have been made using endpoints agreed in the EU review of acetamiprid.

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

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

Appendix 2 contains a consideration to the approved product label for Germany.

Appendix 3 of this document contains no copy of a letter of access to the protected data / third party data that was needed for evaluation of the formulation due to the fact that it is not required since all data including Annex II data belongs to the applicant.

1 Details of the application

1.1 Application background

This application was submitted by :

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as a complete application on 7 February 2012.

- The application was for approval of Mospilan SG, a SG formulation containing 200 g/kg acetamiprid for use as a insecticide in potatoes, for control of Colorado beetle.

1.2 Approval

Acetamiprid was included on Annex I of Directive 91/414/EEC on 1st January 2005 under Inclusion Directive 2004/99/EC.

The Annex I Inclusion Directive for Acetamiprid (2004/99/EC) was implemented under 540/2011/EC and contains the restriction to only uses as insecticide may be authorised and furthermore provides specific provisions under Part B which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation.

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on Acetamiprid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 29 June 2004 shall be taken into account. In this overall assessment:

Member States must pay particular attention to:

- worker exposure,
- to the protection of aquatic organisms.

These concerns were all addressed.

1.3 Regulatory approach

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

This application was submitted in order to allow a label extension of Mospilan for use in potatoes with spray application in Germany.

1.4 Data protection claims

Data protection is claimed for all studies submitted and which are still under protection because first registration on country level is less than 10 years. Some studies were generated specially for this risk assessment and data protection for 10 years is claimed.

1.5 Letters of Access

A letter of access for Annex II data is not required since the applicant is owner of all data including all Annex II data

2 Details of the authorisation

2.1 Product identity

Product Name	Mospilan SG
Authorization Number (for re-registration)	005655-00
Function	insecticide
Applicant	Nisso Chemical Europe GmbH
Composition	200 g/kg acetamiprid
Formulation type	Soluble Granule [Code: SG]
Packaging	Not relevant for the application

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 1999/45/EC

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

Symbol(s)/Indication(s) of danger:	
N	Dangerous for the environment
Xn	Harmful
Risk phrases:	
R20/22	Harmful by inhalation and if swallowed.
R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Safety phrases:	
S2	Keep out of the reach of children.
S13	Keep away from food, drink and animal feeding stuffs.
S35	This material and its container must be disposed of in a safe way.
S46	If swallowed, seek medical advice immediately and show this container or label.
S57	Use appropriate container to avoid environmental contamination.
Specific labelling requirement:	
To avoid risks to man and the environment, comply with the instructions for use.	

2.2.2 R and S phrases under Regulation (EU) No 547/2011

Uses in greenhouses

EO005-1	SPo 5: Treated areas may not be entered until spray coating has dried.
EO005-2	SPo 5: Ventilate greenhouses thoroughly before re-entry.

Outdoor uses

SF245-01	Treated areas/crops may not be entered until the spray coating has dried.

2.2.3 Other phrases

2.2.3.1 Restrictions linked to the PPP

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

Labelling phrases for human health protection

SB001	Avoid any unnecessary contact with the product. Misuse can lead to health damage.

Ecosystem protection

NW263 The product is toxic for aquatic invertebrates.

NW468 Fluids left over from application and their remains, products and their remains, empty containers and packaging, and cleansing and rinsing fluids must not be dumped in water. This also applies to indirect entry via the urban or agrarian drainage system and to rain-water and sewage canals.

2.2.3.2 Specific restrictions linked to the intended uses

The authorisation of certain intended uses of the PPP is linked to the following conditions (mandatory labelling):

Ecosystem protection

NT102 In a strip at least 20 m wide which is adjacent to other areas, the product must be applied using loss reducing equipment which is registered in the index of 'Loss Reducing Equipment' of 14 October 1993 (Federal Gazette No 205, p. 9780) as amended, and be registered in at least drift reducing class 75 % (except agriculturally or horticulturally used areas, roads, paths and public places). Loss reducing equipment is not required if the product is applied with portable plant protection equipment or if adjacent areas (field boundaries, hedges, groups of woody plants) are less than 3 m wide or the product is applied in an area which has been declared by the Biologische Bundesanstalt in the "Index of regional proportions of ecotones" of 7 February 2002 (Federal Gazette no. 70 a of 13 April 2002), as amended, as agrarian landscape with a sufficient proportion of natural and semi-natural structures.

Use 001

NW609-1 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 observing the minimum buffer zone stated below. It is not necessary to observe this buffer zone if the product is applied using equipment which is registered in the index of 'Loss Reducing Equipment' of 14 October 1993 (Federal Gazette No 205, p. 9780) as amended. Irrespective of this, 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. Violations may be punished by fines of up to 50 000 EUR.

Use 001: 5 m

2.3 Product uses

PPP (product name/code) Mospilan SG
active substance 1 acetamiprid

Formulation: Type: SG
Conc. of as 1: 200 g/kg

Applicant: Nisso Chemical Europe GmbH
Zone(s): central

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:** 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		
1	BE, CZ, DE: IE. LU, HU, NL, AT, PL, RO, SI, SK, UK	(SOLTU) Potato	F	(LEPTDE) Colorado potato beetle	spraying	Spring to summer	a) 1 b) 2	a) 0,125 g b) 0,250 g	a) 25 g b) 50 g	300 - 600	7	Restrictions: NT102, NW609-1 (5 m)

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

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:

There is no change regarding the Section 1 of the Part B of the Registration Report compared to the main application. Therefore no evaluation is necessary.

Implications for labelling: *none*

Compliance with FAO specifications:
Not relevant for this application.

Compliance with FAO guidelines:
Not relevant for this application.

Compatibility of mixtures:
Not relevant for this application.

Nature and characteristics of the packaging:
Not relevant for this application.

Nature and characteristics of the protective clothing and equipment:
Not relevant for this application.

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

There is no change regarding the Section 2 of the Part B of the Registration Report compared to the main application. Therefore no evaluation is necessary.

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

The PPP is already registered in Germany according to Directive 91/414/EEC.
There is no change regarding the Section 3 of the Part B of the Registration Report compared to the main application. Therefore no new evaluation is necessary.
If used properly and according to the intended conditions of use, adverse health effects for operators, workers, bystanders and residents will not be expected.

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

The residue behaviour of the active substance acetamiprid was evaluated within the EU review process. Information about metabolism is sufficient to evaluate the intended use in potatoes.

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

The data available is considered sufficient for risk assessment. None of the supervised field trials submitted exceeded the respective LOQ of 0.01 for the residue. A total of 4 residue trials on potatoes were available, all overdosed compared to the intended use (3x 50 g as/ha). However, at harvest (PHI: 7 days) no acetamiprid residues above the LOQ of 0.01 mg/kg were found in potatoes. Thus, an exceedance of the current MRL of 0.01* mg/kg for acetamiprid in potatoes as laid down in Reg. (EC) No 396/2005 is not expected. Furthermore, no exceedance of the MRLs for animal products is expected.

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

The chronic and the short-term intake of acetamiprid residues is unlikely to present a public health concern. Based on the residue acetamiprid, the maximum utilization of the ADI value (0.07 mg/kg bw) was 27 %, based on German children aged 2-4 years representing the most critical population. For the acute intake, resulting in 1.5 % utilization of the ARfD (0.1 mg/kg bw) based on UK infants.
Based on the different calculations made to estimate the risk for consumer though diet and other means it can be concluded that the use of product Mospilan SG in potatoes does not lead to unacceptable risk for consumer when applied according to the recommendations.

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

The plant protection product Mospilan SG is already authorised in Germany. A full exposure assessment for the plant protection product Mospilan SG in its use in potatoes as intended according to the application for extension is documented in detail in the core assessment performed by zRMS Germany.
The following chapters summarise the specific exposure assessment for soil and surface water and the specific risk assessment for groundwater for Mospilan SG in Germany according to its intended use in potatoes (use 16-001).

Metabolites
No new study on the fate and behaviour of acetamiprid or Mospilan SG has been performed. Hence no potentially new metabolites need to be considered for environmental risk assessment.

Acetamiprid
The risk assessment for the metabolites of acetamiprid has already been performed for EU approval (see Review report SANCO/1392/2001-final 16 June 2004). The metabolites are considered to be ecotoxicologically not relevant and are not expected to leach into groundwater. Therefore no new risk assessment hence no exposure assessment for these metabolites is necessary. For details see Part B, core assessment, section 5, chapter 5.3.1.3 Table 5.3-3.
However, in the specific groundwater risk assessment for Germany considering the entry path surface run-off and drainage with subsequent bank infiltration the soil metabolites of acetamiprid are included.
No new laboratory studies on the degradation of acetamiprid in soil or water/sediment system have been performed. Based on the kinetic modelling of Reinken 2001 and Hardy 2002/2003 the zRMS Germany has derived new modelling endpoints for soil degradation of acetamiprid and its metabolites according to recommendations of FOCUS kinetics (2006). These are summarised in the Core assessment Part B, Section 5 and are used in further risk assessment (for details see Part B, core assessment, section 5, chapter 5.4).
The risk assessment for groundwater by direct leaching for the application of the plant protection product and its intended use includes the soil metabolites of acetamiprid.

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

For the intended use of the plant protection product Mospilan SG in potatoes according to use No. 16-001 PEC_{soil} was calculated for the active substance acetamiprid considering a soil depth of 2.5 cm. Due to the fast degradation of the active substance acetamiprid in soil the accumulation potential of acetamiprid was not considered. Details are given in Part B National Addendum-Germany, Section5, chapter 5.5.
The results for PEC_{soil} for the active substance and its metabolites were used for the ecotoxicological risk assessment.

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

Direct leaching to groundwater

Results of modelling with FOCUS_PELMO 4.4.3 show that the active substance acetamiprid is not expected to leach into groundwater at concentrations of ≥ 0.1µg/L in the intended use in potatoes.
Also for the metabolites IM 1-2, IM 1-4, IM 1-5 and IC-0 concentrations of ≥ 0.1µg/L in groundwater are not expected for the intended use in potatoes.
For details see Part B, National Addendum-Germany, Section 5, chapter 5.7.1.

Ground water contamination by bank infiltration due to surface water exposure via run-off and drainage

According to modelling with EXPOSIT 3, groundwater contamination at concentrations ≥ 0.1 µg/L by the active substance acetamiprid due to surface run-off and drainage into the adjacent ditch with subsequent bank infiltration can be excluded. Because of the same mobility class, but lower relevant soil concentrations of the four metabolites IM 1-2, IM 1-4, IM 1-5 and IC-0 compared with acetamiprid, groundwater contamination at concentrations ≥ 0.1 µg/L by the metabolites due to surface run-off and drainage into the adjacent ditch with subsequent bank infiltration can be excluded.
For details see Part B, National Addendum-Germany, Section 5, chapter 5.7.2.

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

For the intended use of the plant protection product Mospilan SG in potatoes according to use No. 16-001 PECsw was calculated for the active substance acetamiprid considering the two routes of entry (i) spray drift and volatilisation 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 acetamiprid is $< 10^{-5}$ Pa. Hence the active substance acetamiprid is regarded as non-volatile. Therefore, exposure of surface water by the active substance acetamiprid due to deposition following volatilization was not considered.
The concentration of the active substance acetamiprid in adjacent ditch due to surface runoff and drainage was calculated using the model EXPOSIT 3.
Details are given in Part B, National Addendum-Germany, Section5, chapter 5.6.
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 IIIA 9.9)

Calculation of PEC_{Air} is deemed not relevant due to the low volatility of the active substance.

3.1.5.5 Implications for labelling resulting from environmental fate assessment:

Based on the data on the active substance acetamiprid the plant protection product Mospilan SG is considered to be not readily degradable in the sense of the CLP regulation.
R-Phrase R53 should be added to the label.

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

A full risk assessment according to Uniform Principles for the plant protection product Mospilan SG in its intended uses in potatoes is documented in detail in the core assessment of the plant protection product Mospilan SG performed by zRMS Germany.
The following chapters summarise specific risk assessment for non-target organisms and hence risk mitigation measures for the authorization of Mospilan SG in Germany according to its intended use in potatoes (use no. 16-001).

3.1.6.1 Effects on Terrestrial Vertebrates (Part B, Section 6, Points IIIA 10.1 and IIIA 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).
Two avian studies are available for the active substance acetamiprid, with the relevant acute endpoint (LD_{50} = 98.0 mg a.s./kg bw, *Anas platyrhynchos*) as well as the relevant long-term endpoint (NOEL = 25.1 mg a.s./kg bw/d, *Anas platyrhynchos*). The relevant endpoints are agreed during the EU review process (see SANCO/1392/2001-Final. 16 June 2004), and are used for the risk assessment of this submission. The provision of further data on the formulation Mospilan SG is not considered essential as the available data on acetamiprid are deemed to be sufficient to assess the risk of birds exposed to Mospilan SG. For details please refer to the core dossier for the central zone, Part B, Section 6, Chapter 6.2.
For terrestrial vertebrates other than birds, one acute oral- and one long-term study for the active substance acetamiprid as well as one acute oral toxicity study for the formulation Mospilan SG have been conducted under laboratory conditions. Studies are evaluated as part of the EU review of acetamiprid (DAR from March 2001; RMS: GR). Relevant endpoints were agreed during EU review process (see SANCO/1392/2001-Final. 16 June 2004) and are used in the risk assessment.
Based on the presumptions of the screening standard scenarios, representing the “reasonable worst case”, according to the GAP and according to Regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2., the TER-results of the assessment indicate an acceptable risk for birds and other terrestrial vertebrates. For details please refer to the core dossier for the central zone, Part B, Section 6, Chapters 6.2 and 6.3.
According to the new EFSA birds and mammals Guidance Document (EFSA Journal 2009; 7(12): 1438), no risk for birds and other terrestrial vertebrates is expected exposed to acetamiprid via drinking water.
Exposure of avian wildlife via dietary intake of residues from food items is considered in the DAR for acetamiprid from March 2001 (RMS: GR). It has been concluded that the application rate of 0.200 kg acetamiprid/ha is not expected to pose any risk to avian wildlife via spray residues in food items, which is

1.6-times higher than the application rate of the intended use 16-001 of Mospilan SG. Therefore, risk from secondary poisoning is not considered essential in this submission.
According to EFSA birds and mammals Guidance Document, no formal risk assessment from secondary poisoning due to exposure to Mospilan SG (use No. 16-001) was performed for terrestrial vertebrates other than birds since a negligible potential for bioaccumulation in animal tissues is indicated (log P_{OW} < 3).

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

For authorisation in Germany, exposure assessment of surface water considers the two routes of entry (i) spray drift and volatilisation with subsequent deposition and (ii) run-off, drainage separately in order to allow for risk mitigation measures separately for each entry route.
Results of aquatic risk assessment for the intended use of Mospilan SG in potatoes based on FOCUS Surface Water PEC values are presented in the core dossier for the central zone, Part B, Section 6, chapter 6.4.
In accordance with the proposal of the applicant, the aquatic risk assessment is solely based on the 2 d LC_{50} *C. riparius* of 19.6 µg a.s./L, recalculated from Mospilan SG (LC_{50} = 98.1 µg prep./ha), since it is the lowest effect value and reflecting the worst case scenario for the risk to aquatic organisms (please refer to the core dossier for the central zone, Part B, Section 6.4.1.1).
The product Mospilan SG is toxic for aquatic invertebrates, demonstrated by several studies. The relevant endpoint is given due to the most sensitive tested sediment dwelling organisms *Chironomus riparius* with the LC_{50} of 0.0196 mg a.s./L, recalculated from Mospilan SG. Thus, the labelling NW263 is required.

Exposure via spraydrift and deposition following volatilization

Surface water exposure via spray drift is estimated with the model EVA 2.1. The calculation of concentrations in surface water is based on spray drift data according to spray-drift predictions of Ganzelmeier & Rautmann (2000)[1]. For the active substance acetamiprid deposition into surface water following volatilisation is not expected since its vapour pressure is below 10^{-5} Pa at 20°C and hence is not volatile.
Based on the relevant toxicity of the active substance acetamiprid the calculated TER-values for the risk to aquatic organisms resulting from an exposure of surface water by spray drift to Mospilan SG according to the use No. 16-001 achieve only the acceptability criteria of TER ≥ 100, according to Regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2, if appropriate risk mitigation measures are applied (Label restriction NW609-1: observance of a buffer zone of 5 m width or use of drift reducing application technique).
For further details see Part B, National Addendum-Germany, Section 6, Chapter 6.3.

Exposure by surface run-off and drainage

Using the model EXPOSIT 3.01 for an adjacent ditch, surface water exposure to the active substance acetamiprid via run-off and drainage is estimated. For modelling of run-off exposure of the sediment dweller *C. riparius* (LC_{50} of 0.0196 mg a.s./L), the total load from run-off, which includes the desolved as well as the particle bound load from run-off, was used.
The calculated TER values are above the trigger of 100 for acute effects of the active substance acetamiprid on aquatic biocenoses and result in an acceptable risk for the indication 16-001 for the entry

[1] Ganzelmeier H. and Rautmann D. (2000) Drift, drift-reducing sprayers and sprayer testing. Pesticide Application, Aspects of Applied Biology 57

pathways via total load from run-off and drainage, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2.
For further details see Part B, National Addendum-Germany, Section 6, Chapter 6.3.

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

Bees

The risks of Mospilan SG to honey-bees was assessed from hazard quotients between toxicity endpoints, estimated from acute oral and contact studies with active ingredient and formulated product.
All the hazard quotients are considerably less than 50, indicating that the active ingredient poses a low risk to bees. Therefore a low risk to bees is expected from the application of Mospilan SG according to the recommended use pattern.
Regarding effects on bees the recommended use is covered by the honey bee risk assessment for the main application.

Implications for labelling resulting from bee assessment:

NB6612	The product must not be used in combination with fungicides from the group of ergosterol-biosynthesis-blockers on plants which are in flower or which are visited by bees. Mixtures with ergosterol-biosynthesis-blockers must be applied in such a way that plants which are in flower are not also treated. See Bee Protection Ordinance of 22 July 1992, BGBl. (Federal Law Gazette) I p. 1410.
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)

Other non-target arthropods

Risk assessments for non-target arthropods other than bees, conducted following the Guidance Document on regulatory testing and risk assessment procedures for plant protection products with non-target arthropods (ESCORT 2; adapted to German national requirements).
In extended laboratory studies conducted with Mospilan SG, the LR_{50} values for the indicator species *Aphidius rhopalosiphi* and *Typhlodromus pyri*, were estimated to be 9.7 (2 d, 3-dimensional) and 143.48 g product/ha (14 d, 2-dimensional), respectively.
The calculation of PEC after exposure via spray drift is performed using the model EVA 2.1. The relevant endpoint for risk assessment is the LR_{50} of 1.94 g a.s./ha (*Aphidius rhopalosiphi*) from an extended 3-dimensional study recalculated from Mospilan SG.
Based on the acceptability criterium of TER $\geq$ 5, the risk resulting from an exposure of non-target arthropods to Mospilan SG, according to the intended use 16-001 is acceptable, according to commission implementing regulation (EU) 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2, if risk mitigation measures according to restriction NT102 are fulfilled. According to the restriction NT102 for use, drift reducing technique of at least 75% or an untreated 5 m buffer, is required.
For further details see Part B, National Addendum-Germany, Section 6, Chapter 6.5.

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

The results of the risk assessment indicate an acceptable acute and chronic risk for earthworms exposed to Mospilan SG, acetamiprid as well as the major soil degradation products IM-1-2 and IM-1-5, regarding the intended use 16-001. Due to the fast degradation of the active substance acetamiprid in soil (DT_{90} < 365 d, SFO, field data) the accumulation potential does not need to be considered.
Other soil non-target macro-organisms are not at risk as well, following treatment with Mospilan SG.
For further details see Part B, National Addendum-Germany, Section 6, Chapter 6.6.
It is concluded that the proposed use of Mospilan SG will not pose an unacceptable risk to populations of earthworms or other soil macro-organisms, when applied according to the recommended use pattern.

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

Tests on organic matter breakdown were not performed. Since no risk was identified for soil fauna, soil micro-organisms and non-target arthropods from the use of Mospilan SG in potatoes, data on the effects on organic matter breakdown (litterbag test) is not required for the active substance, formulation as well as the major soil metabolites, although the metabolite IM-1-5 meets the trigger on degradation in soil.
For further details see Part B, core dossier for the central zone, Section 6, Chapter 6.7.
There is no indication of unacceptable adverse effects on soil macro-organisms relevant for the maintenance of soil quality.

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

For the active ingredient in Mospilan SG and metabolites, the soil concentrations, which caused no deviations greater than ±25% in the activity of the soil micro-organisms, namely 200 g a.s./ha soil dw, are about 10-times higher than the corresponding maximum PEC_{soil}. The resulting margins of safety (NOEC/expected environmental concentrations) would be approximately 11.32 for Mospilan SG. Thus, the highest recommended rate of acetamiprid applied according to the intended use of Mospilan SG, does not elicit a toxic response.
For further details see Part B, National Addendum-Germany, Section 6, Chapter 6.7.

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

Terrestrial plants

Regarding the insecticidal mode of action of the one active substance acetamiprid in the formulation Mospilan SG, estimated effect values, relevant in risk assessment for terrestrial biocoenoses, are much higher for terrestrial arthropods than for terrestrial plants. Thus, a specific off-crop risk assessment for terrestrial non-target plants is not necessary.
The risk to terrestrial non-target plants exposed to Mospilan SG according to the proposed use with an application rate of 125 g prep./ha poses no unacceptable risk.
For further details see Part B, core dossier for the central zone, Section 6, Chapter 6.9.

Implications for labelling resulting from ecotoxicological assessment:

For the authorisation of the plant protection product Mospilan SG following labelling and conditions of use are mandatory:

Classification and labeling of the formulation

Relevant toxicity	Active substance: Acetamiprid (content 20%) 2 d LC_{50} = 0,024 mg/L (*C. riparius*), M-factor = 10 2 d LC_{50} = 0,0196 mg/L (*C. riparius*), recalculated from Mospilan SG
Classification and labelling according to Directive 67/548/EC, 78/631/EC and 1999/45/EC	
Hazard symbol	N, dangerous for the environment
Risk phrases	R 50/53
Classification and labelling according to Regulation 1272/2008	
Hazard sysmbol	GHS09
Signal word	Warning
Hazard statement	H400/H410

Other labels/ conditions of use

Labelling:

NW263 The product is toxic for aquatic invertebrates.

Conditions of use:

All uses:

NW468 Fluids left over from application and their remains, products and their remains, empty containers and packaging, and cleansing and rinsing fluids must not be dumped in water. This also applies to indirect entry via the urban or agrarian drainage system and to rain-water and sewage canals.

Indication/ Use No. 16-001:

NW609-1 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 observing the minimum buffer zone stated below. It is not necessary to observe this buffer zone if the product is applied using equipment which is registered in the index of 'Loss Reducing Equipment' of 14 October 1993 (Federal Gazette No 205, p. 9780) as amended. Irrespective of this, 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. Violations may be punished by fines of up to 50 000 EUR.
5 m

NT102 In a strip at least 20 m wide which is adjacent to other areas, the product must be applied using loss reducing equipment which is registered in the index of 'Loss Reducing Equipment' of 14 October 1993 (Federal Gazette No 205, p. 9780) as amended, and be registered in at least drift reducing class 75 % (except agriculturally or horticulturally used areas, roads, paths and public places). Loss reducing equipment is not required if the product is applied with portable plant protection equipment or if adjacent areas (field boundaries, hedges, groups of

woody plants) are less than 3 m wide or the product is applied in an area which has been declared by the Biologische Bundesanstalt in the "Index of regional proportions of ecotones" of 7 February 2002 (Federal Gazette no. 70 a of 13 April 2002), as amended, as agrarian landscape with a sufficient proportion of natural and semi-natural structures.

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

All the data regarding the efficacy of the product have been submitted. These data demonstrate that Mospilan SG fulfils all criteria for the authorization of preparations described in the Uniform Principles (Regulation (EC) No. 546/2011).

Climatic differences play a role for Colorado potato beetle pest infection pressure. The trials which have been conducted in different EPPO climatic zones of the central zone all show a similar degree of activity independent of the climatic region. All presented trials indicate that 125 g/ha (25 g a.s./ha) of Mospilan SG is the minimum effective dose rate against adults and larvae in potato. The application of 125 g/ha of Mospilan SG provides a sufficient high level of protection of nearly 100% against larvae and beetles for a period of about 2 weeks and exceeds the control achieved by several reference products. A warning indicating that the product should only be used if regional threshold values are exceeded or that prophylactic treatments should be avoided should be present on national labels.
Mospilan SG is even at rates higher than 125 g/ha not expected to have any negative effects on yield and quality of potato and no negative effects were detected neither in field trials nor in special phytotoxicity trials. Mospilan SG can be safely applied to potato. No negative effect is expected on parts of plant used for propagating purposes or on succeeding or adjacent crops.
Resistance development is likely and sensitivity data were provided which will allow following any resistance development in future. A resistance strategy applicable for all neonicotinoids used in potatoes should be used in countries where frequent control of *L. decemlineata* is necessary to avoid resistance development. For these reasons, Mospilan SG may be registered in all countries of the Central Zone with the exception of countries, in which the beetles is not present (such as in UK and IE) at a rate of 125 g product/ha to control adults and larvae of Colorado potato beetle in potato.

3.2 Conclusions

As there are no changes for identity, physical and chemical properties and technical properties of the product as well as for the analytical methods for the product and residue analytical methods, an authorisation can be granted.

Based on the data on efficacy and sustainable use of the product, an authorisation can be granted.
Based on the data on residues and toxicology, an authorisation can be granted.

Harmful effects on ground water consequent to the intended use of the product Mospilan SG have not to be apprehended. Specific additional risk mitigation measures are required to protect aquatic organisms and non-target arthropods in adjacent areas. Unacceptable effects on other non-target organisms can be excluded.

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

AnnexIII point	Data
	none
	…

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

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

Appendix 4 – Copy of product authorisation

Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

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

Mit Zustellungsurkunde

Nisso Chemical Europe GmbH
European Regulatory Affaires
Berliner Allee 42
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IHR ZEICHEN
IHRE NACHRICHT VOM

AKTENZEICHEN 200.22100.005655-00/16.64366
(bitte bei Antwort angeben)

DATUM 19. August 2013

ZV1 005655-00/16

Mospilan SG

Zulassungsverfahren für Pflanzenschutzmittel

Ergänzungsbescheid

Die Zulassung des oben genannten Pflanzenschutzmittels

mit dem Wirkstoff:	200 g/kg	Acetamiprid
Zulassungsnummer:	005655-00	
Versuchsbezeichnung:	NCE-20025-I-1-SG	
Antrag vom:	7. Februar 2012	

ändere ich wie folgt:

Zusätzliche Anwendungsgebiete bzw. Anwendungen

Die Zulassung wird um folgende Anwendungsgebiete bzw. Anwendungen erweitert (siehe Anlage 1):

Anwendungs-nummer	**Schadorganismus/ Zweckbestimmung**	**Pflanzen/-erzeugnisse/ Objekte**	**Verwendungszweck**
005655-00/16-001	Kartoffelkäfer	Kartoffel	

BVL_FO_05_2476_200_V1.1

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) festgesetzt:

(NW468)
Anwendungsflüssigkeiten und deren Reste, Mittel und dessen Reste, entleerte Behältnisse oder Packungen sowie Reinigungs- und Spülflüssigkeiten nicht in Gewässer gelangen lassen. Dies gilt auch für indirekte Einträge über die Kanalisation, Hof- und Straßenabläufe sowie Regen- und Abwasserkanäle.
Begründung:
Aufgrund der Auswirkungen des Wirkstoffs Acetamiprid gegenüber aquatischen Organismen (z.B. Chironimus riparius LC50 = 0,024 mg/L) besitzt das o.g. Pflanzenschutzmittel einen den Naturhaushalt schädigenden Charakter, so dass jeder weitergehende, d.h. den als Folge der sachgerechten und bestimmungsgemäßen Anwendung des Pflanzenschutzmittels Mospilan SG 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, ist es unverzichtbar, der Gefahr, die eine Verbringung von Pflanzenschutzmitteln in Gewässer mit sich bringt, durch die bußgeldbewehrte Auflage im Sinne der Zweckbestimmung des Pflanzenschutzgesetzes (§ 1 Nr. 3 PflSchG) durchsetzbar zu begegnen.

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

Auflagen

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

Siehe Anlage 1, jeweils unter Nr. 2.

Vorbehalt

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

Abgelehnte Anwendungsgebiete bzw. Anwendungen

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

Hinsichtlich der Gebühren erhalten Sie einen gesonderten Bescheid.

Rechtsbehelfsbelehrung

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

Mit freundlichen Grüßen
im Auftrag

gez. Dr. Hans-Gerd Nolting
Abteilungsleiter

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

Anlage

Anlage 1 zugelassene Anwendung: 005655-00/16-001

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Kartoffelkäfer

Pflanzen/-erzeugnisse/Objekte: Kartoffel

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
- Erläuterungen:	
Anwendung im Haus- und Kleingartenbereich:	Nein
Erläuterung zum Schadorganismus:	
Stadium des Schadorganismus:	
- Erläuterungen:	
Erläuterung zur Kultur:	
Stadium der Kultur:	
- Erläuterungen:	
Anwendungszeitpunkt:	Frühjahr bis Sommer
- Erläuterungen:	
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	2
- für die Kultur bzw. je Jahr:	2
- Abstand:	
- Erläuterungen Anzahl Behandlungen:	zeitlicher Abstand der Behandlungen mindestens 14 Tage
Mischungspartner:	
- Erläuterungen:	
Anwendungstechnik:	spritzen
- Erläuterungen:	
Aufwand:	
-	125 g/ha in 300 bis 600 l Wasser/ha
- Erläuterungen:	
Sonstige Ergänzungen und Hinweise:	- keine -

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

7 Tage Freiland: Kartoffel

3 Anwendungsbezogene Anwendungsbestimmungen

(NT102)
Die Anwendung des Mittels muss in einer Breite von mindestens 20 m zu angrenzenden Flächen (ausgenommen landwirtschaftlich oder gärtnerisch genutzte Flächen, Straßen, Wege und Plätze) mit einem verlustmindernden Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung, mindestens in die Abdriftminderungsklasse 75 % eingetragen ist. Bei der Anwendung des Mittels ist der Einsatz verlustmindernder Technik nicht erforderlich, wenn die Anwendung mit tragbaren Pflanzenschutzgeräten erfolgt oder angrenzende Flächen (z. B. Feldraine, Hecken, Gehölzinseln) weniger als 3 m breit sind oder die Anwendung des Mittels in einem Gebiet erfolgt, das von der Biologischen Bundesanstalt im "Verzeichnis der regionalisierten Kleinstrukturanteile" vom 7. Februar 2002 (Bundesanzeiger Nr. 70a vom 13. April 2002) in der jeweils geltenden Fassung, als Agrarlandschaft mit einem ausreichenden Anteil an Kleinstrukturen ausgewiesen worden ist.
Begründung:
Das Pflanzenschutzmittel Mospilan SG bzw. der darin enthaltene Wirkstoff Acetamiprid weist ein hohes Gefährdungspotenzial für terrestrische Nichtzielarthropoden auf. Bewertungsbestimmend ist hier die LR50 von 1,94 g a.s./ha für Aphidius rhopalosiphi, umgerechnet aus dem Effektwert für Mospilan SG, im erweiterten Labortest (3D). Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 5 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NT102 erforderlich, um einen ausreichenden Schutz von terrestrischen Nichtzielarthropoden in Saumbiotopen vor Auswirkungen des Mittels Mospilan SG zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Sektion 6, Kapi-tel 6.5.3).

(NW609-1)
Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mindestens mit unten genanntem Abstand erfolgen. Dieser Abstand muss nicht eingehalten werden, wenn die Anwendung mit einem Gerät erfolgt, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Unabhängig davon ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten. Zuwiderhandlungen können mit einem Bußgeld bis zu 50.000 Euro geahndet werden.
5 m
Begründung:
Das Pflanzenschutzmittel Mospilan SG bzw. der darin enthaltene Wirkstoff Acetamiprid weist ein sehr hohes Gefährdungspotenzial für aquatische Organismen, insbesondere aquatische Invertebraten auf. Bewertungsbestimmend ist hier die LC50 für aquatische sedimentbewoh-

nende Invertebraten, wie hier Chironomus riparius, von 19,6 g a.s./L, umgerechnet aus dem Effektwert für Mospilan SG. Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 100 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW609-1 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Mittels Mospilan SG in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Sektion 6, Kapitel 6.3.2.1).

REGISTRATION REPORT
Part B

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

Section 2: Analytical Methods

Detailed summary of the risk assessment

Product code: Mospilan SG

Active Substance: Acetamiprid 200 g/kg

Country: Germany

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Nisso Chemical Europe GmbH

Date: 20.06.2013

Table of Contents

This document summarises the information related to the identity, the physical and chemical properties, the data on application, further information, analytical methods and the classification for the product Morspilan SG containing the active substance acetamiprid which was included into Annex I of Directive 91/414 (Commission Directive 2004/99/EC of the year 2005) and implemented under 540/2011/EC.

Where appropriate this document refers to the conclusions of the EU review of acetamiprid. 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.

The Summary Report (2003), the DAR for acetamiprid, the Addenda to the DAR (October 2002, March 2003 and January 2004) and the SANCO report for acetamiprid (SANCO/1392/2001 - Final, 16 June 2004) are considered to provide the relevant review information or a reference to where such information can be found.

IIIA 1 IDENTITY OF THE PLANT PROTECTION PRODUCT

IIIA 1.1 Applicant

Nisso Chemical Europe GmbH
Berliner Allee 42
40212 Düsseldorf / Germany

Contact person:	Heiko Thomas
Tel.No.:	+49 (0)211-1306686-14
Fax No:	+49 (0) 211-328231
e-mail:	Thomas@nisso-chem.de

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

Acetamiprid:
minimum purity: 990 g/kg

typical/average purity: not given

No changing regarding the composition compared to the main application.

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

Trade name: Mospilan SG

Applicant's code number (development code): EXP6161884A

Alternative names/codes: Acetamiprid 20 SG, Mospilan SG, Gazelle, Profil, Supreme, Hylobi Forest, Identical composition: Acetamiprid 20 SP, Morspilan SP, Gazelle)

Manufacturer's code number: EXP60707A, EXP60707B, NI-25 20SP

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

IIIA 1.4.1 Content of active substance and formulants

Pure active substance

Content of pure active substance:	**200 g/kg**	
Limits :	188 g/kg	212 g/kg

Technical active substance

Content of technical active substance:	**202 g/L**	
Limits :	189.9 g/L	214.1 g/L
At a minimum purity of the technical active substance of 990 g/kg		

No changing regarding the composition compared to the main application.

Formulants
No changing regarding the composition compared to the main application.

IIIA 1.4.5 Formulation process

IIIA 1.4.5.1 Description of formulation process

This is not a requirement according to Commission Regulation (EC) No. 1107/2009 and the corresponding data requirements as implemented by Reg. (EC) No 544/2011 and 545/2011 (former Annex II and Annex III to Council Directive 91/414/EEC).

IIIA 1.4.5.2 Discussion of the formation of impurities of toxicological concern

Not relevant.

IIIA 1.5 Type of Preparation and Code

Type: soluble granule
Code: SG

IIIA 1.6 Function

Insecticide

There is no change regarding the Sections 1 and 2 of the Part B of the Registration Report compared to the main application. Therefore no evaluation is necessary.

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

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Yes/No	Owner

DRAFT REGISTRATION REPORT
Part B

Section 4: Metabolism and Residues

Detailed summary of the risk assessment

Product code: Mospilan SG

Active Substance: 200 g/kg Acetamiprid

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Nisso Chemical Europe GmbH

Date: 20 June 2013

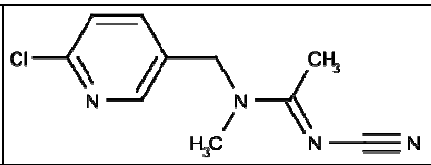
Table of Contents

IIIA 8 METABOLISM AND RESIDUES DATA

IIIA 8.1 Evaluation of the active substances

IIIA 8.1.1 Acetamiprid

Table IIIA 8.1-1: Identity of the active substance

Structural formula	
Common Name	Acetamiprid
CAS number	160430-64-8

IIIA 8.1.1.1 Storage stability

A brief summary of the storage stability data on acetamiprid is given in the following table. Data, which has been previously evaluated at EU level is described in detail in the DAR (ASB2010-10159) and in EFSAs Reasoned Opinion concerning the Review of the existing MRLs for acetamiprid (ASB2012-3249).

Table IIIA 8.1-2: Stability of residues (Annex IIA, point 6.1)

Stability of acetamiprid	No significant degradation (recovery >70 %) was observed for acetamiprid during one year at -18 °C in apples (fruit, juice, pomace), tomatoes, head cabbage, cotton (seeds, oil, hulls), cucumber, oranges (fruit, oil, juice) and lettuce (15 months). In potatoes acetamiprid was stable for at least 8 months.

IIIA 8.1.1.2 Metabolism in plants and plant residue definition(s)

A brief summary of the metabolism of acetamiprid in plants is given in the following table. Data, which has been previously evaluated at EU level is described in detail in the DAR (ASB2010-10159) and in EFSAs Reasoned Opinion concerning the Review of the existing MRLs for acetamiprid (ASB2012-3249).

Table IIIA 8.1-3: 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	Eggplants, apples, head cabbage, carrots spraying, ^{14}C label at positions 2 and 6 of the pyridine ring, in head cabbage also granular treatment and treatment with ^{14}C-cyano-acetamiprid The degradation of acetamiprid was moderate but pronounced translocation occurred showing the systemic character of acetamiprid. Acetamiprid was the main component of the radioactive residues in directly treated crop parts (up to almost 100 % of TRR), but also in carrot roots and in cabbage (aerial parts and roots) following soil treatment (33 % of TRR). Several metabolites were

	detected in the edible parts of the crops with maximum levels of 7 % of the TRR for the demethylated acetamiprid metabolite IM-2-1 in cabbage and 26 % of the TRR for the metabolite 6-chloronicotinic acid (IC-015) in carrots. These metabolites were observed in the rat metabolism as well and were considered as toxicologically not relevant.
Rotational crops	No study required due to a short DT_{50} of acetamiprid in soil: 2.9 d
Metabolism in rotational crops similar to metabolism in primary crops? (yes/no)	Not applicable
Distribution of the residue in peel/ pulp	Not applicable
Processed commodities (nature of residue)	No degradation of acetamiprid (^{14}C label at positions 2 and 6 of pyridine ring) was observed in a hydrolysis study simulating typical processing conditions (pasteurisation, baking, brewing and boiling and sterilisation).
Residue pattern in raw and processed commodities similar? (yes/no)	Yes
Plant residue definition for monitoring	Acetamiprid This is in line with Reg. (EC) No 396/2005.
Plant residue definition for risk assessment	Acetamiprid
Conversion factor(s) (monitoring to risk assessment)	None

IIIA 8.1.1.3 Metabolism in livestock and animal residue definition(s)

A brief summary of the metabolism of acetamiprid in livestock is given in the following table. Data, which has been previously evaluated at EU level is described in detail in the DAR (ASB2010-10159) and in EFSAs Reasoned Opinion concerning the Review of the existing MRLs for acetamiprid (ASB2012-3249).

Table IIIA 8.1-4: Metabolism in livestock (Annex IIA, point 6.2.2 to 6.2.5 and 6.7.1)

Animals covered	Lactating goats, laying hens, ^{14}C label at positions 2 and 6 of the pyridine ring Following the repeated oral administration of radio-labelled acetamiprid to goats and laying hens, a high proportion of the dose was eliminated in the excreta. There was no evidence of any significant accumulation of radioactivity in milk, eggs or edible tissues. In goats highest residue levels were found in liver and kidney, in chicken highest residue levels were found in liver and eggs. The part of the dose that was absorbed was extensively metabolised and rapidly eliminated resulting in low residues. The major residues in milk, eggs and edible tissues were attributed to metabolite IM-2-1 (N-desmethyl-acetamiprid), except for goat muscle where metabolite IM-2-2 (the amide of N-desmethyl-acetamiprid) was the predominant compound.
Time needed to reach a plateau concentration in milk and eggs	3-4 d (milk), about 8 d (eggs)
Animal residue definition for monitoring	Sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid This is in line with Reg. (EC) No 396/2005.

Animal residue definition for risk assessment	Sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid
Conversion factor(s) (monitoring to risk assessment)	None
Metabolism in rat and ruminant similar (yes/no)	Yes
Fat soluble residue: (yes/no)	No, log $P_{O/W}$ = 0.8 at 25 °C

IIIA 8.1.1.4 Residues in rotational crops

Field rotational crop studies on acetamiprid were neither available nor required. This has already been discussed in the DAR (ASB2010-10159) and in EFSAs Reasoned Opinion concerning the Review of MRLs for acetamiprid (ASB2012-3249).

Table IIIA 8.1-5: Residues in rotational crops (Annex IIA, point 6.6.3)

Field studies	Not required (DT_{50} in soil: 2.9 d) Significant residues are not expected in food and feed commodities obtained from succeeding crops (consequent to uses in compliance with cGAP).

IIIA 8.1.1.5 Residues in livestock

An actual calculation of the dietary burden (based on all relevant uses authorized in Germany) is provided in Table IIIA 8.1-6.

Table IIIA 8.1-6: Calculation of the dietary burden (based on all relevant uses authorized in Germany)

Feedstuff	**% DM**	**Percent of daily livestock diet (dry feed basis)**				**Residue (mg/kg)**	**Intake (mg/kg, dry feed basis)**			
		Chicken 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**
Cabbage	14	5	35	35	15	0.73 [a]	0.261	1.825	1.825	0.782
Potatoes	15	20	30	60	60	0.01 [a]	0.013	0.020	0.040	0.040
Oilseed rape	86	10	30	5	20	0.01 [a]	0.001	0.003	0.001	0.002
Intake (mg/kg dry weight feed)							0.275	1.848	1.866	0.824
Intake (mg/kg bw/d)							0.017	0.067	0.080	0.033
Intake (mg/animal/d)							0.033	36.970	27.984	2.473

a HR, based on the following cGAP: 2x 0.06 kg as/ha, PHI: 7 d
b HR, based on the following cGAP: 1x 0.05 kg as/ha, PHI: 14 d
c STMR, based on the following cGAP: 1x 0.04 kg as/ha, PHI: N

Table IIIA 8.1-7: Conditions of requirement of livestock feeding studies on acetamiprid

	Ruminant:	**Poultry:**	**Pig:**
Expected intakes by livestock ≥0.1 mg/kg diet (dry weight basis) (yes/no – If yes, specify the level)	Yes 1.87	Yes 0.28	yes 0.82
Potential for accumulation (yes/no):	No	No	See ruminant
Metabolism studies indicate potential level of residues ≥0.01 mg/kg in edible tissues (yes/no)	Yes	Yes	See ruminant

A brief summary of the available livestock feeding study/studies is given in the following table. Data, which has previously been evaluated at EU level is described in detail in the DAR (ASB2010-10159) and in EFSAs Reasoned Opinion concerning the Review of the MRLs for acetamiprid (ASB2012-3249).

Table IIIA 8.1-8: Results of livestock feeding studies (Annex IIA, point 6.4)

	Ruminant:	**Poultry:**	**Pig:**
Feeding levels (mg/kg feed dry matter) in feeding studies	Dairy cow: 5.77; 17.4; 58.6	Laying hens: 1 (metabolism study*)	See ruminant
Relevant dosing levels in feeding study:	5.77	1	5.77 (ruminant study)
	Expected residue levels in animal matrices (mg/kg)**:		
Muscle	0.017	<0.01	<0.01
Liver	0.052	<0.05	0.022
Kidney	0.084	<0.01	0.036
Fat	0.013	<0.01	<0.01
Milk	<0.02	–	–
Eggs	–	<0.01	–

* A feeding study for poultry is available (RIP2000-413, ASB2010-9275) but was not yet evaluated at EU level. It is not needed for the present evaluation.

** according to DoR, i.e. including metabolite IM-2-1 (conversion f actor IM-2-1 → Acetamiprid: 1.067)

IIIA 8.2 Evaluation of the intended use(s)

IIIA 8.2.1 Selection of critical use and justification

The critical GAP used for consumer intake and risk assessment is presented in Table IIIA 8.2-1. It is the only individual GAP reported in the central zone for potatoes.

Table IIIA 8.2-1: 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)**	**kg product / ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**g as/ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**Water L/ha** **min / max**		
1	DE	Potatoes	F	Colorado potato beetle	Spraying	Spring to summer	a) 2 (14 days) b) 2 (14 days)	a) 0.125 b) 0.25	a) 25 b) 50	300-600	14	

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

IIIA 8.2.2 Potatoes

IIIA 8.2.2.1 Residues in primary crops

The following table gives a brief overview of the supervised residue trials selected for the assessment of acetamiprid in potatoes. Data, which has been previously evaluated at EU level is described in detail in EFSAs Reasoned Opinion concerning the Review of the existing MRLs for acetamiprid (ASB2012-3249).

Table IIIA 8.2-2: Overview of the selected supervised residue trials for acetamiprid in potatoes

Commodity	Region [(a)]	Outdoor/ Indoor	Individual trial results (mg/kg)		STMR (mg/kg) [(b)]	HR (mg/kg) [(c)]	Median CF [(d)]
			Enforcement (acetamiprid)	Risk assessment (acetamiprid)			
Potatoes	NEU	Outdoor	<0.01 (4)	<0.01 (4)	0.01	0.01	1

(a): NEU, SEU, EU or Import (country code). In the case of indoor uses there is no necessity to differentiate between NEU and SEU.
(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.

IIIA 8.2.2.2 Distribution of the residue in peel/pulp

Not relevant.

IIIA 8.2.2.3 Residues in processed commodities

Not relevant. Due to low residues at harvest, no processing studies are required.

IIIA 8.2.2.4 Proposed pre-harvest intervals, withholding periods

For the intended use on potatoes a pre-harvest interval (PHI) of 14 days was proposed. All available trials were performed with a PHI of 7 days. Based on these trials a shorter PHI of 7 days would also be possible.

IIIA 8.3 Consumer intake and risk assessment

The consumer intake and risk assessment is based on the appropriate input values given in Table IIIA 8.3-1 and the toxicological reference values stated in Table IIIA 8.3-2. For the detailed calculation results it is referred to Appendix 3.

Table IIIA 8.3-1: 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	MRL	0.01	HR = LOQ
All other commodities	various	MRLs according to Reg. (EC) No 396/2005	Not applicable	

Table IIIA 8.3-2: Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

ADI	0.07 mg/kg bw
TMDI (% ADI) according to EFSA PRIMo	25 % (based on 2-4 years old German children*)
NTMDI (% ADI) according to NVS II model	27 % (based on 2-4 years old German children, individual consumption/body weight ratio*)
IEDI (% ADI) according to EFSA PRIMo	Not necessary
NEDI (% ADI) according to NVS II model	Not necessary
Factors included in IEDI and NEDI	None
ARfD	0.1 mg/kg bw
IESTI (% ARfD) according to EFSA PRIMo	Potatoes: 1.5 % (based on UK infants)
NESTI (% ARfD) according to NVS II model	Potatoes: 1 % (based on 2-4 years old German children)
Factors included in IESTI and NESTI	None

* The underlying consumption data for DE children are the same in both cases, but the data aggregation is different.

IIIA 8.4 Proposed maximum residue levels (MRLs)

No new MRLs are required. The existing EU MRLs for the crops applied for and animal products are sufficient to cover residues expected from the intended uses.

IIIA 8.5 Conclusion

The data available is considered sufficient for risk assessment. A total of 4 residue trials on potatoes were available, all overdosed compared to the intended use (3x 50 g as/ha). However, at harvest (PHI: 7 days) no acetamiprid residues above the LOQ of 0.01 mg/kg were found in potatoes. Thus, an exceedance of the current MRL of 0.01* mg/kg for acetamiprid in potatoes as laid down in Reg. (EC) No 396/2005 is not expected. Furthermore, no exceedence of the MRLs for animal products is expected.

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

As far as consumer health protection is concerned, BfR/Germany agrees with the authorization of the intended use.

Appendix 1 List of data submitted in support of the evaluation

No new data were submitted in support of the evaluation.

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Storage stability

No further study on storage stability submitted/needed.

A 2.2 Residues in primary crops

No further study on primary crops submitted/needed.

A 2.3 Residues in processed commodities

No new study on residues in processed commodities has been submitted and none is needed due to low residues at harvest.

A 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)

Acetamiprid (R)			
Status of the active substance:		Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0,07**	ARfD (mg/kg bw):	**0,1**
Source of ADI:	**SANCO/1392/2**	Source of ARfD:	**SANCO/1392/2001**
Year of evaluation:	**2004**	Year of evaluation:	**2004**

Explain choice of toxicological reference values.

The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity the highest national MRL was identified (proposed temporary MRL = pTMRL).
The pTMRLs have been submitted to EFSA in September 2006.

Chronic risk assessment

	TMDI (range) in % of ADI minimum - maximum
	3 25
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)
24,7	DE child	12,7	Pome fruit	6,6	Citrus fruit	1,2	Spinach	
20,1	NL child	6,8	Pome fruit	5,8	Citrus fruit	2,1	Spinach	
15,1	FR toddler	4,0	Spinach	3,3	Citrus fruit	2,9	Pome fruit	
11,0	ES child	3,3	Citrus fruit	3,0	Lettuce	1,6	Pome fruit	
10,9	WHO Cluster diet B	2,6	Lettuce	2,2	Citrus fruit	1,4	Pome fruit	
10,0	FR infant	2,8	Pome fruit	2,5	Spinach	1,8	Milk and cream,	
9,2	ES adult	3,8	Lettuce	2,1	Citrus fruit	1,1	Pome fruit	
9,1	IE adult	3,8	Citrus fruit	1,5	Pome fruit	0,7	Spinach	
8,3	UK Toddler	3,3	Citrus fruit	1,9	Pome fruit	1,5	Milk and cream,	
7,6	UK Infant	2,8	Milk and cream,	1,9	Citrus fruit	1,8	Pome fruit	
7,6	NL general	2,7	Citrus fruit	1,4	Pome fruit	0,9	Lettuce	
7,3	WHO regional European diet	2,7	Lettuce	1,2	Citrus fruit	0,9	Pome fruit	
7,0	DK child	3,0	Pome fruit	1,0	Lettuce	0,9	Milk and cream,	
6,5	SE general population 90th percentile	2,0	Citrus fruit	1,4	Pome fruit	0,9	Milk and cream,	
6,5	IT adult	2,7	Lettuce	1,0	Pome fruit	0,8	Citrus fruit	
6,4	WHO Cluster diet F	2,1	Lettuce	1,6	Citrus fruit	0,8	Pome fruit	
6,2	IT kids/toddler	2,1	Lettuce	1,2	Pome fruit	1,1	Citrus fruit	
5,9	WHO cluster diet E	1,2	Citrus fruit	1,0	Pome fruit	0,7	Lettuce	
4,7	UK vegetarian	1,5	Citrus fruit	1,0	Lettuce	0,7	Pome fruit	
4,5	FR all population	1,2	Table and wine grapes	0,9	Citrus fruit	0,7	Lettuce	
4,0	PT General population	1,4	Pome fruit	1,1	Citrus fruit	0,8	Table and wine grapes	
3,9	WHO cluster diet D	0,8	Pome fruit	0,7	Citrus fruit	0,4	Milk and cream,	
3,9	LT adult	2,0	Pome fruit	0,5	Lettuce	0,3	Head cabbage	
3,7	FI adult	1,6	Citrus fruit	0,6	Lettuce	0,4	Pome fruit	
3,6	PL general population	2,3	Pome fruit	0,3	Head cabbage	0,2	Tomatoes	
3,5	UK Adult	1,0	Citrus fruit	0,8	Lettuce	0,5	Pome fruit	
2,8	DK adult	1,0	Pome fruit	0,4	Table and wine grapes	0,4	Milk and cream,	

Conclusion:

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

REGISTRATION REPORT
Part B
Section 5 Environmental Fate
Detailed summary of the risk assessment

Product code: **Mospilan SG**

Active Substance(s): **Acetamiprid 200 g/kg**

Central Zone
Zonal Rapporteur Member State: Germany (DE)

CORE ASSESSMENT

Applicant: **Nisso Chemical Europe GmbH**

Date: **20.06.2013**

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 Mospilan SG containing the active substance acetamiprid.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 Mospilan SG

Code	EXP61884A		
plant protection product	Mospilan SG		
applicant	Nisso Chemicals Europe GmbH		
date of application	31/10/2011		
Formulation type (WP, EC, SC, …; density)	SG		
active substance	Acetamiprid		
Concentration of as	200 g/kg		

5.2 Proposed use pattern

The critical GAP used for exposure assessment is presented in Table 5.2-1. It has been selected from the individual GAPs in the central zone for potatoes. A list of all intended uses within the central zone is given in Appendix 3.

Table 5.2-1: Critical use pattern of Mospilan SG

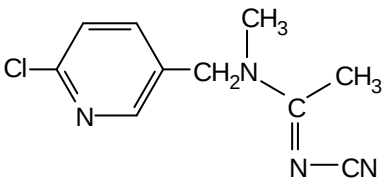
Group/ use No	Crop/growth stage	Application method Drift scenario	Number of applications, Minimum application interval, application time, interception	Application rate, cumulative (g as/ha)	Soil effective application rate (g as/ha)
16-001	Potatoes BBCH 20-39	spraying	2 x, 14 d, 1. 50 % interception, 6 days after 1st emergence in the year 2. 50 % interception, 20 days after 1st emergence in the year	acetamiprid 2 x 25 = 50	acetamiprid 1. 12.5 2. 12.5

5.3 Information on the active substances

5.3.1 Acetamiprid

5.3.1.1 Identity, further information of acetamiprid

Table 5.3-1: Identity, further information on acetamiprid

Active substance (ISO common name)	Acetamiprid
IUPAC	(E)-N1-[(6-chloro-3-pyridyl)methyl]-N2-cyano-N1-methylacetamidine
Function (e.g. fungicide)	Insecticide
Status under Reg. (EC) No 1107/2009	approved
Date of approval	01/01/2005
Conditions of approval	Only uses as insecticide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on Acetamiprid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 29 June 2004 shall be taken into account. In this overall assessment Member States — should pay particular attention to worker exposure, — should pay particular attention to the protection of aquatic organisms. Risk mitigation measures should be applied where appropriate.
Confirmatory data	no
RMS	Greece
Minimum purity of the active substance as manufactured (g/kg)	990
Molecular formula	$C_{10}H_{11}ClN_4$
Molecular mass	222.7
Structural formula	

5.3.1.2 Physical and chemical properties of acetamiprid

Physical and chemical properties of acetamiprid as agreed at EU level (see SANCO/1392/2001-final 16 June 2004) and considered relevant for the exposure assessment are listed in Table 5.3-2.

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

	Value	**Reference**
Vapour pressure (at 20 °C) (Pa)	1.73×10^{-7} Pa at 50 °C (>99%).	SANCO/1392/2001-final 16 June 2004

	Expected <1x10^{-6} Pa at 25 ^{o}C	
Henry's law constant (Pa × m^{3} × mol^{-1})	<5.3x10^{-8} Pa m^{3} mol^{-1} at 25 ^{o}C	
Solubility in water (at 25 °C in mg/L)	In distilled water: 4.25 g/l at 25 ^{o}C (>99%) pH 5: 3.48 g/l at 25 ^{o}C (>99%) pH 7: 2.95 g/l at 25 ^{o}C (>99%) pH 9: 3.96 g/l at 25 ^{o}C (>99%)	
Partition co-efficient (at 25 °), log P_{OW}	log P_{ow}= 0.80 at 25 ^{o}C (>99%) pH: Not determined (neutral conditions)	
Dissociation constant, pKa	pKa: 0.7 at 25 ^{o}C	
Hydrolytic degradation	pH 4: Stable at 22 ^{o}C, 35 ^{o}C and 45 ^{o}C pH 5: Stable at 22 ^{o}C, 35 ^{o}C and 45 ^{o}C pH 7: Stable at 22 ^{o}C, 35 ^{o}C and 45 ^{o}C pH 9: at 22 ^{o}C, DT_{50}=812 days at 35 ^{o}C, DT_{50}=52.9 days at 45 ^{o}C, DT_{50}=13.0 days Calculated at 25 ^{o}C: DT_{50}=420 days	
Photolytic degradation	pH 7: DT_{50}= 34 days under xenon lamp (irradiation: 12 hours/day)	
Quantum yield of direct phototransformation in water > 290 nm	Φ = 0.10	
Photochemical oxidative degradation in air (calculation according to Atkinson)	DT_{50} =1.679 hours (AOP version: 1.70, 1.5 × 10^{6} radicals/cm³, 12 h day)	

5.3.1.3 Metabolites of acetamiprid

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

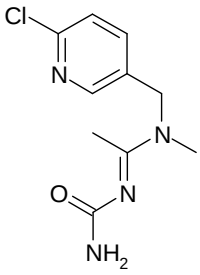
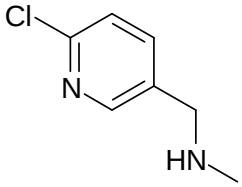
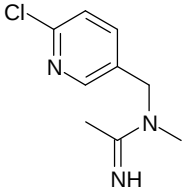
No new study on the fate and behaviour of acetamiprid or Mospilan SG has been performed. Hence no potentially new metabolites need to be considered.

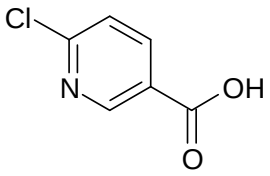
The risk assessment for these metabolites has already been performed for EU approval (see SANCO/1392/2001-final 16 June 2004). Therefore no new risk assessment hence no exposure assessment for these metabolites is necessary.

Potential ground water contamination by the soil metabolites IM 1-4 were evaluated for EU approval of acetamiprid. PECgw modelled with PELMO 3.0 and by soil metabolites IM 1-2, IM 1-5 and IC-0 with FOCUS –PELMO 3.2.2 was less than 0.1µg/L for the metabolites based on an application of 2 x 100 g as/ha in citrus, wheat and apples.

A reassessment of input parameter under consideration of the new available studies for degradation in soil and adsorption has been performed and therefore the leaching potential into groundwater of the soil metabolites IM 1-4, IM 1-2, IM 1-5 and IC-0 will be reassessed for the application of the plant protection product Mospilan SG and its intended use using FOCUS-PELMO 4.4.3.

Table 5.3-3: Metabolites of acetamiprid 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)

Metabolit	**Structural formula/Molecular formula**	**occurence in compartements (Max. at day/**	**Satus of Relevance from ecotoxicological point of view Origin of information: 1) DAR 2001 2) This submission**
IM -1-2		Soil: Max. 55 % at day 1 Water: Max. 11 % at day 7	**This submission:** Aquatic organism: low risk Water: non relevant (see Section 6.4.4) Sediment: non relevant Terrestrial organism: non relevant (see Section 6.3.4 and 6.7.2) Groundwater: non relevant
IM-1-4		Soil: Max. 72 % at day 30 Water: Max. 12.3 % at day 62 Sediment: Max. 31 % at day 30	**DAR 2001:** Aquatic organism: minimal risk Water: non relevant Sediment: non relevant Terrestrial organism: insecticidal inactivity, no risk to earthworms non relevant Groundwater: non relevant
IM-1-5		Soil: Max. 20.2 % at day 13	**This submission:** Aquatic organism: Water: non relevant Sediment: non relevant Terrestrial organism: non relevant (see Section 6.3.4 and 6.7.2) Groundwater: non relevant
IC-0		Soil: Max. 11.3 % at day 120 Water: Max. 26 % at day 62	**DAR 2001:** Aquatic organism: minimal

			risk Water: non relevant Sediment: non relevant Terrestrial organism: insecticidal inactivity, no risk to earthworms non relevant Groundwater: non relevant

1) DAR March 2001 = DAR March 2001; RMS: Greece, cRMS: France; see Volume 3, Annex B-9: Ecotoxicology

2) This submission, Part B, Section 6

5.4 Summary on Inputparameter for environmental exposure assessment

5.4.1 Rate of degradation in soil

5.4.1.1 Laboratory studies

Acetamiprid

No new studies have been submitted regarding route and rate of degradation in soil of acetamiprid. Based on the results of kinetic modeling of Reinken (2001), Hardy (2002) and (Hardy 2003) the zRMS has derived new DT_{50} endpoints for environmental exposure assessment according to recommendations of FOCUS degradation kinetics guidance (2006). The recalculation of Reinken 2001 showed biphasic degradation of acetamiprid in the four soils of Morgenroth 1997 and Burr 1997. The kinetic parameters were provided in the calculation. The rate constants of slow phases were choosen as worst case approach for PEC modeling of parent. The rate constants of fast phases were choosen as worst case approach for PEC modeling of metabolites. These recalculated SFO DT50 values were aggregated to derive the two relevant modelling endpoint for acetamiprid. The actualized DT_{50} values from the laboratory studies after recalculation are summarized in Table 5.4-1 and .Table 5.4-2.

Table 5.4-1: Summary of aerobic degradation rates for acetamiprid - laboratory studies (worst case approach for PECgw of acetamiprid)

Soil type	pH	T (°C)	Moisture during study	DT50 (d)	DT90 (d)	EU (2004) DT50 20 °C pF2	DT50 20 °C pF2/10 kPa according FOCUS (2006)	Kinetic, Fit	Reference
Collombey, loamy sand	7.6	20	50 % FC	k1: 0,525 k2: 0,025 tb:5		1.4**	27.7	HS slow phase.	Morgenroth, 1997 Reinken 2001
clay loam	7.4	20	45 % of MWHC	k1: 0,129 k2: 0,012 tb:13		5.4**	57.8	HS slow phase.	Burr 1997 Hardy 2002
sandy loam	5.6	20	45 % of MWHC	k1: 0,260 k2: 0,026 tb: 9		2.7**	26.6	HS slow phase.	
silty clay	7.9	20	45 % of MWHC	k1: 0,818		0.8**	8.3	HS slow	

loam				k2: 0,083 tb: 3				phase.	
L.Shelford,UK,, sandy loam	8.0	20	45 % of MWHC	1.1	3.6	1.1	1.1	SFO	Simmonds 2002 Hardy 2002
Royston,UK, clay	7.7	20	45 % of MWHC	1.4	3.5	1.4	1.4	SFO	
Ongar,UK, clay loam	7.9	20	45 % of MWHC	1.2	3.1	1.2	1.2	SFO	
UK, Sandy loam	8.4	20	75% 1/3 bar	5.6		4.0	3.1	SFO	Simmonds 2003* Hardy 2003
USA, Sandy loam,	8.7	20	75% 1/3 bar	2.0		1.4	1.0	SFO	
Aggregated DT_{50} (n=9)		**Coefficient of variation (%)**					138		
		Geometric mean (d)					5.0	Used for PECgw of parent as worst case approach for core assessment	
		90th percentile					33.7	Used for PECgw as worst case approach for the national addendum	

* Aged Residue Column Leaching Study in Two Calcareous Soils:

** fast phase DT50 from HS (not recommended in FOCUS kinetics 2006)

Table 5.4-2: Summary of aerobic degradation rates for acetamiprid - laboratory studies (worst case approach for PECgw of metabolites)

Soil type	**pH**	**T (°C)**	**Moisture during study**	**DT50 (d)**	**DT90 (d)**	**EU (2004) DT50 20 °C pF2**	**DT50 20 °C pF2/10 kPa according FOCUS (2006)**	**Kinetic, Fit**	**Reference**
Collombey, loamy sand	7.6	20	50 % FC	k1: 0,525 k2: 0,025 tb:5	4.7	1.4	1.4	HS fast phase	Morgenroth, 1997 Reinken 2001
clay loam	7.4	20	45 % of MWHC	k1: 0,129 k2: 0,012 tb:13	67.3	5.4	5.4	HS fast phase.	Burr 1997 Hardy 2002
sandy loam	5.6	20	45 % of MWHC	k1: 0,260 k2: 0,026 tb: 9	8.9	2.7	2.7	HS fast phase	
silty clay loam	7.9	20	45 % of MWHC	k1: 0,818 k2: 0,083 tb: 3	2.8	0.8	0.8	HS fast phase.	

L.Shelford,UK,, sandy loam	8.0	20	45 % of MWHC	1.1	3.6	1.1	1.1	SFO	Simmonds 2002 Hardy 2002
Royston,UK, clay	7.7	20	45 % of MWHC	1.4	3.5	1.4	1.4	SFO	
Ongar,UK, clay loam	7.9	20	45 % of MWHC	1.2	3.1	1.2	1.2	SFO	
UK, Sandy loam	8.4	20	75% 1/3 bar	5.6		4.0	3.1	SFO	Simmonds 2003 Hardy 2003
USA, Sandy loam,	8.7	20	75% 1/3 bar	2.0		1.4	1.0	SFO	
Aggregated DT_{50} (n=9)		**Coefficient of variation (%)**					74		
		Geometric mean (d)					1.7	Used as worst case approach for PECgw simulation of metabolites for core assessment	

The DT_{50} values of acetamiprid do not show any pH dependency.

Metabolites of acetamiprid

No new studies have been submitted regarding route and rate of degradation in soil of metabolites of acetamiprid.

Based on the results of kinetic modeling of Reinken (2001), Hardy (2002) and (Hardy 2003) the zRMS has derived new DT_{50} endpoints for environmental exposure assessment according to recommendations of FOCUS degradation kinetics guidance (2006). The actualized DT_{50} values from the laboratory studies after recalculation are summarized in Table 5.4-3 to Table 5.4-6.

Table 5.4-3 Summary of aerobic degradation rates for metabolite IM 1-4 - laboratory studies

Soil type	pH (H_2O)	T (^oC)	Moisture	DT_{50}/ DT_{90} (d)	f.f.	DT_{50} (d) 20 °C pF2/10kPa	Kinetic, Fit	Reference
Collombey, loamy sand	7.6	20	50 % FC	32.1		26.8	SFO	Morgenroth, 1997
clay loam	7.4	20	45 % of MWHC	226.5		226.5	SFO	Burr (1997)
sandy loam	5.6	20	45 % of MWHC	168.5		168.5	SFO	
silty clay loam	7.9	20	45 % of MWHC	4.1		4.1	SFO	
L.Shelford,UK, sandy loam	8.0	20	45 % of MWHC	5.6		5.6	SFO	Simmonds (2002)

Royston,UK, clay loam	7.7	20	45 % of MWHC	3.3		3.3	SFO	
Ongar,UK, clay loam	7.9	20	45 % of MWHC	3.7		3.7	SFO	
UK, Sandy loam	8.4	20	75% 1/3 bar	3.9		4.2	SFO	Simmonds 2003 , Hardy 2003
USA, Sandy loam,	8.7	20	75% 1/3 bar	18.5		19.5	SFO	
Aggregated DT_{50} (n=9)		**Coefficient of variation (%)**				165		
		Geomean (d)				14.2		
		Median				5.6		
		90^{th} /10^{th} perzentil				180.1/ 3.6		

Table 5.4-4: Summary of aerobic degradation rates for metabolite IM 1-2 - laboratory studies

Soil type	**pH (H_2O)**	**T (^oC)**	**Moisture**	**DT_{50}/ DT_{90} (d)**	**f.f.**	**DT_{50} (d) 20 °C pF2/10kPa**	**Kinetic, Fit**	**Reference**
L.Shelford, UK, sandy loam	8.0	20	45 % of MWHC	1.6		1.6	SFO	Simmonds (2002)
Royston,UK, slay loam	7.7	20	45 % of MWHC	1.4		1.1	SFO	
Ongar,UK, clay loam	7.9	20	45 % of MWHC	1.2		1.1	SFO	
Sandy loam,UK	8.4	20	75% 1/3 bar	2.0		2.2	SFO	Simmonds 2003 (leaching study), Hardy (2003)
Sandy loam, USA	8.7	20	75% 1/3 bar	2.5		2.6	SFO	
Aggregated DT_{50} (n=5)		**Coefficient of variation (%)**				41		
		Geomean (d)				1.6		
		90^{th} percentile				2.4		

Table 5.4-5: Summary of aerobic degradation rates for metabolite IM 1-5 - laboratory studies

Soil type	**pH (H_2O)**	**T (^oC)**	**Moisture**	**DT_{50}/ DT_{90} (d)**	**f.f.**	**DT_{50} (d) 20 °C pF2/10kPa**	**Kinetic, Fit**	**Reference**
Silty clay loam	7.9	20	45 % of MWHC	450		450	SFO-SFO	Burr 1997

Ongar,UK, clay loam	7.9	20	45 % of MWHC	430		388	SFO-SFO	Simmonds 2002
Sandy loam (02/016)	8.4	20	75 % bei 1/3 bar	250		180	SFO-SFO	Simmonds 2003 leaching study
Sandy loam (02/017)	8.7	20	75 % bei 1/3 bar	90		64	SFO-SFO	
Aggregated DT_{50} (n=4)		Coefficient of variation (%)				66		
		Geomean (d)				211.8		
		90^{th} percentile				431.4		

Table 5.4-6: Summary of aerobic degradation rates for metabolite IC-0 - laboratory studies

Soil type	**pH (H_2O)**	**T (^oC)**	**Moisture**	**DT_{50}/ DT_{90} (d)**	**f.f.**	**DT_{50} (d) 20 °C pF2/10kPa**	**Kinetic, Fit**	**Reference**
Sandy loam	7.2	20	45 % of MWHC	3.5*	8.3	3.5	SFO	Lowden et al (1997)
silty clay loam	6.7	20	45 % of MWHC	2.9	6.6	2.9	SFO	
clay loam	7.8	20	45 % of MWHC	6.5	13.3	5.2	SFO	
Sandy loam				1.5		1.5	SFO-SFO	Hardy 2003c
Clay				2.5		2.0	SFO-SFO	
Clay loam				2.0		1.8	SFO-SFO	
Sandy loam,UK	8.4	20	75% 1/3 bar	35.7		25.7	SFO-SFO	Simmonds 2003 (column leaching study.) Hardy (2003)*
Sandy loam, USA	8.7	20	75% 1/3 bar	58.5		41.7	SFO-SFO	
Aggregated DT_{50} (n=8)		**Coefficient of variation (%)**				143		
		Geomean (d)				4.8		
		90^{th} percentile				30.5		

5.4.1.2 Field studies

Acetamiprid

The field dissipation rates of acetamiprid were evaluated during EU assessment. No additional studies have been performed.

A new study (Heimann, 2002) on the recalculation of the degradation rate of acetamiprid under field conditions (Wicks 1997) has been submitted. The DT_{50} values of the new study together with the DT_{50} values from the EU assessment are summarized in Table 5.4-7.

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Table 5.4-7: Field degradation studies of acetamiprid

soil / location	**pH**	**depth (cm)**	**DT_{50} (d)**	**DT_{90} (d)**	**Fit, Kinetic, Parameters**	**DT_{50} (d) 20 °C, pF2**	**Fit, Kinetic**	**Reference**
Italy, Bologna, clay loam	8.9	0-30	0.4	18.4	r^2 0.881 k1 1.6105 k2 0.0398 tb 1		HS	Wicks, 1999, Reinken 2001 DAR
UK, Manningtree, sandy loam	5.9	0-30	5.4	19.9	r^2 0.892 k1 0.1567 k2 0.1111 tb 2		HS	Wicks, 1999, Reinken 2001 DAR
			5.25	17.45	r^2 0.900	5.25	1st order, linear	Heimann 2002
France, Mereville, silty clay ,loam	8.7	0-30	4.1	31.2	r^2 0.821 k1 0.5110 k2 0.0594 tb 1		HS	Wicks, 1999, Reinken 2001 DAR
			6.1	20.3	r^2 0.860	6.1	1st order, linear	Heimann 2002
Spain, Seville, sandy loam	7.0	0-30	1.6		k1 0.4443 k2 0.1518 tb 1		HS	Wicks, 1999, Reinken 2001 DAR
DT50 aggregated	Maximum					6.1	SFO for PEC soil	

Comment of zRMS

Because applicant did not provided a new evaluation of field study according to FOCUS Degradation Kinetics guideline (2006), zRMS re-calculated the relevant trigger endpoints and inputs for the PEC soil calculation for acetamiprid. ..The results of the recalculation of field study (Wicks, 1997) are presented in **Fehler! Verweisquelle konnte nicht gefunden werden.** and Table 5.4-8. The detailed information are presented in Appendix 2.

The results are summarized in.

Table 5.4-8: Recalculated best fit DT50 /DT90 values of acetamiprid from field dissipation study (Wicks 1999) for derivation of persistence endpoints by zRMS

soil / location	pH	depth (cm)	DT_{50} (d)	DT_{90} (d)	Kinetic Parameters	Fit	DT_{50} (d) SFO recalulated according FOCUS (2006)	Reference
Italy, Bologna, clay loam	8,9	0-30	0.09	23.93	DFOP k1 0.05365 k2 1.609 g 0.361	chi^2 12.7	12.9 slow phase	Wicks 1999, zRMS 2012
UK, Manningtree, sandy loam	5,9	0-30	3.38	11.22	SFO k 0.20507	chi^2 20.8	3.38	Wicks 1999, zRMS 2012
France, Mereville, silty clay ,loam	8,7	0-30	10.9	36.33	SFO k 0.06336	chi^2 12.44	10.94	Wicks 1999, zRMS 2012
Spain, Seville, sandy loam	7,0	0-30	0.0255	na	DFOP k1 14.89 k2 0.1677 g 0.5714	chi^2 9.05	4.11 Slow phase	Wicks 1999, zRMS 2012
DT50 aggregated n = 4	**Maximum (PEC soil) soil Mereville/ France**						**10.94**	SFO

Table 5.4-9: Field degradation studies of acetamiprid- recalculation of degradation rates for metabolite IM 1-4 according to FOCUS Degradation Kinetics 2006 by zRMS

soil / location	pH	depth (cm)	DT_{50} (d)	DT_{90} (d)	Fit	DT_{50} (d) SFO recalulated according FOCUS (2006)	Kinetic	Reference
Italy, Bologna, clay loam	8,9	0-30	30.6	101.7	36.1	30.6	SFO-SFO	Wicks 1999, zRMS 2012
UK, Manningtree, sandy loam	5,9	0-30	38.4	127.5	15.3	38.4	SFO-SFO	Wicks 1999, zRMS 2012
France, Mereville, silty clay ,loam	8,7	0-30	45.7	151.8	29.9	45.7	SFO-SFO	Wicks 1999, zRMS 2012
Spain, Seville, sandy loam	7,0	0-30	26.8	89.4	26.8	26.8	SFO-SFO	Wicks 1999, zRMS 2012
DT50 aggregated n = 4	**Maximum (PEC soil) soil Mereville /France**					**45.7**	**SFO**	

Normalised $DegT_{50}$ values from the field dissipation study were not provided, so $DegT_{50}$ values cannot be used for PEC_{GW} modeling.

5.4.2 Adsorption/desorption

Acetamiprid

A new study (Liu, 1997) on the adsorption / desorption behaviour of acetamiprid has been submitted. A detailed evaluation of this study is presented in Appendix 2. The loamy sand I was excluded from evaluation because of an organic carbon content of < 0.3 % considering the recommendations of OECD 106 guideline. The K_{foc} values of the new study together with those values from the EU assessment are summarized in Table 5.4-10.

Table 5.4-10: K_f, K_{foc} and 1/n (Freundlich exponent) values for acetamiprid

Soil Type	OC (%)	pH (-)	K_f (mL g^{-1})	K_{foc} (mL g^{-1})	1/n (-)	Reference
I sand	0.43	5.7	0.600	138	0.842	Flückiger, 1997
II loamy sand	1.00	7.6	1.350	130	0.825	
III sandy loam	1.57	7.1	1.120	71	0.893	
IV silt loam	1.39	7.7	1.690	122	0.835	
V silt loam	4.39	7.1	3.130	71	0.907	
Loamy sand II	1.5	6.2	3.210	218	0.8295	Liu, 1997a
Silt loam	0.44	6.6	1.247	283	0.9272	
Clay	1.19	7.5	3.719	313	0.9297	
sandy loam, Pond sediment,	2.5	5.6	3.429	137	0.8385	
Arithmetic mean (n = 9)			**2.17**	**165**	**0.87**	

The K_{foc}/K_f values of acetamiprid do not show any pH dependency ..

Metabolites of acetamiprid

No new studies on the adsorption / desorption behaviour of the metabolites of acetamiprid has been submitted. The K_{foc} values of the studies evaluated during EU assessment and are summarized in Table 5.4-11 to Table 5.4-14.

Table 5.4-11: K_f, K_{foc} and 1/n (Freundlich exponent) values for metabolite IM 1-2

Soil Type	OC (%)	pH (-)	K_f (mL g^{-1})	K_{foc} (mL g^{-1})	1/n (-)	Reference

clay loam, (Hertforshire,UK)	2.3	8.1	0.45	19	0.886	MacKenzie, 2003
Sandy loam, (Lincolnhire,UK)	1.3	8.0	0.27	21	0.856	
Clay loam, (Lamberton, Minnesota,USA)	3.8	6.6	3.60	95	0.927	
Arithmetic mean (n = 4)			**1.12**	**45**	**0.890**	

The consideration of the inclusion of sandy soil (Fresno, CA) in spite of the oC content of 0.2 % described in Addendum 2 (2003) of EU assessment was not in line with the recommendations of the OECD guideline 106 and this soil should be excluded now in the further evaluation.
The K_{foc}/K_f values of IM 1-2 do not show any pH dependency.

Table 5.4-12: K_f, K_{foc} and 1/n (Freundlich exponent) values for metabolite IM 1-4

Soil Type	OC (%)	pH (-)	K_f (mL g^{-1})	K_{foc} (mL g^{-1})	1/n (-)	Reference
I sand	0.43	5.7	2.10	448	0.597	Mamouni, 1997
II loamy sand	1.0	7.6	2.24	223	0.714	
III sandy loam	1.57	7.1	2.16	138	0.712	
IV silt loam	1.39	7.7	2.67	192	0.816	
V silt loam	4.39	7.1	5.79	132	0.813	
Arithmetic mean (n = 5)			**2.99**	**235**	**0.730**	

The K_{foc}/K_f values of IM 1-4 do not show any pH dependency .

Table 5.4-13: K_f, K_{foc} and 1/n (Freundlich exponent) values for metabolite IM 1-5

Soil Type	OC (%)	pH (-)	K_f (mL g^{-1})	K_{foc} (mL g^{-1})	1/n (-)	Reference
Sandy loam,UK	1.3	8.4		563	1.0	Simmonds 2003
Sandy loam, USA	1.6	8.7		453	1.0	
Worst case (Minimum) n = 2				**453**	**1.0**	

Table 5.4-14: K_f, K_{foc} and 1/n (Freundlich exponent) values for metabolite IC-0

Soil Type	OC (%)	pH (-)	K_f (mL g^{-1})	K_{foc} (mL g^{-1})	1/n (-)	Reference

II loamy sand	1.47	6.2	1.027	70	1.007	Liu, 1997b
III silt loam	0.44	6.6	0.569	129	0.871	
IV clay	1.19	7.5	0.833	70	0.894	
V clay loam	0.82	8.3	0.690	84	0.926	
Arithmetic mean (n = 9)			**0.78**	**88**	**0.925**	

Deviating from decision in Addendum 2 (2003) of EU assessment the soil I (loamy sand) with an oC content of 0.25 % will not be considered in the further evaluation. The K_{foc}/K_f values of IC-0 do not show any pH dependency .

5.4.3 Rate of degradation in water

Acetamiprid

No new water/sediment study has been submitted. The exposure modeling is based on the results of the water/sediment study of acetamiprid and its metabolites (McMillan-Staff, 1997) recalculated by French, 2001 and reviewed in the DAR. However, since no SFO DT_{50} values for the whole system were available as required for deriving PEC_{SW} values for acetamiprid and its metabolites, they were back-calculated from DT_{90} biphasic/3.32 according to FOCUS Degradation Kinetics, 2006.

The DT_{50} values of acetamiprid from the water/sediment study are summarized in Table 5.4-15

Table 5.4-15: Degradation in water/sediment of acetamiprid

Water/sediment system	**$DegT_{50}$ / $DegT_{90}$ whole system**	**Kinetic, Fit**	**$DissT_{50}$/ $DissT_{90}$ water**	**Kinetic, Fit**	**$DissT_{50}$/ $DissT_{90}$ sed.**	**Kinetic, Fit**	**Reference**
I (Manningtree)	21.2/ 94.3	LoEP 2004 biphasic	3.6/ 31.1	LoEP 2004 biphasic	44.4/ 138.5	LoEP 2004 biphasic	McMillan-Staff, 1997
II (Ongar)	28.9/ 121.9	LoEP 2004 biphasic	5.8/ 36.6	LoEP 2004 biphasic	40.1/ 179.5	LoEP 2004 biphasic	
Maximum DT50 (n = 2)	**36.7/**	**SFO max. $DegT_{90}$/3.32**	**11.0**	**SFO max. $DissT_{90}$/3.32**	**54.1**	**SFO max. $DissT_{90}$/3.32**	**Relevant endpoint for PECsw**

Metabolites of acetamiprid

The DT_{50} values of metabolite IM 1-4 and IC-0 from the water/sediment study are summarized in Table 5.4-15 to Table 5.4-17.

Table 5.4-16: Degradation in water/sediment of metabolite IM 1-4

Water/sediment system	**$DegT_{50}$ / $DegT_{90}$ whole system**	**Kinetic, Fit**	**$DissT_{50}$/ $DissT_{90}$ water**	**Kinetic, Fit**	**$DissT_{50}$/ $DissT_{90}$ sed.**	**Kinetic, Fit**	**Reference**
I (Manningtree)	165/ 335	LoEP 2004 biphasic	27.8/ 107	LoEP 2004 biphasic	stabil	LoEP 2004 biphasic	McMillan-Staff, 1997
II (Ongar)	98/ 225	LoEP 2004 biphasic	-	LoEP 2004 biphasic	-	LoEP 2004 biphasic	McMillan-Staff, 1997
Maximum (n = 2)	**100.9**	**SFO $DegT_{90}$/3.32**	**32.2**	**SFO $DissT_{90}$/3.32**	**-**	**SFO $DissT_{90}$/3.32**	**Relevant endpoint for PECsw**

Table 5.4-17: Degradation in water/sediment of metabolite IC-0

Water/sediment system	**$DegT_{50}$ / $DegT_{90}$ whole system**	**Kinetic, Fit**	**$DissT_{50}$/ $DissT_{90}$ water**	**Kinetic, Fit**	**$DissT_{50}$/ $DissT_{90}$ sed.**	**Kinetic, Fit**	**Reference**
II (Ongar)	-	-	84.5	0.97	-	-	McMillan-Staff, 1997

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 for acetamiprid as presented in Table 5.5-1.

Table 5.5-1: Input parameter for active substance for PEC_{soil} calculation

Active substance	**DT_{50}**
acetamiprid	10.94 d (SFO, Maximum, Field studies, see Sec 5 point 5.4.1.2 Table 5.4-8)
IM 1-4	45.7 d (SFO, Maximum Field studies, see Sec 5 point 5.4.1.2 Table 5.4-9)
IM 1-5	450 d (Maximum, Laboratory conditions, see Sec 5 point 5.4.1.1 Table 5.4-5)
IM 1-2	2.6 d (Maximum, Laboratory conditions, see Sec 5 point 5.4.1.1 Table 5.4-4)
IC-0	41.7 d (Maximum, Laboratory conditions, see Sec 5 point 5.4.1.1 Table 5.4-6)

Due to the fast degradation of acetamiprid in soil (DT_{90} <365 d, SFO, field data) the accumulation potential of acetamiprid does not need to be considered. 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 5.5-2.

Table 5.5-2: Results of PEC_{soil} calculation (soil bulk density 1.5 g/cm^{-3}, soil depth 5 cm)

plant protection product:		Mospilan SG				
use:		16-001, potatoes (BBCH 20-39)				
Number of applications/interval		2 x, 14 days interval				
application rate:		25 g ai/ha				
crop interception:		50 %				
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)**
acetamiprid	2 x 12.5 = 25	0.0235	0.0141	-	-	-
IM 1-4 (max. 72 %, MG-ratio 0.704)	2 x 6.34 = 12.68	0.0153	0.0131	-	-	-
IM 1-5 (max. 20.2 %, MG-ratio 0.89)	2 x 2.25 = 4.5	0.0059	0.0058	20	0.0020	0.0079
IM 1-2 (max. 55 %, MG-ratio 1.08)	2 x 7.43 = 14.86	0.0101	0.0035	-	-	-
IC-0 (max. 11.3 %, MG-ratio 0.7)	2 x 1.0. = 2.0	0.0024	0.0020	-	-	-

5.6 Estimation of concentrations in surface water and sediment (PEC_{sw}/PEC_{sed}) (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 run-off.

As for the formulation Mospilan SG only an application in Germany is sought PECsw and PECsed FOCUS Surface Water Step 2 are calculated to provide PEC values for risk assessment. For authorization in Germany an individual exposure assessment is performed and described in the national addendum of this report.

The relevant input parameters for the acetamiprid used for PEC calculation are summarized in Table 5.6-1 .

Table 5.6-1 : Input parameters for active substance for $PEC_{SW/sed}$ calculations

Parameter	**Endpoint used for $PEC_{SW/sed}$ calculation**	**Values in accordance to EU endpoint in LoEP**	**Remarks**
Active substance	acetamiprid		
$DT_{50,soil}$ (d)	5.0	no	Geometric mean , n = 9, SFO (see 5.4.1.1 Table 5.4-1)
$DT_{50,wholesystem}$ (d)	36.7	no	Maximum, DT90/3.32 (see 5.4.3 Table 5.4-15)

$DT_{50,water}$ (d)	36.7 (Step 2)	no	Maximum, DT90/3.32 (see 5.4.3 Table 5.4-15)
$DT_{50,sed}$ (d)	36.7 (Step 2)	no	Maximum, DT90/3.32 (see 5.4.3 Table 5.4-15)
$K_{f,oc}$ (mL g^{-1})	165	yes	Arithmetic mean, n = 9 (see 5.4.2.1 Table 5.4-10)
1/n (-)	0.87	yes	Arithmetic mean, n = 9 (see 5.4.2.1 Table 5.4-10))
Max. occurrence sediment (%)	39 % at day 14	yes	See Wicks 1997
Water solubility (g L^{-1})	2.950	yes	

Results of FOCUS SW calculations for the worst-case application scenario of Mospilan SG are summarized in Table 5.6-2. Beside PEC_{act} value also PEC_{twa}, 21 d is given as it is necessary for risk assessment for birds and mammals.

The highest global maximum FOCUS surface water PEC_{SW} and PEC_{sed} values for acetamiprid for intended use are summarized in Table 5.6-2.

Table 5.6-2: Summary of highest global maximum FOCUS surface water PEC_{SW} and PEC_{sed} values

Plant protection product		Mospilan SG		
Use No evaluated		16-001		
Crop		Potatoes		
Application method		spraying		
Growth stage at first application (BBCH)		BBCH 20-39		
Crop interception		50		
Number of applications/intervall		2 x, 14 days interval		
Application rate		25 g ai/ha		
Active Substance		acetamiprid		
FOCUS STEP	**Scenario**	**PEC_{SW} (µg/L)**		**PEC_{SED} (µg/kg)**
		Actual, 0 h	**TWA, 21 d**	**Actual, 0 h**
1		7.06	4.72	11.36
2	South Europe March - May	1.04	0.70	1.67
2	South Europe June-Sept.	0.82	0.54	1.31
2	North Europe March - May	0.59	0.39	0.95
2	North Europe June-Sept.	0.59	0.39	0.95

5.7 Risk assessment ground water (KIIIA1 9.6)

5.7.1 Predicted environmental concentration in groundwater (PEC_{GW}) calculation for active substance and its metabolites (Tier 1 and 2)

Groundwater contamination by direct leaching of the active substance and its metabolites, degradation or reaction products through soil is generally assessed by groundwater model calculations.

The PEC values of acetamiprid and its metabolites IM-1-2, IM-1-4, IM-1-5 and IC-0 in ground water have been assessed with standard FOCUS scenarios to obtain outputs from the FOCUS PELMO 4.4.3. The FOCUS calculation was performed by zRMS Germany for the intended uses of Mospilan SG as outlined in Table 5.7-1.

Table 5.7-1: Input parameters related to the intended use of Mospilan SG for PEC_{gw} modelling

use evaluated	16-001
application rate (g as/ha)	2 x 25 = 50 (kumulative)
crop (crop rotation)	potatoes
date of application	5 days after emergence (Hamburg 15.05)
interception (%)	50
soil moisture	100 % FC
Q10-factor	2.58
moisture exponent	0.7
plant uptake factor	0

The input parameters for acetamiprid and its metabolites for the PECgw modelling are summarized in to Table 5.7-3.

Table 5.7-2 Input parameters related to acetamiprid for PEC_{GW} modelling

Parent	**acetamiprid**	**Remarks/Reference**
molecular mass	222.7	See 5.3.1.1 Table 5.3-1 of Part B, Section 5 of the core assessment
DT50 in soil (d)	5.0	Geometric mean, laboratory conditions, (see 5.4.1.1 Table 5.4-1 Part B, Section 5 of the core assessment) worst case for PECgw of parent
	1.7	Geometric mean, laboratory conditions, (see 5.4.1.1 Table 5.4-2 Part B, Section 5 of the core assessment) worst case for PECgw of metabolites
Kfoc	165	Arithmetic mean (see 5.4.2 Table 5.4-10 of

		Part B, Section 5 of the core assessment)
1/n	0.86	Arithmetic mean (see5 4.2.1 Table 5.4-10 of Part B, Section 5 of the core assessment)

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

Metabolite 1	**IM 1-4**	**Remarks/Reference**
molecular mass	156.7	See LoEP 2004
Formation fraction	1.0	default (see LoEP 2004)
DT_{50} in soil (d)	14.2	Geometric mean, laboratory conditions, (see 5.4.1.1 Table 5.4-3 Part B, Section 5 of the core assessment)
K_{foc}	235	Arithmetic mean (see 5.4.2 Table 5.4-12 of Part B, Section 5 of the core assessment)
1/n	0.73	Arithmetic mean (see 5.4.2 Table 5.4-12 of Part B, Section 5 of the core assessment)
Metabolite 2	**IM 1-2**	**Remarks/Reference**
molecular mass	240.7	See LoEP 2004
Formation fraction	1.0	default (see LoEP 2004)
DT_{50} in soil (d)	1.6	Geometric mean, laboratory conditions, (see 5.4.1.1 Table 5.4-4 Part B, Section 5 of the core assessment)
K_{foc}	45	Arithmetic mean (see 5.4.2 Table 5.4-11 of Part B, Section 5 of the core assessment)
1/n	0.890	Arithmetic mean (see5 4.2 Table 5.4-11 of Part B, Section 5 of the core assessment)
Metabolite 3	**IM 1-5**	**Remarks/Reference**
molecular mass	197.7	See LoEP 2004
Formation fraction	0.2	default (see LoEP 2004)
DT_{50} in soil (d)	211.8	Geometric mean, laboratory conditions, (see 5.4.1.1 Table 5.4-5 Part B, Section 5 of the core assessment)
K_{foc}	453	Arithmetic mean (see 5.4.2 Table 5.4-13 of Part B, Section 5 of the core assessment)
1/n	1.0	Default (see5 4.2 Table 5.4-13 of Part B, Section 5 of the core assessment)
Metabolite 4	**IC-0**	**Remarks/Reference**
molecular mass	155.7	See LoEP 2004

Formation fraction	0.5	see LoEP 2004
DT_{50} in soil (d)	4.8	Geometric mean, laboratory conditions, (see 5.4.1.1 Table 5.4-6 Part B, Section 5 of the core assessment)
K_{foc}	88	Arithmetic mean (see 5.4.2 Table 5.4-14 of Part B, Section 5 of the core assessment)
1/n	0.925	Arithmetic mean (see5 4.2 Table 5.4-14 of Part B, Section 5 of the core assessment)

In accordance with the decision of the PECgw-modelling approach of EU assessment 2004 the simulation approach of applicant based on kinetic modelling of Hardy 2003 using only degradation data from the aged leaching study of Simmonds 2003 was not accepted by zRMS. Two different halflives of acetamiprid were used. The first simulation considered the slow phase degradation rates (HS kinetic) of acetamiprid to provide a conservative leaching estimation for the parent compound. The other four separate simulations considered the faster (bi-phasic) degradation half-life of acetamiprid, in order to provide conservative estimations with regard to the leaching of the metabolites.

Four separate FOCUS-PELMO-simulations for each of the relevant metabolites were done with the formation fractions agreed in the LoEP 2004. The plant uptake factor for the active substance was set to 0 as worst case approach. Acetamiprid is a foliar applied insecticide of the chloronicotinyl group, acting by ingestion and by contact. Data about its systemic character are not provided. The plant uptake factors for the metabolites were also set to 0 as conservative approach.

The results of the PECgw simulations for acetamiprid and its metabolites with FOCUS-PELMO 4.4.3 are summarized in Table 5.7-4.

Table 5.7-4: PEC_{GW} at 1 m soil depth for acetamiprid and its metabolites following the intended application pattern of Mospilan SG in potatoes

Use No /crop	**Szenario**	**80th Percentile PEC_{GW} at 1 m Soil Depth (µg L^{-1}) groundwater model: FOCUS-PELMO 4.4.3**				
		acetamiprid	**Metabolit IM 1-4**	**Metabolit IM 1-2**	**Metabolit IM 1-5**	**Metabolit IM IC-0**
A potatoes	**Châteaudun**	< 0.001	< 0.001	0.001	0.037	< 0.001
	Hamburg	< 0.001	< 0.001	0.003	0.062	< 0.001
	Jokioinen	< 0.001	< 0.001	0.001	0.017	< 0.001
	Kremsmünster	< 0.001	< 0.001	0.003	0.054	< 0.001
	Okehampton	< 0.001	< 0.001	0.004	0.068	< 0.001
	Piacenza	< 0.001	< 0.001	0.003	0.057	< 0.001
	Porto	< 0.001	< 0.001	0.002	0.045	< 0.001
	Sevilla	< 0.001	< 0.001	< 0.001	0.003	< 0.001
	Thiva	< 0.001	< 0.001	< 0.001	0.023	< 0.001

According to the PEC_{GW} modelling with FOCUS-PELMO 4.4.3 a groundwater contamination of the active substance acetamiprid at a concentration of ≥ 0.1 µg/L is not expected for all nine FOCUS groundwater scenarios following the intended application pattern of Mospilan SG in potatoes

For the metabolites IM 1-2, IM 1-4, IM1-5 and IC-0 a groundwater concentration of ≥ 0.1 µg/L can be excluded in all nine FOCUS groundwater scenarios.

5.8 Potential of active substance for aerial transport

The fate and behaviour in air of acetamiprid was evaluated during the Annex I Inclusion. No additional studies have been performed.

The volatility study showed that only small amounts of acetamiprid of < 1 % of the applied dose was volatilised from soil and plant surfaces within a test period of 24 hours. The rate of the photochemical transformation of acetamiprid in the atmosphere under tropospheric conditions was estimated and the resulting half-life at 298K (25°C) was found to be 1.679 hours or 0.140.

The vapour pressure at 20 °C of the active substance acetamiprid is < 10^{-5} Pa. Hence the active substance acetamiprid is regarded as non-volatile. Therefore exposure of surface water by the active substance acetamiprid due to deposition following volatilization should not be considered.

Appendix 1 List of data submitted in support of the evaluation

Table A. 5-1: 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*
KIIIA-9.1.1/01	Simmonds, M.B.	2002	[^{14}C]-Acetamiprid: Rate of degradation in three calcareous soils at 20°C. Batelle AgriFood Ltd, UK, Report No. CX/01/013, Aventis No. C019428, Document No. RD-00168 GLP, not published	Y	Nisso	already accepted and considered in Addendum 2 (June 2003)
KIIIA-9.2.1/01	Heimann, S.	2002	Acetamiprid. Recalculation of the degradation rate of Acetamiprid in soil. DHD-Consulting, Report No. NCE-2002-01, Document No. RD-00672 No GLP, not published	Y	Nisso	not considered (study not relevant for evaluation)
KIIIA-9.3/01	Liu, A.	1997	NI-25: Soil adsorption / desorption study Rhone-Poulenc Ag Company; EC-97-381 Doc. No. RD-9970 GLP, not published	Y	Nisso	accepted (study valid and considered for evaluation)
KIIIA-9.3/02	Mackenzie, E., Price, O.	2003	[^{14}C].IM-1-2: Adsorption to and desorption from four soils and one sediment. Batelle AgriFood Ltd, UK, Report No. CX02082, Aventis No. C030079, Document No. RD-03056 GLP, not published	Y	Nisso	already accepted and considered in Addendum 2 (June 2003)
KIIIA-9.3.2/01	Simmonds, M.B.	2003	[^{14}C]-Acetamiprid: Aged residue column leaching study in two calcareous soils. Batelle AgriFood Ltd, UK, Report No. CX02018, Aventis No. C029849, Document No. RD-03061 GLP, not published	Y	Nisso	already accepted and considered in Addendum 2 (June 2003)
KIIIA-9.3.2/02	Hardy, I.A.J.	2003	Acetamiprid: Kinetic modelling analysis of data from a laboratory aged residue column leaching study. Batelle AgriFood Ltd, UK,	Y	Nisso	not accepted in Addendum 2 (calculation not considered for evaluation)

			Report No. CX/03/028a, Aventis No. C029734, Document No. RD-03054 GLP, not published			(June 2003)
KIIIA-9.6.1/01	Heimann, S.	2010	Mospilan - Calculation of PECgw for Acetamiprid and degradation products using PELMO 3.2.2. DHD-Consulting GmbH, D-31141 Hildesheim Report No. NCE-2010-01-DE No GLP, not published	Y	Nisso	calculation, not considered for evaluation

*

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

Appendix 2 Detailed evaluation of studies relied upon

The following chapters contain only studies, which have not previously been evaluated within a peer reviewed process at EU level.

KIIA 7 Fate and Behaviour in the Environment – Acetamiprid

KIIA 7.1.1 Heimann, 2002

Reference:	KIIA 7.1.1.2.2
Author:	Heimann,
Report:	Recalculation of the degradation rate of Acetamiprid in soil , RD-00672,
Date:	17.05.2002
Guideline(s):	not applicable
Deviations:	not adressed
GLP:	No
Acceptability:	data not considered in evaluation (see Part B, Section 5 of the core assessment Point 5.4.1.2)

KIIA 7.1.1 zRMS, 2012

Reference:	KIIA 7.1.1.2.2
Author:	zRMS
Report:	Recalculation of transformation rates of the field sdissipation study (Wicks 1999) according to FOCUS kinetics 2006 to derive trigger endpoint and input for PECsoil calculation by zRMS
Date:	01.09.2012
Guideline(s):	not adressed, recalculation with Kingui II
Deviations:	not adressed
GLP:	not adressed
Acceptability:	Yes

Materials and methods

zRMS Germany recalculated the trigger endpoints (DT50 and DT90) representing the dissipation rate of acetamiprid under field conditions in the field dissipation study of Wicks (1999), according to the recommendations in the FOCUS Kinetics guidance (2006) for trigger endpoints. The maximum DT50 value is also the relevant input parameter for PECsoil calculation.

For each dataset the kinetic model which provided the best fit has been selected on the basis of both a visual and a statistical assessment.
A maximum value of the $\chi 2$ error% for the overall model fit of 15% has been used to determine statistically acceptable goodness of fit. Due to the inherent uncertainty associated with unnormalized data from field dissipation studies fits with a $\chi 2$-error > 15% have been accepted where justification has been provided for the acceptability of the fit.

Where two models are appropriate to fit the data, the choice of best fit has been based on the lowest $\chi 2$ error.

The kinetic calculations based on the residual values of soil degradation in the four soils summarized in Table A.5-2.

Table A.5-2: Measured residual values in the four soils of field dissipation study (Wicks 1999)

Manningtree			Mereville			Bologna/ Italy			Sevilla		
	mg/kg			mg/kg			mg/kg			mg/kg	
d	**parent**	**IM 1-4**	**d**	**parent**	**IM 1-4**	**d**	**parent**	**IM 1-4**	**d**	**parent**	**IM 1-4**
0	394.9	<LOQ	0	164.9	<LOQ	0	207.8	<LOQ	0	350.9	28.5
1	344.5	nd	1	149	nd	1	57.1	nd	1	122.9	nd
2	188.9	nd	2	139.5	nd	2	70.6	nd	2	124.3	nd
4	132.6	nd	4	149.4	nd	4	67.3	nd	4	56.9	nd
7	150.4	40.7	8	118.9	75	7	56.9	40.7	7	48.9	76.5
15	40.1	101	14	37.8	56	13	47.2	101	14	25.9	125.9
30	43.2	121.3	28	39.3	143.1	28	0.005	121.3	31	0.005	152
61	0.01	31.8	61	0.005	107.3	61		31.8	60		40.7
92	0.005	0.005	99		45.4	91		0.005	92		0.005
			123		0.005						

Results and discussions

The summarized recalculated best fit DT50 values of acetamiprid and the metabolite IM 1-4 from field dissipation study of Wicks 1999 are provided in Table A. 5-3 and Table A. 5-4.

The results of the kinetic calculations of the persistence endpoints for acetamiprid with Kingui II are given in Table A. 5-5 and Figure A. 1 to Figure A. 4 for Bologna soil, in Table A. 5-6 and Figure A. 5 to Figure A. 8 for Manningtree soil, in Table A. 5-7 and Figure A. 9 to Figure A. 12 for Mereville soil and in Table A. 5-8 and Figure A. 13 to Figure A. 16 for Sevilla soil.

The results of the kinetic calculations of the persistence endpoints for metabolite IM1-4 with Kingui II are are derived in the same manner and are not provided in detail.

Table A. 5-3: Recalculated best fit DT50 /DT90 values of acetamiprid from field dissipation study (Wicks 1999) for derivation of persistence endpoints

soil / location	pH	depth (cm)	DT_{50} (d)	DT_{90} (d)	Kinetic Parameters	Fit	DT_{50} (d) SFO recalulated according FOCUS (2006)	Reference
Italy, Bologna, clay loam	8.9	0-30	0.09	23.93	DFOP k1 0.05365 k2 1.609	chi^2 12.7	12.9 slow phase	Wicks 1999, zRMS 2012

					g 0.361			
UK, Manningtree, sandy loam	5.9	0-30	3.38	11.22	SFO k 0.20507	chi^2 20.8	3.38	Wicks 1999, zRMS 2012
France, Mereville, silty clay ,loam	8.7	0-30	10.9	36.33	SFO k 0.06336	chi^2 12.44	10.94	Wicks 1999, zRMS 2012
Spain, Seville, sandy loam	7.0	0-30	0.0025	na	DFOP k1 14.89 k2 0.1677 g 0.5714	chi^2 9.05	4.11 Slow phase	Wicks 1999, zRMS 2012
DT50 aggregated n = 4	**Maximum (PEC soil) soil Mereville /France**						**10.94**	SFO

Table A. 5-4: Recalculated best fit DT50 /DT90 values of Metabolite IM 1-4 from field dissipation study (Wicks 1999) for derivation of persistence endpoints

soil / location	pH	depth (cm)	DT_{50} (d)	DT_{90} (d)	Fit,	DT_{50} (d) SFO recalulated according FOCUS (2006)	Kinetic	Reference
Italy, Bologna, clay loam	8.9	0-30	30.6	101.7	36.1	30.6	SFO-SFO	Wicks 1999, zRMS 2012
UK, Manningtree, sandy loam	5.9	0-30	38.4	127.5	15.3	38.4	SFO-SFO	Wicks 1999, zRMS 2012
France, Mereville, silty clay ,loam	8.7	0-30	45.7	151.8	29.9	45.7	SFO-SFO	Wicks 1999, zRMS 2012
Spain, Seville, sandy loam	7.0	0-30	26.8	89.4	26.8	26.8	SFO-SFO	Wicks 1999, zRMS 2012
DT50 aggregated n = 4	**Maximum (PEC soil) soil Mereville/France**					**45.7**	SFO	

Table A. 5-5: Acetamiprid –flow charts for trigger endpoints in soil Bologna (Wick 1999)

Kinetic	M0	k	DT50 (d)	DT90 (d)	DT50 recalc. SFO	Chi2	Std	Prop>t	Visual Fit

SFO	137.3	0.11669	5.9	19.7	5.9	47.8	0.07610	0.08187	+ acceptable.
FOMC	207.7	Alpha 0.25538 beta 0.01759	0.25	144.9	43.6	19.05	0.15204 0.05597	0.084159 0.384513	- not accept.able
DFOP	207.8	kslow 0.05365 kfast 1.609 g 0.361	0.09	23.9	12.9	12.7	2.099e-02 1.043e+03 5.727e-02	0.494349 0.004036 0.004036	++ good
HS	165.4	kslow 0.00113 kfast 0.3253 tb 0.0			613.4	49.5	na	na	-- not acceptable
Best fit DT50 for Bologna soil					**12.9**	**12.7**	**SFO recalc. (kslow DFOP)**		

Figure A. 1: Bologna (Wicks 1999) –Acetamiprid SFO

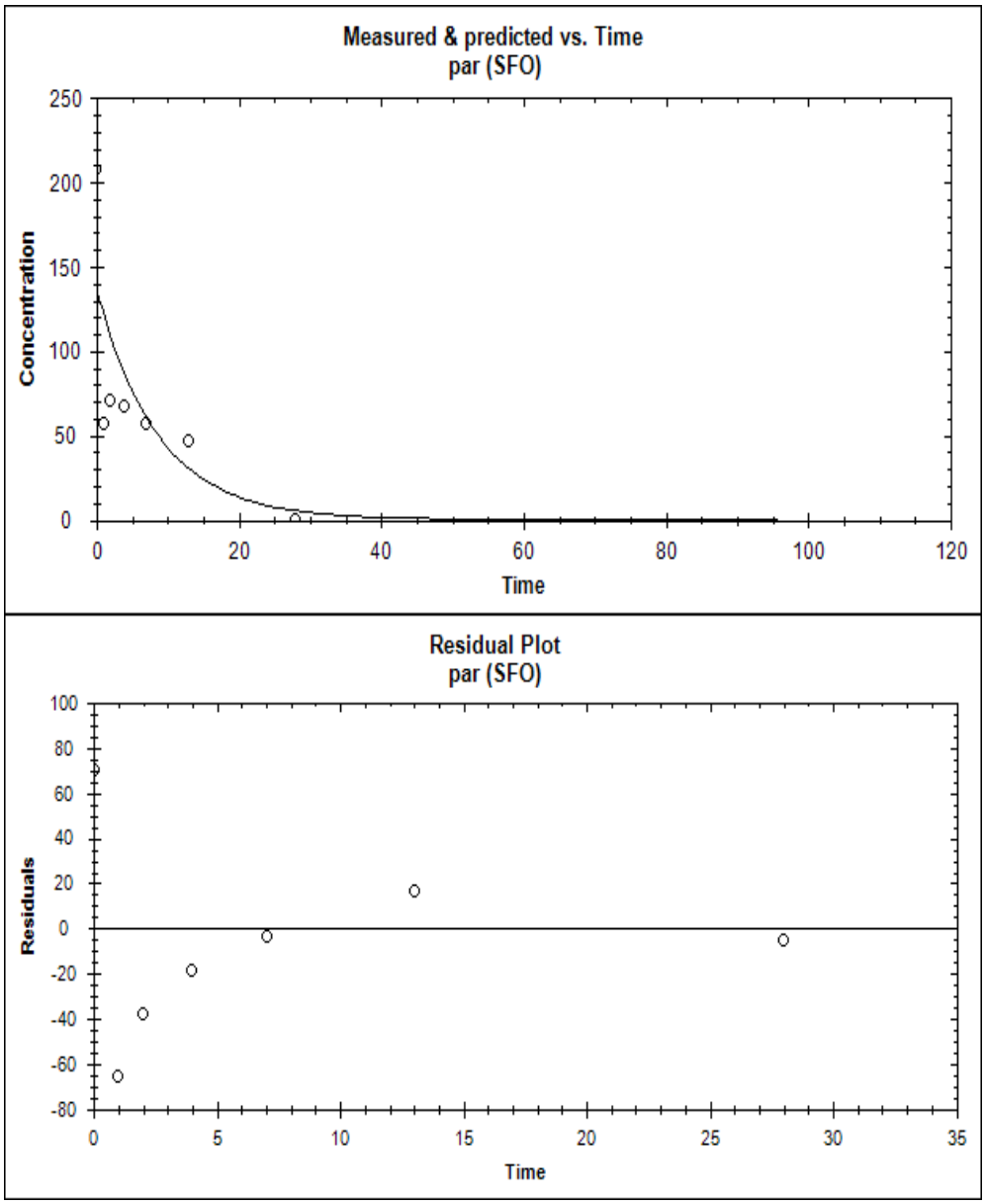


Figure A. 2: Bologna (Wicks 1999) –Acetamiprid FOMC

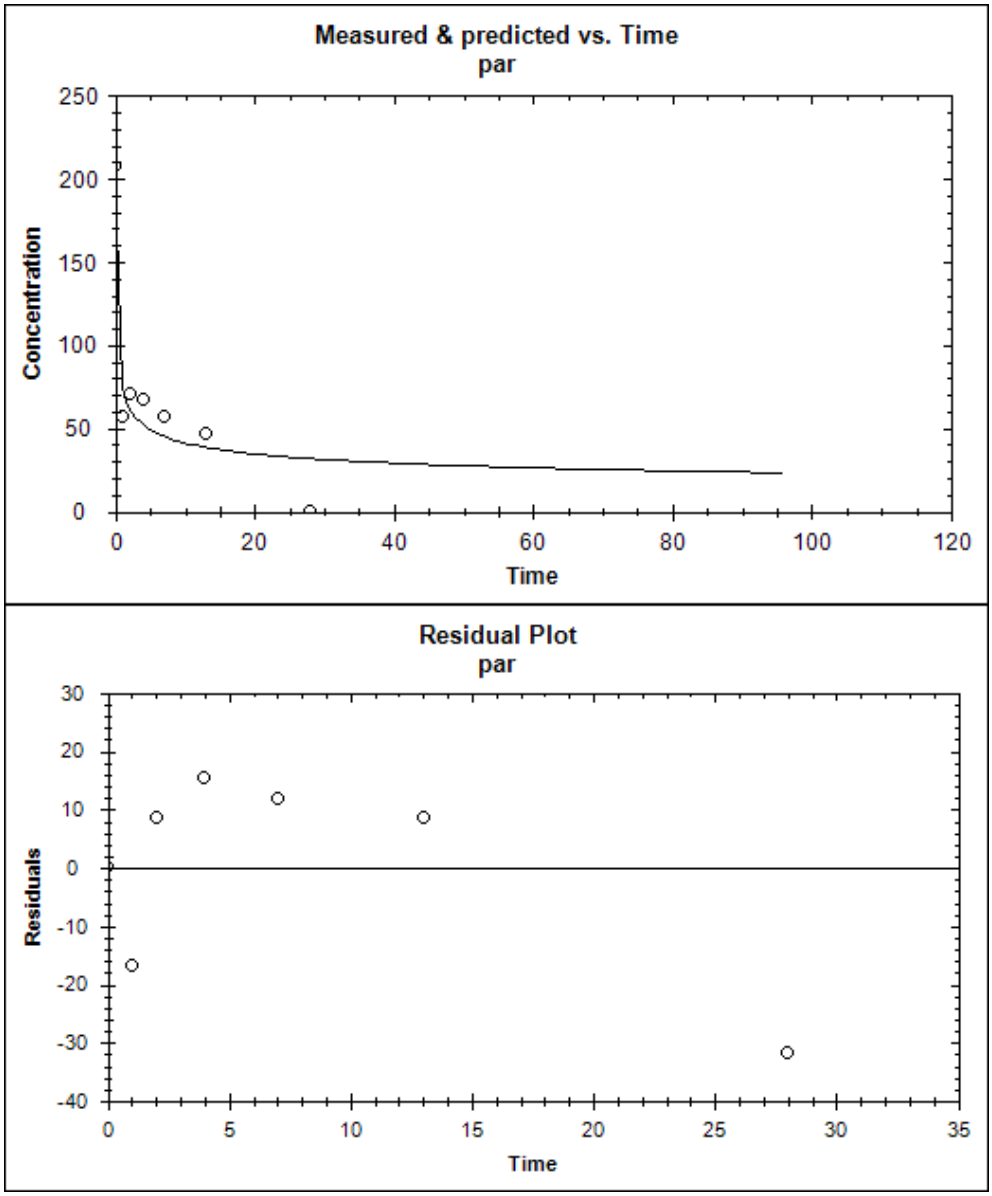


Figure A. 3: Bologna (Wicks 1999) –Acetamiprid DFOP

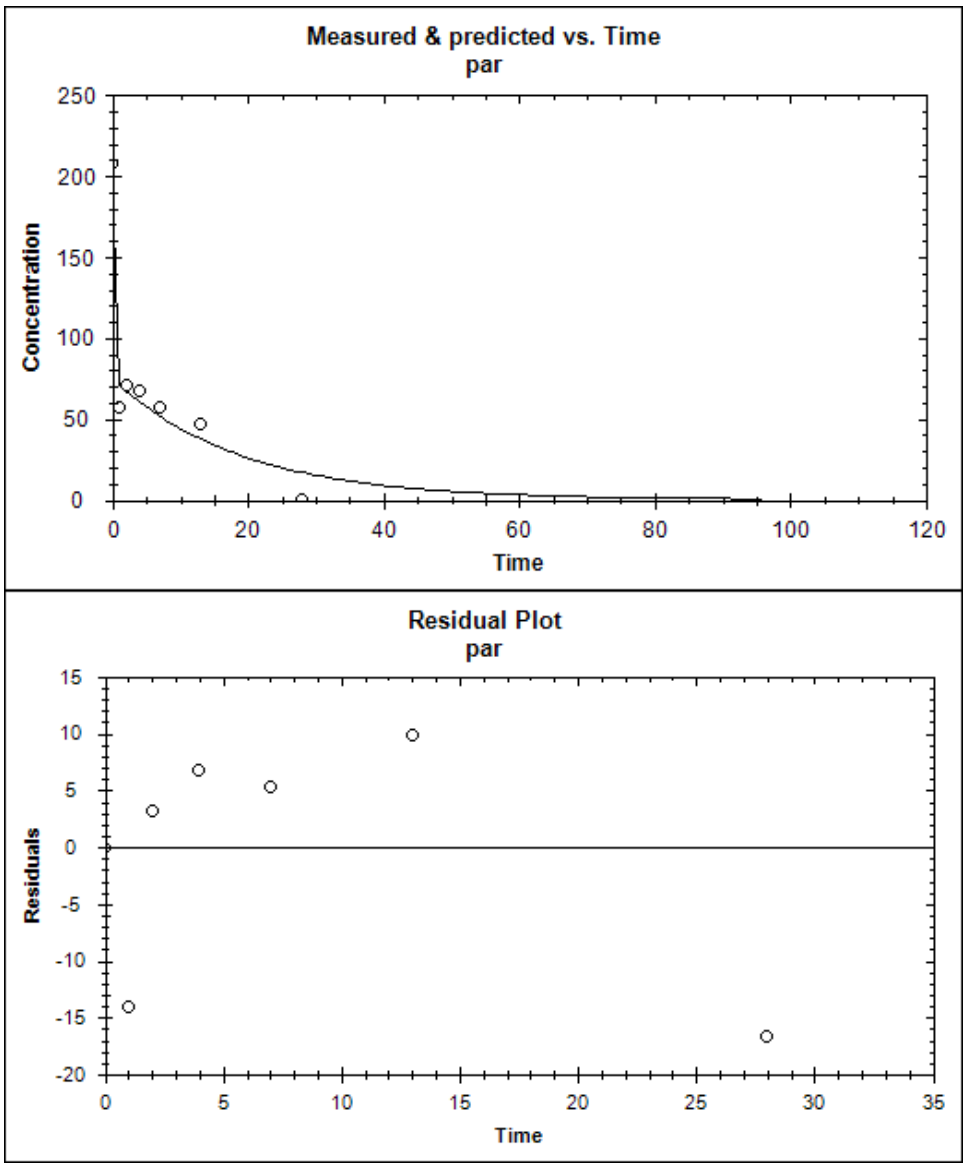


Figure A. 4: Bologna (Wicks 1999) –Acetamiprid HS

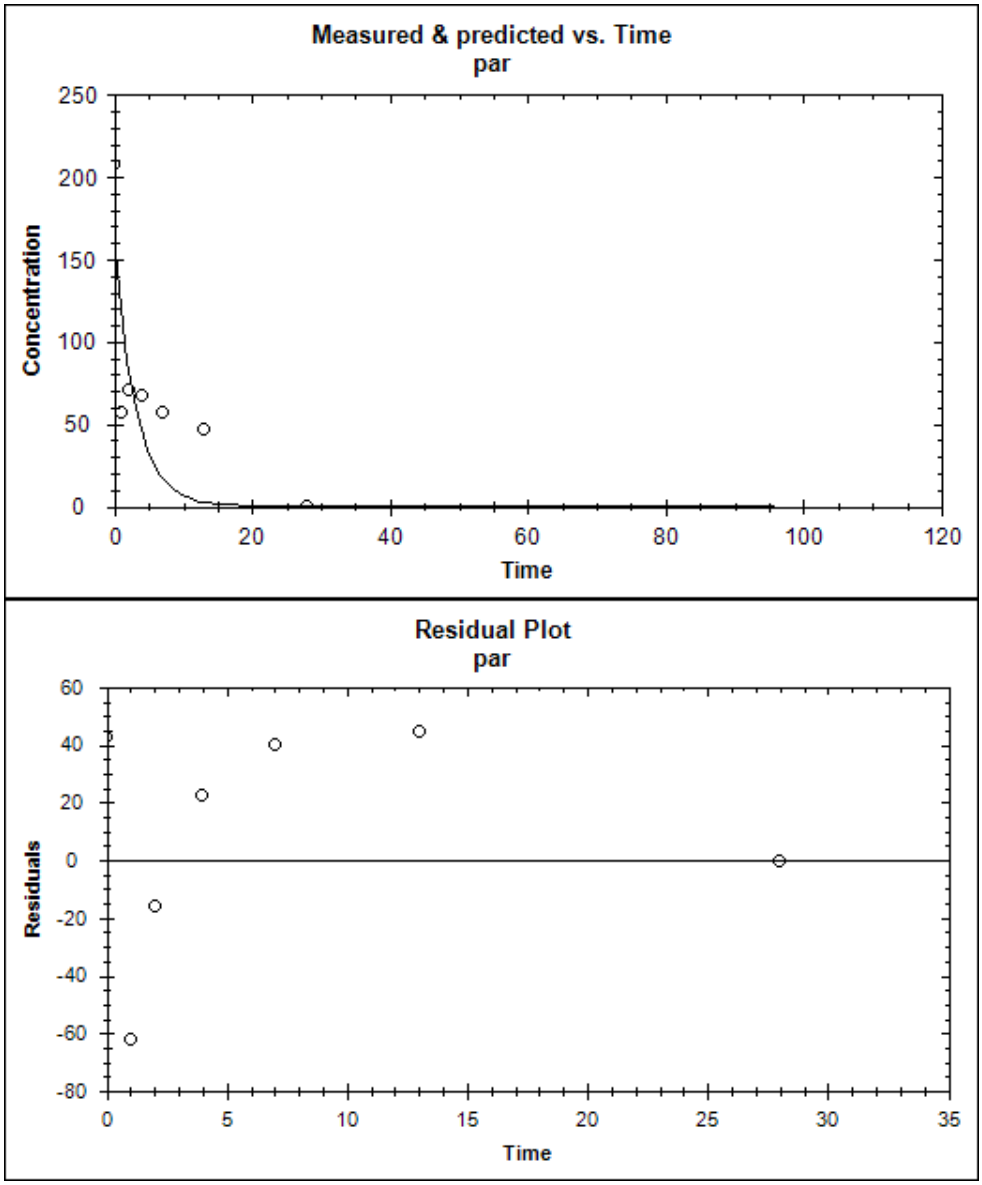


Table A. 5-6: Acetamiprid –flow charts for trigger endpoints in soil Manningtree (Wick 1999)

8

Kinetic	M0	k	DT50 (d)	DT90 (d)	DT50 recalc. SFO (d)	Chi^2	Std	Prop>t	visual fit
SFO	380.7	0.20518	3.4	11.22	3.38	20.8	0.0561	9.12e-06	+- acceptable
FOMC	405.6	alpha 1.1442 beta 3.1587	2.6	20.47	6.2	17.1	0.56680 2.52902	0.045 0.129	+ acceptable
DFOP	409.4	kfast 0.0563 kslow 0.5356 g 0.37897	2.4	23.65	54.8	17.4	0.04912 0.30220 0.23252	0.1516 0.0683 0.0820	++ good

HS	380.7	Kfast 0.009! Kslow 0.2052 Tb 1.048e-07	<0.0001	na	76.2	23.4	na 6.637e-02 2.999e-04	na 0.013559 0.499867	- not acceptable
Best Fit DT50 for Manningtree soil					**3.38**	**20.8**	**SFO**		

Figure A. 5: Manningtree (Wicks 1999) –Acetamiprid SFO

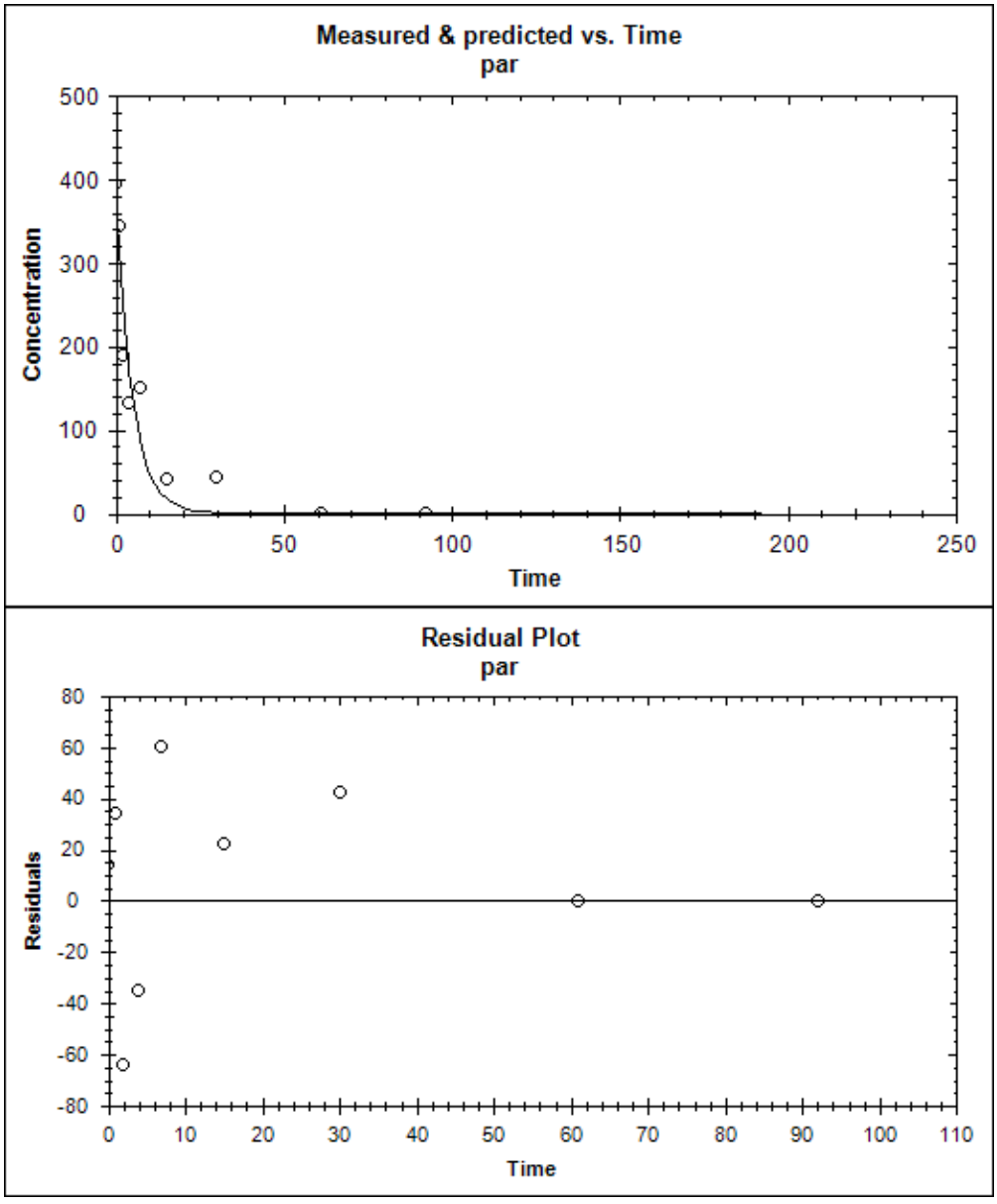


Figure A. 6: Manningtree (Wicks 1999) –Acetamiprid FOMC

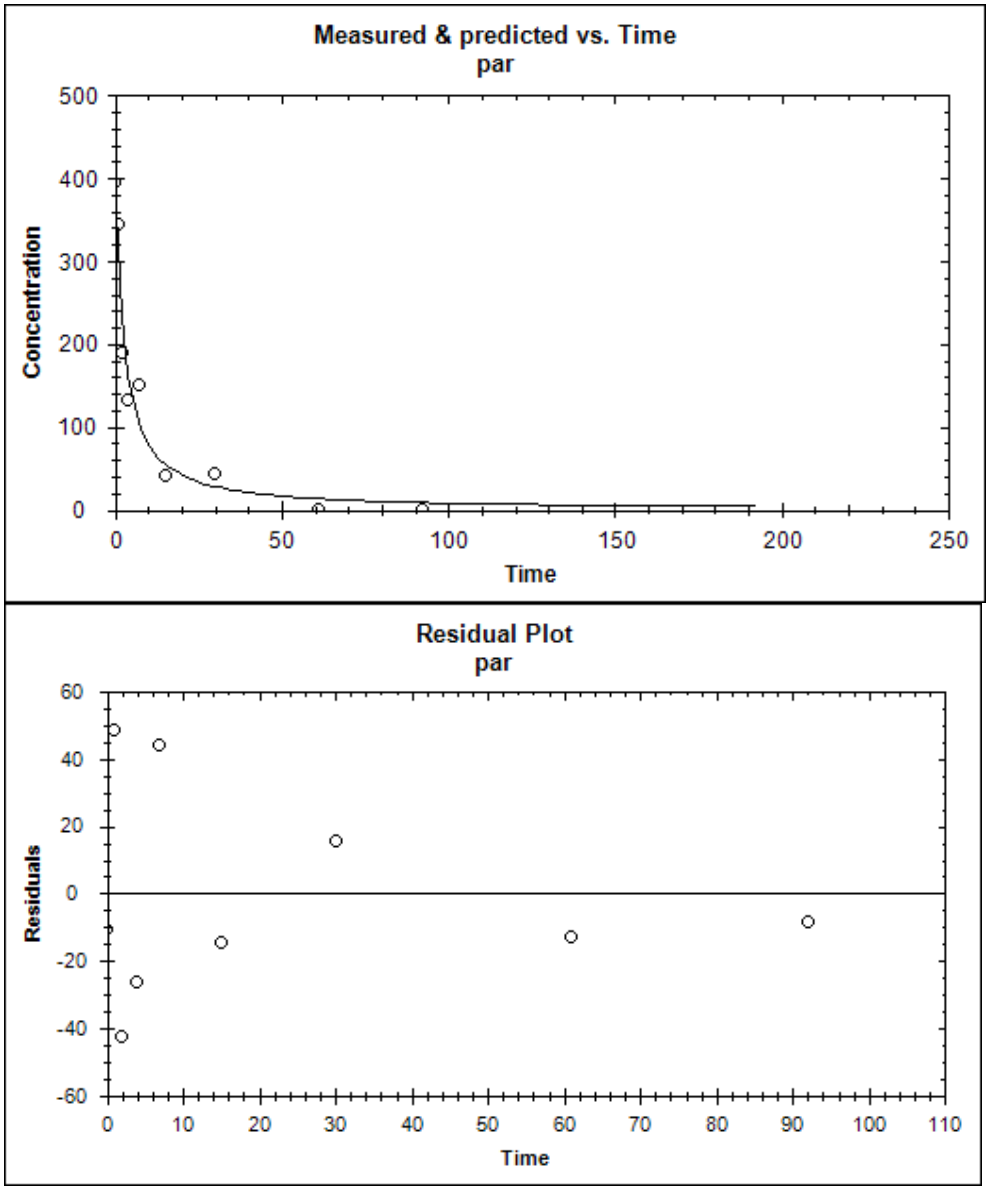


Figure A. 7: Manningtree (Wicks 1999) –Acetamiprid DFOP

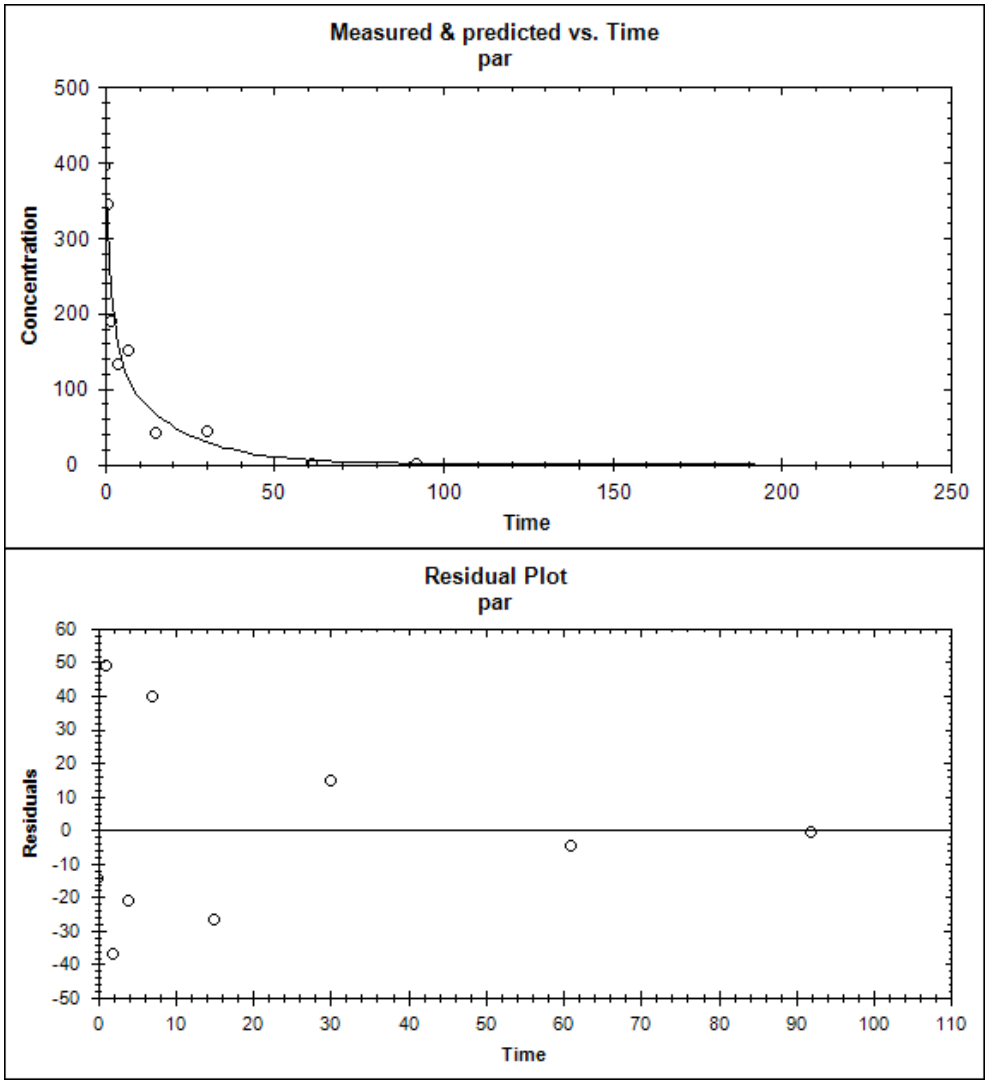


Figure A. 8: Manningtree (Wicks 1999) –Acetamiprid HS

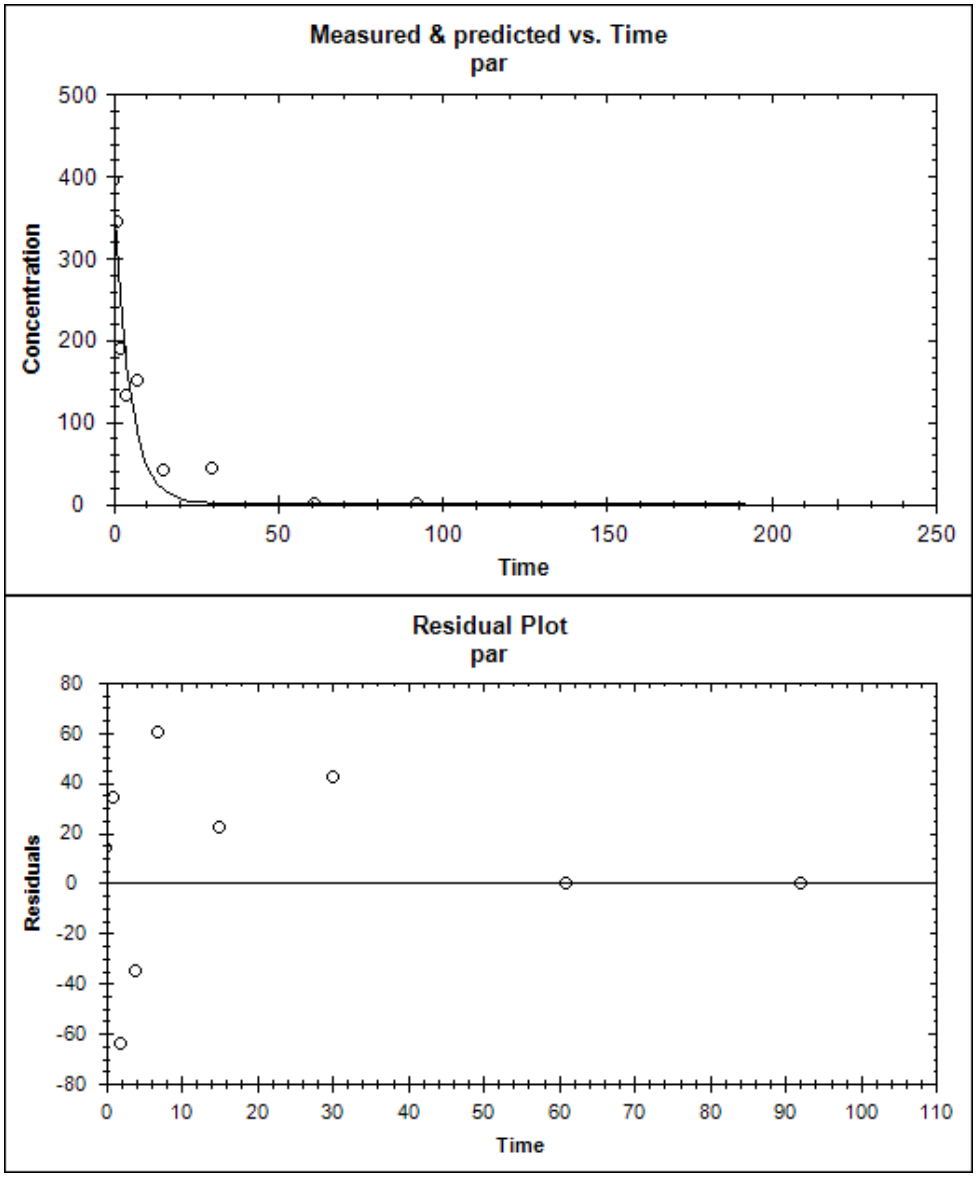


Table A. 5-7: Acetamiprid –flow charts for trigger endpoints in soil Mereville (Wick 1999)

Kinetic	M0	k	DT50 (d)	DT90 (d)	DT50 recalc. SFO (d)	Chi^2	Std	Prop>t	Visual fit
SFO	166.8	0.06337	10.94	36.33	10.94	12.44	0.01336	0.0159	+- acceptable .
FOMC	166.8	alpha 1.451e+03 beta 2.288e+04	2.63	20.47	6,2	13.26	6.804e+04 1.074e+06	0.492 0.492	+ acceptable
DFOP	166.8	kfast 0.06337 kslow 0.01598 g 0.37897	10.94	36.35	43.4	14.33	0.04912 0.30220 0.23252	0.1516 0.0683 0.0820	+ good

HS	380.7	kslow 0.0234 kfast 0.1143 tb 6.38	6.4	na	6.06	12.2	0.0436 0.0849 4.005	0.3103 0.1247 0.0932	- not acceptable
Best fit DT50 for Mereville soil					**10.94**	**12.44**	**SFO**		

Figure A. 9: Mereville (Wicks 1999) –Acetamiprid SFO

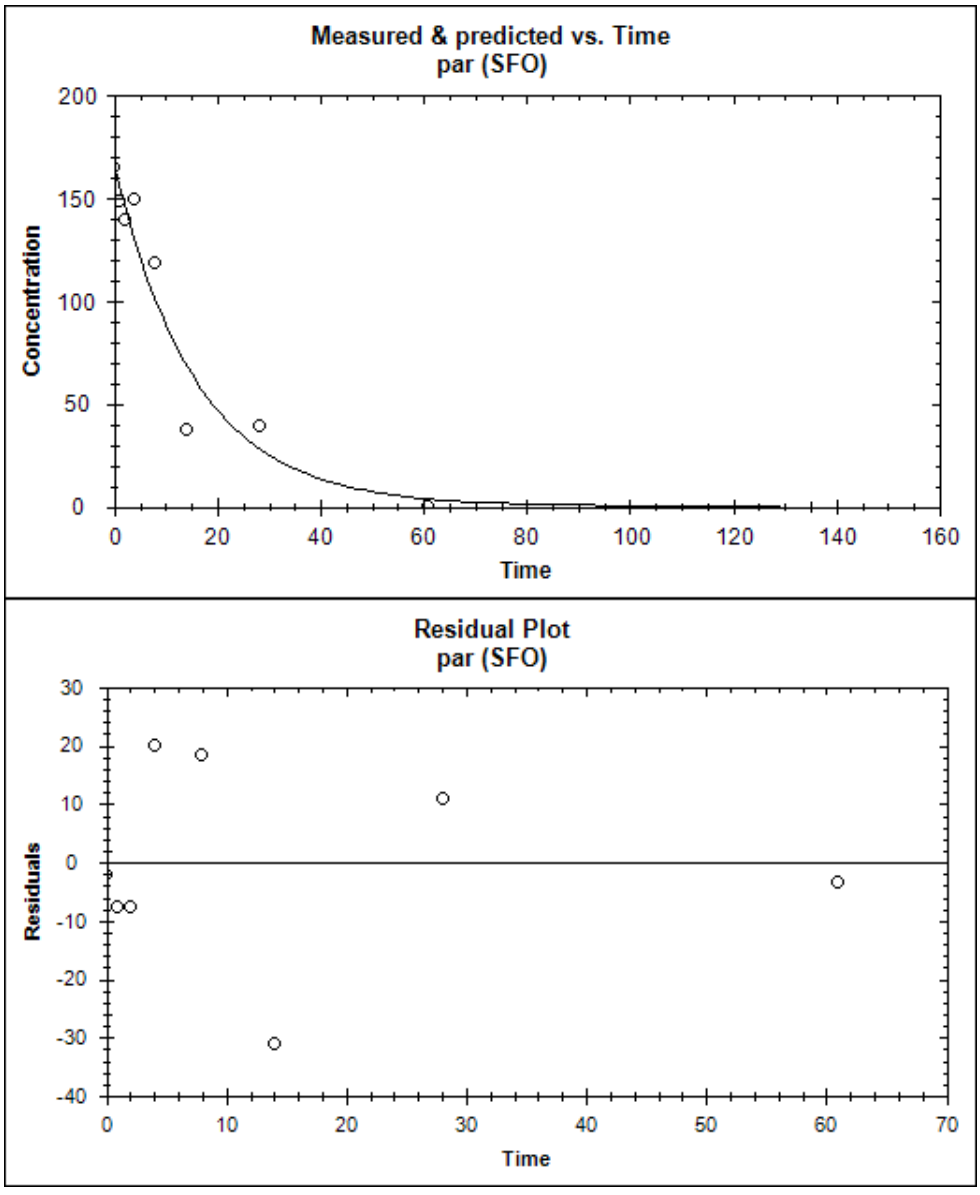


Figure A. 10: Mereville (Wicks 1999) –Acetamiprid FOMC

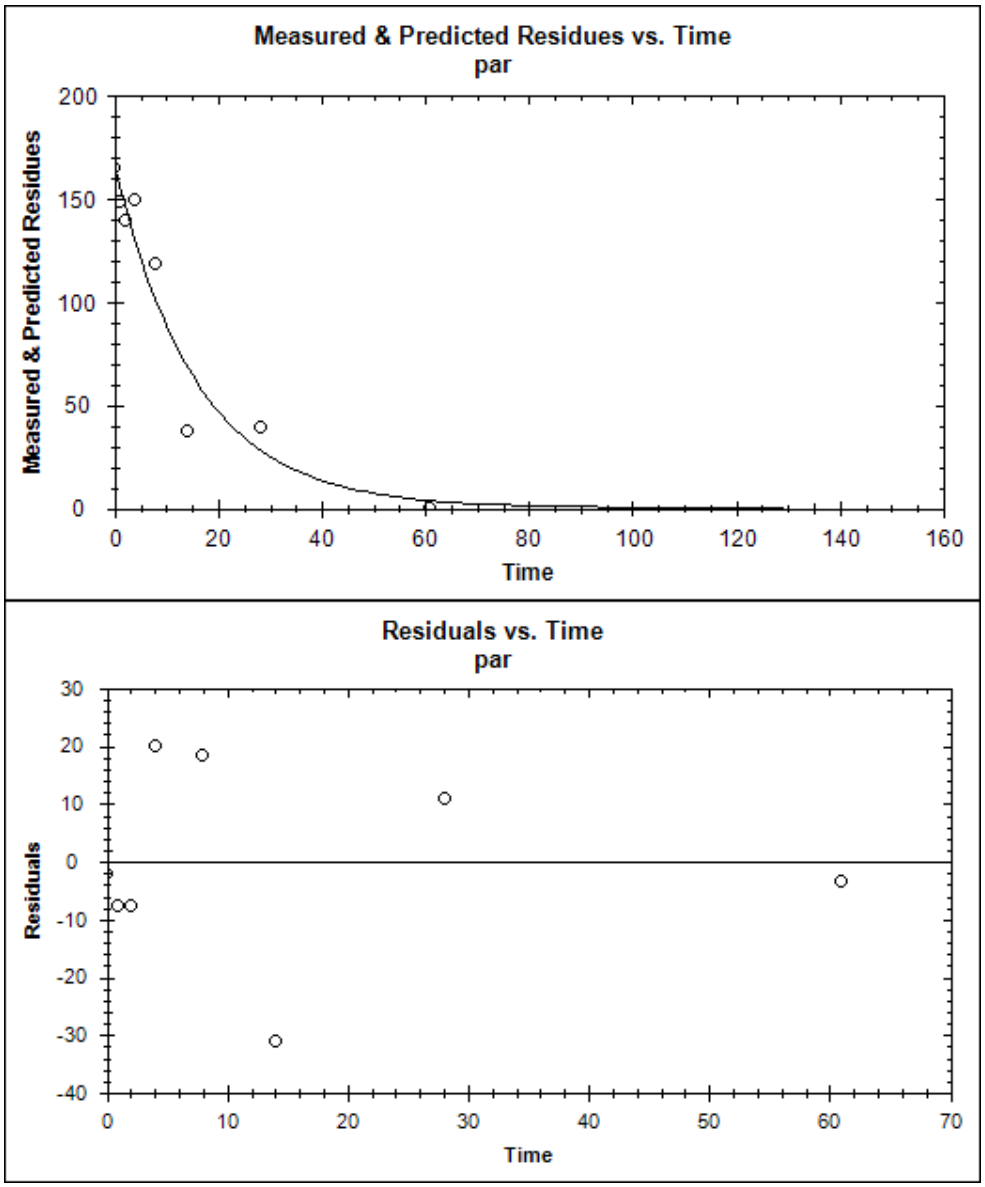


Figure A. 11: Mereville (Wicks 1999) –Acetamiprid DFOP

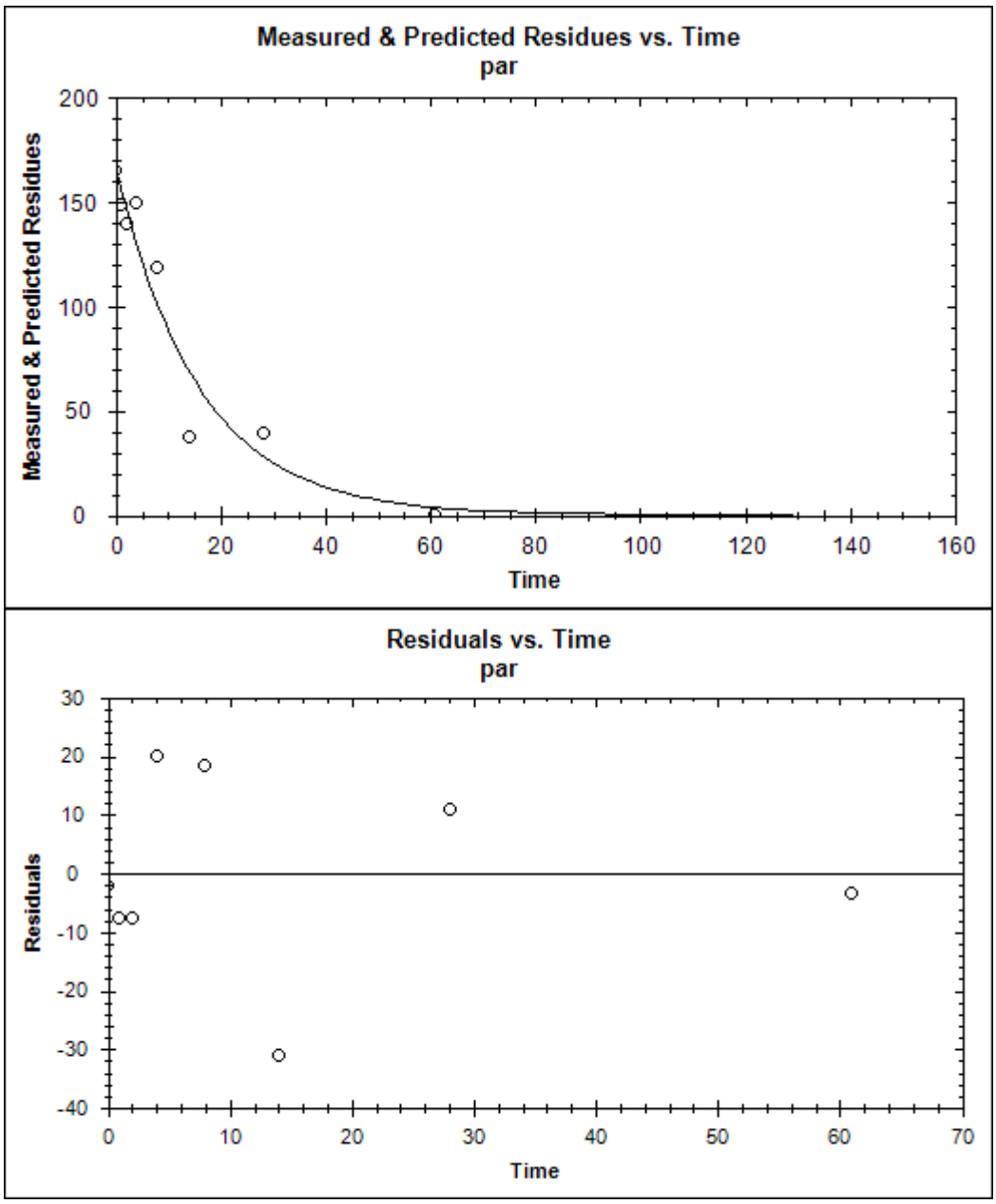


Figure A. 12: Mereville (Wicks 1999) –Acetamiprid HS

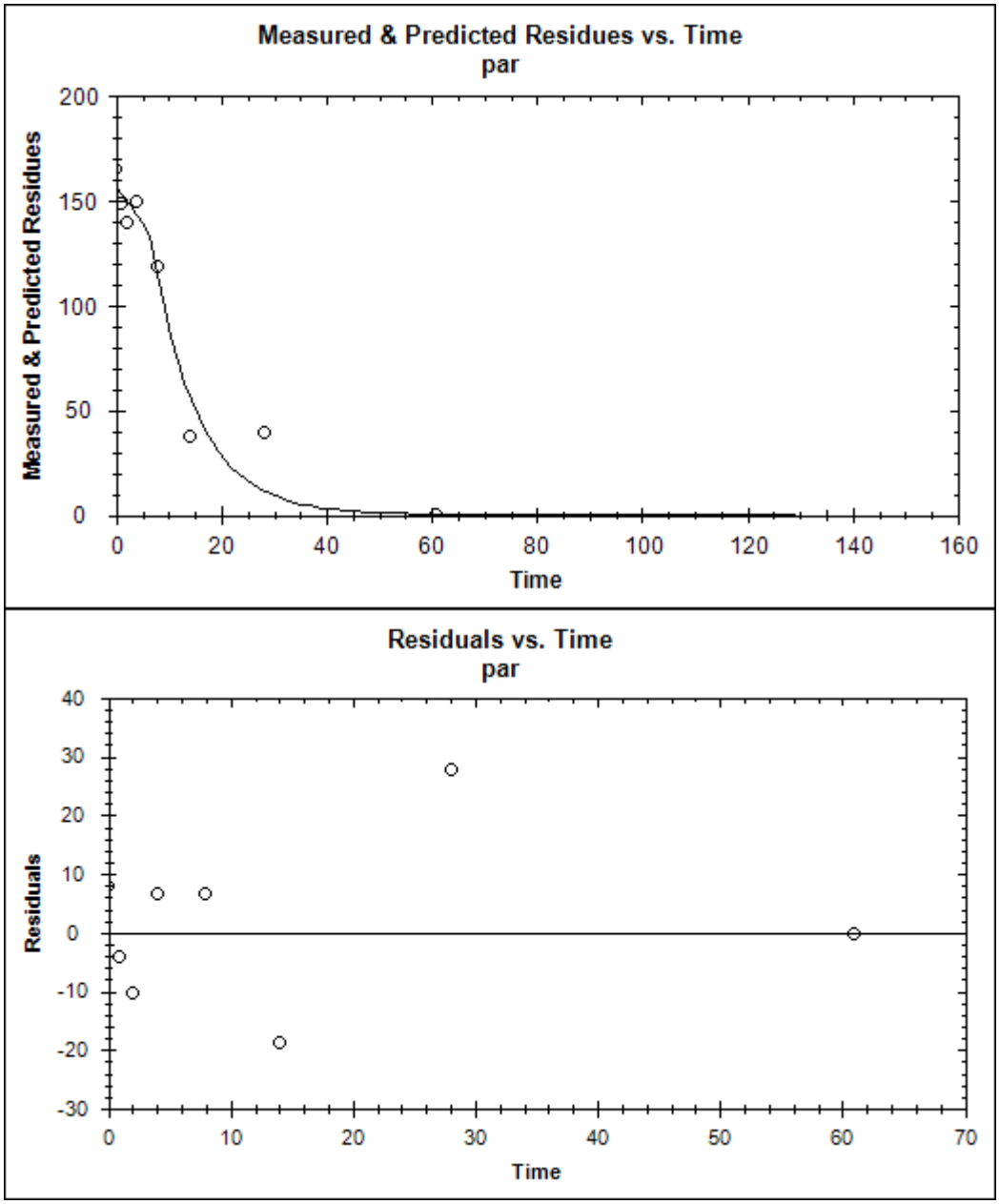


Table A. 5-8: Acetamiprid –flow charts for trigger endpoints in soil Sevilla (Wick 1999

Kinetic	M0	k	DT50 (d)	DT90 (d)	DT50 recalc. SFO (d)	Chi^2	Std	Prop>t	Visual Fit
SFO	331.9	0.6183	1.12	3.72	1.12	25.4	0.1969	0.01283	- not acceptable
FOMC	350.2	alpha 0.6772 beta 0.3483	0.621	10.09	3.04	11.8	0.2082 0.2592	0.0156 0.1251	+ acceptable

DFOP	350.9	kfast 14.89 kslow 0.1677 g 0.5714	0.0255	na	4.11	9.05	978.8 0.0522 0.0661	0.494 0.0244 0.00163	++ good
HS	340.5	kfast 0.7214 kslow 0.0887 tb 2.19	0.96	10.29	7.81	21.4	0.1915 0.1203 1.19	0.0163 0.2572 0.08169	+ acceptable
Best fit DT50 for Sevilla					**4.11**	**9.05**	**SFO recalc.(kslow DFOP)**		

Figure A. 13: Sevilla (Wicks 1999) –Acetamiprid SFO

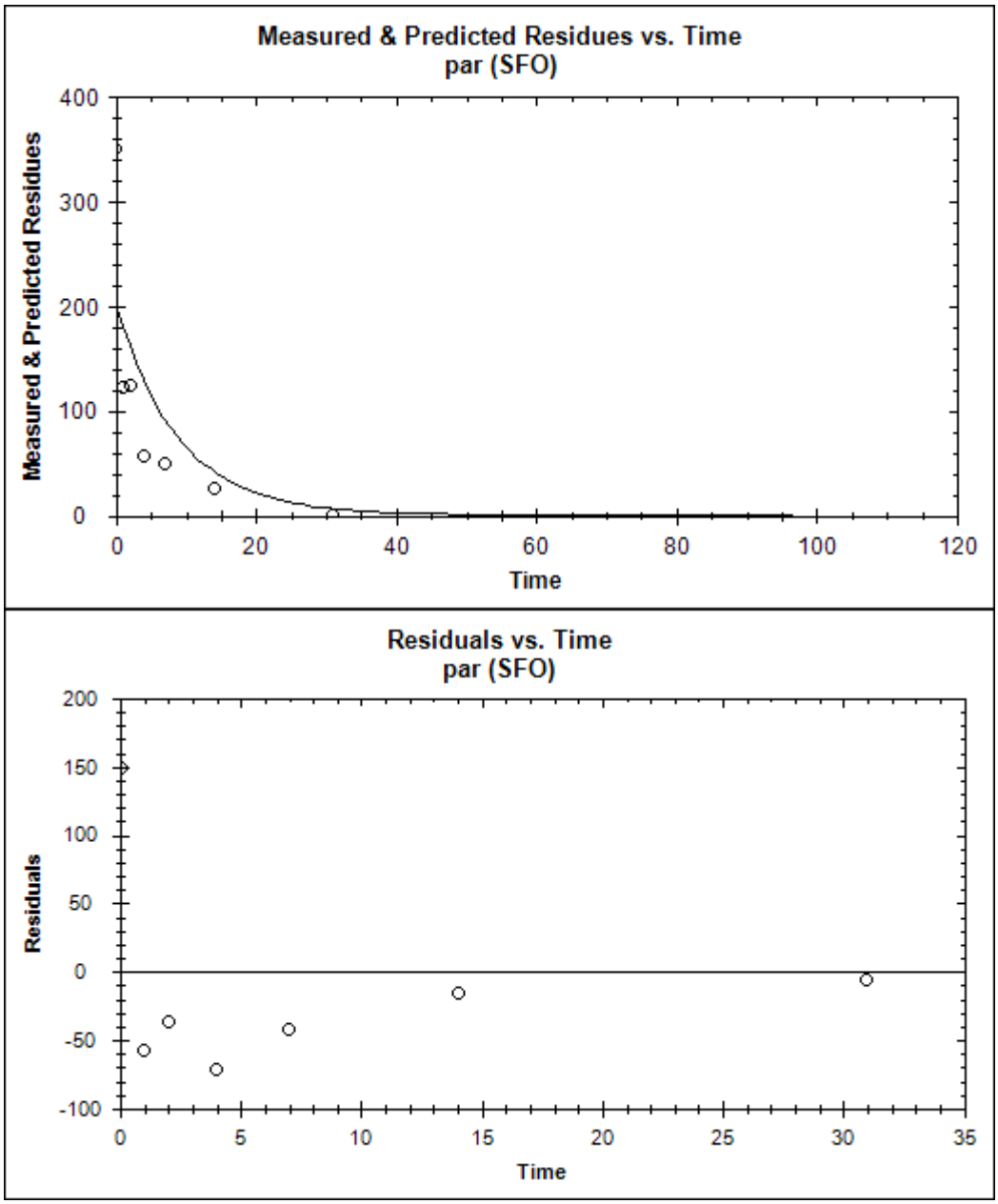


Figure A. 14: Sevilla (Wicks 1999) –Acetamiprid FOMC

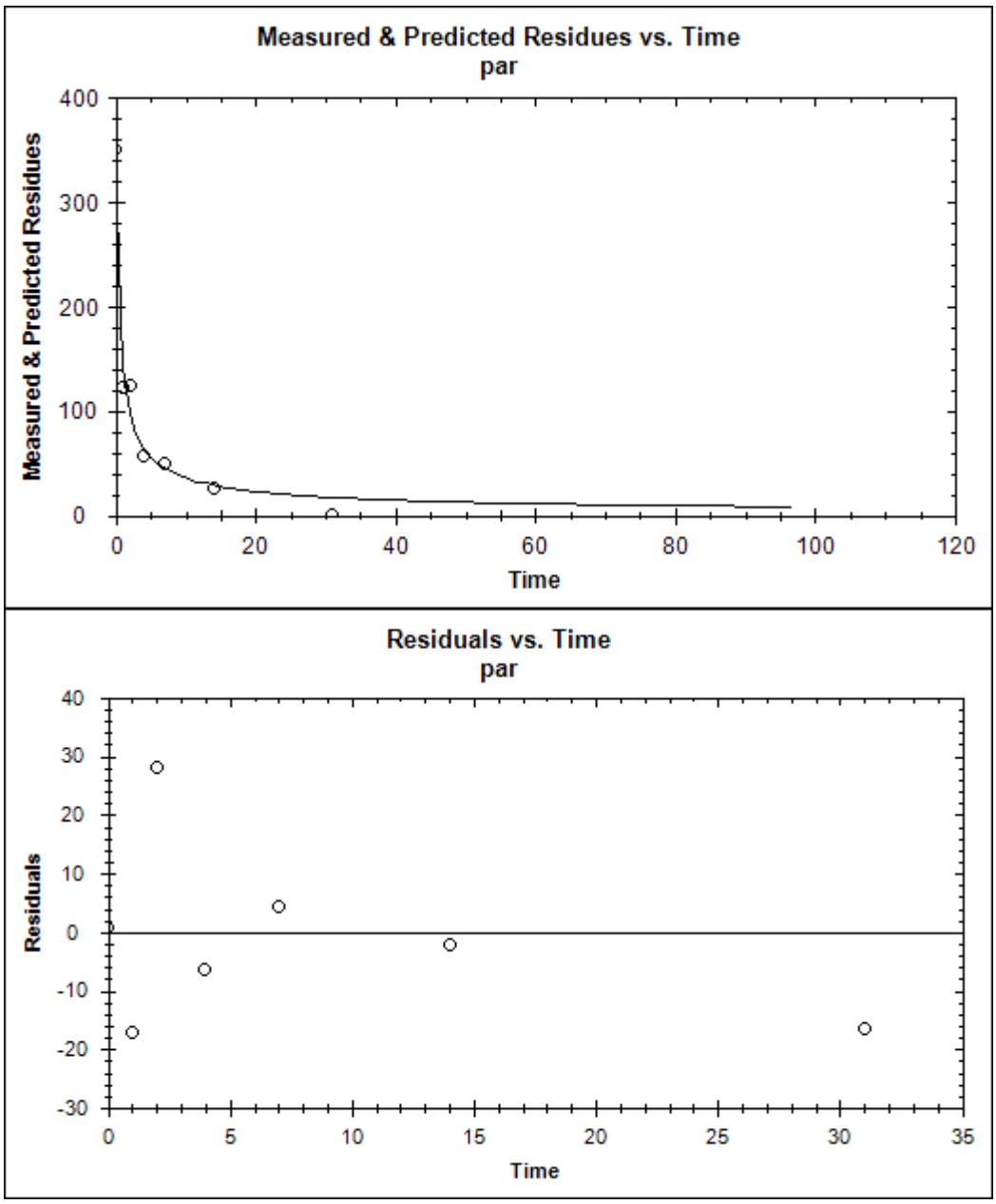


Figure A. 15: Sevilla (Wicks 1999) –Acetamiprid DFOP

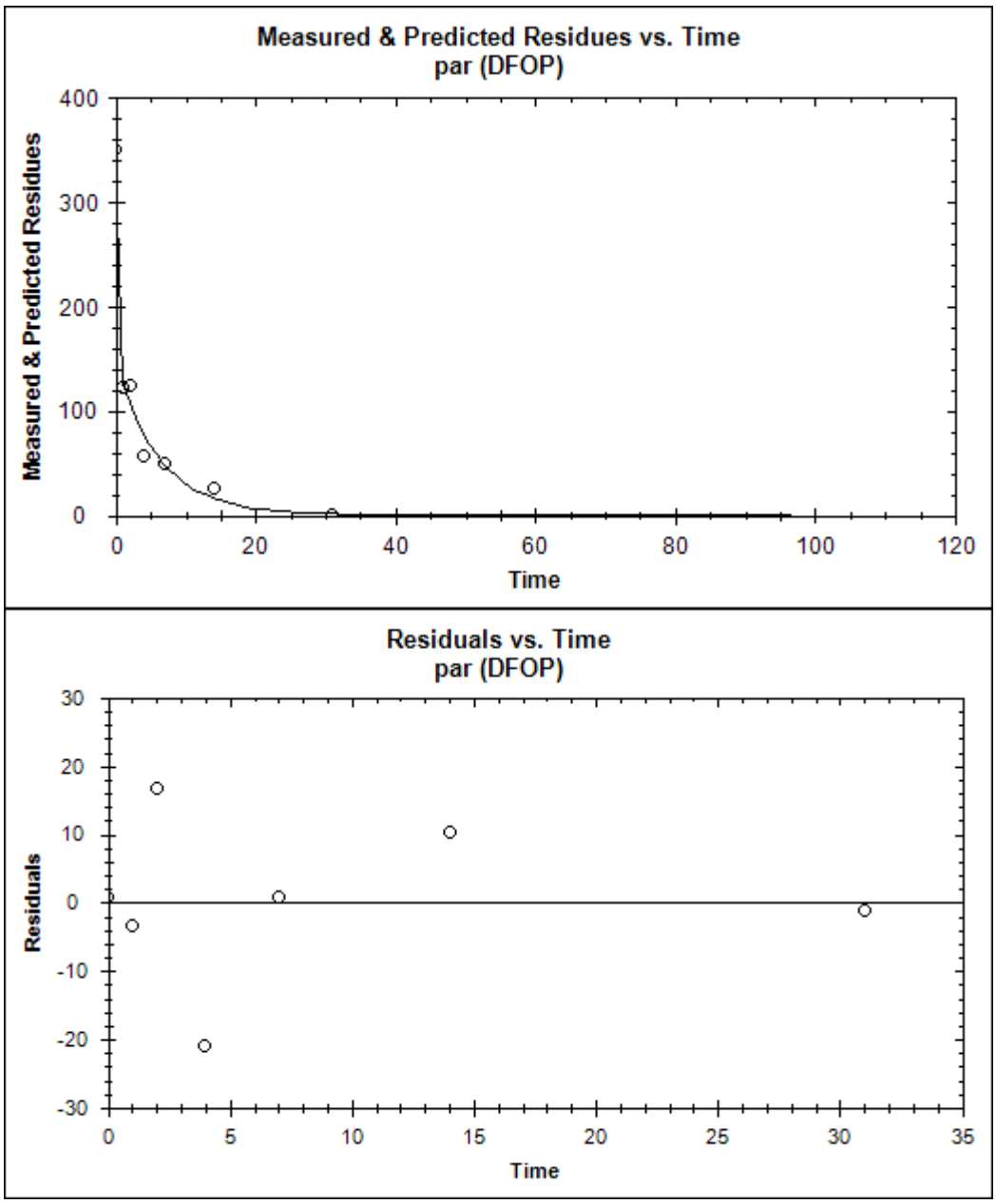
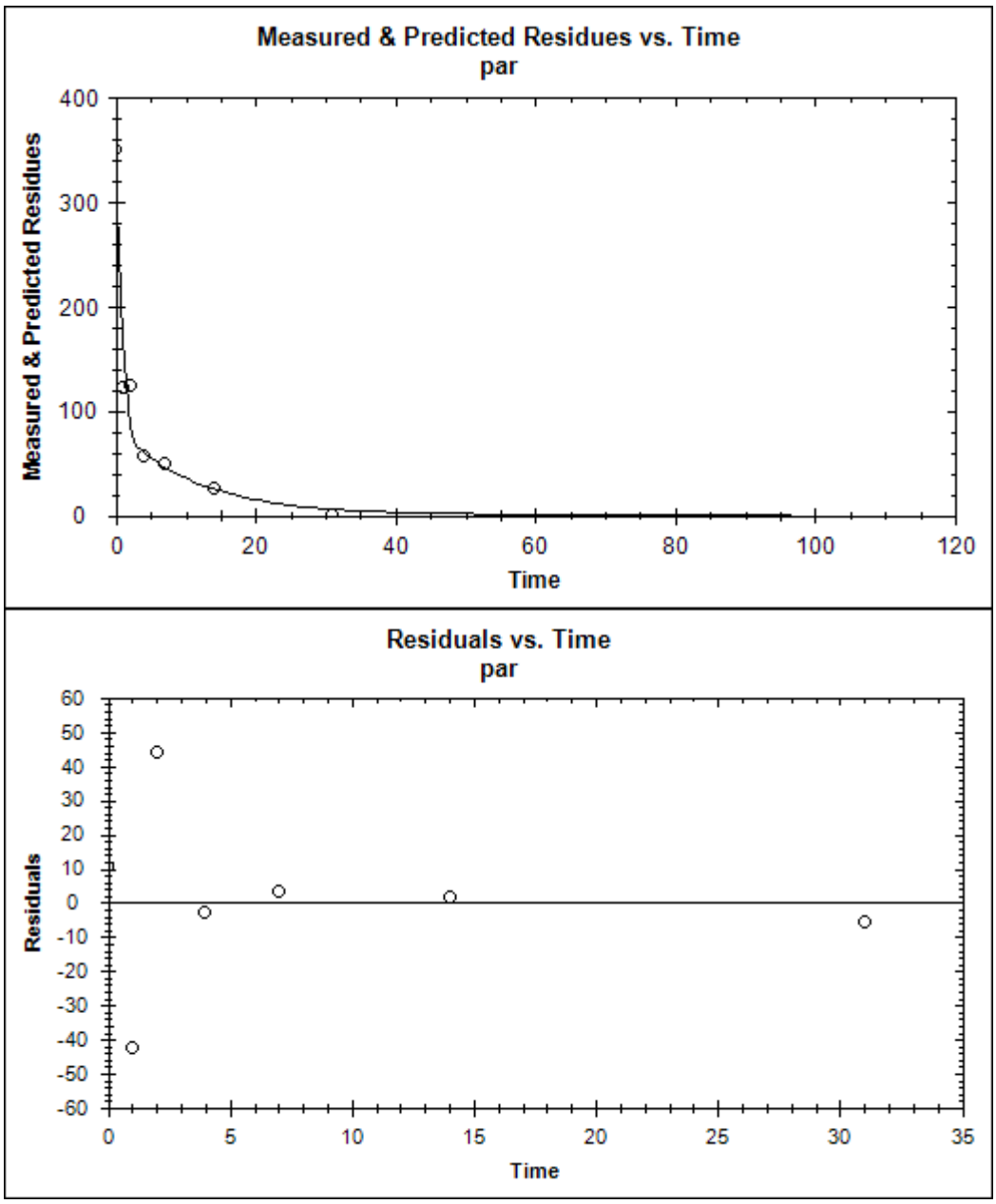


Figure A. 16: Sevilla (Wicks 1999) –Acetamiprid HS



Comments of zRMS

Soil degradation kinetics of acetamiprid have been recalculated by zRMS for all four soils of field dissipation study of Wicks (1999). Considering the recommendations of FOCUS Kinetics 2006 the soil Bologna /Italy has been identified as worst case soil because of the highest DT50 value derived from slow phase of DFOP kinetic. The kinetic parameters of the DFOP kinetic of soil Bologna can be used in PECsoil calculations with ESCAPE. As conservative approach the recalculated SFO DT50 d (slow phase) of 12.9 days can also be used.

KIIA 7.1.2 Liu, 1999

Reference:	KIIA 7.1.2
Author:	Liu, A.
Report:	NI-25: Soil adsorption / desorption study, RD-9970, EC-97-381
Date:	15.10.1997
Guideline(s):	Yes (EPA 163-1)
Deviations:	No
GLP:	Yes (
Acceptability:	Yes

Materials and methods

The soil adsorption/desorption of acetamiprid (NI-25), ^{14}C labeled at pyridine··2,6 position, was studied in four soils (loamy sand I, loamy sand II, silt loam, and c1ay) as weIl as in an aquatic pond sediment. The study was conducted at 20±1°C in the dark at four different concentrations (0.100, 0.299, 0.996, and 1.984 ppm) in a 0.01 M $CaC1_2$ solution (equivalent to 0.499, 1.495,4.977, and 9.916 ppm in the soil, respectively, at a soil:water ratio of 1 :5). The preliminary range-finding study was conducted using loamy sand II, silt loam and pond sediment and . The adsorption equilibrium was reached at 9 hours to 16 hours. No significant degradation was observed by the end of 16 hour adsorption. The desorption equilibrium was reached at 5 hours to 9 hours for loamy sand II and silt loam, and reached at 9 hours for pond sediment. No significant degradation was öbserved by the end of 9 hour desorption except pond sediment with approximately 13 % degradation into IM-I-4. The adsorption cyc!e was carried out for 16 hours and desorption cyc!es were carried out for 9 hours in the definitive study. No adsorption of acetamiprid to glass was observed.
The presence of actamiprid was determined by HPLC and confinned by LCIMS. The identification of IM-1-4 in first desorption supernatant of pond sediment was also confrrmed by LCIMS

Table A. 5-9: Soil and sediment characterization information (Liu, 1997)

Soil or Sediment	**Soil**	**Soil**	**Soil**	**Soil**	**Pond Sediment**
Collection Location	Clayton,NC	Clayton, NC	Leland, MS	Leland, MS	Clayton, NC
% Sand	83.6	77.6	29.6	13.6	61.6
% Silt	12.0	16.0	60.0	36.0	24.0
%Clay	4.4	6.4	10.4	50.4	14.4
% Organic Matter	0.43	2.54	0.76	2.05	4.3
pH	4.4	6.2	6.6	7.5	5.6
Cation Exchange Capacity (meq/100g)	1.15	3.82	6.05	28.22	6.48
% Moisture at saturation	18.21	28.91	35.06	61.92	41.38'
% Moisture at 1/3 bar	3.84	9.03	16.50	36.43	20.36
Bulk Density	1.60	1.44	1.11	1.19	1.32

Results and discussions

Total radioactivity recovery for all the soils averaged 100.1 % and ranged from 97.1 to 103.0 %. The radiochemical balance was determined by summing the percent of the applied dose in each adsorption supernatant, desorption supernatant, and soil residue.
The concentration of ^{14}C-·acetamiprid in the soil (or sediment) and solution along with concentration dependent adsorption distribution constants (K) were determined for each concentration within each soil.

The results were summarized in Table A. 5-10.

Table A. 5-10: Calculated Freundlich Adsorption constants and Koc

Soil type	OM (%)	1/n	r^2	$log_{10}Kf$	Kf ≈ Kd	Koc
Loamy Sand I	0.43	0.8756	0.992	-0.28277	0.521	209
Loamy Sand II	2.54	0.8295	0.973	0.50645	3.210	218
Silt Loam	0.76	0.9272	0.996	0.09585	1.247	283
Clay	2.05	0.9297	0.999	0.57045	3.719	313
Pond Sediment	4.32	0.8385	0.978	0.53517	3.429	137

The above adsorption Kf results show that the adsorption of ^{14}C-·acetamiprid to soil is soil dependent. The Freundlich adsorption constant (Kf) ranged from approximately 0.521 for loamy sand I to 3.719 for clay. The Koc values for all soils/sediment ranged from 137 for pond sediment to 313 for clay, averaging 232. According to the McCall designation, the results indicate ratings of medium mobility for ^{14}C-acetamiprid in loamy sand I, loamy sand II, silt loam, clay and high mobility in pond sediment.

Using a similar method to the adsorption calculations, concentration dependent distribution constants (K') for each of three desorption cycles were determined. These K' values are the concentration remaining in the soil (Cd) divided by the concentration in water (Cw) for each concentration within each soil.
The results were summarized in Table A. 5-11.

Table A. 5-11: Average % of applied acetamiprid remaining in the supematants of each phase in eaeh soil/pond sediment

Soil type	Adsorption Supernatant	Desorption I Supernatant	Desorption II Supernatant	Desorption III Supernatant
Loamy Sand I	89.30 %	8.45 %	1.28%	0.32%
Loamy Sand II	54.43 %	15.80 %	7.33 %	3.89%
Silt Loam	78.22 %	14.40 %	3.47%	1.16%
Clay	52.37 %	21.91 %	10.43 %	5.13 %
Pond Sediment	52.82 %.	17.89 %	7.98%	4.65 %

As shown above, after adsorption phase, greater than 40 % of acetamiprid was adsorbed in loamy sand II, c1ay, and pond sediment, about 22 % of acetamiprid in silt loam, and only 10 % in loamy sand I.

After desorption I, less than .3 % of acetamiprid was remained in loamy sand I. Therefore, Kdes2 and Kdes3 were not measurable.
The results were summarized in Table A. 5-12 to Table A. 5-14

Table A. 5-12 Calculated desorption constants for desorption cycle 1

Soil type	**OM (%)**	**r^2**	**1/n**	**log_{10}Kdes1**	**Kdes1**
Loamy Sand I	0.43	0.759	0.6523	-0.40982	0.389
Loamy Sand II	2.54	0.997	0.8438	0.79140	6.186
Silt Loam	0.76	0.987	0.8754	0.26794	1.853
Clay	2.05	0.991	0.9293	0.70032	5.016
Pond Sediment	4.32	0.996	0.8285	0.72417	5.299

Table A. 5-13: Calculated desorption constants for desorption cycle 2

Soil type	**OM (%)**	**r^2**	**1/n**	**log_{10}Kdes2**	**Kdes2**
Loamy Sand I	0.43	*	*	*	*
Loamy Sand II	2.54	0.990	0.9231	1.0674	11.679
Silt Loam	0.76	0.946	0. 8357	0. 4540	2.845
Clay	2.05	0.993	0.8718	0.7025	5.040
Pond Sediment	4.32	0.988	0.8105	0.8067	6.407

*Value may not be accurate due to only less than 3 % of applied acetamiprid remaining in the loamy sand I after desorption I.

Table A. 5-14: Calculated desorption constants for desorption cycle 3

Soil type	**OM (%)**	**r^2**	**1/n**	**log_{10}Kdes3**	**Kdes3**
Loamy Sand I	0.43	*	*	*	*
Loamy Sand II	2.54	0.992	0.9894	1.3460	22.182
Silt Loam	0.76	0.782	0.6518	0.30168	2.003
Clay	2.05	0.994	0.9249	0.86462	7.322
Pond Sediment	4.32	0.985	0.8653	0.99925	9.983

*Value may not be accurate due to only less than 1 % of applied acetamiprid remaining in the loamy sand I after desorption II

Conclusions

The Freundlich adsorption (Kf) values ranged from 0.521 for loamy sand I to 3.719 for c1ay, averaging 2.425. Adsorption Koc values ranged from 137 for pond sediment to 313 for clay, averaging 232. Therefore ^{14}C-acetamiprid is classified as medium to high mobility according to McCall. The desorption constant, Kdes1, ranged from 0.389 to 6.186, averaging 3.749, Kdes2, ranged from 2.845 to 11.679 (not included loamy sand I), Kdes3, ranged from 2.003 to 22.182 (not including loamy sand I).. Reasonably similar Kf and Kdes1 values for the soils and sediment indicated a generally reversible equilibrium between adsorption and the first desorption phases.

Comment zRMS

The study is acceptable. The loamy sand I soil was excluded from evaluation because of an organic carbon content of <0.3 % considering the recommendations of the OECD guideline 106. The remaining four soils are used in further risk assessment.

Appendix 3 Table of Intended Uses justification and GAP tables

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 as/hL min max	water L/ha min max	kg as/ha min max		
potatoes	central	005655-00/16-001 Mospilan SG	F	Colorado beetle	SG	200g/kg	spraying	BBCH 20-39 spring and summer	2	14		300 - 600	0.025	14	Professional use

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: **Mospilan SG**

Active Substance: **200 g/kg Acetamiprd**

Central Zone
Zonal Rapporteur Member State: Germany (DE)

NATIONAL ADDENDUM – Germany

Applicant: **Nisso Chemical Europe GmbH**

Date: **20.06.2013**

Table of Contents

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

The exposure assessment of the plant protection product Mospilan SG in its intended uses in potatoes is documented in detail in the core assessment of the plant protection product Mospilan SG performed by zRMS Gernmany

This document comprises the risk assessment for groundwater and the exposure assessment of surface water and soil for authorization of the plant protection product Mospilan SG 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 Part B Section 6 National addendum and Part A).

5.1 General Information on the formulation

Table 5.1-1: General information on the formulation Mospilan SG

Code	005655-00/16		
plant protection product	Mospilan SG (EXP61884A)		
applicant	Nisso Chemicals Europe GmbH		
date of application	31/10/2011		
Formulation type (WP, EC, SC, …; density)	SG		
active substance	Acetamiprid		
Concentration of as	200 g/kg		

Data pool/task force	
letter of access/cross reference	
existing authorisations in DE	005983-00 CEL 265 43 AE (till 31.12.2016)
	005686-60- Klick&Go Schädlingsfrei Careo Konzentrat (till 31.12.2015)
	005633-60 Mospilan Schädlings-Frei Granulat (till 31.12.2015)
	005655-00 Mospilan SG (till 31.12.2016)
	005632-60 Mospilan Tandem –Stäbchen (till 31.12.2015)
	005982-00 Schädlingsfrei Careo (till 31.12.2016)
	005633-00 Schädlingsfrei Careo Combi –Granulat (till 31.12.2015)
	005632-00 Schädlingsfrei Careo Combi –Stäbchen (till 31.12.2015)

	005686-00 Schädlingsfrei Careo Konzentrat (till 31.12.2015)
	005982-60 Schädlingsfrei Careo Rosenspray (till 31.12.2016)
	005983-60 Schädlingsfrei Careo Spray (till 31.12.2016)

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.

Table 5.2-1: Classification of intended uses in Germany for Mospilan SG

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)
16-001	Potatoes BBCH 20-39	spraying	2 x, 14 d, 1. 50 % interception, 6 days after 1st emergence in the year 2. 50 % interception, 20 days after 1st emergence in the year	acetamiprid 2 x 25 = 50	acetamiprid 1. 12.5 2. 12.5

5.3 Information on the active substances

5.3.1 Acetamiprid

See core assessment

5.4 Summary on Inputparameter for environmental exposure assessment

5.4.1 Rate of degradation in soil

5.4.1.1 Laboratory studies

Acetamiprid

No new studies have been submitted regarding route and rate of degradation in soil of acetamiprid. Based on the results of kinetic modeling of Reinken (2001), Hardy (2002) and (Hardy 2003) the zRMS has derived new DT_{50} endpoints for environmental exposure assessment according to recommendations of FOCUS degradation kinetics guidance (2006). The recalculation of Reinken 2001 showed biphasic degradation of acetamiprid in the four soils of Morgenroth 1997 and Burr 1997. The kinetic parameters were provided in the calculations. As worst case approach the rate constants of slow phases were choosen for PEC modeling of parent. The rate constants of fast phases were choosen as worst case approach for PEC modeling of metabolites. These recalculated SFO DT50 values were aggregated to derive the two relevant modelling endpoint for acetamiprid.

The actualized DT_{50} values of acetamiprid from the laboratory studies after recalculation by zRMS are summarized in Table 5.4-1 and Table 5.4-2.

Table 5.4-1: Summary of aerobic degradation rates for acetamiprid - laboratory studies (worst case approach for PECgw of acetamiprid)

Soil type	pH	T (°C)	Moisture during study	DT50 (d)	DT90 (d)	EU DT50 20 °C pF2	DT50 20 °C pF2/10 kPa according FOCUS (2006)	Kinetic, Fit	Reference
Collombey, loamy sand	7.6	20	50 % FC	1.4	4.7	1.4*	27.7	HS slow phase.	Morgenroth, 1997 Reinken 2001
clay loam	7.4	20	45 % of MWHC	5.4	67.3	5.4*	57.8	HS slow phase.	Burr 1997 Hardy 2002
sandy loam	5.6	20	45 % of MWHC	2.7	8.9	2.7*	26.6	HS slow phase.	Burr 1997 Hardy 2002
silty clay loam	7.9	20	45 % of MWHC	0.8	2.8	0.8*	8.3	HS slow phase.	Burr 1997 Hardy 2002
L.Shelford,UK,, sandy loam	8.0	20	45 % of MWHC	1.1	3.6	1.1	1.1	SFO	Simmonds 2002 Hardy 2002
Royston,UK, clay	7.7	20	45 % of MWHC	1.4	3.5	1.4	1.4	SFO	
Ongar,UK, clay loam	7.9	20	45 % of MWHC	1.2	3.1	1.2	1.2	SFO	
UK, Sandy loam	8.4	20	75% 1/3 bar	5.6		4.0	3.1	SFO	Simmonds 2003 (leaching study), Hardy 2003
USA, Sandy loam,	8.7	20	75% 1/3 bar	2.0		1.4	1.0	SFO	
Aggregated DT50 (n=9)		Coefficient of variation (%)					138		
		Geometric mean (d)					5.0		
		90th percentile					33.7	Used for PECgw of parent as worst case approach in the national addendum	

** fast phase DT50 from HS (not recommended in FOCUS kinetics 2006)

Table 5.4-2: Summary of aerobic degradation rates for acetamiprid - laboratory studies (worst case approach for PECgw of metabolites)

Soil type	pH	T (°C)	Moisture during study	DT50 (d)	DT90 (d)	EU DT50 20 °C pF2	DT50 20 °C pF2/10 kPa according FOCUS (2006)	Kinetic, Fit	Reference

Collombey, loamy sand	7.6	20	50 % FC	1.4	4.7	1.4*	1.4	HS fast phase	Morgenroth, 1997 Reinken 2001
clay loam	7.4	20	45 % of MWHC	5.4	67.3	5.4*	5.4	HS fast phase.	Burr 1997 Hardy 2002
sandy loam	5.6	20	45 % of MWHC	2.7	8.9	2.7*	2.7	HS fast phase	Burr 1997 Hardy 2002
silty clay loam	7.9	20	45 % of MWHC	0.8	2.8	0.8*	0.8	HS fast phase.	Burr 1997 Hardy 2002
L.Shelford,UK,, sandy loam	8.0	20	45 % of MWHC	1.1	3.6	1.1	1.1	SFO	Simmonds 2002 Hardy 2002
Royston,UK, clay	7.7	20	45 % of MWHC	1.4	3.5	1.4	1.4	SFO	
Ongar,UK, clay loam	7.9	20	45 % of MWHC	1.2	3.1	1.2	1.2	SFO	
UK, Sandy loam	8.4	20	75% 1/3 bar	5.6		4.0	3.1	SFO	Simmonds 2003 (leaching study), Hardy 2003
USA, Sandy loam,	8.7	20	75% 1/3 bar	2.0		1.4	1.0	SFO	
Aggregated DT50 (n=9)		Coefficient of variation (%)					74		
		Geometric mean (d)					1.7	Used as worst case approach for PECgw simulation of metabolites for core assessment	

Metabolites of acetamiprid

In case of metabolites of acetamiprid additional PECgw calculations for national authorization are performed, which are based on previous PECgw calculations in the national authorization procedure. The previous used DT50 (lab) values of all studies were normalised to reference conditions (20°C; pF2) with the Q10 factor of 2.58 and default values for moisture content according the FOCUS groundwater report (2000) and are summarized in Table 5.4-3 to Table 5.4-6.

Table 5.4-3: Summary of aerobic degradation rates for metabolite IM 1-4 - laboratory studies

Soil type	**pH (H_2O)**	**T (^oC)**	**Moisture**	**DT_{50}/ DT_{90} (d)**	**f.f.**	**DT_{50} (d) 20 °C pF2/10kPa**	**Kinetic, Fit**	**Reference**
Collombey, loamy sand	7.6	20	50 % FC	32.1		26.8		Morgenroth, 1997
clay loam	7.4	20	45 % of MWHC	226.5		226.5		Burr (1997)

sandy loam	5.6	20	45 % of MWHC	168.5		168.5		
silty clay loam	7.9	20	45 % of MWHC	4.1		4.1		
L.Shelford,UK, , sandy loam	8.0	20	45 % of MWHC	5.6		5.6		Simmonds (2002)
Royston,UK, clay	7.7	20	45 % of MWHC	3.3		3.3		
Ongar,UK, clay loam	7.9	20	45 % of MWHC	3.7		3.7		
UK, Sandy loam	8.4	20	75% 1/3 bar	3.9		4.2		Simmonds 2003 (leaching study), Hardy (2003
USA, Sandy loam,	8.7	20	75% 1/3 bar	18.5		19.5		
Aggregated DT_{50} (n=9)		**Coefficient of variation (%)**				165		
		Geomean (d)				14.2		
		90^{th} /10^{th} percentile				180.1/3.6	Used for PECgw of IM 1-4 as worst case approach in the national addendum	

Table 5.4-4: Summary of aerobic degradation rates for metabolite IM 1-2 - laboratory studies

Soil type	pH (H_2O)	T (^oC)	Moisture	DT_{50}/ DT_{90} (d)	f.f.	DT_{50} (d) 20 °C pF2/10kPa	Kinetic, Fit	Reference
L.Shelford,UK, , sandy loam	8.0	20	45 % of MWHC	1.6		1.6		Simmonds (2002)
Royston,UK, clay	7.7	20	45 % of MWHC	1.4		1.1		
Ongar,UK, clay loam	7.9	20	45 % of MWHC	1.2		1.1		
Sandy loam,UK	8.4	20	75% 1/3 bar	2.0		2.2		Simmonds 2003 (leaching study), Hardy (2003)
Sandy loam, USA	8.7	20	75% 1/3 bar	2.5		2.6		
Aggregated DT_{50} (n=5)		**Coefficient of variation (%)**				41		
		Geomean (d)				1.6	Used for PECgw of IM 1-2 as worst case approach in the national addendum	
		90^{th} percentile				2.4	Used for PECs of IM 1-2 in the national addendum	

Table 5.4-5: Summary of aerobic degradation rates for metabolite IM 1-5 - laboratory studies

Soil type	pH (H_2O)	T (^oC)	Moisture	DT_{50}/ DT_{90} (d)	f.f.	DT_{50} (d) 20 °C pF2/10kPa	Kinetic, Fit	Reference
Silty clay loam	7.9	20	45 % of MWHC	450		450	SFO-SFO	Burr 1997
Ongar,UK, clay loam	7.9	20	45 % of MWHC	430		388	SFO-SFO	Simmonds 2002
Sandy loam (02/016)	8.4	20	75 % bei 1/3 bar	250		180	SFO-SFO	Simmonds 2003 leaching study, Hardy 2003
Sandy loam (02/017)	8.7	20	75 % bei 1/3 bar	90		64	SFO-SFO	
Aggregated DT_{50} (n=4)		**Coefficient of variation (%)**				66		
		Geomean (d)				211.8	Used for PECgw of IM 1-5 as worst case approach in the national addendum	
		90^{th} percentile				431.4	Used for PECs of IM 1-5 in the national addendum	

Table 5.4-6: Summary of aerobic degradation rates for metabolite IC-0 - laboratory studies

Soil type	pH (H_2O)	T (^oC)	Moisture	DT_{50}/ DT_{90} (d)	f.f.	DT_{50} (d) 20 °C pF2/10kPa	Kinetic, Fit	Reference
Sandy loam	7.2	20	45 % of MWHC	3.5		3.5	KIM	Lowden et al (1997)
silty clay loam	6.7	20	45 % of MWHC	2.9		2.9	KIM	
clay loam	7.8	20	45 % of MWHC	6.5		5.2	KIM	
Sandy loam	8,0	20	45 % von MWHC	1.5		1.5	SFO	Simmonds 2002, Hardy 2003c
Clay	7,7	20	45 % von MWHC	2.5		2.0	SFO	
Clay loam	7,9	20	45 % von MWHC	2.0		1.8	SFO	
Sandy loam,UK	8.4	20	75% 1/3 bar	35.7		25.7	SFO	Simmonds 2003 (column leaching study.) Hardy (2003)
Sandy loam, USA	8.7	20	75% 1/3 bar	58.5		41.7	SFO	
Aggregated DT_{50} (n=8)		**Coefficient of variation (%)**				143		
		Geomean (d)				4.8		

	90th percentile	30.5	Used for PECgw for IC-0 as worst case approach and for PECs in the national addendum

5.4.1.2 Field studies

The field dissipation rates of acetamiprid were evaluated during EU assessment. No additional studies have been performed.

As applicant did not provided a new evaluation of the field study according to FOCUS Degradation Kinetics guideline (2006), zRMS re-calculated the relevant trigger endpoints and inputs for the PEC soil calculation for acetamiprid. The results of the recalculation are presented in Table 5.4-7 for acetamiprid and in Table 5.4-8 for metabolite IM 1-4. The detailed information are presented in Appendix 2 of core assessment.

Table 5.4-7: Field degradation studies of acetamiprid- recalculation according to FOCUS Degradation Kinetics 2006 by zRMS

soil / location	pH	depth (cm)	DT_{50} (d)	DT_{90} (d)	Fit, Kinetic Parameters	DT_{50} (d) SFO recalculated	Kinetic	Reference
Italy, Bologna, clay loam	8.9	0-30	0.09	23.93	chi^2 12.7 k1 0.05365 k2 1.609 g 0.361	12.9 slow phase	DFOP	Wick 1999 zRMS 2012
UK, Manningtree, sandy loam	5.9	0-30	3.38	11.22	chi^2 20.8 k 0.2051	3.38	SFO	Wick 1999 zRMS 2012
France, Mereville, silty clay ,loam	8.7	0-30	10.94	36.33	chi^2 12.44 k 0.0634	10.94	SFO	Wick 1999 zRMS 2012
Spain, Seville, sandy loam	7.0	0-30	**0.0255**	**na**	chi^2 9.05 k1 14.89 k2 0.1677 g 0.5714	4.11 Slow phase	DFOP	Wick 1999 zRMS 2012
DT50 aggregated **n = 4**	**Maximum (PEC soil) soil Mereville /France**					**10.94**	**SFO**	

Table 5.4-8: Field degradation studies of acetamiprid- recalculation of degradation rates for metabolite IM 1-4 according to FOCUS Degradation Kinetics 2006 by zRMS

soil / location	pH	depth (cm)	DT_{50} (d)	DT_{90} (d)	Fit, Kinetic, Parameters	DT_{50} (d) SFO recalculated	Fit, Kinetic	Reference

Italy, Bologna, clay loam	8.9	0-30	30.6	101.7	chi^2 36.1	30.6	SFO-SFO	Wicks 1999, zRMS 2012
UK, Manningtree, sandy loam	5.9	0-30	38.4	127.5	chi^2 15.3	38.4	SFO-SFO	Wicks 1999, zRMS 2012
France, Mereville, silty clay ,loam	8.7	0-30	45.7	151.8	chi^2 29.9	45.7	SFO-SFO	Wicks 1999, zRMS 2012
Spain, Seville, sandy loam	7.0	0-30	26.8	89.4	chi^2 26.8	26.8	SFO-SFO	Wicks 1999, zRMS 2012
DT50 aggregated n = 4	**Maximum (PEC soil) soil Mereville /France**					**45.7**	**SFO**	

Normalised $DegT_{50}$ values from the field dissipation study were not provided, so $DegT_{50}$ values can not be used for PEC_{GW} modeling.

5.4.2 Adsorption/desorption

Acetamiprid

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). The results and the statistic values according to INPUT DECISION 3.2 for acetamiprid are summarized in Table 5.4-9 and Table 5.4-10.

Table 5.4-9: K_f, K_{foc} and 1/n (Freundlich exponent) values for acetamiprid

Soil Type	OC (%)	pH (-)	K_f (mL g^{-1})	K_{foc} (mL g^{-1})	1/n (-)	Reference
I sand	0.43	5.7	0.600	138	0.842	Flückiger, 1997
II loamy sand	1.00	7.6	1.350	130	0.825	
III sandy loam	1.57	7.1	1.120	71	0.893	
IV silt loam	1.39	7.7	1.690	122	0.835	
V silt loam	4.39	7.1	3.130	71	0.907	
Loamy sand II	1.5	6.2	3.210	218	0.8295	Liu, 1997a
Silt loam	0.44	6.6	1.247	283	0.9272	
Clay	1.19	7.5	3.719	313	0.9297	

sandy loam, Pond sediment,	2.5	5.6	3.429	137	0.8385	
Arithmetic mean (n = 9)			**2.17**	**165**	**0.87**	

Table 5.4-10: Statistic values according to INPUT DECISION 3.2 for acetamiprid for PEC_{GW} modelling

Does the active substance dissociate ?	no	pKa = 0.7 (25 °C)
correlation K_f and oc	Kendall-τ:0.389 p-value:0.088	not positive (p-Wert > significance level)
coefficient of variation K_{foc}	52	Small enough (< 60%)
Correlation K_f and pH	Kendall-τ:0.028 p-value:1.000	not significant (p-Wert > significance level)
Correlation K_{foc} and pH	Kendall-τ:-0,085 p-value:0.834	not significant (p-Wert > significance level)
Correlation K_f and other soil parameter (clay, CEC)		not relevant/ positiv/not significant
K_{foc}/K_f for PEC_{GW}	165	Arithmetic mean (all soils) n= 9
1/n PEC_{GW}	0.87	arithmetic mean all soils n= 9

Metabolites of acetamiprid

IM 1-2

For the metabolite IM 1-2 the coefficient of variation of the measured K_{foc} /K_f values is > 60%/ >100 % and no correlation could be found between the K_{foc} / K_f values and pH of the soils. In this case, the 10th percentile of the K_f values are used for the first three soil horizons of the model scenario Hamburg in FOCUS PELMO 4.4.3 together with a default value of zero for the soil horizons 4-6. The results are summarized in Table 5.4-11 and Table 5.4-12.

Table 5.4-11: K_f, K_{foc} and 1/n (Freundlich exponent) values for metabolite IM 1-2

Soil Type	**OC (%)**	**pH (-)**	**K_f (mL g^{-1})**	**K_{foc} (mL g^{-1})**	**1/n (-)**	**Reference**
clay loam, (Hertforshire,UK)	2.3	8.1	0.45	19	0.886	MacKenzie, 2003
Sandy loam, (Lincolnhire,UK)	1.3	8.0	0.27	21	0.856	MacKenzie, 2003
Clay loam, (Lamberton,	3.8	6.6	3.60	95	0.927	MacKenzi

Minnesota,USA)						e, 2003
Sandy loam, (Fresno,California,USA)*	0.2	8.6	0.16	80	0.944	MacKenzie, 2003

*not considered in national assessment because of oC-content < 0.3 %

Table 5.4-12: Statistic values according to INPUT DECISION 3.2 for metabolit IM 1-2 for PEC_{GW} modelling

Does the substance dissociate ?	no	
correlation K_f and oc	Kendall-τ:1.000 p-value:0.500	not positive (p-Wert > significance level)
coefficient of variation K_{foc}	96	Too high (> 60%)
coefficient of variation K_f	130	too high (> 100%)
Correlation K_f and pH	Kendall-τ:-0.333 p-value:1.000	not significant (p-Wert > significance level)
Correlation K_f and other soil parameter (clay, CEC)		not relevant
K_{foc}/K_f for PEC_{GW}* für national addendum	1.-3- horizon 0.31 4.-5. Horizon: 0	Hamburg-szenario with kf-values: 10^{th} percentile, CV > 100 %, n= 3
1/n PEC_{GW}	0.890	arithmetic mean n= 3

IM 1-4

For the metabolite IM 1-4 the coefficient of variation of the measured K_{foc}/K_f values is > 60%/ >100 % and no correlation could be found between the K_{foc} / K_f values and pH of the soils. In this case, the 10^{th} percentile of the K_f values are used for the first three soil horizons of the model scenario Hamburg in FOCUS PELMO 4.4.3 together with a default value of zero for the soil horizons 4-6. The results are summarized in Table 5.4-13 and Table 5.4-14.

Table 5.4-13: K_f, K_{foc} and 1/n (Freundlich exponent) values for metabolite IM 1-4

Soil Type	**OC (%)**	**pH (-)**	**K_f (mL g^{-1})**	**K_{foc} (mL g^{-1})**	**1/n (-)**	**Reference**
I sand	0.43	5.7	2.10	448	0.597	Mamouni, 1997
II loamy sand	1.0	7.6	2.24	223	0.714	
III sandy loam	1.57	7.1	2.16	138	0.712	
IV silt loam	1.39	7.7	2.67	192	0.816	

V silt loam	4.39	7.1	5.79	132	0.813	

Table 5.4-14: Statistic values according to INPUT DECISION 3.2 for metabolit IM 1-4 for PEC_{GW} modelling

Does the active substance dissociate ?	no	
correlation K_f and oc	Kendall-τ:0.600 p-value:0.110	not positive (p-Wert > significance level)
coefficient of variation K_{foc}	63	too high (> 60%)
coefficient of variation K_{foc}	53	Low enough (< 100 %)
Correlation K_f and pH	Kendall-τ:0.527 p-value:0.312	not significant (p-Wert > significance level)
Correlation K_{foc} and pH	Kendall-τ:-0,105 p-value:1.000	not significant (p-Wert > significance level)
Correlation K_f and other soil parameter (clay, CEC)		not relevant
K_{foc}/K_f for PEC_{GW} für national addendum	1.-3. Horizon: Kf = 2.99 4.-6. Horizon: Kf = 0	"Hamburg Scenario with k_f-values specific for soil horizons: arithmetic mean, CV < 100 %, n= 5
1/n PEC_{GW}	0.73	arithmetic mean all soils n= 5

IM 1-5

For the metabolite IM 1-5 only two soils were investigated in the column leaching study of Simmonds (2003). Therefor the minimum value of Kfoc was used as inputparameter for the PECgw modeling with FOCUS-PELMO 4.4.3. The results are summarized in Table 5.4-15.

Table 5.4-15: K_{foc} values for metabolite IM 1-5

Soil Type	**OC (%)**	**pH (-)**	**K_f (mL g^{-1})**	**K_{foc} (mL g^{-1})**	**1/n (-)**	**Reference**
Sandy loam,UK	1.3	8.4		563		Simmonds, 2003
Sandy loam, USA	1.6	8.7		453		
Koc for PECgw	**Worst case**			**453**		

IC-0

For the metabolite IC-0 the coefficient of variation of the measured K_{foc} /K_f values is > 60%/ >100 % and no correlation could be found between the K_{foc} / K_f values and pH of the soils. In this case, the 10th percentile of the K_f values are used for the first three soil horizons of the model scenario Hamburg in FOCUS PELMO 4.4.3 together with a default value of zero for the soil horizons 4 - 6.
The results are summarized in Table 5.4-16 and Table 5.4-17.

Table 5.4-16: K_f, K_{foc} and 1/n (Freundlich exponent) values for metabolite IC-0

Soil Type	**OC (%)**	**pH (-)**	**K_f (mL g^{-1}**	**K_{foc} (mL g$^{-1)}$**	**1/n (-)**	**Reference**
II loamy sand	1.47	6.2	1.027	70	1.007	Liu, 1997
III silt loam	0.44	6.6	0.569	129	0.871	
IV clay	1.19	7.5	0.833	70	0.894	
V clay loam	0.82	8.3	0.690	84	0.926	

Table 5.4-17: Statistic values according to INPUT DECISION 3.2 for metabolit IC-0 for PEC_{GW} modelling

Does the active substance dissociate ?	no	
correlation K_f and oc	Kendall-τ: -1.000 p-value:0.089	positive and significant (p-Wert < significance level)
coefficient of variation K_{foc}	32	Small enough (< 60 %)
Correlation K_f and pH	Kendall-τ:-0.913 p-value:0.149	not significant (p-Wert > significance level)
Correlation K_f and other soil parameter (clay, CEC)		not relevant
K_{foc}/K_f for PEC_{GW}	88	arithmetic mean all soils n= 4
1/n PEC_{GW}	0.925	arithmetic mean all soils n= 4

5.4.3 Rate of degradation in water

Acetamiprid

See core assessment Table 5.4-15 of Part B, Section 5.4.3

Metabolites of acetamiprid

See core assessment Table 5.4-16 and Table 5.4-17 of Part B, Section 5.4.3

5.5 Estimation of concentrations in soil (KIIIA1 9.4)

The input parameters for acetamiprid and its metabolites for PEC_{soil} calculation are summarized in Table 5.5-1.

Results of PECsoil calculation for acetamiprid and its metabolites according to EU assessment considering 5 cm soil depth are given in Table 5.5-2 of Part B, Section 5.5 of the core assessment.

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 substance acetamiprid in soil (DT_{90} < 365 d, DFOPslow phase, field data) the accumulation potential of acetamiprid does not need to be considered

The PEC_{soil} calculations were performed with ESCAPE 2.0 based on the input parameters for acetamiprid as presented in Table 5.5-1.

Table 5.5-1: Input parameter for acetamiprid for PEC_{soil} calculation

Active substance	**DT_{50}**
acetamiprid	10.94 d (SFO, Maximum, Field studies, see Sec 5 point 5.4.1.2 Table 5.4-7
IM 1-4	45.7 d (SFO, Maximum Field studies, see Sec 5 point 5.4.1.2 Table 5.4-8
IM 1-5	431.4 d (90th percentile, Laboratory conditions, see Sec 5 point 5.4.1.1 Table 5.4-5)
IM 1-2	2.4 d (90th percentile, Laboratory conditions, see Sec 5 point 5.4.1.1 Table 5.4-4)
IC-0	30.5 d (90th percentile, Laboratory conditions, see Sec 5 point 5.4.1.1 Table 5.4-6)

Additional $PEC_{soil,act}$ was calculated for the formulation Mospilan SG for a soil depth of 2.5 cm. No short-term and long-term PEC_{soil} were calculated since $PEC_{soil,act}$ is considered sufficient for German risk assessment.

The calculated PEC_{soil} used for German risk assessment for acetamiprid and for the formulation Mospilan SG 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:		Mospilan SG				
use:		16-001, potatoes (BBCH 20-39)				
Number of applications/intervall		2 x, 14 days interval				
application rate:		25 g ai/ha				
crop interception:		50 %				
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)**
acetamiprid	2 x 12.5 = 25	2.5	0.0471	-	-	-
IM 1-4 (max. 72 %, MG-ratio 0.704)	2 x 6.34 = 12.68	2.5	0.0306	-	-	
IM 1-5 (max. 20.2 %, MG-ratio 0.89)	2 x 2.25 = 4.5	2.5	0.0119	20	0.0019	0.0137
IM 1-2 (max. 55 %, MG-ratio 1.08)	2 x 7.43 = 14.86	2.5	0.0202	-	-	-
IC-0 (max. 11.3 %, MG-ratio 0.7)	2 x 1.0. = 2.0	2.5	0.0046	-	-	-

5.6 Estimation of concentrations in surface water and sediment (KIIIA1 9.7)

Results of PECsw calculation of acetamiprid for the intended for uses of Mospilan SG in potatoes using FOCUS Surface Water are given in Table 5.6-2 of Part B, Section 5.6 of the core assessment.

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 volatilisation

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 acetamiprid is $< 10^{-5}$ Pa. Hence the active substance acetamiprid is regarded as non-volatile. Therefore exposure of surface water by the active substance acetamiprid 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.

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 active substance acetamiprid used for the PEC_{SW} calculations with EVA 2.1

Parameter	Active substance acetamiprid	Reference
vapour pressure at 20 °C (Pa)	< 1x10^{-6} Pa (25 °C)	See Table 5.3-2 core assessment
Solubility in water (mg/L)	1.95 g /L	See Table 5.3-2 core assessment
$DissT_{50}$ water (d)	11.0	See Table 5.4-15 core assessment
DT_{50} water/sediment study, total system (d)	36.1	See Table 5.4-15 core assessment
hydrolysis/photolysis	1000	default

The calculated PECsw values after exposure via spray drift for the active substance acetamiprid for the intended for use in potatoes are summarized in Table 5.6-2.

Table 5.6-2 PEC_{SW} for the active substance acetamiprid after exposure via spray drift and volatilization with subsequent deposition modelled with EVA 2.1

active substance			acetamiprid					
use pattern/gap:			16-001					
application rate/number of applications / interval			2 x 25 g as/ha (worst case), 14 days interval					
$DissT_{50}$ (SFO) in water			11.0					
relevant PEC if applicable twa-interval			actual					
scenario/percentile:			82th percentile					
distance (m)	PECsw via drift		PECsw via volatilisation		PECsw (via drift and volatilisation) (µg/L) depending on application technique (drift reduction)			
	(%)	(µg/L)	(%)	(µg/L)	common	90% red.	75% red.	50% red.
0	100.00	11.78	-	-	11.78	1.18	2.95	5.89
1	2.38	0.280	-	-	0.280	0.03	0.07	0.14
5	0.47	0.055	-	-	0.055	0.01	0.01	0.03
10	0.24	0.028	-	-	0.028	0.00	0.01	0.01
15	0.16	0.019	-	-	0.019	0.00	0.00	0.01
20	0.12	0.014	-	-	0.014	0.00	0.00	0.01

5.6.2 PEC_{SW} after exposure by surface run-off and drainage

The concentration of the active substance acetamiprid in adjacent ditch due to surface runoff and drainage is calculated using the model EXPOSIT 3.01.

The endpoints for acetamiprid used for modelling surface water exposure via run-off and drainage in an adjacent ditch with EXPOSIT 3.01 are summarized in Table 5.6-3.

Table 5.6-3: Input parameters for acetamiprid used for PEC_{SW} calculations with EXPOSIT 3.0

Parameter	acetamiprid	Reference
$K_{foc, Runoff}$	165	Part B, Section 5, Core assessment , 5.4.2 Table 5.4-10
$K_{foc, mobility class}$	165	Part B, Section 5, Core assessment , 5.4.2 Table 5.4-10
DT_{50} soil (d)	10.94 (SFO, Maximum, field studies)	Part B, Section 5, Core assessment , 5.4.1.2 Table 5.4-7
Solubility in water (mg/L)	2.95 g/L	Part B, Section 5, Core assessment 5.3.1.2 Table 5.3-2

The calculated PEC_{SW} in an adjacent ditch due to surface run-off and drainage for the active substance acetamiprid for the intended for use in potatoes (worst case application rate) are summarized in Table 5.6-4.

Table 5.6-4: PEC_{SW} of acetamiprid in an adjacent ditch due to surface run-off and drainage

Active substance:	acetamiprid
Use pattern/GAP:	16-001
Application rate:	2 x 25 g ai/ha, 50 % Interception (worst case), 14 days interval
Exposure by surface runoff	
vegetated buffer strip (m)	**PECsw in adjacent ditch (µg/L)**
0	0.14
5	0.12
10	0.10
20	0.07
Exposure by drainage	
time of application	**PECsw in adjacent ditch (µg/L)**
autum/winter/early spring	0.14
Spring/summer	0.05

5.7 Risk assessment for groundwater (KIIIA1 9.6)

Results of PECgw calculation of acetamiprid for the intended uses of Mospilan SG in potatoes according to EU assessment using FOCUS PELMO 4.4.3 are given in Table 5.7-6 of Part B, Section 5.7.1 of the core assessment.

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 Mospilan SG 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 4.4.3

use evaluated	16-001
application rate (kg as/ha)	2 x 25 g ai/ha
crop (crop rotation)	potatoes
date of application	15.05./29.05.
interception (%)	50
soil moisture	100 % FC
Q10-factor	2.58
moisture exponent	0.7
plant uptake	0
simulation period (years)	26

Acetamiprid

The endpoints used for groundwater modelling for acetamiprid according to INPUT DECISION 3.1 are summarized in Table 5.7-2 ..

Table 5.7-2 Input parameters related to acetamiprid for PEC_{GW} modelling

Parent	**acetamiprid**	**Remarks/Reference to Part B, Section 5, Core assessment**
molecular mass	222.7	See LoEP
DT_{50} in soil (d)	33.7	worst case approach for PECgw parent 90^{th} percentile (SFO, n = 9) see Table 5.4-1
	1.7	worst case approach for PECgw metabolites geometric mean, (SFO, n = 9) see Table 5.4-2
K_{foc}	165	Part B, Section 5, 5.4.2 Table 5.4-10
1/n	0.860	Part B, Section 5, 5.4.2 Table 5.4-10

Metabolites of acetamiprid

The endpoints used for groundwater modelling for the metabolites of acetamiprid IM 1-2, IM 1-4, IM 1-5 and IC-0 according to INPUT DECISION 3.1 are summarized in Table 5.7-3.

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

Metabolite 1	**IM 1-4**	**Remarks/Reference**
molecular mass	156.7	See LoEP
Formation fraction	1.0	parent to IM 1-4
DT_{50} in soil (d)	180.1	90^{th} percentile (worst case approach for IM 1-4) see Table 5.4-3
K_f	1.-3. Horizon: 2.99 4.-6. Horizon: 0	"Hamburg Scenario with k_f-values specific for soil horizons: arithmetic mean, CV < 100 %, n= 5, see Table 5.4-13 and Table 5.4-14
1/n	0.73	Part B, Section 5, 5.4.2 see Table 5.4-13 and Table 5.4-14
Metabolite 2	**IM 1-2**	**Remarks/Reference**
molecular mass	240.7	See LoEP
Formation fraction	1.0	Parent to IM 1-2
DT_{50} in soil (d)	1.6	Geometric mean, n = 5, see Table 5.4-4
K_f	1.-3. Horizon: 0.31 4.-5. Horizon: 0	Hamburg-szenario with kf-values: 10^{th} percentile, CV > 100 %, n= 3, see Table 5.4-11 and Table 5.4-12

1/n	0.890	Arithmetic mean, n = 3, see Table 5.4-11 and Table 5.4-12
Metabolite 3	**IM 1-5**	**Remarks/Reference**
molecular mass	197.7	See LoEP
Formation fraction	0.2	Parent to IM 1-5 see LoEP 2004
DT_{50} in soil (d)	211.8	Geometric mean, n = 5, see Table 5.4-5
K_{foc}	453	Part B, Section 5, 5.4.2 see Table 5.4-15
1/n	1.0	Part B, Section 5, 5.4.2 see Table 5.4-15
Metabolite 4	**IC-0**	**Remarks/Reference**
molecular mass	155.7	See LoEP
Formation fraction	0.5	parent to IC-0
DT_{50} in soil (d)	30.5	90th percentile, laboratory conditions, n = 8, see Table 5.4-6
K_{foc}	88	Arithmetic mean, n = 4, see Table 5.4-16 and Table 5.4-17
1/n	0.925	Arithmetic mean, n = 4, see Table 5.4-16 and Table 5.4-17

In accordance with the decision of the PECgw-modelling approach of EU assessment 2004 the simulation approach of applicant based on kinetic modelling of Hardy 2003 using only degradation data from the aged leaching study of Simmonds 2003 was not accepted by zRMS. Two different halflives of acetamiprid were used. The first simulation considered the slow phase degradation rates (HS kinetic) of acetamiprid to provide a conservative leaching estimation for the parent compound. The other four separate simulations considered the faster (bi-phasic) degradation half-life of acetamiprid, in order to provide conservative estimations with regard to the leaching of the metabolites.

Four separate FOCUS-PELMO-simulations for each of the relevant metabolites were done with the formation fractions agreed in the LoEP 2004. The plant uptake factor for the active substance was set to 0 as worst case approach. Acetamiprid is a foliar applied insecticide of the chloronicotinyl group, acting by ingestion and by contact. Data about its systemic character are not provided. The plant uptake factors for the metabolites were also set to 0 as conservative approach.

The results of the PECgw simulations for acetamiprid and its metabolites with FOCUS-PELMO 4.4.3 are summarized in Table 5.7-4.

Table 5.7-4 PEC_{GW} at 1 m soil depth of acetamiprid and its metabolites IM 1-2, IM 1-4, IM 1-5 and IC-0 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 4.4.3				
		acetamiprid	Metabolite IM 1-2	Metabolite IM 1-5	Metabolite IM 1-4	Metabolite IC-0
16-001 Simulation I	Hamburg	< 0.001	-	-	-	-
16-001 Simulation II	Hamburg	< 0.001	< 0.001	0.062	< 0.001	< 0.001

According to the results of the groundwater simulation with FOCUS-PELMO 4.4.3, a groundwater contamination of the active substance acetamiprid and its metabolites IM 1-2, IM 1-4, IM 1-5 and IC-0 in concentrations of ≥ 0.1 µg/L is not expected for the intended use in potatoes.

5.7.1.2 Summary on risk assessment for groundwater after direct leaching

Results of modelling with FOCUS_PELMO 4.4.3 show that the active substance acetamiprid is not expected to penetrate into groundwater at concentrations of ≥ 0.1µg/L in the intended for uses in potatoes.

For the metabolites IM 1-2, IM 1-4, IM 1-5 and IC-0 concentrations 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

Acetamiprid

The input parameters for acetamiprid 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 5.7-5.

Table 5.7-5 Input parameters for acetamiprid used for PEC_{GW} calculations with EXPOSIT 3.0

Parameter	acetamiprid	Reference to Part B, Section 5, Core assessment
$K_{foc, Runoff}$	165	Part B, Section 5, Core assessment , 5.4.2.1 see Table 5.4-10
$K_{foc, mobility class}$	165	Part B, Section 5, Core assessment , 5.4.2.1 see Table 5.4-10
DT_{50} soil (d)	10.94 (SFO, Maximum, Field	Part B, Section 5, Core assessment ,

	studies, see Sec 5 point 5.4.1.2 Table 5.4-7)	5.4.1.2 see Table 5.4-8
Solubility in water (mg/L)	2950	Part B, Section 5, Core assessment 5.3.11.2 Table 5.3-2
Mobility class	2	Exposit 3.0
Reduction by bank filtration	75	Exposit 3.0

The calculated PECgw for acetamiprid after surface run-off and drainage with subsequent bank filtration are summarized in Table 5.7-6.

Table 5.7-6 PEC_{gw} for acetamiprid after surface run-off and drainage with subsequent bank filtration (modelled with EXPOSIT 3.01)

Active substance		**acetamiprid**			
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)**
16-001	2 x 25 g ai/ha 50 % interception	0	0.003	autumn/winter/ early spring	0.003
		5	0.002		
		10	0.002	spring/summer	0.001
		20	0.001		
required labelling		no			

According modelling with EXPOSIT 3, groundwater contamination at concentrations ≥ 0.1 µg/L by the active substance acetamiprid due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

Metabolites of acetamiprid

The soil metabolites of acetamiprid IM 1-2, IM 1-4, IM 1-5 and IC-0 (see Part B core assessment, Section 5, Table 5.3-3) 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, in principle.
Because of the same mobility class, but lower relevant soil concentrations of the four metabolites IM 1-2, IM 1-4, IM 1-5 and IC-0 compared with acetamiprid, groundwater contamination at concentrations ≥ 0.1 µg/L by the metabolites due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

Consequences for authorization:

The authorization of the plant protection product Mospilan SG is linked with following labeling:

None

Appendix 1 List of data submitted in support of the evaluation

No additional data for national assessment submitted.

Appendix 2 Detailed evaluation of studies relied upon

KIIA1 7.1 Fate and Behaviour in the Environment

KIIA1 7.1.1 Heimann, 2002

Reference:	KIIA 7.1.1.2.2
Author:	Heimann,
Report:	Recalculation of the degradation rate of Acetamiprid in soil , RD-00672,
Date:	17.05.2002
Guideline(s):	not adressed
Deviations:	
GLP:	Yes/No (If no, give justification, e.g., state that GLP was not compulsory at the time the study was performed)
Acceptability:	data not considered in evaluation (see Part B, Section 5 of the core assessment Point 5.4.1.2)

The study contains a new kinetic evaluation of the field dissipation study of Wicks (1999), which were not considered in the evaluation. ZRMS Germany recalculated the degradation rates according to FOCUS kinetics (2006). Details of the recalculation and the new persistence endpoint of acetamiprid and its metabolite IM 1-4 are provided in the core assessment in Appendix 3. This DT50 values are used for the PECs calculations in the national authorization procedure.

KIIA1 7.1.1 zRMS, 2012

Reference:	KIIA 7.1.1.2.2
Author:	zRMS
Report:	Recalculation of transformation rates of the field sdissipation study (Wicks 1999) according to FOCUS kinetics 2006 to derive trigger endpoint and input for PECsoil calculation by zRMS
Date:	01.09.2012
Guideline(s):	not adressed, Recalculation with Kingui II
Deviations:	not adressed
GLP:	not adressed
Acceptability:	Yes

ZRMS Germany recalculated the degradation rates of the field dissipation study of Wicks (1999) according to FOCUS kinetics (2006). Details of the recalculation and the new persistence endpoint of acetamiprid and its metabolite IM 1-4 are provided in the core assessment in Appendix 3. This DT50 values are used for the PECs calculations in the national authorization procedure.

KIIA1 7.1.2 Liu, A. (1997)

Reference:	KIIA 7.1.2
Author:	Liu, A.
Report:	NI-25: Soil adsorption / desorption study, RD-9970, EC-97-381
Date:	15.10.1997
Guideline(s):	Yes (EPA 163-1)
Deviations:	No
GLP:	Yes (
Acceptability:	Yes

Details oft the new adsorption/ desorption study are provided in the core assessment in Appendix 3. Results are considered in the national authorization procedure (see 5.4.2 table 5.4-9).

KIIIA1 9 Fate and Behaviour in the Environment

KIIIA1 9.6. Heimann 2010

Reference:	KIIIA1 9.6
Author	Heimann, S.
Report:	Calculation of PECgw for acetamiprid and its degradation products using PELMO 3.22, Report No. NCE-2010-01-DE,
Date:	10.12.2010
Guideline(s):	Not applicable
Deviations:	No
GLP:	Not applicable
Acceptability:	additional information only

PECgw calculations were performed by Germany. The study by Heimann, 2010 is used as information only.

Appendix 3 Table of Intended Uses in Germany (according to BVL 17.04.2012)

PPP (product name/code) **Mospilan SG/ 005655-00/16** **Formulation type:** **soluble granulate (SG)**
active substance 1 **acetamiprid** **Conc. of acetamiprid:** **200 g ai/ kg**

1	2	3	4	5	6	7	8	10	11	12	13
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)
					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	
16-001	DE	potatoes	F	Colorado beetle	spraying	spring and summer BBCH 20-39	a) 2 (14) b) 2 (14)	a) 0.125 b) 0.250	a) 0.025 b) 0.050	300 - 600	14

REGISTRATION REPORT
Part B

Section 6 Ecotoxicological Studies
Detailed summary of the risk assessment

Product code: **Mospilan SG**
Active Substance: **200 g/kg Acetamiprid**

Central Zone
Zonal Rapporteur Member State: Germany (DE)

CORE ASSESSMENT

Applicant: **Nisso Chemical Europe GmbH**
Submission Date: **20/06/2013**

Table of content

Sec 6 ECOTOXICOLOGICAL STUDIES

This document reviews the ecotoxicological studies for the product Mospilan SG containing the active substance Acetamiprid, which is currently approved under Reg. (EC) No 1107/2009 (repealing Directive 91/414/EEC) and fulfills the criteria according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2.Acetamiprid was included into Annex I of Directive 91/414 (Commission Directive 2004/99/EC) in the year 2005. The Annex I Inclusion Directive for Acetamiprid (2004/99/EG) provides specific provisions which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation.

Mospilan SG is a SG-formulation with 200 g/kg acetamiprid as active ingredient for the control of insects (e.g. aphids and whiteflies) in field crops, pome fruits, vegetables and ornamentals. In DE it is registered for control of aphids in potato and pollen beetle in seed rape (use-No. 005655-00-00).

Mospilan SG was not the representative formulation considered in the EU review process as part of the approval of the active substance Acetamiprid, but is chemically identical with it and is formulated as soluble granule (SG) instead of soluble powder (SP).

A full risk assessment according Commission Regulation (EU) No 546/2011 is provided.

Addenda are included containing country specific assessments for some annex points. In those cases this document should be read in conjunction with the relevant addenda.

Where appropriate, this document refers to the conclusions of the EFSA, especially when data on the active substance is relied upon in the risk assessment of the formulation. Since no EFSA conclusion was available, the SANCO report for Acetamiprid (SANCO/1392/2001 – Final 16 June 2004) is considered to provide the relevant review information or a reference to where such information can be found. Each section will begin with a table providing the EU endpoints used in this evaluation.

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

Appendix 2 of this document reports the detailed evaluation of studies relied upon.

Appendix 3 of this document is the table of intended uses for Mospilan SG.

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

6.1 Proposed use pattern and considered metabolites

Introduction

Section 6 of the submission summarises the ecotoxicological effects of the formulation Mospilan SG containing 200 g/kg of the active substance Acetamiprid and provides the results of the risk assessment to various representatives of terrestrial, aquatic and soil organisms for the intended uses of Mospilan SG. Full details or the proposed use patterns that will be assessed are shown in Appendix 3 of this document and summarized below. Moreover, an overview of the metabolites of acteamiprid that will be addressed in the risk assessment is given below.

Information on the active ingredients (Uptake and Mode of Action)

Acetamiprid is a systemic insecticide with translaminar activity and with contact and stomach action. Acetamiprid is classified by the Insecticide Resistance Action Committee (IRAC) due to the primary site of action in the main group 4 of the nicotinic acetylcholine receptor agonists/ antagonists (Version: MoA Classification v. 7.2, February 2012). This class of materials functions by binding to the nicotinic acetylcholine receptor in the postsynaptic neurons of the insect central nervous system. This binding causes the ion pore in the receptor to open and allows an overloading of the postsynaptic cells with sodium ions. This leads to hyper excitation of the nervous system and eventual death of the insect. The chemical sub-group for acetamiprid is the group 4A of the neocotinoids. More active ingredients of the chemical class are clothianidin, dinotefuran, imidacloprid, nitenpyram, thiacloprid and thiamethoxam.

6.1.1 Proposed use pattern

The critical GAP used for exposure assessment is presented in Table 6.1-1 that reports also a classification of intended uses for Mospilan SG (see also Section 5of this submission). A list of all intended uses within the EU is given in Appendix 3.

Table 6.1-1: Critical use pattern of Mospilan SG:

Group/ use No	Crop/growth stage	Application method Drift scenario	Number of applications, Minimum application interval, application time, interception	Application rate, cumulative (g a.s./ha)	Soil effective application rate (g a.s./ha)
16-001	Potatoes/ BBCH 20-39	spraying	2 x, 14 d, 1. 50 % interception, 6 days after 1st emergence in the year 2. 50 % interception, 20 days after 1st emergence in the year	Acetamiprid 2 x 25 = 50	Acetamiprid 1. 12.5 2. 12.5

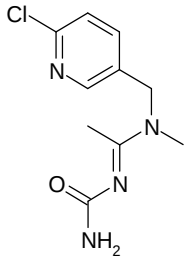
6.1.2 Consideration of metabolites

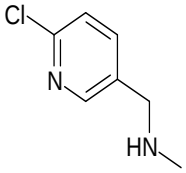
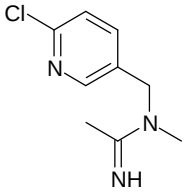
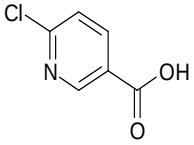
The occurrence and risk from potentially ecotoxicologically relevant metabolites have been considered for the EU approval (see DAR for Acetamiprid from March 2001; RMS: Greece, cRMS: France and SANCO/1392/2001-Final. 16 June 2004). No new information on the relevance of Acetamiprid metabolites is given.

Environmental metabolites of Acetamiprid, such as IM-1-2, IM-1-4, IM-1-5 and IC-0, occurring with more than 10 % in the compartiments after the application of 2 x 125 g Mospilan SG /ha (corresponding to 2 x 25 g a.s./ha), are summarized in Table 6.1-2 below. Further informations are provided in Part B, Section 5.3.1.3 of this submission. The ectoxicological relevance of the metabolites of Acetamiprid IM-1-4 and IC-0 has been considered in the ecotoxicological part of the EU approval (see DAR for Acetamiprid from March 2001), but not of IM-1-2 and IM-1-5. Hence IM-1-5 and IM-1-2 will be considered in this submission.

For IM-1-4 and IC-0 a reassessment is not necessary since both metabolites have been regarded as ecotoxicologically non relevant, based on the application of 100 g a.s./ha and according to the listed compartiments, soil and water, in Table 6.1-2 (see DAR for Acetamiprid from March 2001). Thus in this core assessment IM-1-4 and IC-0 will not be considered further.

Table 6.1-2: Metabolites of Acetamiprid 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)

Metabolit	**Structural formula/Molecular formula**	**occurence in compartements (Max. at day x)**	**Satus of Relevance from ecotoxicological point of view Origin of information: 1) DAR 2001 2) This submission**
IM-1-2		Soil: Max. 55 % at day 1 Water: Max. 11 % at day 7	**This submission:** Aquatic organism: low risk Water: non relevant (see Section 6.4.4) Sediment: non relevant Terrestrial organism: non relevant (see Section 6.3.4 and 6.7.2) Groundwater: non relevant

IM-1-4		Soil: Max. 72 % at day 30 Water: Max. 12.3 % at day 62 Sediment: Max. 31 % at day 30	**DAR 2001:** Aquatic organism: minimal risk Water: non relevant Sediment: non relevant Terrestrial organism: insecticidal inactivity, no risk to earthworms non relevant Groundwater: non relevant
IM-1-5		Soil: Max. 20.2 % at day 13	**This submission:** Aquatic organism: Water: non relevant Sediment: non relevant Terrestrial organism: non relevant (see Section 6.3.4 and 6.7.2) Groundwater: non relevant
IC-0		Soil: Max. 11.3 % at day 120 Water: Max. 26 % at day 62	**DAR 2001:** Aquatic organism: minimal risk Water: non relevant Sediment: non relevant Terrestrial organism: insecticidal inactivity, no risk to earthworms non relevant Groundwater: non relevant

1) DAR March 2001 = DAR March 2001; RMS: Greece, cRMS: France; see Volume 3, Annex B-9: Ecotoxicology

6.2 Effects on Birds

6.2.1 Overview and summary

Avian acute oral and long-term reproduction studies have been carried out with Acetamiprid. Full details of avian toxicity studies are provided in the respective EU DAR for Acetamiprid from March 2001 (RMS: GR, cRMS: FR). The studies with the relevant acute and long-term endpoints were agreed during the EU review process (see SANCO/1392/2001-Final. 16 June 2004) and are used for the risk assessment.

Effects on birds of Mospilan SG were not evaluated as part of the EU review of Acetamiprid. However, the provision of further data on the formulation Mospilan SG is not considered essential as the available data on Acetamiprid are deemed to be sufficient to assess the risk of birds exposed to Mospilan SG.

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

6.2.1.1 Toxicity

The studies with the relevant acute and long-term endpoints which are used in the risk assessment procedure are listed in the following table:

Table 6.2-1: Toxicity of Acetamiprid to birds with reference to agreed endpoints

Species	**Substance**	**Exposition Duration System**	**Results Toxicity**	**Reference Author Date Report No.**	**ICS-No.**
Anas platyrhynchos	Acetamiprid	Acute oral (1 d) Mortality	LD50 = 98.0 mg a.s./kg bw	[redacted] 1994 NPS 62/932516 SANCO - LoEP	42622
Anas platyrhynchos	Acetamiprid	Long-term (154 d) Reproduction	NOEL = 25.1 mg a.s./kg bw/d	[redacted] 1999 EBA-029708 SANCO - LoEP	42626

Sanco – LoEP = SANCO/1392/2001 – Final. 16 June 2004

As indicated above, an acute oral study with the formulated product has not been conducted. Consequently, the toxicity of Mospilan SG has been assessed considering data generated on the one active substance Acetamiprid in the formulation.

Concerning short-term dietary, the only and therefore the relevant study with the active substance Acetamiprid, conducted by [redacted] (DocID: NPS 62/932516) was run for the mallard duck and resulted in a LD_{50} of 98.0 mg a.s./kg bw.

A bird reproduction study ([redacted], DocID: EBA-029708) was not only run for the mallard duck but also for the bobwhite quail. The study with the duck resulted in a lower and therefore relevant NOEL of 25.1 mg a.s./kg bw/d compared to the one for the bobwhite quail (NOEL = 35.1 mg a.s./kg bw/d).

Both relevant endpoints used for the following risk assessment are listed in the EU review report SANCO/1392/2001 – Final. 16 June 2004.

6.2.1.2 Exposure

Mospilan SG is an insecticide formulation containing Acetamiprid as active substance. The product is formulated as a water soluble granule (SG). It will be used against Colorado beetle (*Leptinotarsa decemlineata*) in potatoes.

Exposure to standard generic focal species was estimated according to the Guidance Document on Risk Assessment for Birds and Mammals (EFSA Journal 2009; 7(12): 1438)

$$DDD = \sum_i \frac{PD_i \times FIR_{total}}{bw} \times RUD \times AR \times PT$$
$$= \sum_i \frac{FIR_i}{bw} \times RUD \times AR \times PT$$

where:

DDD = Daily dietary dose [mg/kg bw/day]
PDi = composition of diet obtained from treated area
FIRi = Food intake rate of indicator species i [g fresh weight/d]
bw = Body weight [g]
RUD = Residue per unit dose, bases on an application rate of 1 kg a.s./ha and assuming broadcast seedling
AR = Application rate (kg/ha)
PT = Proportion of diet obtained in the treated area (0…1)

In a first tier approach, it is assumed that birds do not avoid contaminated food items, that they feed exclusively in the treated area and on a single food type. Factors PT and PD are therefore equal to 1.

The risk assessment procedure follows a stepwise approach. A first screening step involves standard scenarios and default values for the exposure estimate, representing a “reasonable worst case”. If a risk is indicated in the screening step, then one or several refinement steps (Tier 1, Tier2) may follow. According to the Guidance Document, no further assessment is required if all uses are safe in the screening step.

6.2.1.3 Risk Assessment –overall conclusions

The results of the acute and reproductive risk assessments are summarized in the following table:

Table 6.2-2: TER for birds

Compound	Risk assessment level	Indicator species	Time scale	TER	TER trigger
Acetamiprid	Screening	Small omnivorous bird	Acute	20.6	10
	Screening	Small omnivorous bird	Long-term	20.9	5
TER shown in bold are below the relevant trigger					

Based on the presumptions of the screening step, the calculated TER values for the acute and long-term risk resulting from an exposure of birds to the active substance Acetamiprid according to the GAP of the formulation Mospilan SG achieve the acceptability criteria TER ≥ 10 and TER ≥ 5, respectively, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific

principles, point 2.5.2. The results of the assessment indicate an acceptable risk for birds, no further refinement is necessary.

Drinking water risk assessment

Drinking water assessment is not required as the ratio of effective treatment rate to toxicological endpoint does not exceed the trigger. Please refer to chapter 6.2.3.

Food chain behaviour

An assessment of the risk from secondary poisoning is not required due to log P_{OW} value of Acetamiprid being below the trigger. Please refer to chapter 6.2.5.

6.2.2 Toxicity to exposure ratio for birds

6.2.2.1 Acute toxicity to exposure ratio (TER_A)

Screening step

In the screening step, the risk to indicator bird species from an exposure to Mospilan SG is assessed. These indicators are considered to have highest exposure in a specific crop at a particular time due to their size and feeding habits and represent a worst case scenario.

To estimate the daily dietary doses, following equations were used:

Daily dietary dose (DDD):

$$DDD_{\text{single application}} = \text{application rate [kg a.s./ha]} \times \text{shortcut value}^{1}$$

In case of multiple applications, the daily dietary dose for a single application is multiplied with an appropriate multiple application factor for 90th percentile residue data (MAF_{90}; see Table 7 of EFSA/2009/1438). A specific MAF_{90} may be calculated according to Appendix H of EFSA/2009/1438 for non-standard application intervals.

$$DDD_{\text{multiple application}} = DDD_{\text{single application}} \times MAF_{90}{}^{1}$$

Toxicity exposure ratio (acute):

$$TER_A = \frac{LD_{50}\ [\text{mg/kg bw/day}]}{\text{Acute DDD}\ [\text{mg/kg bw/day}]}$$

The resulting TER_A values are summarised in the following table, a long with the indicator species and the respective shortcut values.

[1] see section 4.1 of EFSA/2009/1438

Table 6.2-3: Acute screening risk assessment (TER_A) for birds. See text for details

Substance	Indicator species	Application rate [kg/ha]	Shortcut value, acute	MAF	DDD [mg/kg bw]	LD50 [mg/kg bw]	TERA
Acetamiprid	small omnivorous bird	0.025	158.8	1.2	4.764	98.0	20.57
TERs shown in bold fall below the relevant trigger.							

Based on the highly conservative presumptions of the screening step, the calculated TER values for the acute risk resulting from an exposure of birds to the active substance Acetamiprid according to the GAP of the formulation Mospilan SG achieve the acceptability criteria TER ≥ 10, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. for acute effects. The results of the assessment indicate an acceptable risk for birds, no further refinement is necessary.

6.2.2.2 Short -term toxicity exposure ratio (TER_{ST})

There is no requirement for the calculation of TER_{ST} for birds under the EFSA birds and mammals guidance document (EFSA Journal 2009; 7(12): 1438) and, consequently, a risk assessment for short-term toxicity will not be conducted.

6.2.2.3 Long-term toxicity exposure ratio (TER_{LT})

Screening step

For the reproductive risk assessment, the calculation of the long-term toxicity exposure ratio (TER_{LT}) in principle follows the same procedure as for the acute risk assessment. However, the defined daily dose is obtained by multiplying the application rate with the mean short-cut values (based on mean RUD according to the new Guidance Document (EFSA, 2009)) as summarized in the following table:

Table 6.2-4: Avian generic focal species for the intended uses of Mospilan SG and relevant shortcut values for long-term exposure

Crop	Indicator species	Shortcut value (mean RUD)
Potatoes	Small omnivorous bird	64.8

As stated in the guidance document, it is justified to apply a time-weighted average (TWA) factor of 0.53 based on a default observation interval of 21 days and a default DT_{50} of 10 days for the calculation of the DDD (daily dietary dose):

DDD = application rate [kg/ha] × shortcut value × TWA^2 × MAF_m^2

Toxicity exposure ratio (Long-term):

$$TER_{LT} = \frac{NOEL\,[mg/kg\,bw/day]}{Long\text{-}term\,DDD\,[mg/kg\,bw/day]}$$

The relevant lowest NOEL for the reproduction exposure scenario for the active substance Acetamiprid is 25.1 mg/kg bw/d. Full details of the avian toxicity studies are provided in the respective EU DAR for Acetamiprid from March 2001. The relevant long-term endpoint is provided in the following table as well as the calculated long-term toxicity exposure ratio (TER_{LT}) for birds exposed to Acetamiprid following applications of Mospilan SG.

Table 6.2-5: Long-term screening risk assessment (TER_{LT}) for birds exposed to Mospilan SG according to the intended uses

Substance	Indicator bird	Application rate [kg/ha]	Shortcut value (long-term)	f_{TWA}	MAF_m	DDD [mg/kg bw/day]	NOEL [mg/kg bw/day]	TER_{LT}
Acetamiprid	Small omnivorous bird	0.025	64.8	0.53	1.4	1.202	25.1	20.88
TERs shown in bold fall below the relevant trigger.								

Based on the highly conservative presumptions of the screening step, the calculated TER values for the long-term risk resulting from an exposure of birds to the active substance Acetamiprid according to the GAP of the formulation Mospilan SG achieve the acceptability criteria TER ≥ 5, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. for long-term effects. The results of the assessment indicate an acceptable risk for birds, no further refinement is necessary.

6.2.3 Drinking water exposure

According to the new Guidance Document from EFSA (EFSA Journal 2009; 7(12): 1438), no specific calculations of drinking water exposure and TER-values are necessary if the ratio of effective application rate (in g/ha) to the relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/kg). This is due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by birds (for further details please refer to chapter 5.5. of the Guidance Document).

[2] see section 4.3 of EFSA/2009/1438

The ratio of the effective application rate of 25 g a.s./ha Acetamiprid to the relevant endpoint (NOEC =25 mg a.s./kg bw/d for *A. platyrhynchos*, AF = 5) does not exceed the value of 50 for Acetamiprid with a Koc of 106.5 L/kg and therefore, no risk for birds is expected exposed to Acetamiprid via drinking water.

6.2.4 Details on formulation type in proportion per item

6.2.4.1 Baits: Concentration of active substance in bait in mg/kg

Mospilan SG is not formulated as bait.

6.2.4.2 Pellets, granules, prills or treated seed

Mospilan SG is not formulated as pellets, granules, prills or treated seeds.

Amount of active substance in or on each item

Not applicable.

Proportion of active substance LD_{50} per 100 items and per gram of items

Not applicable.

Size and shape of pellet, granule or prill

Not applicable.

6.2.4.3 Acute toxicity of the formulation

Avian acute toxicity tests with the formulation were not performed and are not considered necessary.

6.2.4.4 Metabolites

Avian toxicity tests with metabolites of Acetamiprid were not performed and are not considered necessary.

6.2.4.5 Supervised cage or field trials

The risk assessment above has demonstrated that the proposed uses of Mospilan SG pose no unacceptable acute or long-term risks to birds, and therefore further studies are not considered necessary.

6.2.4.6 Acceptance of bait, granules or treated seeds (palatability testing)

Mopilan SG is intended for use as a foliar spray, and therefore this information is not required.

6.2.5 Effects of secondary poisoning

The EFSA birds and mammals guidance document (EFSA Journal 2009; 7(12): 1438) states that a $\log P_{ow} \geq 3$ is used to indicate that there might be a potential for bioaccumulation (see chapter 5.6

"Bioaccumulation and food chain behaviour"). Since the log P_{ow} value of Acetamiprid is 0.8 (pH not determined (neutral conditions)), this active substance is deemed to have a negligible potential to bioaccumulate in animal tissues.

Exposure of avian wildlife via dietary intake of residues from food items is considered in the DAR for Acetamiprid from March 2001 (RMS: GR). It has been concluded that the application rate of 0.200 kg Acetamiprid/ha is not expected to pose any risk to avian wildlife via spray residues in food items, which is 1.6-times higher than the application rate of the intended use 16-001 of Mospilan SG. Therefore, risk from secondary poisoning is not reassessed in this submission.

6.3 Effects on Terrestrial Vertebrates Other Than Birds

6.3.1 Overview and summary

For terrestrial vertebrates other than birds, acute oral- and long-term studies for the active substance Acetamiprid as well as acute oral toxicity study for the formulation Mospilan SG have been conducted under laboratory conditions. Studies are evaluated as part of the EU review of Acetamiprid (DAR from March 2001; RMS: GR). Relevant endpoints were agreed during EU review process (see SANCO/1392/2001-Final. 16 June 2004) and are used in the risk assessment.The risk assessment is carried out according to the European Food Safety Authority Guidance Document on Risk Assessment for Birds and Mammals (EFSA Journal 2009; 7(12): 1438).

6.3.1.1 Toxicity

All relevant study data for the assessment of the risk to terrestrial vertebrates other than birds from the intended uses of Mospilan SG are provided in the following **Fehler! Verweisquelle konnte nicht gefunden werden.**. Besides, the applicant provided further studies on the risk for terrestrial vertebrates other than birds (see DAR for Acetamiprid – Volume 3, Annex B-6: Toxicology and Metabolism, from March 2001; RMS: GR).

[redacted] (1997) calculated the acute oral LD_{50} value for Acetamiprid to be 314 mg a.s./kg b.w. (95% confidence interval of 239-432 mg a.s./kg b.w.) for female rats, and 417 mg a.s./kg bw (95% confidence interval of 273-640 mg a.s./kg bw) for male rats.

[redacted] (1997) determined the acute oral LD_{50} value for EXP 60707B (chemically identical with Mospilan SG) to be 1065 mg prep/kg bw (95% confidence interval of 710-1683 mg prep/kg bw) for female rats under the conditions of the study. Thus, LD_{50} is corresponding to be 213 mg a.s./kg bw with a 95% confidence interval of 142-337 mg a.s./kg bw). The acute oral LD_{50} value could not be determined precisely for male rats but it was found to be between 1000 and 2000 mg prep/kg bw (corresponding to 200-400 mg a.s./kg bw).

In conclusion, these EU-conform acute oral toxicity data for rats show slightly (1.5-times) higher toxicity of the preparation Mospilan SG compared to the active substance Acetamiprid. Hence, the relevant endpoint in the risk assessment for acute toxic effects of Mospilan SG is the LD_{50} of 1065 mg prep/kg bw (corresponding to LD_{50} = 213 mg a.s./kg bw).

Table 6.3-1: Toxicity of Acetamiprid to mammals with reference to agreed endpoints

Species	Substance	Exposition Duration System	Results Toxicity	Reference Author Date Report No.	ICS-No.

Rat	Acetamiprid	Acute oral toxicity	$LD50_{female}$ = 314 mg a.s./kg bw	[redacted] 1997 SANCO - LoEP	-/-
Rat	EXP 60707B (chemically identical to Mospilan SG)	Acute oral toxicity	$LD50_{female}$ = 1065 mg prep/kg bw (= 213 mg a.s./kg bw)	[redacted] 1997 RD-9943 16249 TAR SANCO - LoEP	79356
Rabbit	Acetamiprid	Long-term toxicity: teratogenity	NOEL = 15 mg/kg bw/d	[redacted] 1997 SANCO - LoEP	-/-

Sanco – LoEP = SANCO/1392/2001 – Final. 16 June 2004

6.3.1.2 Exposure

Mospilan SG is an insecticide formulation containing Acetamiprid as active substance. The product is formulated as a water soluble granule (SG). It will be used against Colorado beetle (*Leptinotarsa decemlineata*) in potatoes.

Exposure to standard generic indicator species was estimated according to the 'EC Guidance Document on Risk Assessment for Birds and Mammals Council (EFSA/2009/1438). Please see chapter 6.2.1.2, page 9 for detailed information on the estimation of daily intake rates.

6.3.1.3 Risk assessment – overall conclusions

The overall conclusion on the risk assessment for mammals and the calculated TER-values are shown in the following table.

Table 6.3-2: Minimum TER values for mammals after the intended use of Mospilan SG

Substance	**Risk assessment level**	**Indicator mammal**	**Time scale**	**TER**	**TER trigger**
Mospilan SG	Screening	Small herbivorous mammal	Acute	60	10
Acetamiprid	Screening	Small herbivorous mammal	Long-term	17	5
TERs shown in bold fall below the relevant trigger.					

Based on the presumptions of the screening, the calculated TER values for the acute and long-term risk resulting from an exposure of mammals to the active substance Acetamiprid according to the GAP of the formulation Mospilan SG achieve the acceptability criteria TER $\geq$ 10 and TER $\geq$ 5, respectively,

according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for mammals, no further refinement is necessary.

Drinking water risk assessment

Drinking water assessment is not required as the ratio of effective treatment rate to toxicological endpoint does not exceed the trigger. Please refer to chapter 6.2.3.

Food chain behaviour

An assessment of the risk from secondary poisoning is not required due to log P_{OW} value of 0.8 for Acetamiprid being below the trigger. Please refer to chapter 6.2.5.

6.3.2 Toxicity exposure ratio

6.3.2.1 Acute toxicity exposure ratio (TER_A)

Screening step

In the screening step, indicator species are used. These indicators are considered to have highest exposure in a specific crop at a particular time due to their size and feeding habits and represent a worst case scenario.

The indicator mammal species for the intended uses is listed in the following table:

Table 6.3-3: Indicator species for mammals according to intended use of Mospilan SG and shortcut values. Shortcut values from section 4.1 of EFSA/2009/1438

Crop	Indicator species	Shortcut value (90th percentile RUD)
Potatoes	Small herbivorous mammal	118.4

The EU-conform relevant LD_{50} for the acute exposure scenario for Mospilan SG,is 1065 mg prep/kg bw (corresponding to 213 mg a.s./kg bw) for rats. This endpoint is most relevant for risk assessemnt because it is 1.5-times more toxic than the active substance Acetamiprid (LD_{50} = 314 mg/kg bw for rats. For the description of the estimation of daily dietary doses (DDD) and the calculation of TER-values please refer to section 6.2.2.1.

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Table 6.3-4: Acute screening risk assessment (TER_A) for mammals. See text for details

Substance	Indicator species	Application rate [kg/ha]	Shortcut value, acute	MAF	DDD [mg/kg bw]	LD_{50} [mg/kg bw]	TER_A
Mospilan SG	Small herbivorous mammal	0.125	118.4	1.2	17.76	1065	60
TER-values shown in bold fall below the relevant trigger.							

Based on the highly conservative presumptions of the screening step, the calculated TER values for the acute risk resulting from an exposure of mammals to the active substance Acetamiprid according to the GAP of the formulation Mospilan SG achieve the acceptability criteria TER ≥ 10, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. for acute effects. The results of the assessment indicate an acceptable risk for mammals due to the intended use of Mospilan SG in potatoes according to the label, no further refinement is necessary.

6.3.2.2 Short-term toxicity exposure ratio (TER_{ST})

There is no requirement for the calculation of TER_{ST} for mammals under the EFSA birds and mammals guidance document (EFSA Journal 2009; 7(12): 1438) and, consequently, a risk assessment for short-term toxicity has not been peformed.

6.3.2.3 Long-term toxicity exposure ratio (TER_{LT})

Screening step

For the reproductive risk assessment, the calculation of the long-term toxicity exposure ratio (TER_{LT}) follows in principle the same procedure as for the acute risk assessment.

The defined daily dietary dose is obtained by multiplying the application rate with the mean short-cut value (based on the mean RUD according to the new Guidance Document (EFSA, 2009)) as summarized in the following table.

Table 6.3-5: Mammal generic focal species for the intended uses of Mospilan SG and relevant shortcut values for long-term exposure

Crop	Indicator species	Shortcut value (mean RUD)
Potatoes	Small herbivorous mammal	48.3

Please refer to section 6.2.2.3 for the equation employed in the estimation of the daily dietary doses and the calculation of TER-values.

The EU-conform relevant NOEL for the long-term exposure scenario for Acetamiprid is 15 mg a.s./kg bw/d. The following table reports the calculated long-term toxicity exposure ratios (TER_{LT}) for mammals exposed to Acetamiprid following applications of Mospilan SG.

Table 6.3-6: Long-term screening risk assessment (TER_{LT}) for mammals exposed to Mospilan SG according to the intended uses

Substance	Indicator species	Application rate [kg/ha]	Shortcut value (long-term)	f_{TWA}	MAF	DDD [mg/kg bw/day]	NOEL [mg/kg bw/day]	TER_{LT}
Acetamiprid	Small herbivorous mammal	0.025	48.3	0.53	1.4	0.896	15	17
TER-values shown in bold fall below the relevant trigger.								

Based on the highly conservative presumptions of the screening step, the calculated TER values for the long-term risk resulting from an exposure of mammals to the active substance Acetamiprid according to the GAP of the formulation Mospilan SG achieve the acceptability criteria TER ≥ 5, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. for long-term effects. The results of the assessment indicate an acceptable risk for mammals due to the intended use of Mospilan SG in potatoes according to the label, no further refinement is necessary.

6.3.3 Drinking water exposure

According to the new Guidance Document from EFSA (EFSA Journal 2009; 7(12): 1438), no specific calculations of drinking water exposure and TER-values are necessary if the ratio of effective application rate (in g/ha) to the relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/kg). This is due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by birds (for further details please refer to chapter 5.5. of the Guidance Document).

The ratio of the effective application rate of 25 g a.s./ha Acetamiprid to the relevant endpoint (NOEL =15 mg a.s./kg bw/d for the rabbit, AF = 5) does not exceed the value of 50 for Acetamiprid with a Koc of 106.5 L/kg and therefore, no risk for terrestrial vertebrates other than birds is expected exposed to Acetamiprid via drinking water.

6.3.4 Details on formulation type in proportion per item

Please refer to section 6.2.4, page 14 for details on the formulation type of Mospilan SG.

6.3.4.1 Baits: Concentration of active substance in bait in mg/kg

Please refer to section 6.2.4.1.

6.3.4.2 Pellets, granules, prills or treated seed

Please refer to section 6.2.4.2.

Amount of active substance in or on each item

Please refer to section 6.2.4.2.

Proportion of active substance LD50 per 100 items and per gram of items

Please refer to section 6.2.4.2.

Size and shape of pellet, granule or prill

Please refer to section 6.2.4.2.

6.3.4.3 Acute toxicity of the formulation

Please refer to section 6.3.1 for an overview of the submitted data on the toxicity of Mospilan SG to mammals and the outcome of the risk assessment for mammals.

6.3.4.4 Metabolites

Regarding to the EU review SANCO/1392/2001-Final. 16 June 2004 the following informations of toxic effects of metabolites on mammals are known:

> The metabolites IM-0, IM-1-3, IM-2-3 and IM-1-4 are considered harmful after single oral administration.
>
> The metabolite IM-1-5 is considered toxic after single oral administration.
>
> No evidence of genotoxicity in the Ames bacterial reverse mutation assay for the metabolites IM-1-2, IM-1-4, IM-1-5, IC-0, IM-0, IM-1-3, IM-2-1, IM-2-3, IS-1-1, IB-1-1.

According to the DAR for Acetamiprid from March 2001 (RMS: GR) Volume 3; Annex B-6: Toxicology and metabolism, page 167/168, the acute toxicity of IM-1-5 with the LD_{50} of 104 and 119 mg/kg bw was observed for female and male rats, respectively. Thus the toxicity of IM-1-5 is about 2-times higher compared to the acute toxicity of the parent compound Acetamiprid with the LD_{50} of 213 mg/kg bw for rats.

However, it is assumed that the toxicity of the metabolite IM-1-5 to terrestrial vertebrates is covered by the acute- as well as long-term toxicity data for the active substance Acetamiprid since:

- Acetamiprid is rapidly and nearly completely absorbed in rats within 24 hours after administration
- Acetamiprid is extensively metabolised with 4.5% to IM-1-5 in rats. The other metabolites mentioned above are formed in higher rates and are less toxic than the parent.

- Excretion of Acetamiprid is rapid with more than 90% within 96 hours
- IM-1-5 is not formed in plants

References:

- DAR for Acetamiprid from March 2001, Volume 1, Level 2, Chapter 2.4.1
- BfR (German Federal Institute for Risk Assessment) dossier for the formulation Mospilan SG (ZN1 005655-00/06) from 2008 (AL6-2501-4865343/ AL6-2501-4877071), page 13

Thus, Acetamiprid metabolites are not further considered for the risk assessment of terrestrial vertebrates other than birds, in this submission.

6.3.4.5 Supervised cage or field trials

The risk assessment above has demonstrated that the proposed uses of Mospilan SG pose no unacceptable acute or long-term risks to mamamls, and therefore further studies are not considered necessary.

6.3.4.6 Acceptance of bait, granules or treated seeds (palatability testing)

Mospilan SG is intended for use as a foliar spray, and therefore this information is not required.

6.3.5 Effects of secondary poisoning

The EFSA birds and mammals guidance document (EFSA Journal 2009; 7(12): 1438) states that a $\log P_{ow} \geq 3$ is used to indicate that there might be a potential for bioaccumulation (see chapter 5.6 "Bioaccumulation and food chain behaviour"). Since the $\log P_{ow}$ value of Acetamiprid is 0.8 (pH not determined (neutral conditions)) and of IM-1-5 is -0.68 (EPI suite vs. 1.68; EPI web vs. 4.1), this active substance as well as this metabolite IM-1-5 are deemed to have a negligible potential to bioaccumulate in animal tissues. No formal risk assessment from secondary poisoning is therefore required.

6.4 Effects on Aquatic Organisms

6.4.1 Overview and summary

Toxicity endpoints for aquatic organisms exposed to the active substance Acetamiprid, its major metabolites as well as the formulation Mospilan SG are shown in Table 6.4-1.

Besides endpoints reported in the Conclusion on the Peer review of Acetamiprid (SANCO/1392/2001 – Final. 16 June 2004), the applicant provided further studies on the risk for aquatic organisms with Mospilan SG and Acetamiprid. All relevant study data for the assessment of the risk to aquatic organisms from the intended use of Mospilan SG are provided here. New studies are listed in Appendix 1 and summarized in Appendix 2.

For the Acetamiprid metabolites IM-1-4 and IC-0, reassessment of aquatic risk is not necessary (see section 6.1.2). The metabolite IM-1-2 will be considered in the aquatic risk assessment because it occurs with about 11 % in the water compartment and was not previously evaluated.

6.4.1.1 Toxicity

The endpoints for aquatic organisms relevant for the risk assessment are indicated in the following Table 6.4-1.

Endpoints indicated in bold deviate from EU agreed endpoints or represent just recently submitted data.

Table 6.4-1: Ecotoxicological endpoints for aquatic species exposed to Acetamiprid, its metabolite IM-1-2 and Mospilan SG with indication to agreed endpoints

Species	**Substance**	**Exposition Duration System**	**Results Toxicity**	**Reference Date author Report No.**	**ICS-No.**
Acute toxicity to fish					
Rainbow trout (*Oncorhynchus mykiss*)	Acetamiprid	4 d static	LC50 > 100.0 mg a.s./L nom	[redacted] 1997 H 088 SANCO - LoEP	42627
Fish, early life stage toxicity					
Fathead minnow (*Pimephales promelas*)	Acetamiprid	35 d flow through ELS-test	NOEC = 19.2 mg a.s./L nom (growth)	[redacted] 1997 SA 96123 SANCO - LoEP	42629
Fish bioconcentration study (not available, not required, trigger values are not reached)					
Invertebrates, acute toxicity					

Gammarus fasciatus	**Acetamiprid**	**4 d static**	**LC50 = 0.1 mg a.s./L mm**	**Putt, A. 2003 12681.6105 RD-03143**	**50458**
Daphnia magna	Acetamiprid	2 d static	EC50 = 49.8 mg a.s./L nom	Saika, O. 1997 H100 RD-09765 SANCO - LoEP	42630
Daphnia magna	EXP 60707A (chemically identical to Mospilan SG)	2 d static	EC50 > 159.0 mg prep/L nom (> 31.8 mg a.s./L)	Suteau, P. 1997 RD-00015 SA 96126 SANCO - LoEP	42656
Daphnia magna	IM-1-2 (Acetamiprid Metabolite)	2 d semi static	EC50 > 99.8 mg/L nom	Mc Elligott, A. 1997 SA 97046 RD-9940 SANCO - LoEP	42647
Invertebrates, long-term toxicity					
Daphnia magna	Acetamiprid	21 d semi static	NOEC = 5.0 mg a.s./L nom (reproduction)	Suteau, P. 1997 SA 96122 SANCO - LoEP	42650
Sediment dwelling organisms, acute toxicity					
Chironomus riparius	**Acetamiprid**	**2 d static**	**LC50 = 0.024 mg a.s./L mm**	**Putt, A. 2003 12681.6104 RD-03144**	**50455**
Chironomus riparius	**Acetamiprid 20% SP (chemically identical to Mospilan SG)**	**2 d static**	**LC50 = 0.0981 mg prep/L nom (= 0.0196 mg a.s./L)**	**Stäbler, D. 2005 20041020/01-AACr RD-00894**	**52313**
Sediment dwelling organisms, long-term toxicity					
Chironomus riparius	Acetamiprid	28 d static sediment water system with spiked water	NOEC = 0.005 mg a.s./L nom (hatching and development)	Mc Elligott, A. 1999 SA 99273 SANCO - LoEP	42721
Algae					

Scenedesmus subspicatus	Acetamiprid	3 d static	EbC50 > 98.3 mg as /L nom NOEC = 98.3 mg as /L nom	Suteau, P. 1996 SA 96121 RD-09931 SANCO - LoEP	42651
Scenedesmus subspicatus	EXP 60707B (chemically identical to Mospilan SG)	3 d static	EbC50 > 97.8 mg prep/L mm (> 19.6 mg a.s./L)	Mc Elligott, A. 1997 SA 97196 RD-00016 SANCO - LoEP	42657
Aquatic higher plants					
Lemna gibba	Acetamiprid	14 d semi-static	EC50 > 1.0 mg a.s./L NOEC = 1.0 mg a.s./L nom	Hoberg, J.R. 1997 SLI 97-7-7029 RD-00223 SANCO - LoEP	42652
Mesocosm study (not available, not required, no refinemend necessary)					

Bold = endpoint deviates from EU agreed endpoint or represents new data, prep = preparation, as = active substance, nom = nominal concentration, mm = mean measured concentrations; SANCO - LoEP = SANCO/1392/2001 – Final. 16 June 2004

The results of the aquatic toxicity effects of the tested organisms with the active substance Acetamiprid, its metabolite IM-1-2 and the formulation Mospilan SG are summarised above. The data demonstrate that the sediment-dwelling invertebrate *Chironomus riparius* is the most sensitive to Acetamiprid compared to the other tested aquatic species. Data for acute and long-term toxicity effects, with LC_{50} of 0.0196 mg a.s./L (recalculated from Mospilan SG, AF 100) and NOEC of 0.005 mg a.s./L (AF 10) on this species were shown, respectively. Hence, acute and long-term effect concentrations of Acetamiprid lay close together.

Based on all aquatic studies as well as the corresponding safety factors, the relevant endpoint is the LC_{50} of 0.0196 mg a.s./L for the sediment dwelling invertebrate *Chironomus riparius* (recalculated from Mospilan SG, AF = 100). The RAC-value for this endpoint results is the lowest compared to the other RAC-values. Thus, the risk assessment was performed using this endpoint. The RAC-value is the quotient of the ecotoxicological endpoint divided by the corresponding safety factor.

The proposal of the applicant, namely the reduction of the “assessment factor acute” for the aquatic risk assessment, was not followed on the reason that criteria of the GD on Aquatic Ecotoxicology are not fulfilled. Therefore, the “safety factor acute” = 100 still remains.

6.4.1.2 Exposure

Mospilan SG is an insecticide formulation containing Acetamiprid as active substance. The product is formulated as a water soluble granule (SG). According to the GAP table of intended uses (Appendix 3) maximal two applications are considered to take place during spring and summer with a minimum interval of 14 days between applications. It will be used against Colorado beetle (*Leptinotarsa decemlineata*) in potatoes.

Aquatic organisms may be exposed to plant protection products as a result of emission from treated fields. When Mospilan SG is applied according to good agricultural practice, the active ingredients can reach surface waters unintentionally by spraydrift during application, by run-off and drainage.

The predicted environmental concentrations in surface water (PEC_{SW}) have been calculated based on the application rates of 2 x 25 g Acetamiprid/ha. For details see Section 5, Part 5.6. of this submission.

The relevant global maximum FOCUS Step 1 and 2 PEC_{SW} for risk assessments covering all proposed use patterns are summarized in the following Table 6.4-2.

Table 6.4-2: Summary of highest global maximum FOCUS surface water PECsw and PECsed values for Acetamiprid - Step 1 and 2

Plant protection product		Mospilan SG		
Use No evaluated		16-001		
Crop		Potatoes		
Application method		Spraying		
Growth stage at first application (BBCH)		BBCH 20-39		
Crop interception		50		
Number of applications/intervall		2 x, 14 days interval		
Application rate		25 g ai/ha		
Active Substance		Acetamiprid		
FOCUS STEP	**Scenario**	**PEC_{SW} (µg/L)**		**PEC_{SED} (µg/kg)**
		Actual, 0 h	**TWA, 21 d**	**Actual, 0 h**
1		7.06	4.72	11.36
2	Southern Europe, March - May	1.04	0.70	1.67
2	Southern Europe, June - Sept.	0.82	0.54	1.31
2	Northern Europe, March - May	0.59	0.39	0.95

2	Northern Europe, June - Sept.	0.59	0.39	0.95

6.4.1.3 Risk assessment – overall conclusions

Based on the FOCUS Step 2 PECs, the aquatic TER values for Acetamiprid are below the trigger of 10, indicating an unacceptable acute and chronic risk for aquatic organisms from Acetamiprid in surface water out of spring and summer relevant FOCUS Surface Water Scenarios following application of Mospilan SG in potatoes (BBCH 20-39) at the proposed application rates. Metabolites of Acetamiprid are not considered; see section 6.1.2, page 7.

TER_A values for the most sensitive aquatic organisms based on PEC_{SW}-FOCUS calculations are summarized in the following Table 6.4-3: Aquatic TER_A values for the active substance Acetamiprid after applications of the formulation Mospilan SG.

Test organism	**EC50 (µg/L)**	**FOCUS Step**	**Scenario**	**Max. PEC_{SW} worst case (µg/L)**	**TER_A**	**Trigger value**
Chironomus riparius	19.6	2	Southern Europe, March - May	1.04	**18.8**	100
		2	Southern Europe, June - Sept.	0.82	**23.9**	
		2	Northern Europe, March - May	0.59	**33.2**	
		2	Northern Europe, June - Sept.	0.59	**33.2**	
TER-values in bold are below the relevant trigger						

and 6.4-4, page 29.

Table 6.4-3: Aquatic TER_A values for the active substance Acetamiprid after applications of the formulation Mospilan SG.

Test organism	**EC50 (µg/L)**	**FOCUS Step**	**Scenario**	**Max. PEC_{SW} worst case (µg/L)**	**TER_A**	**Trigger value**
Chironomus riparius	19.6	2	Southern Europe, March - May	1.04	**18.8**	100

		2	Southern Europe, June - Sept.	0.82	**23.9**	
		2	Northern Europe, March - May	0.59	**33.2**	
		2	Northern Europe, June - Sept.	0.59	**33.2**	
TER-values in bold are below the relevant trigger						

Acetamiprid

Regarding highest global maximum FOCUS surface water PECsw values for Acetamiprid – Step 1 and 2, TER_A values are lower than the acceptabilty trigger value of 100. This indicates that the active substance Acetamiprid poses an unacceptable risk to aquatic organisms following application of Mospilan SG at the proposed application rates in spring and summer. For the intended use 16-001, risk mitigation measures are required. Exemplarily, one possibility of requirements for risk mitigation measures is shown in the corresponding addendum from Germany (DRR Part B - Section 6, Chapter 6.3.1.3).

6.4.2 Toxicity to Exposure ratio

The risk for aquatic organisms exposed to Acetamiprid and its metabolites was assessed according to the intended uses (Appendix 3).

As first step, the initial maximum PEC_{SW} values (Step 1 and 2) were compared to the relevant acute and long-term toxicity endpoints available for Acetamiprid. Based on all studies on aquatic toxicity as well as the corresponding safety factors, the relevant endpoint for Acetamiprid is the NOEC of 0.005 mg Acetamiprid/L (*Chironomus riparius).* Risk assessment is driven by this endpoint; the ratio endpoint/corresponding safety factor is higher for all other organisms. In the Table 6.4-4 below, the TER values relative to the most sensitive endpoint of each organisms' group are given.

Table 6.4-4: Aquatic organisms: PECsw for Acetamiprid and relevant ecotoxicological endpoints for each organism' group.

Scenario	**PECsw global max (µg/L)**	**Fish acute (4 d)**	**Fish ELS (35 d)**	**Invertebrates acute**	**Invertebrates acute**	**Invertebrates prolonged**	**Sed. dweller acute**	**Sed. dweller prolonged**	**Algae**	**Aquatic higher Plants**
		Oncorhynchus mykiss	***Pimephales promelas***	***Gammarus fasciatus***	***Daphnia magna***	***Daphnia magna***	***Chironomus riparius***	***Chironomus riparius***	***Scenedesmus subspicatus***	***Lemna gibba***
		LC50 (µg/L) **>100000**	**NOEC (µg/L)** **19200**	**LC50 (µg/L)** **100**	**EC50 (µg/L)** **49800**	**NOEC (µg/L)** **5000**	**LC50 (µg/L)** **19,6**	**NOEC (µg/L)** **5**	**EbC50 (µg/L)** **>97800**	**EC50 (µg/L)** **>1000**
FOCUS Step 1										
	7.06	>14164.3	2719.5	**14.2**	7053.8	708.2	**2.8**	**0.7**	>13852.7	>141.6
FOCUS Step 2										
North Europe, March - May	0.59	>169491.5	32542.4	169.5	84406.8	8474.6	**33.2**	**8.5**	>165762.7	>1694.9
North Europe, June - Sept.	0.59	>169491.5	32542.4	169.5	84406.8	8474.6	**33.2**	**8.5**	>165762.7	>1694.9
South Europe, March - May	1.04	>96153.8	18461.5	**96.2**	47884.6	4807.7	**18.8**	**4.8**	>94038.5	>961.5
South Europe, June - Sept.	0.82	>121951.2	23414.6	122	60731.7	6097.6	**23.9**	**6.1**	>119268.3	>1219.5
TER criterion		100	10	100	100	10	100	10	10	10
TER-values in bold are below the relevant trigger										

Risk assessment – overall conclusion

Based on the calculated concentrations of Acetamiprid in surface water (PEC_{SW} FOCUS Step 1 and 2), the calculated TER values for the acute and long-term risk resulting from an exposure of aquatic organisms to Acetamiprid according to the GAP of the formulation Mospilan SG does not achieve the acceptability criteria TER ≥ 100 and TER ≥ 10, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. for acute and long-term effects. The results of the assessment indicate an unacceptable risk for aquatic organisms due to the intended use of Mospilan SG in potatoes (BBCH 20-39) according to the label.

For the intended use 16-001, risk mitigation measures are required.

6.4.3 Acute toxicity and chronic toxicity of the formulation

Please refer to Section 6.4.1.1, page 23, for a summary of the provided studies on the effects of Mospilan SG on aquatic organisms. Section 6.4.2, page 28, gives the details of the risk assessment for aquatic organisms on the basis of all available data.

6.4.4 Metabolites of Acetamiprid

For the metabolites IM-1-4 and IC-0 the aquatic risk assessment was performed during the peer review of the active substance with suitable application rates according to the indented use of Mospilan SG (16-001), please refer to Section 6.1.2, Page 6 of this submission.

According to the occurrence of max. 11 % in the water phase at day 7, but not sediment, IM-1-2 is considered further in this submission.

The applicant provided an acute toxicity study for the metabolite IM-1-2 with a LC_{50} of > 99.8 mg/L on *Daphnia magna*. Hence the metabolite IM-1-2 shows less acute toxicity to aquatic invertebrates compared to the parent compound Acetamiprid (LC_{50} = 49.8 mg a.s./L).

Taking into account, that the aquatic invertebrates long-term exposure to the active substance Acetamiprid is more toxic to invertebrates than the acute exposure, with a NOEC of 5 mg a.s./L and a LC_{50} of 49.8 mg a.s./L for *Daphnia magna*, respectively, a risk assessment of long-term effects of IM-1-2 is required.

No long-term studies are provided by the applicant, addressing long-term effects of IM-1-2 on invertebrates. However, the applicant provided a 28-day static sediment-water study, observing the long-term effects of the parent compound Acetamiprid on the species *Chironomus riparius* (NOEC = 5 µg a.s./L). This long-term study was conducted with Acetamiprid-spiked water and concentration of Acetamiprid, but not of IM-1-2, has been analysed in this study. However in the compartiment water, the Acetamiprid metabolite IM-1-2 occurs with its maximum concentration of 11% at day 7 (see Table 6.1-2, page 7). Therefore it is plausible that the long-term study of toxic effect of Acetamiprid on *C. riparius*,

captures any effects of the water metabolite IM-1-2. Therefore and due to the lack of occurrence of IM-1-2 in sediment, no further studies are necessary.

6.4.5 Accumulation in aquatic non-target organisms

Bioaccumulation of the active substance Acetamiprid (log Pow = 0.8) under natural conditions is not expected to occur and a study is not necessary to determine bioaccumulation in aquatic non-target organisms.

6.5 Effects on Bees

Regarding effects on bees the recommended use is covered by the honey bee risk assessment for the main application.

6.5.1 Hazard quotients for bees to

6.5.2 Acute toxicity of the formulation to bees

6.5.3 Effects on bees of residues on crops

6.5.4 Cage tests

6.5.5 Field tests

6.5.6 Investigation into special effects

6.5.7 Tunnel tests

6.6 Effects on Arthropods Other Than Bees

6.6.1 Overview and summary

Effects on arthropods other than bees for Mospilan SG were evaluated as part of the EU review of Acetamiprid (SANCO/1392/2001 – Final. 16 June 2004). They are considered adequate to assess the risk for non-target arthropods following the application of Mospilan SG according to the intended use against Colorado beetle in potatoe plants (indication 16-001). No new data are available.

6.6.1.1 Toxicity

The critical endpoints employed in the risk assessment for non-target arthropods are indicated in the Table 6.6-1 below. The applicant provided aged residue studies with Mospilan SG for four different species. However, the aged residue study with *Chrysoperla carnea* (indicated in bold in Table 6.6-1) is not valid and therefore disregarded in the risk assessment (see Appendix 1).

Table 6.6-1: Toxicity of Mospilan SG to non-target arthropods with reference to agreed endpoints

Species	**Substance**	**Exposition Duration System**	**Results Toxicity**	**Reference Author Date Report No.**	**ICS-No.**
Laborator tests					
Aphidius rhopalosiphi	EXP 60707A (chemically identical to Mospilan SG)	laboratory study	100 % mortality at rates of 200 and 400 g a.s./ha (recalculated from Mospilan SG)	Candolfi, M.P. 1997 96-044-1013 RD-00020 SANCO - LoEP	42713
Typhlodromus pyri	EXP 60707A (chemically identical to Mospilan SG)	laboratory study	100 % mortality at rates of 90 and 180 g a.s./ha (recalculated from Mospilan SG)	Candolfi, M.P. 1997 97-048-1013 RD-00021 SANCO - LoEP	42714
Coccinella septempunctata	EXP 60707A (chemically identical to Mospilan SG)	laboratory study	100 % mortality at rates of 90 and 180 g a.s./ha (recalculated from Mospilan SG)	Candolfi, M.P. 1997 97-051-1013 RD-00022 SANCO - LoEP	42715
Poecilus cupreus	EXP 60707A (chemically identical to Mospilan SG)	laboratory study	3.3 % mortality at rates of 200 and 0 % at 400 g a.s./ha (recalculated from Mospilan SG)	Candolfi, M.P. 1997 RD-00019 SANCO - LoEP	42710

Extended laboratory study					
Aphidius rhopalosiphi	Acetamiprid 20% SP (chemically identical to Mospilan SG)	2 d extended laboratory study (3 D)	LR50 = 9.7 g prep/ha nom (mortality) (= 1.94 mg a.s./ha)	Moll, M. 1999 6022002 RD-IIM059 C008456 SANCO - LoEP	42722
Typhlodromus pyri	Acetamiprid 20% SP (chemically identical to Mospilan SG)	14 d extended laboratory study (2 D)	LR50 (7 d) = 143.48 g prep/ha nom (mortality) (= 29.7 g a.s./ha)	Lührs, U. 1999 6021062 C008457 SANCO - LoEP	42723
Extended laboratory study - Aged residue					
Aphidius rhopalosiphi	EXP60707A (chemically identical to Mospilan SG)	Aged residue test with fresh (0 d) as well as 7, 14 and 21 days old residues of the formulation	LR50 (2 d) < 65 g prep/ha fresh residue (mortality) (< 13 g a.s./ha) 65 g prep/ha (13 g a.s./ha): Mortality corr.: 90 % (0 d), 10 % (7 d), 0.0 % (14 d), 0.0 % (21 d) Reproduction: -/- (0 d) 42.4 % (7 d), -10.6 % (14 d), 32.5 % (21 d) 500 g prep/ha (100 g a.s./ha): Mortality corr.: 70 % (0 d), 66.7 % (7 d), 31.6 % (14 d), 0.0 % (21 d) Reproduction: -/- (0 d), 54.7 % (7 d), 20.7 % (14 d), 34.6 % (21 d)	Schuld, M. 2001 20011073/01-NEAp RD-II 02083 SANCO - LoEP	50485
Typhlodromus pyri	EXP60707A (chemically identical to Mospilan SG)	Aged residue test with fresh (0 d) as well as 7 and 14 days old residues of the formulation	LR50 (7 d) > 500 g prep/ha (mortality) (> 100 g a.s./ha) 65 g prep/ha (13 g a.s./ha): Mortality corr.: -1.1 % (0 d), -2.1 % (7 d) Reproduction: 6.3% (0 d)	Adelberger, I. 2001 20011073/01-NETp RD-II 02082 SANCO - LoEP	50493

			500 g prep/ha (100 g a.s./ha): Mortality corr.: 39.1 % (0 d), 13.8 % (7 d), 5.1 % (14 d) Reproduction: -1.1 % (14 d)		
Coccinella septempunctata	EXP60707A (chemically identical to Mospilan SG)	Aged residue test with fresh as well as 7, 14, 21 and 28 days old residues of the formulation	LR50 < 65 g prep/ha mortality (< 13 g a.s./ha) 65 g prep/ha (13 g a.s./ha): Mortality corr.: 41.7 % (0 d), 2.1 % (7 d), 2.1 % (14 d) Reproduction: - 18.7 % (7 d) 500 g prep/ha (100 g a.s./ha): Mortality corr.: 100 % (0 d), 44.7 % (7 d), 63.8 % (14 d), 23.9 % (21 d), 26 % (28 d)	Hirth, N. 2002 20011073/01-NECs RD-II 02081 SANCO - LoEP	50513
Chrysoperla carnea	**EXP60707A (chemically identical to Mospilan SG)**	**Aged residue test with fresh as well as 7 and 14 days old residues of the formulation**	**LR50 > 500 g prep/ha mortality (> 100 g a.s./ha)** **65 g prep/ha (13 g a.s./ha):** **Mortality corr.: 4.5 % (0 d), 10 % (7 d), -4.4 % (14 d)** **Reproduction: 92% (0 d), 91.2 % (7 d)** **500 g prep/ha (100 g a.s./ha):** **Mortality corr.: 18.2 % (0 d), 6.3 % (7 d), 6.7 % (14 d)** **Reproduction: 89 % (0 d), 87.2 % (7 d)**	**Hirth, N.** **2001** **20011073/01-NECc** **RD-II 02084** **SANCO - LoEP**	**50516**

Bold = endpoint disregarded in risk assessment, SANCO – LoEP = SANCO/1392/2001 – Final. 16 June 2004, prep = preparation, nom = nominal concentration,

As shown in the Table 6.6-1 above, for the assessment of the risk by Mospilan SG to terrestric arthropods following intended use, several endpoints and effect values are available. From the non-target arthropod species tested on artificial substrate, the most sensitive species is the leaf dwelling parasitoid *Aphidius rhopalosiphi* with a LR_{50} of 9.7 g formulation per ha.

6.6.1.2 Exposure

In field

Mospilan SG is an insecticide formulation containing Acetamiprid as active substance. The product is formulated as a water soluble granule (SG). According to the GAP table of intended uses (Appendix 3) maximal two applications are considered to take place during spring and summer with a minimum interval of 14 days between applications. It will be used against the leaf-dwelling Colorado beetle (*Leptinotarsa decemlineata*) in potatoes.

Non-target arthropods living in the crop can be exposed to residues from Mospilan SG by direct contact either as a result of overspray or through contact with residues on plants and soil or in food items.

The in-field exposure, given as predicted environmental rates, PER, for non-target arthropods resulting from the intended uses of Mospilan SG is calculated according to published agreement after ESCORT 2 workshop (Candolfi *et al.* 2001[3] -hereafter referred to as 'Guidance Document') using the following equation:

$$PER_{in-field} = Application\ rate\,(\text{g prep / ha}) \times \text{MAF}$$

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

MAF values for given numbers of applications are listed in the Guidance Document, Appendix III (Candolfi *et al.* 2001[3]).

Since Mospilan SG will be applied in leafy potatoe plants (BBCH 20-39) by spraying in foliar and soil (with interception) application schemes, the worst case application scheme "foliar" was identified and chosen for the risk assessment. The realistic worst case scenario is the "foliar- or leaf application scenario", because due to interception through arable crops, the exposure of leaves is expected to be higher than the exposure of the soil-surface. Furthermore, from the tested non-target leaf and soil dweller

[3] 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.

arthropods, the leaf dwelling group is obviously more sensitive (see Table 6.6-1 above), as shown for example with the parasitoid *A. rhopalosiphi* (LR_{50} = 9.7 g prep/ha), being the most sensitive tested species and regarding the intended use of Mospilan SG, potatoe plants at BBCH 20 -39 are sprayed against the leaf dwelling Colorado beetle (*Leptinotarsa decemlineata*).

The maximum predicted environmental rate occurring in the field ($PER_{in\text{-}field}$) after application of Mospilan SG (equation above), at the maximum application of 2 x 125 g Mospilan SG per hectar, is 212.5 g preparation per hectar, as presented in the following Table 6.6-2.

Table 6.6-2: In-field predicted environmental rates (PER) for the intended use of Mospilan SG.

Substance	**Application rate [g prep/ha]**	**MAF**	**$PER_{in\text{-}field}$ [g prep/ha]**
Mospilan SG	125	1.7	212.5

Off-field

Exposure of non-target arthropods living in non-target off-field areas to Mospilan SG 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[4]) as shown in the following equation:

$$PER_{off-field} = \frac{Max\ \ PER_{in-field}\ x \left(\%-drift \Big/ 100 \right)}{vegetation\, distribution\ \ factor\ (vdf)}$$

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 vdf of 10 is recommended by the Guidance Document, but has been questioned. The risk assessment procedure here considers a vdf of 5 more appropriated. For endpoints resulting from 3-dimensional studies, i.e. where spray treatment is applied onto whole plants, the vdf is not used.

[4] BBA (Biologische Bundesanstalt für Land- und Forstwirtschaft) (2000): Abtrifteckwerte für Flächen- und Raumkulturen sowie für den gewerblichen Gemüse-, Zierpflanzen- und Beerenobstanbau. Bundesanzeiger 100, 26. Mai 2000, Köln, pp. 9879.

Available data for the effects of Mospilan SG on non-target arthropods, other than bees, indicate that *A. rhopalosiphi* is the most sensitive of all tested species. Relevant for the risk assessment are the results from a 3-dimensional extended laboratory study with *Aphidius rhopalosiphi* with a LR_{50} of 9.7 g Mospilan SG/ha (see Table 6.6-1 above). Regarding the results of the 3-dimensional extended laboratory study with *Aphidius rhopalosiphi* exposed to Mospilan SG, the vdf does not have to be considered.

Reduction of the amount of drift reaching the off-field areas can be achieved by implementing an in-field buffer strip of a given width. The resulting drift values (according also to spray-drift predictions of Ganzelmeier & Rautmann (2000)[5]) as well as the predicted environmental off-field rates ($PER_{off\text{-}field}$; equation above) of Mospilan SG are given in the Table 6.6-3 below.

The drift factor (= drift [%] / 100) of the application rate (2 applications; 82nd percentile) is at 1 m distance 0.0238, at 5 m distance 0.0047 and at 10 m distance 0.0024.

Table 6.6-3: Off-field predicted environmental rates (PER) of Mospilan SG at increasing distances from the sprayed areas following intended uses

Study type	max. application rate (g prep/ha)	MAF	max. $PER_{in\text{-}field}$ (g prep/ha)	Drift (%)	Vegetation distribution factor (vdf)	$PER_{off\text{-}field}$ (g prep/ha)
3-dimensional	125	1.7	212.5	2.38 (1 m)	1	5
				0.47 (5 m)		1
				0.24 (10 m)		0.5

Risk assessment – overall conclusions

The outcome of the risk assessment for non-target arthropods exposed to Mospilan SG is given in Table 6.6-6 below.

Higher tier

[5] Ganzelmeier H., Rautmann D. (2000) Drift, drift-reducing sprayers and sprayer testing. Pesticide Application, Aspects of Applied Biology 57

Table 6.6-4: Acceptability criteria for higher tier data and minimal TER values for arthropod species other than bees after use of Mospilan SG

Test substance	Species	Test type	Endpoint LR50 (g prep/ha)	$PER_{in-field}$ (g prep/ha)	effects <50% at calc. rate?	$PER_{off-field}$ (x m) (g prep/ha)	$PER_{off-field}$ x correction factor 5	effects <50% at calc. rate?	$TER_{off-field}$
Mospilan SG	*Aphidius rhopalosiphi*	3 dimensional	9.7	212.5	No	5 (1 m)	25	No	1.94
						1 (5 m)	5	Yes	9.7
						0.5 (10 m)	2.5	Yes	19.4

Based on the higher tier risk assessment for the application of Mospilan SG according to the GAP in in-field areas, the risk resulting from an exposure of non-target arthropods to Mospilan SG achieves more than 50 % toxic effect, 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 unacceptable risk for non-target arthropods other than bees due to the intended use 16-001 of Mospilan SG. However, the applicant provides three valid aged residue studies with *Aphidius rhopalosphi*, *Typhlodromus pyri* and *Coccinella septempunctata* at 500 g prep/ha, which indicate that repopulation 4 weeks after treatment is possible. In conclusion, the proposal of the applicant was followed and therefore the in-field risk for non-target arthropods other than bees, resulting from exposure to Mospilan SG (intended use 16-001), is acceptable.

For the off-field area, an acceptable risk is indicated, if the acceptability criteria, such as less than 50 % effects at calculated drift rates resp. TER $\geq$ 5 (higher Tier) according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. are fulfilled.

Based on the calculated concentrations of Mospilan SG in off-field areas, intended use 16-001 according to the GAP, the risk resulting from an exposure of non-target arthropods does not achieve the acceptability criteria.

The extended laboratory study with *A. rhophalosiphi* in form of an aged-residue-design will not be considered in the refined risk assessment for the off-crop-area, because the exposure with fresh residues is relevant for the risk assessment regarding recovery of the population in the treated area. In the aged-residue-study with *A. rhophalosiphi*, strong effects with 90% mortality were observed following exposure to fresh residues from application rates of 65 and 500 g prep/ha.

Risk mitigation measures are required to reduce the exposure of non-target arthropods to Mospilan SG for the intended use 16-001 in off-field areas comparable to a 5 m in-field buffer strip. Management practices relevant for Germany are given in the respective Addendum.

6.6.2 Risk assessment for Arthropods other than Bees

6.6.2.1 In-field

Higher Tier

The risk for non-target arthropods exposed in-field to Mospilan SG was assessed by comparing the predicted environmental rate (PER $_{\text{in-field}}$) to the lowest lethal rate (LR_{50} = 9.7 g Mospilan SG/ha) estimated in toxicity tests with the leaf-dwelling non-target arthropod *Aphidius rhopalosiphi*. 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.

Table 6.6-5: Risk assessment for non-target arthropods other than bees and acceptability criteria for higher tier data

Species	**LR_{50} (g prep/ha)**	**PER $_{\text{in-field}}$ (g prep/ha)**	**effects < 50% at calc. rate?**
Aphidius rhopalosiphi	9.7	212.5	No

The results indicate that Mospilan SG poses high risk to non-target arthropods in-field following application according to the intended use 16-001.

Risk mitigation measures have to be implemented.

6.6.2.2 Off field

HQ approach

In order to assess the risk of Mospilan SG to non-target arthropods in off-field areas, the predicted environmental rate in the Off-field (see chapter 6.6.1.2) is compared to the toxicity endpoints according to the following formula:

$$Off - field\ \ HQ = \frac{Off - field\ \ PER}{LR_{50}} \times correction\ \ factor$$

where:

Correction factor (also ‘safety factor’) = amounts to 10 in conjunction with Tier I data from tests on glass plates; amounts to 5 for Tier II data from extended laboratory tests/field tests. The factor accounts for extrapolation from testing few representative species to the species diversity expected in off-crop areas.

Higher Tier

With regard to extended laboratory tests and semi-field tests, lethal and sublethal effects of less than 50 % at the calculated deposition rates are considered acceptable provided that the tests covered the appropriate field rate.

Regarding the extended 3-dimensional test system for Aphidius rhophalosiphi a correction factor of 5 is used for the calculation of HQ off-field. Calculated HQ off-field values are given in the following Table 6.6-6.

Table 6.6-6: Acceptability criteria for higher tier non-target arthropods data

Species	Test type	LR50 (g prep/ha)	Distance (m)	PER $_{off-field}$ (g prep/ha)	Deposition rate (PER $_{off-field}$ x correction factor) (g prep/ha)	HQ off-field	effects <50% at calc. rate?
Aphidius rhopalosiphi	3 - dimensional	9.7	1	5	25	2.6	No
			5	1	5	0.5	Yes
			10	0.5	2.5	0.26	Yes

At the calculated deposition rate of 25 g Mospilan SG per ha, calculated for 1 m distance to the off-field area and for the LR_{50} of 9.7 g prep/ha (*A. rhopalosiphi*), effects higher than 50 % are expected to occur (HQ > 2), indicating that Mospilan SG poses an unacceptable risk to non-target arthropods in off-field areas. At the calculated deposition rate of 5 and 2.5 g Mospilan SG per ha, calculated for 5 and 10 m distance, respectively, effects less than 50% are expected to occur (HQ < 2), indicating an acceptable risk of Mospilan SG to non-target arthropods in off-field areas.

Risk mitigation measures have therefore to be implemented, comparable to 5 and 10 m vegetated buffer stripes.

TER approach

Additionally to the HQ-approach (higher tier), the assessment of the off-field risk to non-target arthropods due to an exposure to Mospilan SG was performed on the basis of the calculation of toxicity-exposure ratios (TER values) according the following formula:

$$TER = \frac{L(E)R50}{PER_{Off-field}}$$

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 laboratory or field tests).

The resulting TER off-field values are given in the following Table 6.6-7. Since the calculated TER values for the model species *Aphidius rhopalosiphi* for non-target arthropods were below the trigger of 5, risk mitigation measures have to be implemented. They correspond to 5 meter buffer strip in-field.

Table 6.6-7: Calculated TER values for non-target arthropods exposed to Mospilan SG in off-field areas according to intended uses

Species	Test type	Vegetation distribution factor (vdf)	LR_{50} (g prep/ha)	$PER_{in\text{-}field}$ (g prep/ha)	Distance (m)	Drift [%]	$PER_{off\text{-}field}$ (g prep/ha)	TER (Trigger = 5)
Aphidius rhopalosiphi	3 dimensional	1	9.7	212.5	1	2.38	5	**1.94**
					5	0.47	1	9.7
					10	0.24	0.5	19.4
TER values in bold are below the trigger.								

Based on the calculated drift rates of Mospilan SG in off-field areas, not all of the calculated TER values for the risk resulting from an exposure of non-target arthropods to Mospilan SG according to the GAP of the formulation Mospilan SG 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.

Risk mitigation measures have to be implemented. Exemplarily, management practices are given in the national addendum from Germany.

6.7 Effects on Earthworms, other Non-target Soil Organisms and Organic Matter Breakdown

6.7.1 Overview and summary

Earthworms, other soil non-target macro- and mesofauna as well as soil organisms involved in the breakdown of dead organic matter will be exposed to plant protection products containing Acetamiprid whenever contamination of soil may occur as a result of the intended uses of Mospilan SG.

Effects on earthworms and other soil non-target organisms resulting from an exposure to the active substance Acetamiprid were evaluated as part of the EU review of Acetamiprid (SANCO/1392/2001 – Final. 16 June 2004). All relevant study data for the assessment of the risk to earthworm and other soil non-target macro- and mesofauna from the intended uses of Mospilan SG are provided here. No new data are available.

6.7.1.1 Toxicity

The endpoints for soil organisms relevant for the risk assessment are indicated in the following Table 6.4-1.

Table 6.7-1: Ecotoxicological endpoints for terrestrial non-target soil fauna and organic matter breakdown following exposure to Acetamiprid, its metabolites IM-1-2 and IM-1-5 and Mospilan SG with indication to agreed endpoints

Species	**Substance**	**Exposition** **Duration** **System**	**Results** **Toxicity**	**Reference** **Author** **Date** **Report No.**	**ICS-No.**
Eisenia foetida	Acetamiprid	Acute 14d	LC50 = 9.0 mg a.s./kg soil dw Mortality	Johnson, J.A. 1994 NPS63/932526 SANCO - LoEP	42653
Eisenia foetida	EXP60707A (chemically identical to Mospilan SG)	Acute 14 d	LC50 = 18.3 mg prep/kg soil dw (= 3.66 mg a.s./kg soil dw)	Suteau, P. 1996 SA 96128 RD-00023 SANCO - LoEP	42717
Eisenia foetida	EXP60707A (chemically identical to Mospilan SG)	Chronic 8 weeks	NOEC = 1.26 mg prep/kg soil dw (= 0.252 mg a.s./kg soil dw) Reproduction	Goßmann, A. 1997 2540022 RD-00024 SANCO - LoEP	42718
Eisenia fetida	IM-1-2	Acute 14 d	LC50 > 1000 mg/kg soil dw	Lührs, U. 2003 15261021 B004154 SANCO - LoEP	50427
Eisenia foetida	IM-1-5	Acute 14 d	LC50 > 1000 mg/kg soil dw	Rodgers, M. 2002 NOD 217/024192 C028891 RD-II 02451 SANCO - LoEP	50425

Eisenia fetida	IM-1-5	Chronic 8 weeks	NOEC = 62.5 mg/kg soil dw	Lührs, U. 2003 15723022 C029229 SANCO - LoEP	50426
Folsomia candida	IM-1-5	extended laboratory study (3 D), 28 d	NOAEC = 12.5 mg/kg dw soil (Reproduction) EC50 > 62.5 mg/kg dw soil (Reproduction)	Klein, S. & Rosenkranz, B. 2003 15721016 RD-03058 SANCO - LoEP	50423
Aleochara bilineata	IM-1-5	extended laboratory study (3 D), 28 d	NOEC = 2.5 mg/kg dw soil (Reproduction) EC50 > 62.5 mg/kg dw soil (Reproduction)	Schmitzer, S. 2003 15722070 RD-03101 SANCO - LoEP	50424

Bold = endpoint deviates from EU agreed endpoint or represents new data, prep = preparation, as = active substance, nom = nominal concentration, SANCO – LoEP = SANCO/1392/2001 – Final. 16 June 2004

The proposal of the applicant was followed. Based on all available studies for the effect of the active ingredient Acetamiprid, the relevant acute endpoint for Acetamiprid LC_{50} = 3.66 mg a.s./kg soil dw (*Eisenia foetida*) recalculated from Mospilan SG (LR50 = 18.3 mg prep/kg soil dw. The one and therefore relevant chronic endpoint value for Mospilan SG is the NOEC of 1.26 mg prep/kg soil dw, corresponding to 0.252 mg a.s./kg soil dw (*Eisenia foetida*). Risk assessment is based on the formulation, because it si more toxic than the active substance alone. Both relevant endpoints, used for the following risk assessment, are listed in the EU review report SANCO/1392/2001 – Final. 16 June 2004.

The log P_{OW} value 0.8 for Acetamiprid is below the agreed trigger value of 2. Therefore, no correction of the endpoints is required in order to account for the relatively high organic matter content of the artificial test soil compared to agricultural soils and a resulting lower bioavailability of the active substance to soil organisms.

6.7.1.2 Exposure

According to the GAP table (Appendix 3), the preparation Mospilan SG is intended to be applied two times during spring and summer with a maximum application rate of 125 g formulation/ha, corresponding to 25 g a.s./ha. It will be used against Colorado beetle (*Leptinotarsa decemlineata*) in potatoes.

For the calculation of predicted environmental concentrations in soils (PEC soil), reference is made to the environmental fate section (Part B, Section 5) of this submission. The resulting maximum PEC soil values for the active substances Acetamiprid is presented in the Table 6.7-2 below. The risk of the soil

degradation products of Acetamiprid, such as IM-1-4 and IC-0, will not be reassessed in this submission (please refer to section 6.1.2). The metabolites IM-1-2 and IM-1-5 occur with about 55 and 20 % in the water compartment (see Table 6.1-2), respectively, and were not previously ecotoxicolgically evaluated for the EU approval, therefore they are considered in this submission. For further details please see Part B, Section 5 of this core dossier.

Calculations considered the maximum application of 2 x 125 g formulation/ha and a minimum of 50 % foliar interception for applications to potatoes at growth stage BBCH 20-39. PEC values for the soil metabolites were calculated considering the maximum percentage of their formation observed in either the aerobic or anaerobic soil degradation studies and correcting for molecular weight.

All calculations assumed an even distribution of the substances in the top 5 cm horizon with a soil bulk density of 1.5 g/cm^3. Accumulation in the soil profile due to the persistence of Acetamiprid was considered if necessary.

For the worst-case application scenario of Mospilan SG, results of PEC soil calculations are summarized in the following Table 6.7-2 (please see also Section 5 of this submission).

Table 6.7-2: Maximum predicted environmental concentrations in soil (PEC) following application of Mospilan SG.

plant protection product		**Mospilan SG**				
use		16-001: potatoes (BBCH 20-39)				
Number of applications/intervall		2 / 14 d				
application rate		25 g a.s./ha				
crop interception		50 %				
Acetamiprid / Mospilan SG	**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)**
Acetamiprid	2 x 12.5 = 25	0.0235	0.0141	-	-	-
IM-1-2 (max. 55 %, MG-ratio 1.08)	2 x 7.43 = 14.86	0.0101	0.0035	-	-	-
IM-1-5 (max. 20.2 %, MG-ratio 0.89)	2 x 2.25 = 4.5	0.0059	0.0058	20	0.0020	0.0079

PEC_{act} = maximum annual soil concentration for a soil depth of 5 cm; PEC_{bkgd}= background concentration in soil considering a tillage depth of 20 cm (arable crop) or 5 cm (permanent crops); PEC_{accu} = accumulated soil concentration

6.7.2 Risk assessment – TER values and overall conclusions

Based on the predicted concentrations of Acetamiprid in soils, the TER values describing the acute and longterm risk for earthworms and other non-target soil organisms, following exposure to Acetamiprid according to the GAP of the formulation Mospilan SG, 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.

Results of the risk assessment for earthworms and other soil macro- and mesofauna, exposed to Mospilan SG according to the intended use (16-001), are summarized in the following Table 6.7-3.

Table 6.7-3: Ecotoxicological endpoints, PEC soil values and Toxicity to Exposure ratios to assess the risk for earthworms and other soil macro- and mesofauna following application of Mospilan SG according to the intended uses

Test substance	**Intended use (g a.s./ha)**	**Species**	**Timescale**	**Endpoint (mg/kg dw soil)**	**PEC soil (mg/kg soil dw)**	**TER**	**TER trigger**
Acetamiprid	2 x 25	*E. foetida*	Acute	LC50 = 3.66	0.0235	156	10
		E. foetida	Long-term	NOEC = 0.252		11	5
IM-1-2	-/-	*E. fetida*	Acute	LC50 >1000	0.0101	>99010	10
IM-1-5	-/-	*E. foetida*	Acute	LC50 >1000	0.0059	>169492	10
		A. bilineata	Long-term	NOEC = 2.5		424	5
TER values in bold are below the trigger							

The the acute and chronic risk assessment for soil organisms due to the intended use of Mospilan SG in potatoes according to the label indicate an acceptable risk. The resulting acute and long-term TER-values for Acetamiprid as well as the major soil degradation products IM-1-2 and IM-1-5 are above the trigger.

Consequences for authorization:

None.

6.7.3 Toxicity to Exposure Ratio

6.7.3.1 Acute risk

The potential acute risk for earthworms and other non-target soil macro- and mesofauna resulting from an exposure to Acetamiprid as well as its major soil degradation products IM-1-2 and IM-1-5 by comparing the maximum PEC soil with the 14-day LC_{50} value to generate acute TER values (TER_A).

The TER_A was calculated as follows:

$$TER_A = \frac{LC_{50}\ (mg/kg)}{PEC_{soil}\ (mg/kg)}$$

The resulting TER_A values are shown in Table 6.7-3.

For Acetamiprid as well as the soil metabolites IM-1-2 and IM-1-5 the TER values are above the trigger value 10.

6.7.3.2 Chronic risk

Since the degradation in soil is relatively fast with a DT_{90} of < 365 d (Kinetic, laboratory/field data, Guidance Document on Terrestrial Ecotoxicology SANCO/10329/2002 rev2 final), there is no need to address the long term risk of the active substance Acetamiprid ($DT_{90\ field}$ = 36.33 d; SFO, field data) and its metabolite IM-1-2 ($DT_{90\ max}$= 8.6 d) for earthworms and other soil macro- and mesofauna.

The major soil metabolite IM-1-5 of Acetamiprid degrades slowly with DT_{90} values > 1000 d (for details, see Section 5) and thus meeting the criterium DT_{90} > 365 d. Therefore, a long term risk assessment is conducted as shown in Table 6.7-3 above, resulting in TER_{LT}-value of 424for the NOEC = 2.5 mg/kg dw/soil (*A. bilineata*), which is above the TER trigger value of 5

In conclusion, the chronic risk for earthworms exposed to Acetamiprid as well as the metabolites IM-1-2 and IM-1-5 is assessed as ecotoxicologically non relevant.

According to the Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 rev2 final. 17. October 2002), a test for assessing effects on organic matter breakdown (litterbag) is required where:

- $DT_{90\ field}$ of the active substance is > 365 days or
- $DT_{90\ field}$ of the active substance is between 100 and 365 days and
- Effects on soil microflora > 25 % or TER_{LT} earthworm < 5 or
- Collembola TER_{LT} < 5.

None of these criteria are met for Acetamiprid ($DT_{90\ field}$ = 36.33 d; SFO, field data) and no risk was identified for soil fauna, soil micro-organisms and non-target arthropods. Therefore, there is no need to address the long term terrestrial risk of Acetamiprid. However, long-term TER values are below the trigger and shown in Table 6.7-3, above.

The chronic risk for earthworms, other non-target soil macro- and mesofauna and organic matter breakdown resulting from an exposure to Acetamiprid as well as the soil degradation product IM-1-5 is calculated, by comparing the maximum PEC soil with the NOEC value to generate chronic TER values (TER_{LT}), as shown in the following equation:

$$TER_{LT} = \frac{NOEC\,(mg/kg)}{PEC_{soil}\,(mg/kg)}$$

The resulting TER_{LT} values are shown in Table 6.7-3 above.

6.7.4 Residue content of earthworms

The log P_{OW} value of Acetamiprid is < 3. Thus, Acetamiprid is not deemed to bioaccumulate in earthworms. Therefore, studies determining residue content of Acetamiprid in earthworms are not necessary.

6.8 Effects on Soil Microbial Activity

6.8.1 Overview and summary

Soil microorganisms will be exposed to plant protection products containing Acetamiprid whenever contamination of soil may occur as a result of the intended uses of Mospilan SG.

Effects on soil microorganisms resulting from an exposure to Mospilan SG were evaluated as part of the EU review of Acetamiprid. All relevant study data for the assessment of the risk to soil microorganisms from the intended uses of Mospilan SG are provided here. No new studies are available.

6.8.1.1 Toxicity

Table 6.8-1: Ecotoxicological endpoints for soil microbial activity following exposure to Acetamiprid with indication to agreed endpoints

Process	**Substance**	**Exposition Duration System**	**Results Toxicity**	**Reference Author Date Report No.**	**ICS-No.**
C-transformation	Acetamiprid	200 g a.s./ha (= 0.267 mg a.s./kg soil dw (5 cm)) 28d	effects < 25% compared to untreated control	Foster, J. 1997 SANCO - LoEP	-/-
N-tranformation	Acetamiprid	200 g a.s./ha (= 0.267 mg	effects < 25% compared to untreated control	Foster, J. 1997	-/-

		a.s./kg soil dw (5 cm)) 28d		SANCO - LoEP	

SANCO – LoEP = SANCO/1392/2001 – Final. 16 June 2004

6.8.1.2 Exposure

Please refer to section 6.7.1.2 above for the predicted environmental concentrations in soil (PEC soil) of Acetamiprid.

6.8.1.3 Risk assessment –overall conclusions

The Predicted Environmental Concentrations of the active substance Acetamiprid and the major soil degradation products are below the concentrations at which acceptable effects (>± 25%) regarding the soil microbial activity were observed after 28 days of exposure to Acetamiprid. The results of the comparison expressed as Margin of Safety (MoS) are presented in the following Table 6.8-2.

In the ecotoxicological risk assessment, margin of safety is calculated by dividing the threshold effect level (or concentration) of toxicity (e.g. NOEC) by the expected (or predicted) environmental concentration (PEC). It can be expressed in the equation form as follows:

$$MoS = NOEC/PEC$$

Table 6.8-2: Summary of risk assessment for soil micro-organisms exposed to Acetamiprid

Substance	**Test type**	**Effects <25% (NOEC) (mg/kg soil dw)**	**Maximum initial PEC soil (mg/kg soil dw)**	**MoS (NOEC/PEC)**
Acetamiprid	C-transformation	0.267	0.0235	11.4
	N-transformation	0.267		11.4

PEC_{act} = maximum annual soil concentration for a soil depth of 5 cm

For the active ingredient in Mospilan SG and metabolites, the soil concentrations, which caused no deviations greater than ±25% in the activity of the soil microorganisms, are at about 10-times higher than the corresponding maximum PEC soil. The resulting margins of safety (NOEC/expected environmental concentrations) would be approximately 11.4 for Mospilan SG. Thus, the highest recommended rate of Acetamiprid applied according to the intended use of Mospilan SG, does not elicit a toxic response. Considering concurrent exposure to the active ingredient in Mospilan SG at the time of application, a low risk to soil microflora is concluded.

Based on the predicted concentrations of Acetamiprid in soils, the risk to soil microbial processes following exposure to Acetamiprid according to the GAP of the formulation Mospilan SG 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.

Risk mitigation measures are not required.

6.9 Effects on Non-Target Plants

6.9.1 Overview and summary

Effects on non-target plants resulting from an exposure to Acetamiprid were evaluated as part of the EU review of Acetamiprid (DAR from March 2001; RMS: GR). In this review Volume 3, Annex B-9, Section B 9.9 a statement on a study summary of phytotoxic and plant regulatory effects of Acetamiprid, on neighboring crops, processed fruits and proliferative material, is given. Regarding relevant effective field application rates of Acetamiprid, no phytotoxicity and plant regulatory effects were observed and therefore a safe use of Acetamiprid at testet rates was concluded. However, the evaluation is not complying with the actual Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 rev2 final. 17. October 2002).

The applicant provided data for the formulation EXP 80667A, containing 71.1% Acetamiprid WP (wettable powder), but not for Mospilan SG (water soluble granule), containing 20% Acetamiprid. Detailed identity of EXP 80667A is unknown, thus comparability of Mospilan SG and EXP80667A is unknown. Therefore, effects of co-formulants of the formulation Mospilan SG are not covered by the data and should optionally be provided at the national level.

However based on the two provided studies, in form of vegetative vigour and seedling emergence, effect rates can be obtained for Acetamiprid, recalculated from the formulation EXP 80667A.

On the basis of the provided data the risk of toxic effects to non-target terrestrial plants, due to exposure according to the intended use of Mospilan SG, is acceptable. No uncertainty is given based on the effect concentrations for the active substance Acetamiprid, recalculated from the formulations EXP-80667A (71.1% Acetamiprid, wettable powder (WP)) and Mospilan SG (20% Acetamiprid, water soluble granule (SG)), but effects of co-formulants are not covered. Typically, the active substance is responsible for the toxic effects in plants and for insecticides, such as Mospilan SG, no toxic effects are expected to occur in plants. In this context, available study data are suitable for the risk assessment in this submission for non-target plants exposed to Mospilan SG according to the inteded use 16-001.

The most sensitive species *Lactuca sativa* reacted with the lowest and relevant endpoint, ER_{50} of 51.7 g a.s./ha in the vegetative vigour test, for the risk assessment for the exposure of non-target plants to the active substance Acetamiprid, according to th intended use of Mospilan SG.

6.9.1.1 Toxicity

There are no agreed end-points in the EU-Review of Acetamiprid (SANCO/1392/2001 – Final. 16 June 2004).

For the active substance Acetamiprid, recalculated from the formulation EXP 80667A (71.1% Acetamiprid WP), data of the seedling emergence test as well as of the vegetative vigour test with four monocotylic and 6 dicotylic plants are available and summarised in Table 6.9-1 below. From the tested species, the relevant endpoint was found for *Lactuca sativa*, which reacted most sensitive in the vegetative vigour test with ER_{50} of 51.7 g a.s./ha, recalculated from the formulation EXP 80667A. Due to the fact that, the active substance is typically responsible for toxic effects in plants and for insecticides, such as Mospilan SG, no toxic effects are expected to occur in plants and this endpoint is accepted for the risk assessment in this submission.

Table 6.9-1: Ecotoxicological endpoints for non-target plants following exposure to Acetamiprid with indication to agreed endpoints

Species	**Substance**	**Exposition Duration System**	**Results Toxicity**	**Reference Author Date Report No.**	**ICS-No.**
Seedling emergence					
Most sensitive sp. = *C. sativus* 10 species were tested: *Brassica oleracea, Zea mays* (mono), *Cucumis sativus, Lactuca sativa, Avena sativa* (mono), *Allium cepa* (mono), *Lolium perenne* (mono), *Glycine max, Lycopersicon esculentum, Brassica rapa*	Acetamiprid 71.1 % WP (EXP-80667A)	Seedling emergence 14 d	ER50 = 650.2 g a.s./ha (recalculated from formulation) NOEC = 90.8 g a.s./ha (recalculated from formulation) Stem length	Teixeira, D. 1999 97-12-7184 RD-II 02121	50538
Vegetative vigour					
Most sensitive sp. = *L. sativa* 10 species were tested: *Brassica oleracea, Zea mays* (mono), C*ucumis sativus, Lactuca sativa, Avena sativa* (mono), *Allium cepa* (mono), *Lolium perenne* (mono), *Glycine max, Lycopersicon esculentum, Brassica rapa*	Acetamiprid 71.1 % WP (EXP-80667A)	Vegetative vigour 14 d	ER50 = 51.7 g a.s./ha (recalculated from formulation) NOEC = 10.8 g a.s./ha (recalculated from formulation) Plant weight	Teixeira, D. 1999 97-12-7184 RD-II 02121	50538

6.9.1.2 Exposure

Effects on non-target plants are of concern in the off-field environment, where they may be exposed to spray drift. The amount of spray drift reaching off-crop habitats is calculated using the 90th percentile estimates derived by the BBA (2000) from the spray-drift predictions of Ganzelmeier & Rautmann (2000). Any dilution over the 3-dimensional vegetation surface is accounted for in the study design. Therefore, in contrast to the assessment of risks to arthropods from standard laboratory tests, no vegetation distribution factor is considered here as shown in the following equation:

$$PER_{off-field} = Max\ \ PER_{in-field}\ x\left(\%-drift/100\right)$$

For calculation of PER in-field, the following equation was used:

$$PER_{in-field} = Application\ rate\,(\text{g as / ha}) \times \text{MAF}$$

The maximum predicted environmental rate occurring in the field (equation above) after application of Mospilan SG, at the maximum application of 2 x 25 g Acetamiprid per hectar, is 42.5 g active substance per hectar, as presented in the following Table 6.9-2.

Table 6.9-2: In-field predicted environmental rates (PER in-field) for the intended use of Mospilan SG.

Substance	**Application rate [g a.s./ha]**	**MAF**	**PER $_{in-field}$ [g prep/ha]**
Acetamiprid	25	1.7	42.5

The resulting maximum off-field predicted environmental rates (PER $_{off-field}$) for Acetamiprid are summarized in the following Table 6.9-2:

Table 6.9-3: Maximum off-field predicted environmental rates of Acetamiprid following intended uses

Maximum intended in-field rate (PER$_{in-field}$)	**Maximum PER$_{off-field}$ at 1 m (2.38 % drift)**	**Maximum PER$_{off-field}$ at 5 m (0.47 % drift)**	**Maximum PER$_{off-field}$ at 10 m (0.24 % drift)**
	(g Acetamiprid/ha)		
42.5	1.0	0.2	0.1

6.9.1.3 Risk assessment –TER values and overall conclusions

The risk assessment results are summarized in Table 6.9-4 below:

Table 6.9-4: Summary of risk assessment for non-target terrestrial plants exposed to Acetamiprid

Most sensitive Species Test system	**ER_{50} (g a.s./ha)**	**PER $_{in\text{-}field}$ (g a.s./ha)**	**Distance (m)**	**PER $_{off\text{-}field}$ (g a.s./ha)**	**TER (Trigger = 10)**
Lactuca sativa Vegetative vigour	51.7	42.5	1	1.0	52
			5	0.2	259
			10	0.1	517
TER values in bold are below the trigger.					

Based on the predicted environmental rates of Acetamiprid in off-field areas, the TER values describing the risk for non-target plants following exposure to Acetamiprid according to the GAP of the formulation Mospilan SG does achieve the acceptability criteria TER ≥ 10 according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for non-target terrestrial plants due to the intended use of Mospilan SG in potatoes. Risk mitigation measures are not required.

6.10 Other Non-Target Species (Flora and Fauna)

-/-

6.11 Other/Special Studies

-/-

6.11.1 Laboratory studies

-/-

6.11.2 Field studies

-/-

Appendix 1 List of data submitted in support of the evaluation

Table A 1: List of data submitted in support of the evaluation

Annex point/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 registration report** **Study-Status/ Use***
OECD: KIIIA1 10.5.1	Hermann, P.	2000	Gazelle ®: A Laboratory Study to Evaluate the Effects on the Spider, Pardosa ssp. (Araneae, Lycosidae) Report No.: 20001314/01-NLPa ICS No.: 50463 GLP, no published	Y	Nisso Chemical Europe GmbH	3)
OECD: KIIIA1 10.5.2	Hirth, N.	2001	EXP60707A: Toxicity to the Green Lacewing *Chrysoperla carnea* (Neuroptera, Chrysopidae) Using an Extended Laboratory Test with Freshly Applied and Aged residues Following a Single Application at Rates of 13 or 100 g a.i./ha Report No.: 20011073/01-NECc Document No.: RD-II 02084 ICS No: 50516 GLP, no published	Y	Nisso Chemical Europe GmbH	2) The corrected mortality in the toxic reference treatment is below 50 %.
OECD: KIIA 8.3.1.3	Putt, A.E.	2003	Acetamiprid tech. - Acute toxicity to gammarids (*Gammarus fasciatus*) under static conditions Report No.: 12681.6105 Document No.: RD-03143 ICS No.: 50458 GLP, not published	Y	Nisso Chemical Europe GmbH	1)
OECD: : KIIA 8.5.1	Putt, A.E.	2003	Acetamiprid Technical - Acute Toxicity to Midge (*Chironomus riparius*) Under Static Conditions Report No.: 12681.6104 Document No.: RD-03144 ICS-No.: 50455 GLP, no published	Y	Nisso Chemical Europe GmbH	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 registration report Study-Status/ Use***
OECD: KIIIA1 10.2.2.5	Stäbler, D.	2005	Assessment on the Acute Toxicity of Acetamiprid 20 % SP on the Midge *Chironomus riparius* Report No.: 20041020/01-AACr Document No.: RD-00894 ICS No.: 52313 GLP, no published	Y	Nisso Chemical Europe GmbH	1)

*

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

Appendix 2 Detailed evaluation of studies relied upon

Reports only studies, which

(a) have not previously been evaluated within a peer reviewed process at EU level (Annex I inclusion of active substance) or

(b) have been evaluated in a peer reviewed process at EU level but where in exceptional cases derived endpoints have to be revised in the light of current scientific and technical knowledge.

A2-1 Active substance

KIIA 8.3 Toxicity to aquatic species other than fish and aquatic species field testing

KIIA 8.3.1 Acute toxicity to aquatic invertebrates

KIIA 8.3.1.3 Acute toxicity (24 and 48 hour)for representative species of aquatic crustaceans (species unrelated to Daphnia). Analytical data on concentrations in the test media

The following *Gammarus* acute toxicity study on Acetamiprid technical has not previously been EU reviewed and is provided by the applicant in support of this assessment.

KIIA 8.3.1.3/01 Gammarids

Reference:	KIIA 8.3.1.3/01 Actue toxicity – *Gammarus fasciatus*
Report:	Putt, A.E. (2003) Acetamiprid tech. - Acute toxicity to gammarids (*Gammarus fasciatus*) under static conditions. Report No.: 12681.6105 Document No.: RD-03143 ICS No.: 50458 Not published
Guideline(s):	OPPTS 850.1020
Deviations:	None
GLP:	Yes
Acceptability:	Yes
Original study evaluation:	No

Materials and methods

The acute toxicity of the test item Acetamiprid technical (99.3 %, CAS# 135410-20-7) to the Sweet water shrimps *Gammarus fasciatus* was determined according to the US EPA guideline OPPTS 850.1020 "Gammarid Acute Toxicity Test" A total of 140 organisms (5 per replicate, 4 replicates per concentration) were exposed to five concentrations of the test substance, a solvent control and a dilution water control for 96 hours under static conditions. The test concentrations were selected based on the results of preliminary testing. Animals, that passed through a 1.0 mm sieve and were trapped on the 0.71

mm sieve, were exposed to nominal test concentrations of 9.4, 19.0, 38.0, 75.0 and 150.0 µg a.s./L. The actual concentrations were measured using a liquid chromatography method with UV-detections (HPLC-UV). Mortality was recorded at 0, 24, 48, 72 and 96 h of exposure. Biological observation and observations of the physical characteristics of each replicate test solution were also made and recorded at 0, 24, 48, 72, 96 h.

Results and discussions

Water quality parameters of dissolved oxygen and temperature were unaffected by the concentrations of Acetamiprid technical tested. Daily measurement of the temperatures in the test solutions and continuous temperature monitoring of water bath established that the exposure solution temperature was 18 to 19°C during the definitive study. Measurement of Acetamiprid concentrations resulted in recovery rates of ≥ 80% compared to the initial concentrations. The mean measured concentrations were defined as 9.4, 18, 33, 76 and 140 µg a.s./L.

Mortality test results are summarised in the Tables 6.11-1 and 6.11-2 below. Following 96 hours of exposure, 70 %, 35 % and 40 % mortality was observed among gammarids exposed to the 140, 76 and 33 µg treatment levels, respectively. All surviving gammarids at these treatment levels were observed to be lethargic. Mortality of 10 % was observed among gammarids exposed to the 18 µg a.s./L treatment level. No adverse effects were observed to surviving gammarids exposed to this treatment level. No mortality or adverse effects were observed among the gammarids exposed to the 9.4 µg a.s./L treatment level. Mortality of 5 % and no adverse effects were observed among gammarids exposed to both the dilution water control and the solvent control. Based on mean measured concentrations, the 96-h LC_{50} value for this study was estimated to be 100 µg a.s./L, with 95 % confidence intervals of 81 to 130 µg a.s./L. The No-Observed-Effect-Concentration (NOEC) was determined to be 18 µg ai/L.

Table 6.11-1: Mean cumulative mortality of *Gammarus fasciatus* exposed to Acetamiprid technical

Mean measured concentration [µg ai/L]	Mean cumulative mortality of organisms [%]			
	24-hours	48-hours	72-hours	96-hours
Control	0	0	0	5
Solvent control	0	0	0	5
9.4	0	0	0	0
18.0	0	0[b]	10[c]	10
33.0	0[b]	20[b]	20[d]	40[e]
76.0	0[b]	10[b]	15[b]	35[e]
140.0	0[b]	20[b]	30	70[e]

[b] Several gammarids were observed to be at the surface of the test solution

[c] One gammarids was observed to be at the surface of the test solution

[d] Two gammarids were observed to be at the surface of the test solution

[e] All surviving gammarids were observed to be lethargic

Table 6.11-2: The LC_{50} values and No-Observed-Effect-Concentration (NOEC) for Acetamiprid technical and gammarids under static conditions

	LC_{50} (µg ai/L)	**Lower (µg ai/L)**	**Upper (µg ai/L)**
24-hours[a]	> 140	NA	NA
48-hours[a]	> 140	NA	NA
72-hours[a]	> 140	NA	NA
96-hours[b]	100	81	130
NOEC trough 96 hours = 18 µg ai/L			

NA Not applicable

a LC_{50} was empirically estimated

b LC_{50} value and corresponding 95% confidence intervals were calculated by Log-Log analysis

Conclusion

The toxic effect of the test item Acetamiprid technical to *Gammarus fasciatus* was assessed in a static 96h-test system. The following endpoints were deteremined:

96-hour LC_{50} = 100 µg a.s./L

48-hour LC_{50} > 140 µg a.s./L

96-hour NOEC = 18 µg a.s./L

Putt, A.E. (2003)

Comments of zRMS [Commenting box]

Study Comments:	The study is acceptable.
Agreed Endpoints:	The 96-hour LC_{50} of *Gammarus fasciatus* to Acetamiprid is 100 µg a.s./L.

KIIA 8.5 Effects on sediment dwelling organisms

KIIA 8.5.1 Acute test. Analytical data on concentrations in the test media.

The following *Chironomus* acute toxicity study on Acetamiprid technical has not previously been EU reviewed and is provided by the applicant in support of this assessment.

KIIA 8.5.1/01 Sediment dwelling organisms

Reference:	KIIA 8.5.1/01 Acute toxicity – *Chironomus riparius*
Report	Putt, A.E. (2003) Acetamiprid technical - Acute toxicity to midge (*Chironomus riparius*) under static conditions Report No.: 12681.6104 Document No.: RD-03144 ICS-No.: 50455 GLP, no published
Guideline(s):	FIFRA 72-2, EPA 850.1010
Deviations:	None
GLP:	Yes
Acceptability:	Yes
Original study evaluation :	No

Materials and methods

The acute toxicity of the test item Acetamiprid technical (99.3 %, CAS# 135410-20-7) to the midge *Chironomus riparius* was determined according to the US EPA guideline OPPTS 850.1020 "Aquatic Invertebrate Acute Toxicity Test". A total of 140 organisms (5 per replicate, 4 replicates per concentration) were exposed (spiked water) to five concentrations of the test substance and a dilution water control and a solvent control for 48 hours under static conditions. The test concentrations were selected based on the results of preliminary testing. Animals were exposed to nominal test concentrations of 6.3, 13.0, 25.0, 50.0 and 100.0 µg ai/L. The actual concentrations were measured using a liquid chromatography method with UV-detections (HPLC-UV). Mortality was recorded at 0, 24 and 48 h of exposure. Biological observation and observations of the physical characteristics of each replicate test solution were also made and recorded at 0, 24 and 48h.

Results and discussions

Water quality parameters of dissolved oxygen and temperature were unaffected by the concentrations of Acetamiprid technical tested. Daily measurement of the temperature in the test solutions and continuous temperature monitoring of water bath established that the exposure solution temperature was 21 to 22°C during the definitive study.Measurement of Acetamiprid concentrations resulted in recovery rates of ≥ 80% compared to the initial concentrations. The mean measured concentrations were defined as 6.0, 14.0, 26.0, 46.0 and 110.0 mg ai/L.

Mortality test results are summarised in Table 6.11-3 and Table 6.11-4 below. Following 48 hours of exposure, 100 % mortality was observed among organisms exposed to the 46 and 110 µg ai/L treatment levels. Mortality of 65 %, 10 % and 5 % was observed among organisms exposed to the 26.0, 14.0 and 6.0 µg ai/L treatment levels, respectively. No adverse effects were observed among surviving midge in these three treatment levels. No mortality or adverse effect was observed among the midges exposed to the dilution water control and the solvent control.

Based on mean measured concentrations, the 48-h LC_{50} value for this study was estimated by nonlinear interpolation to be 24 µg ai/L, with 95% confidence intervals of 21 and 27 µg ai/L. The No-Observed-Effect Concentration (NOEC) was determined to be 14.0 µg ai/L.

Table 6.11-3: Mean cumulative mortality of *Chironomus riparius* exposed to Acetamiprid technical

Mean measured concentration [mg ai/L]	Mean Cumulative Mortality of Organisms [%]	
	24-hours	48-hours
Control	0	0
Solvent control	0	0

6.0	0	5
14.0	0	10
26.0	0	65
46.0	90	100
110.0	100	100

Table 6.11-4: The LC_{50} values and No-Observed-Effect-Concentration (NOEC) for Acetamiprid technical and midges (*Chironomus riparius*) under static conditions

		95% Confidence Interval	
	LC50 (µg a.i./L)	**Lower (µg a.i./L)**	**Upper (µg a.i./L)**
24-Hour	40	35	46
48-Hour	24	21	27
NOEC through 48 hours = 14 µg a.i./L			

Conclusion

The toxic effect of the test item Acetamiprid technical to *Chironomus riparius* was assessed in a static spiked water 48h-test system. The following endpoints were deteremined:

24-hour LC_{50} = 40 µg a.s./L

48-hour LC_{50} = 24 µg a.s./L

48-hour NOEC = 14 µg a.s./L

Putt, A.E. (2003)

Comments of zRMS [Commenting box]

Study Comments:	The study is acceptable.
Agreed Endpoints:	The 2-day LC_{50} of *Chironomus riparius* to Acetamiprid is 24 µg a.s./L (real).

A2-2 Formulation

Reports only studies, which

(a) have not previously been evaluated within a peer reviewed process at EU level (Annex I inclusion of active substance) or

(b) have been evaluated in a peer reviewed process at EU level but where in exceptional cases derived endpoints have to be revised in the light of current scientific and technical knowledge.

KIIIA 10.2. Effects on aquatic organisms

KIIIA1 10.2.2 Acute toxicity (aquatic) of the preparation

KIIIA1 10.2.2.5 Marine sediment invertebrates, acute toxicity LC_{50}/EC_{50}

The following *Chironomus* acute toxicity study on the product Acetamiprid 20% SP has not previously been EU reviewed and is provided by the applicant in support of this assessment.

KIIIA1 10.2.2.5/01 Sediment dwelling organisms

Reference:	KIIIA1 10.2.2.5 Acute toxicity – *Chironomus riparius*
Report	Stäbler, D. (2005) Assessment on the Acute Toxicity of Acetamiprid 20 % SP on the Midge *Chironomus riparius* Report No.: 20041020/01-AACr Document No.: RD-00894 ICS No.: 52313 GLP, no published
Guideline(s):	OECD 202, EPA 850.1010
Deviations:	None
GLP:	Yes
Acceptability:	Yes
Original study evaluation:	No

Materials and methods

The toxicity of the product Acetamiprid 20 % SP on the larval stage of *Chironomus riparius* was tested in a 48 hour mortality test. The content of the active ingredient Acetamiprid in the formulation Acetamiprid 20 % SP was 199.4 g g/kg. Acetamiprid 20% is chemically identical to Mospilan SG.

Twenty organisms per test concentration (4 replicates of 5 animals each) were used. The test item was evaluated at concentrations of 0, 7.8, 15.6, 31.3, 62.5, 125, 250 and 500 µg prep/L in a static test design. Test media were prepared by dilution of the test item in test medium and application of defined volumes of the dilutions to the test vessels.

Assessments on mortality after 24 and 48 hours and analytical determinations of the test item content in distinct test concentrations were conducted. Endpoint reported is the LC_{50} (48 h). Temperature, pH-value and oxygen concentration [% saturation] of the test solutions measured after 0, 24 and 48 hours are reported. Hardness of the test water was measured on the days of application.

The analytical verification of the test item concentrations in test medium was done by analysing the content of Acetamiprid in the samples at start and at the end of the test after 48 hours. Samples were taken at the concentration levels of 31.3 µg/L, 62.5 µg/L, 125 µg prep/L and control.

The toxicological endpoints were evaluated using nominal concentrations of the test item Acetamiprid 20% SP).

Results and discussions

The total hardness (as $CaCO_2$) of the untreated control was determined to be 14°dH; the pH-value of the untreated control was determined to be 8.46 ± 0.05, the temperature was measured to be 20.1 ± 0.3 °C and the oxygen saturation was determined to be 95 ± 2 %.

The mean measured concentration of the test item was determined to be 93.7% of nominal concentration, calculated with the mean concentrations, based on Acetamiprid content.

Mortality test results are summarised in Table 6.11-5 and Table 6.11-6 below. After 24 hours no mortality or effects were observed at test concentrations up to 62.5 µg prep/L (nominal), representing the NOEC after 24 hours. At 125 µg prep/L (nominal) no mortality was observed, but all test organisms were affected and showed only reduced activity (= LC_0 (24 h)). After 24 hours mortality was 10 % at 250 µg prep/L and 5 % at 500 µg prep/L. After 48 hours no mortality or sublethal effects were observed at test concentrations up to 31.3 µg prep/L (nominal), representing the LC_0 and the NOEC after 48 hours. 100 % mortality was detected at 250 µg prep/L, resulting in a LC_{100} after 48 hours of 250 µg prep/L (nominal).

Based on nominal concentrations, the 48-h LC_{50} value for this study was estimated according to Spearman-Kärber to be 98.1 µg prep/L, with 95% confidence intervals of 83.2 and 116 µg prep/L. The 48-h No-Observed-Effect Concentration (NOEC) was determined to be 31.3 µg prep/L.

Table 6.11-5: Mortality of the midge *Chironomus riparius* exposed to Acetamiprid 20% SP for 24 and 48 hours

[µg/L]	Control	7.8	15.6	Mortality % 31.3	62.3	125	250	500
				24 h				
Group 1	0	0	0	0	0	0	0	0
Group 2	0	0	0	0	0	0	2	0
Group 3	0	0	0	0	0	0	0	1
Group 4	0	0	0	0	0	0	0	0
Σ	0	0	0	0	0	0	2	1
%	0	0	0	0	0	0	10	5

					48 h			
Group 1	0	0	0	0	0	3	5	5
Group 2	0	0	0	0	0	4	5	5
Group 3	0	0	0	0	1	4	5	5
Group 4	0	0	0	0	1	4	5	5
Σ	0	0	0	0	2	15	20	20
%	0	0	0	0	10	75	100	100

Table 6.11-6: The LC_{50} values and No-Observed-Effect-Concentration (NOEC) for Acetamiprid 20% SP and midges (*Chironomus riparius*) under static conditions

		95% Confidence Interval	
	LC50 (µg prep/L)	**Lower (µg prep/L)**	**Upper (µg prep/L)**
24-Hour	>500	-/-	-/-
48-Hour	98.1	83.2	116
NOEC through 48 hours = 31.3 µg prep/L			

Conclusion

The toxic effect of the test item Acetamiprid 20% SP to *Chironomus riparius* was assessed in a static spiked water 48h-test system. The following endpoints were deteremined:

24-hour LC_{50} >500 µg prep/L

48-hour LC_{50} = 98.1 µg prep/L

48-hour NOEC = 31.3 µg prep/L

Stäbler, D. (2005)

Comments of zRMS [Commenting box]

Study Comments:	The study is acceptable.
Agreed Endpoints:	The 2-day LC_{50} of *Chironomus riparius* to Acetamiprid is 98.1 µg product/L, corresponding to 19.6 µg a.s./L.

Appendix 3 Table of Intended Uses justification and GAP tables

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 a.s./hL min max	water L/ha min max	kg a.s./ha min max		
Potatoes	Central	005655-00/16-001	F	Colorado beetle	SG	200 g/kg	Spray	BBCH 20-39, spring and summer	2	14	-/-	300-600	0.025	14	Professional use

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 6: Ecotoxicological Studies

Detailed summary of the risk assessment

Product code: **Mospilan SG**

Active Substance: **200 g/kg Acetamiprid**

Central Zone
Zonal Rapporteur Member State: Germany (DE)

NATIONAL ADDENDUM – Germany

Applicant: Nisso Chemical Europe GmbH

Date: 20.06.2013

Table of content

6. ECOTOXICOLOGICAL STUDIES

Please refer to the core dossier for the central zone (zRMS: DE, Aug. 2012).

This document presents the national addendum for Germany and should be read in conjunction with the core assessment for section 6. The national addendum addresses national requirements differing from the standard EU modelling and risk assessment procedures. It refers moreover to specific management and risk mitigation practices that can be implemented in Germany.

6.1 EFFECTS ON BIRDS

Please refer to the core dossier for the central zone (zRMS: DE, Aug. 2012).

6.2 EFFECTS ON TERRESTRIAL VERTEBRATES OTHER THAN BIRDS

Please refer to the core dossier for the central zone (zRMS: DE, Aug. 2012).

6.3 EFFECTS ON AQUATIC ORGANISMS

6.3.1 Overview and summary

Please refer to the core dossier for the central zone (zRMS: DE, Aug. 2012).

6.3.1.1 Toxicity

Please refer to the core dossier for the central zone (zRMS: DE, Aug. 2012).

6.3.1.2 Exposure

For authorization in Germany, exposure assessment of surface water considers the two routes of entry (i) spray drift 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 is estimated with the model EVA 2.1. The calculation of concentrations in surface water is based on spray drift data according to spray-drift predictions of

Ganzelmeier & Rautmann (2000)[1]. For the active substance Acetamiprid deposition into surface water following volatilisation is not expected since its vapour pressure is below 10^{-5} Pa at 20°C and hence is not volatile. The EVA 2.1 input-parameters as well as the resulting PEC_{SW} values modeled for for the intended use of Mospilan SG in potatoes (worst case application rate) are summarized in

Table 6.3-1 below.

Surface water exposure via surface total load (desolved and particle bounded load) from run-off and drainage is estimated using the model EXPOSIT 3.01. For and further details please see national addendum - Germany, Part B, Section 5.6. The Exposit 3.01 input parameters are shown in Table 6.3-2. The resulting PEC_{SW} values modeled for an adjacent ditch for the intended use of Mospilan SG in potatoes (worst case application rate) are summarized in As shown in Table 6.3-3 below, tTable 6.3-3he calculated TER values are above the trigger of 100 for acute effects on aquatic biocenoses and result in an acceptable risk for the indication 16-001 for the entry pathways total load from run-off and drainage.

Table 6.3-3 below.

6.3.1.3 Overall conclusions

The product Mospilan SG is toxic for aquatic invertebrates, demonstrated by several studies. The most sensitive tested species is *Chironomus riparius* with the LC_{50} of 0.0196 mg a.s./L, recalculated from Mospilan SG. Thus, the label NW 263 is required:

NW 263 The product is toxic for aquatic invertebrates. Acetamiprid, LC_{50} = 0.0196 mg a.s./L (*Chironomus riparius*)

For the intended use 16-001 of Mospilan SG in potatoes, based on the LC_{50} of 0.0196 mg Acetamiprid/L for *Chironomus riparius* (recalculated from Mospilan SG), the following risk mitigation measures are required:

NW 605 Crop: Potatoes Application method: Spraying

Indication 16-001

Drift reduction measures of at least 75% 1 m distance

NW 606 Crop: Potatoes Application method: Spraying

Indication 16-001

Distance: 5 m

[1] Ganzelmeier H. and Rautmann D. (2000) Drift, drift-reducing sprayers and sprayer testing. Pesticide Application, Aspects of Applied Biology 57

6.3.2 Toxicity exposure ratios

Given that for the assessment of effects on aquatic organisms for Mospilan SG, several toxicity endpoints are available, the selection of the crucial toxicity endpoint respectively effect value is based on the lowest ratio of effect value and related PEC_{sw} taking into account the appropriate assessment factor as well as acute and chronic concentration-effect-curve chraracteristics (please refer to the core dossier for the central zone (zRMS: DE, Aug. 2012), Part B, Section 6.4.1.1). As this approach demonstrates the worst case scenario, a risk assessment for other toxicity endpoints, respectively species which are less sensitive, is not required. Ecotoxicological endpoints for aquatic species exposed to Acetamiprid or Mospilan SG are available and listed in the core dossier for the central zone (zRMS: DE, Aug. 2012), Part B, Section 6.4.1.1, Table 6.4-1.

In accordance with the proposal of the applicant, the aquatic risk assessment is solely based on the $LC_{50\ C.\ riparius}$ of 19.6 µg a.s./L, recalculated from Mospilan SG (LC_{50} = 98.1 µg prep/ha), since it is lowest effect value and reflecting the worst case scenario for the risk to aquatic organisms (please refer to the core dossier for the central zone (zRMS: DE, Aug. 2012), Part B, Section 6.4.1.1).

From the LC_{50} of 0.0196 mg a.s./L (*Chironomus riparius*), recalculated from Mospilan SG, and on the LC_{50} of 0.1 mg a.s./L (*Gammarus fasciatus*), it can be concluded that the product is toxic for aquatic invertebrates. Thus, for Mospilan SG the label NW 263 is required.

For the aquatic risk assessment, the entry of Acetamiprid into surface water via spraydrift as well as via run-off and drainage was modeled, using EVA 2.1 and Exposit 3.01, respectively. The resulting PECsw- as well as TER-values for the respective entry pathways are summarized and discussed below.

Consequences for authorization:

Regarding the authorization of the product Mospilan SG the following labeling is required:

Required labeling:

NW 263	The product is toxic for aquatic invertebrates. Acetamiprid, LC_{50} = 0.0196 mg a.s./L (*Chironomus riparius*)

6.3.2.1 Toxicity Exposure Ratios (TER) for the entry into surface waters via spraydrift

For the active substance Acetamiprid deposition into surface water following volatilisation is not expected since its vapour pressure is below 10^{-5} Pa at 20°C and hence is not volatile. Therefore exposure of surface water by the active substance Acetamiprid due to deposition following volatilisation can be excluded.

Regarding the intended use of Mospilan SG, the endpoints used for modelling surface water exposure via spray drift (PEC_{sw}) with EVA 2.1 as well as the resulting TER-values are summarized in the following

Table 6.3-1:

Table 6.3-1: EVA 2.1 input paratmeters for the modelling of and resulting surface water exposure via spray drift values (PEC_{sw}) as well as the calculated TER-values regarding the use of the formulation Mospilan SG

EVA 2.1 input parameters			**Active substance: Acetamiprid (formulation: Mospilan SG)**					
Crop / Application rate			Potatoes / 2 x 25 g a.s./ha (50% interception)					
Growth stage / Season			BBCH 20-39 / Spring/summer (intended use 16-001)					
DissT50 water (SFO)			11.0					
PEC-selection			Actual (PEC act)					
Drift-percentile			82nd percentile					
Buffer zone [m]	Entry via spray drift		Entry via deposition following volatilisation (Assessment is not necessary because VP < 1 x 10^{-6} Pa (25°C)		PECsw [µg a.s./L]; conventional and drift reducing technique (EVA 2.1, PECact –TER)			
	[%]	[µg/L]	[%]	[µg/L]	0% conv.	90% red.	75% red.	50% red.
0	100.00	11.78	-	-	11.78	1.18	2.95	5.89
1	2.38	0.280	-	-	0.280	0.03	0.07	0.14
5	0.47	0.055	-	-	0.055	0.01	0.01	0.03
10	0.24	0.028	-	-	0.028	0.00	0.01	0.01
15	0.16	0.019	-	-	0.019	0.00	0.00	0.01
20	0.12	0.014	-	-	0.014	0.00	0.00	0.01
Relevant toxicity endpoint: LC_{50} = 19.6 µg a.s./L (*C. riparius*) recalculated from Mospilan SG **Relevant TER:** 100								
Buffer zone [m]					**TER**			
0					**1.7**	-/-	-/-	-/-
1					**69.9**	699.0	279.6	139.8
5					353.9	3539.4	1415.8	707.9
10					693.1	6931.3	2772.5	1386.3
15					1039.7	10396.9	4158.8	2079.4
20					1386.3	13862.6	5545.0	2772.5
TER-values in bold are below the relevant trigger.								
Risk mitigation measures	NW 605 (1 m, 50%-, 75%- and 90% -red.) NW 606 (5 m, 0% conv.)							

Based on the relevant toxicity of the active substance Acetamiprid the calculated TER-values for the risk to aquatic organisms resulting from an exposure of surface water by spraydrift to Mospilan SG according to the use No. 16-001 achieve only the acceptability criteria of TER ≥ 100, according to commission

implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2, if appropriate risk mitigation measures are applied. The risk to aquatic organisms following exposure to Mospilan SG according to the GAP for the submitted indication, as well as to the active substance Acetamiprid and the relevant water metabolites, is acceptable for conventional technique if an unsprayed drift buffer of 5 m is used (NW 606) or if drift reducing techniques with at least 50%-, 75%- and 90%-reduction and 1 m buffer ist used (NW 605).

Consequences for authorization:

Regarding the authorization of the product Mospilan SG the following labeling is required:

Conditions for use:

NW 605	Crop: Potatoes	Application method: Spraying
	Indication 16-001	
	Drift reduction measures of at least 75% distance	1 m
NW 606	Crop: Potatoes	Application method: Spraying
	Indication 16-001	
	Conventional, 0% drift reduction	5 m distance

6.3.2.2 Toxicity Exposure Ratios (TER) after exposure of surface waters via run-off and drainage

Using the model EXPOSIT 3.01 for an adjacent ditch, surface water exposure to the active substance Acetamiprid via run-off and drainage is estimated. For modeling of run-off exposure of the sediment dweller *C. riparius* (LC_{50} of 0.0196 mg a.s./L), the total load from run-off, which includes the desolved- as well as the particle bounded load from run-off, was used. The input parameters used for the modelling are summarised in Table 6.3-2. The resulting PEC_{SW}- and TER-values, calculated for the active substance Acetamiprid and the intended use 16-001 of Mospilan SG in potatoes, are summarized in As shown in Table 6.3-3 below, tTable 6.3-3he calculated TER values are above the trigger of 100 for acute effects on aquatic biocenoses and result in an acceptable risk for the indication 16-001 for the entry pathways total load from run-off and drainage.

Table 6.3-3.

Table 6.3-2: Exposit 3.01 input parameters for the active substance Acetamiprid

Exposit 3.01 input parameters	**Active substance: Acetamiprid (formulation: Mospilan SG)**

K foc, Runoff (L/kg)*	165
K foc, mobility class (L/kg)**	165
DT50 soil (d)***	10.94
Solubility in water (g/L)	2.95

*median (see DRR Part B Section5 CA, Table 9.3.1-1)
**arithmetic mean, according to Input Decision 3.1 (used for calculation)
***SFO, Maximum, Field, n = 4

As shown in Table 6.3-3 below, tTable 6.3-3he calculated TER values are above the trigger of 100 for acute effects on aquatic biocenoses and result in an acceptable risk for the indication 16-001 for the entry pathways total load from run-off and drainage.

Table 6.3-3: Calculated TER-values for Acetamiprid regarding the entry pathways total load from run-off and drainage (Model Exposit 3.01) – indication 16-001

Active substance	**Acetamiprid (formulation: Mospilan SG)**	
Culture/Application rate	Potatoes; 2 x 25 g a.s./ha (50 % interception)	
Growth stage and season	BBCH 20-39, spring and summer	
Relevant toxicity endpoint	LC_{50} = 19.6 µg a.s./L (*C. riparius*) recalculated from Mospilan SG	
Relevant TER	100	
Total load from run-off (particle bounded and desolved load)		
Buffer zone [m]	**PEC in adjacent ditch [µg/L]**	**TER**
0	0.14	140.24
5	0.12	161.82
10	0.10	188.78
20	0.07	269.69
Drainage		
Time of application	**PEC in adjacent ditch [µg/L]**	**TER**
Spring/summer (April – October)	0.05	429.78
TER-values in bold are below the relevant trigger.		
Risk mitigation measures	-/-	

6.3.3 Risk from metabolites

Please refer to the core dossier for the central zone (zRMS: DE, Aug. 2012).

6.4 EFFECTS ON BEES

Regarding effects on bees the recommended use is covered by the honey bee risk assessment for the main application.

6.5 EFFECTS ON ARTHROPODS OTHER THAN BEES

6.5.1 Overview and Summary

Risk assessment *in-field*: Please refer to the core dossier for the central zone (zRMS: DE, Aug. 2012).

Risk assessment *off-field*: As shown in the national addendum – Germany, below.

6.5.1.1 Toxicity

From the non-target arthropod species tested on artificial substrate, the most sensitive species is the leaf dwelling parasitoid *Aphidius rhopalosiphi* with LR_{50} of 9.7 g formulation per ha and in the risk assessment using the Model EVA 2.1, as shown in the following Table 6.5-2, the LR_{50} of 1.94 g a.s./ha, recalculated from Mospilan is used.

For further information, please refer to the core dossier for the central zone (zRMS: DE, Aug. 2012).

6.5.1.2 Exposure

Off-field

The risk assessment for areas immediately surrounding the crop is considered important since these areas represent a natural reservoir for immigration, emigration and reproduction of arthropod populations and provide increased species diversity. Exposure of non-target arthropods living in off-field areas to Mospilan SG will mainly be due to spray drift from field applications. Off-field 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:

$$PER_{off-field} = \frac{Max\ \ PER_{in-field}\ x \left(\%-drift \diagup 100 \right)}{vegetation\, distribution\ \ factor\ (vdf)}$$

where:

vdf = vegetation distribution factor used in combination with test results derived from 2-dimensional exposure set-ups

To account for interception and dilution by three-dimensional vegetation in off-crop areas, a vegetation distribution or dilution factor (vdf, see above) is incorporated into the equation when calculating off-field exposure in conjunction with toxicity endpoints derived from two-dimensional studies (e.g. glass plate or leaf discs). A vdf of 10 is recommended by the Guidance Document, but has been questioned. The risk

[2] BBA (Biologische Bundesanstalt für Land- und Forstwirtschaft) (2000): Abtrifteckwerte für Flächen- und Raumkulturen sowie für den gewerblichen Gemüse-, Zierpflanzen- und Beerenobstanbau. Bundesanzeiger 100, 26. Mai 2000, Köln, pp. 9879.

assessment procedure here considers a vdf of 5 more appropriated. For endpoints resulting from 3-dimensional studies, i.e. where spray treatment is applied onto whole plants, the vdf is not used.

Available data for the effects of Mospilan SG on non-target arthropods, other than bees, indicate that *A. rhopalosiphi* is the most sensitive of all tested species. Relevant for the risk assessment are the results from a 3-dimensional extended laboratory study with *Aphidius rhopalosiphi* with a LR_{50} of 9.7 g Mospilan SG/ha (see Table 6.5-1). Regarding the results of the 3-dimensional extended laboratory study with *Aphidius rhopalosiphi* exposed to Mospilan SG, the vdf does not have to be considered.

Reduction of the amount of drift reaching the off-field areas can be achieved by implementing an in-field buffer strip of a given width. The drift factor (= drift [%] / 100) of the application rate (2 applications; 82nd percentile) is at 1 m distance 0.0238, at 5 m distance 0.0047 and at 10 m distance 0.0024.

The resulting drift values (according also to spray-drift predictions of Ganzelmeier & Rautmann (2000)[3]) as well as the predicted environmental off-field rates ($PER_{off\text{-}field}$; equation above) of Mospilan SG are given in the Table 6.5-1 below.

Table 6.5-1: Off-field predicted environmental rates (PER) of Mospilan SG at increasing distances from the sprayed areas following intended uses

Study type	max. application rate (g prep/ha)	MAF	max. $PER_{in\text{-}field}$ (g prep/ha)	Drift (%)	Vegetation distribution factor (vdf)	$PER_{off\text{-}field}$ (g prep/ha)
3-dimensional	125	1.7	212.5	2.38 (1 m)	1	5
				0.47 (5 m)		1
				0.24 (10 m)		0.5

6.5.2 Overall conclusion

Based on the acceptability criterium of TER ≥ 5, the risk resulting from an exposure of non-target arthropods to Mospilan SG, according to the intended use 16-001 and GAP of the formulation Mospilan is acceptable, according to commission implementing regulation (EU) 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2, if risk mitigation measures according to NT 102 are fulfilled.

NT 102 75%-red., 1 m, i.e. use of unsprayed zone and/or drift reducing nozzles or 5 m buffer are necessary.

[3] Ganzelmeier H., Rautmann D. (2000) Drift, drift-reducing sprayers and sprayer testing. Pesticide Application, Aspects of Applied Biology 57

6.5.3 Risk assessment

The risk assessment for non-target arthropods is done on basis of the calculation of toxicity-exposure ratio (TER) values with hte model EVA 2.1 as in line with German national requirements according the following formula:

$$TER = \frac{L(E)R50}{PER_{Off-field}}$$

The risk is considered acceptable if the off-field TER obtained is > 10 (tier 1) or > 5 (higher tier assessment). The input parameters as well as the resulting TER-values are given in the following Table 6.5-2:

Table 6.5-2: Calculated off-field TER-values regarding the entry pathway spray drift (Model: EVA 2.1)

Active substance			Acetamiprid					
Use pattern			16-001					
Number of applications/intervall			2 / 14 days intervall					
Crop/Application rate			potatoes / 25 g a.s./ha (50% interception)					
MAF			1.7					
DissT50 water (d)			11.0					
Scenario/drift-percentile			agriculture / 82nd percentile					
Correction factor (2D/3D)			1 (not necessary)					
distance (m)	Entry via spray drift		Entry via volatilisation/ deposition		PECact (g/ha) (including volatilisation; 2D/ 3D correction)			
	(%)	(g/ha)	(%)	(g/ha)	conv.	90% red.	75% red.	50% red.
1	2.38	1.01	-	1.01	1.01	0.10	0.25	0.51
5	0.47	0.2	-	0.2	0.20	0.02	0.05	0.10
Relevant endpoint	LR_{50} = 1.94 g a.s./ha *A. rhopalosiphi* recalculated from Mospilan SG							
TER criterion	5 (extended laboratory study)							
distance (m)					TER-values			
1					**1.92**	19.18	7.67	**3.84**
5					9.71	97.12	38.85	19.42
TER-values in bold are below the relevant trigger.								
Risk mitigation measures: NT 102 (75%red., 1 m)								

Based on the acceptability criterium of TER ≥ 5, the risk resulting from an exposure of non-target arthropods to Mospilan SG, according to the intended use 16-001 and GAP of the formulation Mospilan is acceptable, according to commission implementing regulation (EU) 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2, if risk mitigation measures according to NT 102 are fulfilled. According to the condition NT 102 for use, drift reducing technique of at least 75% and 1 m distance to the off-field area or a 5 m buffer, is required.

The extended laboratory study with *A. rhophalosiphi* in form of an aged-residue-design will not be considered in the refined risk assessment for the off-crop-area, because the exposure with fresh residues is relevant for the risk assessment regarding recovery of the population in the treated area. In the aged-residue-study with *A. rhophalosiphi*, strong effects with 90% mortality were observed following exposition to fresh residues from application rates of 65 and 500 g prep/ha.

Consequences for authorization:

Conditions for use:

NT 102 75%-red., 1 m, i.e. use of unsprayed zone and/or drift reducing nozzles or 5 m buffer are necessary.

6.6 EFFECTS ON EARTHWORMS AND OTHER SOIL NON-TARGET MACRO-ORGANISMS

6.6.1 Overview and summary

Please refer to the core dossier for the central zone (zRMS: DE, Aug. 2012).

6.6.1.1 Toxicity

Information about ecotoxicological endpoints for earthworms and other soil non-target macro-organisms is considered to be relevant for all countries. Therefore please refer to the core assessment Part B, section 6, chapter 6.7.

6.6.1.2 Exposure

In contrast to the risk assessment for the core dossier for the central zone (zRMS: DE, Aug. 2012), in accordance with the german national guidance (Füll, 2003)4, a reduced thickness of the soil layer of 2.5 cm may be considered for substances with Koc-values below 500 L/kg. A soil depth of 1 cm is considered additionally for substances with Koc-values above 500 L/kg.

The average Koc-value is 106.5 L/kg for Acetamiprid. Thus, PEC soil of Acetamiprid is calculated for a soil layer of 2.5 cm. For full details of the calculation see Part B, Section 5 of the national addendum - Germany. The resulting initial PEC soil value is given in Table 6.6-1.

The risk of the soil degradation products of acetamiprid, such as IM-1-4 and IC-0, will not be reassessed in this submission (please refer to the core dossier for the central zone (zRMS: DE, Aug. 2012), Part B, Section 6.1.2). The metabolites IM-1-2 and IM-1-5 occur with about 55 and 20 % in the water compartment (see Table 6.1-2), respectively, and were not previously ecotoxicolgically evaluated for the EU approval, therefore they are considered in this submission. For further details please see Part B, Section 5 of this core dossier.

Table 6.6-1: Maximum peak soil PEC values for Mospilan SG (expressed as a.s.), and the major soil metabolites

active substance / preparation	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)
Acetamiprid	2 x 12.5 = 25	2.5	0.0471	-/-	-/-	-/-

[4] Füll, C.; Schulte, C.; Kula C. (2003): *Assessment of effects of plant protection products on earthworms*. Umweltwissenschaften und Schadstoff-Forschung 15.2: 78-84

IM 1-4 (max. 72 %, MG-ratio 0.704)	2 x 6.34 = 12.68	2.5	0.0306	-/-	-/-	-/-
IM 1-5 (max. 20.2 %, MG-ratio 0.89)	2 x 2.25 = 4.5	2.5	0.0119	20	0.0019	0.0137
IM 1-2 (max. 55 %, MG-ratio 1.08)	2 x 7.43 = 14.86	2.5	0.0202	-/-	-/-	-/-
IC-0 (max. 11.3 %, MG-ratio 0.7)	2 x 1.0. = 2.0	2.5	0.0046	-/-	-/-	-/-

PEC_{act} = maximum annual soil concentration for a soil depth of 2.5 cm; PEC_{bkgd}= background concentration in soil considering a tillage depth of 20 cm (arable crop) or 5 cm (permanent crops); PEC_{accu} = accumulated soil concentration

6.6.2 Overall conclusion

The results of the risk assessment indicate an acceptable acute and chronic risk for earthworms exposed to Mospilan SG, acetamiprid as well as the major soil degradation products IM-1-2 and IM-1-5, regarding the indicated use 16-001. For the major soil metabolites IM-1-4 and IC-0 a reassessment is not necessary (please refer to the core dossier for the central zone (zRMS: DE, Aug. 2012), Part B, Section 6, Chapter 6.1.2). Other soil non-target macro-organisms are not at risk as well, following treatment with Mospilan SG. No risk mitigation measures are required.

Consequences for authorization:

None.

6.6.2.1 Toxicity exposure ratios, TER_A and TER_{LT} (IIIA1 10.6.1)

The risk assessment according to the German Federal Environment Agency (Füll et al. 2003) is presented below .

Toxicity exposure ratios (TER-values) were calculated for Acetamiprid as well as the relevant major soil degradation products, such as IM-1-2 and IM-1-5. For the major soil metabolites IM-1-4 and IC-0 a reassessment is not necessary (please refer to the core dossier for the central zone (zRMS: DE, Aug. 2012), Part B, Section 6, Chapter 6.1.2).

The resulting acute and chronic TER values for the active substance acetamiprid as well as the major soil degradation products IM-1-2 and IM-1-5 are above the respective trigger values. Other soil non-target macro-organisms are not at risk as indicated by chronic TER values above the trigger.

PEC values were calculated in line with German national requirements.

The risk assessment results are summarized in the following Table 6.6-2.

Table 6.6-2: Toxicity/exposure ratios for soil macro-organisms after applications of Mospilan SG in potatoes

Test substance	soil relevant application rate (g/ha)	Species	Endpoint (mg/kg dw soil)	PEC (mg/kg dw soil)	TER	TER trigger

Earthworms - acute						
Acetamiprid	2 x 12.5 = 25	*E. foetida*	LC50 = 3.66	0.0471	78	10
IM-1-2	2 x 6.34 = 12.68		LC50 >1000	0.0202	> 49504	
IM-1-5	2 x 2.25 = 4.5		LC50 >1000	0.0119	> 84034	
Earthworms - chronic						
Acetamiprid	2 x 12.5 = 25	*E. foetida*	NOEC = 0.252	0.0471	5.4	5
IM 1-5	2 x 2.25 = 4.5	*E. fetida*	NOEC = 62.5	0.0119	> 5252	
Other soil macro-organisms - chronic						
IM 1-5	2 x 2.25 = 4.5	*F. candida*	NOAEC = 12.5	0.0119	>1050	5
	2 x 2.25 = 4.5	*A. bilineata*	NOEC = 2.5	0.0119	210	
TER-values in bold are below the relevant trigger.						
Risk mitigation measures	-/-					

Due to the fast degradation of the active substance Acetamiprid in soil (DT_{90} < 365 d, SFO, field data) the accumulation potential is not considered.

Acute risk

The acute risk of Mospilan SG and the major soil degradation products IM-1-2 and IM-1-5 to earthworms was assessed by calculating acute toxicity exposure ratio values (TER_A), by comparing the LC_{50} values and the maximum instantaneous PEC_{soil} value using the following equation:

$$TER_A = \frac{LC_{50}\ (mg/kg)}{PEC_{soil}\ (mg/kg)}$$

The resulting TER_A values are shown in the following Table:

Table 6.6-3: Acute TER values for earthworms

Test substance	LC_{50}	Maximum instantaneous PEC_{soil} [mg/kg]	TER_A
Acetamiprid	3.66 mg a.s./kg dw soil	0.0471	78
IM-1-2	>1000 mg/kg dw soil	0.0202	>49504
IM-1-5	>1000 mg/kg dw soil	0.0119	> 84034
TER-values in bold are below the relevant trigger.			

Based on the worst case scenario, the acceptability criteria TER ≥ 10 for acute effects, according to Annex VI to directive 1107/2009 (EG), uniform principles, point 2.5.2.5 is reached for the active substance Acetamiprid as well as the major soil metabolites IM-1-2 and IM-1-5.

Consequences for authorization:

None.

Long-term risk

The potential long-term risk of Mospilan SG to earthworms was assessed by calculating long-term TER (TER_{LT}) values by comparing the NOEC values and the maximum instantaneous PEC soil using the following equation:

$$TER_{LT} = \frac{NOEC\,(mg/kg)}{PEC_{soil}\,(mg/kg)}$$

Long-term study data are applied for Acetamiprid and the metabolite IM-1-5. No data on long-term effects of IM-1-2 are available. Since the degradation in soil is relatively fast with a DT_{90} of < 365 d (Kinetic, laboratory/field data, Guidance Document on Terrestrial Ecotoxicology SANCO/10329/2002 rev2 final), there is no need to address the long term risk of the active substance acetamiprid ($DT_{90\ field}$ = 36.33 d; SFO, field data) and its metabolite IM-1-2 ($DT_{90\ max}$= 8.6 d) for earthworms and other soil macro- and mesofauna.

The major soil metabolite IM-1-5 of acetamiprid degrades slowly with normalized DT_{90} values > 1000 d and thus meeting the criterium DT_{90} > 365 d. Therefore, a long term risk assessment is necessary for this metabolite (for details, see Section 5).

However, the resulting TER_{LT} values are presented below in the following Table:

Table 6.6-4: Long-term TER values for earthworms following applications of Mospilan SG

Test substance	NOEC [mg a.s./kg dw soil]	Maximum instantaneous PEC_{Soil} [mg/kg soil]	TER_{LT}
Acetamiprid recalculated from Mospilan SG	0.252	0.0471	5.4
IM-1-5	62.5	0.0119	5252
TER-values in bold are below the relevant trigger.			

Based on the worst case scenario, the acceptability criteria TER ≥ 5 for long term effects, according to directive 1107/2009 (EG), Annex VI, uniform principles, point 2.5.2.5 is reached for acetamiprid as well as the metabolite IM-1-5.

Thus there is low risk identified for the parent compound as well as its major soil metabolites.

Consequences for authorization:

None

6.6.3 Effects on other non-target macro-organisms

According to SANCO/10329/2002 rev2 final tests on other soil non-target organisms are triggered by breaching the soil persistence criteria (DT_{90} > 365 d) for the major soil degradation product IM-1-5 (DT90 > 1000 d). Studies on *Folsomia candida* as well as *Aleochara bilineata* for this metabolite have been assessed during the EU notification process already. For further details please see core dossier for the central zone (zRMS: DE, Aug. 2012).

For the parent compound, studies on other non-target soil macro-organisms are not triggered.

The toxicity long-term endpoints for *Folsomia candida* and *Aleochara bilineata* exposed to IM-1-5 as well as the worst-case initial PEC_{soil} estimates for the relevant substances are summarized in Table 6.6-1 and Table 6.6-5. For details please refer to the core dossier for the central zone (zRMS: DE, Aug. 2012), Part B, Section 6, Chapter 6.7. The resulting TER values are provided in the following Table 6.6-5:

Table 6.6-5: Long-term TER values for non-target soil macro-organisms other than earthworms

Test substance	NOEC [mg/kg soil]	Maximum instantaneous PEC_{Soil} [mg/kg soil]	TER_{LT}
IM-1-5	12.5 (*F. candida*)	0.0119	1050
IM-1-5	2.5 (*A. bilineata*)	0.0119	210
TER-values in bold are below the relevant trigger.			

The resulting TER-values are well above the trigger of 5 indicating a low and acceptable risk for non-target macro-organisms other than earthworms.

Consequences for authorization:

None

6.6.4 Effects on organic matter breakdown

Tests on organic matter breakdown were not performed. Since no risk was identified for soil fauna, soil micro-organism and non-target arthropods from the use of Mospilan SG in potatoes, data on the effects on organic matter breakdown (litterbag) is not required for the active substance, formulation as well as the major soil metabolites, although the metabolite IM-1-5 meets the trigger on degradation in soil.

For further details see Part B, core dossier from Aug. 2012, Section 6, Chapter 6.7.

Consequences for authorization:

None.

6.7 EFFECTS ON SOIL MICROBIAL ACTIVITY

6.7.1 Overview and summary

Please refer to the core dossier for the central zone (zRMS: DE, Aug. 2012).

6.7.1.1 Toxicity

Please refer to the core dossier for the central zone (zRMS: DE, Aug. 2012).

6.7.1.2 Exposure

Please refer to chapter 6.6.1.2 of this document (national addenda).

6.7.1.3 Overall conclusion

Mospilan SG applied at the proposed worst-case use patterns does not pose an unacceptable risk to soil microorganisms.

Consequences for authorization:

None.

6.7.2 Toxicity exposure ratios

SANCO/10329/2002 rev 2-final states that testing soil micro-organisms is always required when contamination of the soil is possible. The risk assessment is presented for the active substance Acetamiprid of the formulation Mospilan SG. The relevant No Observed Effect Concentrations from the soil microflora tests as well as the risk assessment results are summarized in the following table:

In contrast to the risk assessment for the core dossier, in accordance with the german national guidance (Füll, 2003)[5], a reduced thickness of the soil layer of 2.5 cm may be considered for substances with Koc-values below 500 L/kg. A soil depth of 1 cm is considered additionally for substances with Koc-values above 500 L/kg. The average Koc-value is 106.5 L/kg for Acetamiprid. Thus, PEC soil of Acetamiprid is calculated for a soil layer of 2.5 cm. For further details please see Part B, Section 5 of this submission.

[5] Füll, C.; Schulte, C.; Kula C. (2003): *Assessment of effects of plant protection products on earthworms*. Umweltwissenschaften und Schadstoff-Forschung 15.2: 78-84

Table 6.7-1: Summary of risk assessment for soil micro-organisms exposed to Acetamiprid (Mospilan SG)

Test substance	NOEC (< 25% effect at 28 d)	Maximum instantaneous PECsoil [mg/kg]	MoS (NOEC/PEC)
Acetamiprid/ C-transformation	200 g a.s./ha (= 0.533 mg a.s./kg soil dw (2.5 cm))	0.0471	11.32
Acetamiprid/ N-transformation	200 g a.s./ha (= 0.533 mg a.s./kg soil dw (2.5 cm))	0.0471	11.32

In the ecotoxicological risk assessment, margin of safety is calculated by dividing the threshold effect level (or concentration) of toxicity (e.g. NOEC) by the expected (or predicted) environmental concentration (PEC). It can be expressed in the equation form as follows:

$$MoS = NOEC/PEC$$

For the active ingredient in Mospilan SG and metabolites, the soil concentrations, which caused no deviations greater than ±25% in the activity of the soil microorganisms, namely 200 g a.s./ha soil dw, are about 10-times higher than the corresponding maximum PEC soil. The resulting margins of safety (NOEC/expected environmental concentrations) would be approximately 11.32 for Mospilan SG. Thus, the highest recommended rate of Acetamiprid applied according to the intended use of Mospilan SG, does not elicit a toxic response. Considering concurrent exposure to the active ingredient in Mospilan SG at the time of application, a low risk to soil microflora is concluded.

Based on the worst case scenario, the acceptability criteria according to directive 1107/2009 (EG), Annex VI, uniform principles, point 2.5.2.6 is reached.

Consequences for authorization:

None

6.7.2.1 Laboratory testing

Please refer to the core dossier for the central zone (zRMS: DE, Aug. 2012).

6.7.2.2 Additional testing

Please refer to the core dossier for the central zone (zRMS: DE, Aug. 2012).

6.8 EFFECTS ON NON-TARGET PLANTS

6.8.1 Terrestrial plants

6.8.1.1 Overview and summary

Please refer to the core dossier for the central zone (zRMS: DE, Aug. 2012).

6.8.1.1.1 Toxicity

Please refer to the core dossier for the central zone (zRMS: DE, Aug. 2012)

6.8.1.1.2 Exposure

Please refer to the core dossier for the central zone (zRMS: DE, Aug. 2012).

6.8.1.1.3 Overall conclusion

Regarding the insecticidal mode of action of the one active substance Acetamiprid in the formulation Mospilan SG, estimated effect values, relevant for risk assessment for terrestrial biocoenoses, are much higher for terrestrial arthropods than for terrestrial plants. Thus, a specific risk assessment for terrestrial non-target plants is not necessary.

The risk to terrestrial non-target plants exposed to Mospilan SG according to the proposed use with an application rate of 125 g prep/ha poses no unacceptable risk.

Consequences for authorization:

None.

6.8.1.2 Toxicity exposure ratios

Regarding the insecticidal mode of action of the one active substance Acetamiprid in the formulation Mospilan SG, estimated effect values, relevant for risk assessment for terrestrial biocoenoses, are much higher for terrestrial arthropods than for terrestrial plants. Thus, a specific risk assessment for terrestrial non-target plants is not necessary.

Consequences for authorization:

None.

6.9 SUMMARY AND EVALUATION OF POINTS 5 AND 6 (IIA1 10.11)

6.9.1 Predicted distribution and fate in the environment and time courses involved (IIIA1 10.11.1)

Please refer to the core dossier for the central zone (zRMS: DE, Aug. 2012).

6.9.2 Non-target species at risk and extent of potential exposure (IIIA1 10.11.2)

Please refer to the core dossier for the central zone (zRMS: DE, Aug. 2012).

6.9.3 Short and long term risks for non-target species, populations, communities and processes (IIIA1 10.11.3)

Birds

Please refer to the core dossier for the central zone (zRMS: DE, Aug. 2012).

Consequences for authorization:

None.

Terrestrial vertebrates other than birds

Please refer to the core dossier for the central zone (zRMS: DE, Aug. 2012).

Consequences for authorization:

None.

Aquatic organisms

Risk assessments for aquatic organisms were conducted based on the Guidance Document on Aquatic Ecotoxicology (SANCO/3268/2001 rev. 4 final).

The risk assessment for the formulation Mopsilan SG, the active substance Acetamiprid as well as the metabolites was carried out following application according to the proposed use. The initial risk assessments were carried out by comparing the initial maximum PEC_{SW} values with the acute and long-term toxicity endpoints. Based on all aquatic studies as well as the corresponding safety factors, the relevant endpoint is the LC_{50} of 0.0196 mg a.s./L for the sediment dwelling invertebrate *Chironomus riparius* (recalculated from Mospilan SG, AF =

100). The RAC-value for this endpoint results is the lowest compared to the other RAC-values. Thus, the risk assessment was performed using this endpoint. The RAC-value is the quotient of the ecotoxicological endpoint divided by the corresponding safety factor.

Predicted environmental concentrations in surface water have been calculated in accordance with German national requirements for drift, total (desolved- and particle bounded-) load from run-off as well as drainage.

Consequences for authorization:

Based on the LC_{50} = 0.0196 mg a.s./L (*C. riparius*; recalculated from Mospilan SG) linked with an assessment factor of 100 (acute), risk mitigation measurements are necessary to protect aquatic non-target organisms in form of drift reducing nozzles and buffer zones:

The risk to aquatic organisms following exposure to Mospilan SG according to the GAP for the indication 16-001, as well as to the active substance Acetamiprid and the relevant water metabolites is acceptable, if the risk mitigation measures NW 605/606 are fulfilled. For details please refer to section 6.3 of this submission.

NW 605	Crop: Potatoes	Application method: Spraying
	Indication 16-001	
	Drift reduction measures of at least 75% distance	1 m

NW 606	Crop: Potatoes	Application method: Spraying
	Indication 16-001	
	Conventional, 0% drift reduction	5 m distance

The product Mospilan SG is toxic for aquatic invertebrates, demonstrated by several studies. The most sensitive tested species is *Chironomus riparius* with the LC_{50} of 0.0196 mg a.s./L, recalculated from Mospilan SG. Thus, the label NW 263 is required.

NW 263	The product is toxic for aquatic invertebrates. Acetamiprid, LC_{50} = 0.0196 mg a.s./L (*Chironomus riparius*)

As with any application of pesticides not intended for direct application to water, direct overspray of water bodies with Mospilan SG should be strictly avoided.

Honeybees

Please refer to the core dossier for the central zone (zRMS: DE, Aug. 2012).

Arthropods other than bees

Risk assessments for non-target arthropods other than bees, conducted following the Guidance Document on regulatory testing and risk assessment procedures for plant protection products with non-target arthropods (ESCORT 2; adapted to German national requirements).

In extended laboratory studies conducted with Mospilan SG, the LR_{50} values to the indicator species *Aphidius rhopalosiphi* and *Typhlodromus pyri*, were estimated to be 9.7 (2 d, 3-dimensional) and 143.48 g product/ha (14 d, 2-dimensional), respectively.

The calculation of PEC after exposure via spray drift is performed using the model EVA 2.1. The relevant endpoint from an extended 3-dimensional study is the LR_{50} of 1.97 g a.s./ha, recalculated from Mospilan SG.

Consequences for authorization:

Based on those conditions, the following risk mitigation measurements are necessary to protect terrestrial non-target arthropods. For details please refer to section 6.5 of this submission.

NT 102	75% red., 1 m, i.e. use of unsprayed zone and/or drift reducing nozzles or 5 m buffer are necessary

Earthworms and other soil macro-organisms

Risk assessments for earthworms and other soil non-target macro-organisms were conducted based on the Council Directive 91/414/EEC (SANCO/10329/2002 rev. 2 final). Predicted environmental concentrations in soil were calculated based on German national requirements (Füll, 2001[6]), i.e. for a soil penetration depth of 2.5 cm, for substances with K_{OC} < 500 L/kg.

Risk assessments are based on the formulation, because it is more toxic than the active substance alone. The EU-conform relevant LC_{50} for the acute exposure scenario for Acetamiprid, recalculated from Mospilan SG, is 3.66 mg a.s./kg bw. The EU-conform relevant NOEC for the long-term exposure scenario for Acetamiprid, recalculated from Mospilan SG, is 0.252 mg a.s./kg bw.

The acute and long-term TER-values exceed the Annex VI recommended triggers of 10 and 5, respectively, and thus, the results of the risk assessment indicate an acceptable acute and chronic risk for

[6] Füll *et al.* (2001): Bewertung der Auswirkungen von Pflanzenschutzmitteln auf Regenwürmer. Bewertungsverfahren – Zulassung von Pflanzenschutzmitteln. UWSF-Z. Umweltchem Ökotox 13, p. 1 – 7.

earthworms exposed to Mospilan SG as well as the major soil degradation products, regarding the indicated use 16-001. Other soil non-target macro-organisms are not at risk as well, following treatment with Mospilan SG.

Consequences for authorization:

None.

Soil Microbial Activity

The risk assessment for soil microflora functions was conducted following the Guidance Document on Terrestrial Ecotoxicology under Council Directive 91/414/EEC (SANCO/10329/2002 rev. 2 final) based on data for the active substance Acetamiprid.

Studies for the active substance Acetamiprid resulted in no effects greater than ±25% even at treatment levels equivalent to at least eleven times the maximum concentrations expected in soil following applications of Mospilan SG. Use of Mospilan SG in potatoes is thus not expected to pose a risk to soil micro-organisms.

Consequences for authorization:

None.

Non-target plants

Regarding the insecticidal mode of action of the one active substance Acetamiprid in the formulation Mospilan SG, estimated effect values, relevant for risk assessment for terrestrial biocoenoses, are much higher for terrestrial arthropods than for terrestrial plants. Thus, a specific risk assessment for terrestrial non-target plants is not necessary.

The risk to terrestrial non-target plants exposed to Mospilan SG according to the intended use 16-001 poses no unacceptable risk.

Consequences for authorization:

None.

6.9.4 Risk of fish kills and fatalities in large vertebrates or terrestrial predators (IIIA1 10.11.4)

Please refer to the core dossier for the central zone (zRMS: DE, Aug. 2012).

Consequences for authorization:

None.

6.9.5 Precautions necessary to avoid/minimise environmental contamination and to protect non-target species (IIIA1 10.11.5)

The following precautions are necessary to avoid resp. minimise environmental contamination and to protect non-target species due to the intended use (use No. 16-001) of the formulation Mospilan SG:

NW 263 The product is toxic for aquatic invertebrates.

NW 605 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 provided for by state law, § 6 (2) 2nd sentence of the 'PflSchG' (German Plant Protection Act) must be observed for the drift reduction classes marked with "*".

Crop: Potatoes	Application method: Spraying	
Indication 16-001		
Drift reduction measures of at least 90%	:	*1 m
Drift reduction measures of at least 75%	:	*1 m
Drift reduction measures of at least 50%	:	*1 m

NW 606 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.

Crop: Potatoes	Application method: Spraying
Indication 16-001	
Distance:	5 m

NT 102 In a strip at least 20 m wide which is adjacent to other areas, the product must be applied using loss reducing equipment which is registered in the index of 'Loss Reducing Equipment' of 14 October 1993 (Federal Gazette No 205, p. 9780) as amended, and be registered in at least drift reducing class 75 % (except agriculturally or horticulturally used areas, roads, paths and public places). Loss reducing equipment is not required if the product is applied with portable plant protection equipment or if adjacent areas (field boundaries, hedges, groups of woody plants) are less than 3 m wide or the product is

applied in an area which has been declared by the Biologische Bundesanstalt in the "Index of regional proportions of ecotones" of 7 February 2002 (Federal Gazette no. 70 a of 13 April 2002), as amended, as agrarian landscape with a sufficient proportion of natural and semi-natural structures.

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

Please refer to the core dossier for the central zone (zRMS: DE, Aug. 2012).

Appendix 2: Table of Intended Uses

Please refer to the core dossier for the central zone (zRMS: DE, Aug. 2012).

Appendix 3: Additional information provided by the applicant

Please refer to the core dossier for the central zone.

REGISTRATION REPORT

Part B

Section 7: Efficacy Data and Information

Detailed Summary

Product Code: Mospilan SG

Reg. No.: ZV1 005655-00/16

Active Substance: Acetamiprid 200 g/kg

Country: Germany

Central Zone

Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Nisso Chemical Europe GmbH

Date: 20 June 2013

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IIIA1 6 Efficacy Data and Information on the Plant Protection Product

General information

Current report evaluates the efficacy data provided by Nisso Chemical Europe of the plant protection product Mospilan (acetamiprid 200 g/kg). DE acts as the zonal rapporteur member state, all other countries of the EU central zone are concerned member states.

Recent registration situation/history of the PPP

Mospilan SG is a SG-formulation with 200 g/kg acetamiprid as active ingredient for the control of insects (e.g. aphids and whiteflies) in field crops, pome fruits, vegetables and ornamentals. In DE it is registered for control of aphids in potato and pollen beetle in seed rape (Reg. No. 005655-00-00).

Information on the active ingredients (Uptake and mode of action)

Acetamiprid is a systemic insecticide with translaminar activity and with contact and stomach action. Acetamiprid is classified by the Insecticide Resistance Action Committee (IRAC) due to the primary site of action in the main group 4 of the nicotinic acetylcholine receptor agonists/antagonists (Version: MoA Classification v. 7.2, February 2012). This class of materials functions by binding to the nicotinic acetylcholine receptor in the postsynaptic neurons of the insect central nervous system. This binding causes the ion pore in the receptor to open and allows an overloading of the postsynaptic cells with sodium ions. This leads to hyper excitation of the nervous system and eventual death of the insect. The chemical sub-group for acetamiprid is the group 4A of the neocotinoids. More active ingredients of the chemical class are clothianidin, dinotefuran, imidacloprid, nitenpyram, thiacloprid and thiamethoxam.

Information on crops and pests

Potatoes are cultivated in all countries of the EU central zone. The Colorado potato beetle is present in most countries of the central zone, except UK and IE. But occurrence, intensity and damage effects are expected to differ between areas within the zone. More generations and higher pest pressure are expected in areas with dry and warm summers (e.g. HU, south of DE, PO). Potatoes cultivars harvested late in the season may need a higher intensity of control. Because of different climates within the EU Central Zone, EPPO climatic zones have to be considered when generating data to support an EU Central Zone authorization, because EPPO zones are based on climatic/biology factors. Yield losses of potato tubers are often higher than 30%. If left uncontrolled, the beetles (adults as well as larvae feed on leafs of potato) can completely destroy potato crops. Some leaf feeding can be accepted especially at late growing stages of potato without any yield loss. Therefore damage threshold should be followed before taking any control decision. This should be mentioned in the label. Insects of this species also cause significant damage to tomato and eggplant.
For an efficient control of Colorado potato beetle also in the future, especially in growing areas where development of resistance to pyrethroid based products is known, a broad spectrum of active substances with different mode of action should be used.

Information on the intended uses (2012-04-26)

AWG-No.	**005655-00/16-001**
Area of application	Agriculture (field crops)
Crop(s)/object(s)	Potato(SOLTU)

Pest(s)/target(s)/aim(s)	Colorado potato beetle(LEPTDE)
Area of use	Outdoors
Time of treatment	Spring to summer
Max. number of treatments for the use	2
Max. number of treatments per crop or season	2
Application technique/type of treatment	Spraying
Dose rate(s) in amount of water to be used	125 g/ha in 300 to 600 l water/ha
Pre-harvest Interval	Treatments must be at least 14 days apart

IIIA1 6.1 Efficacy data

In total, 22 trials are available for evaluation, performed in AU (6x), F (1x, EU-North), DE (3x), HU (3x), PO (6x) and CH (3x) between 1994 and 2008. No trial was conducted in the northern part of the EU central zone, which is acceptable because the pest is no problem e.g. in UK and IE and causes no or little damage in this region.
Dose rate in the range of the 25 g a.s./ha applied for, which were used in the trials were 30 g a.s/ha in 4 trials, 25 g a.s./ha in 10 trials and 20 g a.s./ha in 13 trials (in some trials more than one of this 3 rates were used). The use of the different dose rates was quite evenly distributed between different EPPO climatic zones. Most trials were carried out under GEP conditions and according to the EPPO Standards, but in some trials less replicates were used. Three trials were conducted in CH, where GEP certification is not required, in 2001 by an official recognized testing institute. Six trials were carried out in 1994 and 1995 before implementation of GEP and four trials were performed in summer 2001 by an institute which was GEP certificated shortly after trial, in October 2001.
The rating schemes of trials were different. To allow comparability generally, all results were presented as efficacy according to Abbott, as calculation of efficacy according to Henderson & Tilton was not always possible due to missing raw data. Abbott values in the BAD have been reported or calculated from the mean values given in the trial reports. If evaluation according to Abbott showed negative values, they were set to 0% efficacy when averaging the data. If calculation of Abbott values was not possible, reported Henderson & Tilton values were used (except Henderson & Tilton values of 100% were used as Abbott values of 100%).
Because of various rating dates in the different trial reports, it was necessary to form evaluation periods to maximize the number of trial results for a specific DAT. Those periods were chosen as short as possible; e.g., if the results of trial A were reported for 3 DAT, 7 DAT and 15 DAT but in trial B only for 2 DAT, 5 DAT and 12 DAT, then periods are headed by 2 - 3, 5 - 7 and 12 - 15 DAT. If more than one trial result had to be allocated in one evaluation period, the assessment date providing the maximum efficacy of intended dose rate was chosen. Effects on larvae and adults were presented separately.

IIIA1 6.1.1 Preliminary range-finding tests

No data were presented.

IIIA1 6.1.2 Minimum effective dose tests

Larvae
Minimum effective dose trials were quite evenly located in the different EPPO climatic zone areas. For testing the minimum effective dose of Mospilan SG for control of *L. decemlineata* larvae of the larval stages L1 - L4, 17 dose verification tests are available. The data were sorted by evaluation periods, shortly after the application (DAT 1) and ca. one week (DAT 5 – 7) resp. two weeks (DAT 12 - 15) after the application.
Efficacy at the intended dose rate of 25 g a.s./ha Mospilan SG was excellent over the whole testing range of two weeks with a minimum efficacy of all the rates between 20 and 30 g a.s/ha of more than 80% and an average of more than 95%. At lower rates of 12 - 16 g a.s./ha a

minimum value of 73% but still a mean of nearly 95% was achieved. This indicates that the dose rate of 25 g a.s./ha is effective also in complicated pest control situations and less product might need to be applied at lower infestation levels or at late infestation periods. A too low dose might create resistance problems.

Adults

For testing the minimum effective dose of Mospilan SG for control of *Leptinotarsa decemlineata* adults, 6 dose verification tests are available comparing 12 g with 25 g a.s./ha respectively 15 - 16 g with 20 g a.s./ha. Tests were carried out in AU, PO and HU, an area with continental climate for which control of adults seems most relevant. An increase in effects was observed from 15/16 to 20 g a.s./ha 13 - 15 d after application from 70 to 87% in 4 trials. Another trial using 25 g a.s./ha was in the same range as 20 g. Increasing the dose from 12 to 25 g a.s./ha resulted in an increased efficacy in 2 trials. The dose applied for seems to be applicable to control adults of Colorado potato beetle similar as for larvae.

IIIA1 6.1.3 Efficacy tests

A total of ten efficacy trials from AU (4), HU (3), PO (2) and DE (1) are available, investigating the efficacy of intended dose rate of 25 g a.s./ha Mospilan SG for control of *Leptinotarsa decemlineata* larvae and adults in potatoes. But additionally 12 experiments using a dose rate of 20 g a.s./ha can also be used for the evaluation, because minimum effective dose data showed no relevant increase in efficacy when comparing 20 to 25 g for larvae and adults.

Larvae

The application of Mospilan SG at the intended dose rate of 25 g a.s./ha resulted in nearly full control of Colorado potato beetle larvae. Efficacy at 25 g a.s./ha was very high over the whole testing range of two weeks (near to 100% between DAT 1 and 15). Compared to the reference products (mainly pyrethroids, Thiodan and Bancol) Mospilan SG showed higher efficacy in most cases. 12 additional trials with 20 g a.s./ha resulted in very similar and only slightly lower efficacy value compared to 25 g. In trials using another neonicotinoid active (Actara) as reference product, efficacy was very comparable to Mospilan SG. In 3 of this trials 30 g a.s./ha was additionally used and had only a small increase of effects compared to 20 g. Assessments after 3 or more weeks in some of the trials showed a decline in efficacy.

Adults

2 trials with 25 g a.s./ha Mospilan SG for control of *L. decemlineata* adults are available. The application of Mospilan SG at the intended dose rate of 25 g a.s./ha resulted the first week after treatment in nearly full control of Colorado potato beetle adults and still was 86% after 2 weeks. Compared to the reference products (Pyrethroids, Bancol and Actara), Mospilan SG showed similar efficacy. 4 additional trials with 20 g a.s./ha resulted in a similar control as the 2 trials with 25 g a.s./ha after 14 days.

The number and distribution of trials within the zone allow an evaluation for the whole EU central zone. Larvae are the main target and sufficient data were produced to decide that efficacy is acceptable. Some supporting data on adults, which need not be controlled less frequently, allow a similar approach taking into account the high efficacy values obtained to control adults and larvae in all trials.

IIIA1 6.1.4 Effects on yield and quality

IIIA1 6.1.4.1 Impact on the quality of plants and plant products

No negative impact of Mospilan SG on the quality of plants or plant products is expected. There are no indications of such effects from the use of the product at farm level until now.

IIIA1 6.1.4.2 Effects on the processing procedure

No negative impact of Mospilan SG on the quality of processing procedure is expected. There are no indications of such effects from the use of the product at farm level until now.

IIIA1 6.1.4.3 Effects on the yield of treated plants and plant products

No negative impact of Mospilan SG on the yield of treated plants is expected. There are no indications of such effects from the use of the product at farm level until now.

IIIA1 6.2 Adverse effects

IIIA1 6.2.1 Phytotoxicity to host crop

The phytotoxicity of Mospilan SG was checked in 9 trials already evaluated for dose justification and efficacy and in three additional trials at rates from 5 to 50 g a.s./ha. Several varieties were tested. No phytotoxic effects were reported in any of the trials, not even at 200% of the intended dose rate (50 g a.s./ha). There are no indications of such effects from the use of the product at farm level until now.

IIIA1 6.2.2 Adverse effects on health of host animals

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

IIIA1 6.2.3 Adverse effects on site of application

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

IIIA1 6.2.4 Adverse effects on beneficial organisms (other than bees)

Effects on relevant beneficial organisms

The toxicity of 60707A and EXP 60707B which are chemically identical to Mospilan SG on beneficial organisms has been investigated by carrying out different laboratory tests on *Aphidius rhopalosiphi*, *Chrysoperla carnea*, *Coccinella septempunctata*, *Poecilus cupreus* and *Typhlodromus pyri.*
500 g/ha 60707A (corresponding to 4 times the recommended field rate/ha and application) are not harmful (effects < 25% in the aged residue test) to *Chrysoperla carnea* (Table 6.2.4-2). But, the recommended application rate of the test item showed strong acute effects on *Aphidius rhopalosiphi* in the tow higher tier tests (Table 6.2.4-1). Hence, the indicator test species *Aphidius rhopalosiphi* is not relevant antagonist in fields with potatoes.
With *Coccinella septempunctata*, 65 g/ha and 500 g/ha (corresponding to 0.5 times and 4.0 times the highest recommended field rate/ha and application) caused lethal effects > 25% and > 50%, respectively (Table 6.2.4-3). Hence, two application of 125 g/ha Mospilan SG are harmful (effects > 50%) for populations of *Coccinella septempunctata.*
The results of the laboratory test on *Poecilus cupreus* are presented in Table 6.2.4-4. Application rates of 960 g/ha and 1920 g/ha (corresponding to 8 times and 15 times the recommended field rate) led to no lethal effects. But, all the living beetles showed behavioral disorders and feeding rate was significant reduced in the first days. Due to the sublethal effects Mospilan SG might reduce populations of *Poecilus cupreus* slightly (up to 50%).
Table 6.2.4-4 shows the results of the three laboratory tests on *Typhlodromus pyri*. An application rate of 500 g/ha 60707A (corresponding to 4.0 times the highest recommended field

rate/ha and application) in the aged residue test (the highest tier test of the tree tests with *Typhlodromus pyri*) caused lethal effects of 39.1%. Therefore, two application of 125 g/ha Mospilan SG might influence populations of *Typhlodromus pyri* slightly (effects up to 50%). But, the indicator test species *Typhlodromus pyri* is not relevant antagonist in fields with potatoes.
With today's level of knowledge, the results for *Typhlodromus pyri* indicate that two applications of the recommended rate of Mospilan SG to potatoes might reduce the population of relevant predatory mites and spiders up to 50%.
Aged residue trials demonstrate that the effects on *Aphidius rhopalosiphi*, *Coccinella septempunctata* and *Typhlodromus pyri* dissipate largely within a month at most.

Effects of EXP 60707A[1] and EXP 60707B[2] on *Aphidius rhopalosiphi* (exposed stage: male and female)

Application rate [g/ha]	Corrected mortality [%]	Effect on parasitisation rate [%]	Reference
1 Laboratory test using glass			Candolfi, M.P. and
1000[1]	100	-	Ott, U., 1997
2000[1]	100	-	RD-00020
2. Laboratory test using barley plants			
1[2]	0	-	Moll, M., 1997
3[2]	9.4	-11.4	C008456
9[2]	53.1	12.5	
27[2]	87.5	-	
81[2]	93.8	-	
LR_{50} : 7.9 g/ha (95% Confidence limits: 7.2 g/ha – 13.0 g/ha)			
3 Laboratory test using leaves from treated apple trees (aged residue test)			
Test item was applied on potted apple trees at two different rates. 0, 7, 14 and 21 days after treatment (T) leaves were collected from apple trees and returned to the laboratory. Aging of the spray residues of the test item on the potted apple trees took place under semi-field conditions during the whole study.			
	0 days after T		Schuld, M., 2001
65[1]	70.0	-	C017048
500[1]	90.0	-	RD-II 02083
	7 days after T		
65[1]	10.3	42.4	
500[1]	66.7	54.7	
	14 days after T		
65[1]	0	-11.0	
500[1]	31.6	20.7	
	21 days after T		
65[1]	0	32.5	
500[1]	0	34.6	

Effects of EXP 60707A on *Chrysoperla carnea* (exposed stage: larva) in an extended laboratory test (aged residue test)

Application rate [g/ha]	Corrected mortality [%]	Effect on fertility [%]	Reference
Test item was applied on potted apple trees at two different rates. 0, 7 and 14 days after treatment (T) leaves were collected from apple trees and returned to the laboratory. Aging of the spray residues of the test item on the potted apple trees took place under semi-field conditions during the whole study.			
	0 days after T		Hirth, N., 2001
65	8.5	4.8	C017675
500	21.3	11.5	RD-II 02084
	7 days after T		
65	8.9	8.4	
500	6.3	19.3	
	14 days after T		
65	0	-	
500	8.7	-	

Effects of EXP 60707A on *Coccinella septempunctata* (exposed stage: larva)

Application rate [g/ha]	Corrected mortality [%]	Effect on fertility [%]	Reference
1 Laboratory test using glass			
430	100	-	Candolfi, M.P., 1997
865	100	-	RD-00022
2 Laboratory test using leaves from treated apple trees (aged residue test)			
Test item was applied on potted apple trees at two different rates. 0, 7, 14, 21 and 28 days after treatment (T) leaves were collected from apple trees and returned to the laboratory. Aging of the spray residues of the test item on the potted apple trees took place under semi-field conditions during the whole study.			
	0 days after T		Hirth, N., 2002
65	42.9	-	RD-II 02081
500	95.9	-	
	7 days after T		
65	6.1	-18.7	
500	46.9	-	
	14 days after T		
65	2.2	-	
500	63.8	-	
	21 days after T		
500	23.9	-	
	28 days after T		
500	26.0	17.5	

Effects of EXP 60707A on *Poecilus cupreus* (exposed stage: male and female) in a laboratory test (substrate: quartz sand)

Application rate [g/ha]	Corrected mortality [%]	Effect on feeding rate [%]	Reference
960	0 + behavioral impairments up to 4 days	0*	Candolfi, M.P., 1996 RD-00019
1920	0 + behavioral impairments up to 4 days	0*	

*0 - 2 d after application = feeding rate was significant < than in control; 10 - 14 d after application = feeding rate was significant > than in control

Effects of EXP 60707A[1] and EXP 60707B[2] on *Typhlodromus pyri* (exposed stage: protonymph)

Application rate [g/ha]	Corrected mortality [%]	Effect on reproduction [%]	Reference
1 Laboratory test using glass			Candolfi, M.P., 1997
430[1]	82.8	100	RD-00021
865[1]	89.3	100	
2. Laboratory test using bean leaves			
51.50[2]	20.5	29.0	Lührs, U., 1999
90.15[2]	43.8	-	C008457
157.73[2]	34.1	-27.5	
276.04[2]	82.6	-	
483.09[2]	94.2	-	
LR_{50} : 143.48 g/ha (95% Confidence limits: 118.60 g/ha – 173.62 g/ha)			
3 Laboratory test using leaves from treated apple trees (aged residue test)			
Test item was applied on potted apple trees at two different rates. 0, 7 and 14 days after treatment (T) leaves were collected from apple trees and returned to the laboratory. Aging of the spray residues of the test item on the potted apple trees took place under semi-field conditions during the whole study.			
	0 days after T		
65[1]	-1.1	6.3	Adelberg, I., 2001
500[1]	39.1	-	RD-II 02082
	7 days after T		
65[1]	-2.1	-	
500	13.8	-1.1	
	14 days after T		
500[1]	5.1	-	

Conclusions

Mospilan SG is classified as not harmful for populations of *Chrysoperla carnea.*
Mospilan SG is classified as slightly harmful for populations of *Poecilus cupreus*.
Mospilan SG is classified as slightly harmful for populations of relevant predatory mites and spiders.
Mospilan SG is classified as harmful for populations of *Coccinella septempunctata.*

Effects on soil quality

Effects on soil macro-organisms being used as indicators of soil quality

Effects on earthworms

Summary of available toxicity data of effects of acetamiprid technical, formulation and degradation products on earthworms

Active substance

Test product	Duration, organism	Endpoint	Value	Dimension	Reference
acetamiprid	acute, 14 d, *Eisenia fetida*	LC_{50}	9.0	mg a.s./kg	RD-09520N

Metabolites

Test product	Duration, organism	Endpoint	Value	Dimension	Reference
IM-1-2	acute, 14 d, *Eisenia fetida*	LC_{50}	> 1000	mg a.s./kg	B004154
IM-1-4	acute, 14 d, *Eisenia fetida*	LC_{50}	> 1000	mg a.s./kg	RD-00780
IC-0	acute, 14 d, *Eisenia fetida*	LC_{50}	> 1000	mg a.s./kg	RD-00781
IM-1-5	acute, 14 d, *Eisenia fetida*	LC_{50}	> 1000	mg a.s./kg	RD-II-02451
	chronic, 56 d, *Eisenia fetida*	NOEC	62.5	mg a.s./kg	C029229

Products

Test product	Duration, organism	Endpoint	Value	Dimension	Reference
EXP60707A	acute, 14 d, *Eisenia fetida*	LC_{50}	3.66	mg a.s./kg	RD-00023
EXP60707A	chronic, 56 d, *Eisenia fetida*	NOEC	0.253 189	mg a.s./kg g a.s./ha	RD-00024

Exposure

Proposed use pattern

Crop	Number of applications	Application rate per treatment	
		Active substance (kg a.s./ha)	Product (g/ha)

Crop	Number of applications	Application rate per treatment	
		Active substance (kg a.s./ha)	Product (g/ha)
Potatoes	1	0.050	125
	2	0.025	125

For PEC calculations a simplified application scheme of 2 x 50 g a.s./ha was assumed, which exceeds worst case conditions.
For the PEC calculations in soil, a uniform distribution of the active substance to a depth of 5 cm soil is assumed, with a soil density of 1.5. Crop interception was chosen from the FOCUS Surface Water guidance document. To account for multiple applications, the MAF factor was calculated based on the mean soil DT_{50} of 6.1 days. Based on these results, the TER values for acetamiprid are calculated:

PECs for acetamiprid and corresponding TER values for earthworms

Appl. Rate [kg a.s./ha]	No. of appl.	Min. interval [days]	crop interception [%]	MAF	Max. rate in/on soil		TERa	TERlt
					[kg a.s./ha]	[mg a.s./ha for 2.5 cm soil depth]		
0.05	2	14	50	1.204	0.0301	0.040	91.2	6.3

Conclusion

The results demonstrate that no significant risk to earthworms is expected.

Field tests

Not required since the risk assessment shows that no unacceptable exposure is to be expected for earthworms.

Residue content of earthworms

Not required since log Pow of acetamiprid as well as of all soil degradation products are <3.

Effects on non-target macro-organisms

Not required for acetamiprid since the DT_{50} in soil is << 100 days.

Effects on organic matter breakdown

Not required for acetamiprid since the DT_{50} in soil is << 100 days.

It is concluded that the proposed use of Mospilan SG will not pose an unacceptable risk to populations of earthworms or other soil macro-organisms, when applied according to the recommended use pattern.

Instructions and information: None

Effects on soil non-target micro-organisms exposed to Mospilan SG

Ecotoxicological endpoints for soil micro-organisms

Test item	Test design[1]	EU agreed endpoints	Reference
acetamiprid	C	No significant effect > 25% at day 28 at 0.2 kg a.s./ha	SANCO/1392/2001
	N	No significant effect > 25% at day 28 at 0.2 kg a.s./ha	

[1] C = Carbon mineralization, N = Nitrogen transformation.

Risk assessment for soil microflora functions

Test substance	NOEC (< 25% effect at 28 d)	Maximum PEC_{soil} [mg/kg]	MoS*
acetamiprid	0.267 mg a.s./kg[a]	0.040	6.68

* Margin of Safety
[a] assuming a soil density of 1.5 and a soil depth of 5 cm

The results of these studies showed no effects of $\geq \pm$ 25% compared to the control on soil microbial activity up to a maximum tested concentration of 0.2 kg a.s./ha, after 28 days. As this maximum tested concentration was 6 times higher than the maximum initial PEC_{soil} (0.267 mg/kg) calculated based on the specific requirements for Germany.
As the proposed use of Mospilan SG an acceptable risk to soil microbial activity can be concluded.

Overall conclusion with respect to effects on soil quality

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

IIIA1 6.2.5 Adverse effects on parts of plant used for propagating purposes

It seems unlikely that the use of acetamiprid may have influence on tubers used for propagation. But 2 trials were conducted in 2003 and 2004 in Greece testing the germination of potato tubers of *Solanum tuberosum* after the application of acetamiprid at a dose of 25 and 50 g/hL, a rate which cannot be easily transferred to g/ha. No effects of acetamiprid on germination ability of potato tubers were detected. There are no indications of such effects from the use of the product at farm level until now. Therefore, there is no indication that Mospilan SG has any effects on plants or parts of plants used for propagation purposes.

IIIA1 6.2.6 Impact on succeeding crops

Acetamiprid is registered in many countries and it is used on a large variety of crops under diverse climatic conditions. No selectivity issue has been reported on any of these crops. There are no indications of such effects from the use of the product at farm level until now.

IIIA1 6.2.7 Impact on other plants including adjacent crops

Acetamiprid is registered in many countries and it is used on a large variety of crops under diverse climatic conditions. No selectivity issue has been reported on any of these crops. There are no indications of such effects from the use of the product at farm level until now.

IIIA1 6.2.8 Possible development of resistance or cross-resistance

Acetamiprid is a broad spectrum insecticide and belongs to the neonicotinoid family. IRAC has published an article about general use of neonicotinoids and resistance risk management. It recommends that application should be made on the basis of label recommendations and GAP (Good Agricultural Practices). The full dose rate has to be used and applied with appropriate equipment. It is indicated that the use of lower or higher dosage might induce resistance. Mode of action alternation is recommended. In the case of modification of susceptibility, neonicotinoids should be avoided.
The probability of appearance of resistant of Colorado potato beetle is high, because this pest is controlled quite regularly in some regions and has shown to develop resistance quite fast to different a.s. in the past. There are some reports from the US of resistance development of this species to a neonicotinoid. There are no reports of such resistance in Europe yet.
A baseline study has been conducted for acetamiprid on larvae of *L. decemlineata* for 5 strains from commercial potato fields at several sites in Germany using thiacloprid and lambda-cyhalothrin as reference products. In this study, potato leaf discs were dipped for 30 sec. into solutions of the test substances and then dried. The sensitivity of newly hatched larvae (1st instar < 24 h old) from the different strains was tested, with determination of mortality after 5 and 24 h exposure to the treated leaf discs. LC90 values varied between 50 and 135 g a.s./ha after 5 hours with thiacloprid varying in the same range, whereas for lambda-cyhalothrin values between 5 and 283 g a.s./ha were detected indicating some resistance for the pyrethroids but no cross resistance between pyrethroid and neonicotinoids.
Additionally sensitivity data especially from regions with a longer use of neonicotinoids to control Colorado potato beetle should be produced in coming years to detect any resistance risk development at an early stage.
As resistance strategy an alternation of products with different modes of action or alternative control strategies should strongly be recommended especially for areas with a frequent control need of the beetle.

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

None

IIIA1 6.6 Summary and assessment of data according to points 6.1 to 6.5

Mospilan SG is an insecticide applied as spray application in order to control Colorado potato beetle (LEPTDE) in potato (SOLTU). It contains 20% acetamiprid per kg. It is requested to be registered at 125 g/ha (25 g a.s./ha) for control of adults and larvae with up to 2 applications with a period between the 2 applications of at least 14 days.
Climatic differences play a role for Colorado potato beetle pest infection pressure. The trials which have been conducted in different EPPO climatic zones of the central zone all show a similar degree of activity independent of the climatic region. All presented trials indicate that 125 g/ha (25 g a.s./ha) of Mospilan SG is the minimum effective dose rate against adults and larvae in potato. The application of 125 g/ha of Mospilan SG provides a sufficient high level of protection of nearly 100% against larvae and beetles for a period of about 2 weeks and exceeds the control achieved by several reference products. A warning indicating that the product should only be used if regional threshold values are exceeded or that prophylactic treatments should be avoided should be present on national labels.
Mospilan SG is even at rates higher than 125 g/ha not expected to have any negative effects on yield and quality of potato and no negative effects were detected neither in field trials nor in special phytotoxicity trials. Mospilan SG can be safely applied to potato. No negative effect is expected on parts of plant used for propagating purposes or on succeeding or adjacent crops.
Resistance development is likely and sensitivity data were provided which will allow following any resistance development in future. A resistance strategy applicable for all neonicotinoids used in potatoes should be used in countries where frequent control of *L. decem*lineata is necessary to avoid resistance development.
For these reasons, Mospilan SG may be registered in all countries of the Central Zone with the exception of countries, in which the beetles is not present (such as in UK and IE) at a rate of 125 g product/ha to control adults and larvae of Colorado potato beetle in potato.

IIIA1 6.7 List of test facilities including the corresponding certificates

Test Institute	Address	Comments
Austrian Private Institutes		
Kwizda	Dr. Karl Lueger-Ring 6, 1011 Wien, Austria	
French Private Institutes		
Eurofins Agroscience Services / Eurofins-GAB GmbH, GAB France Field Station	17 boulevard Archimède 66200 ELNE	
German Plant Protection Service / Private Institutes		
Landwirtschaftskammer Niedersachsen, Pflanzenschutzamt (LWK Hannover)	Wunstorfer Landstrasse 9, 30453 Hannover, Germany	

Test Institute	Address	Comments
Staehler Deutschland GmbH & Co. KG	Stader Elbstrasse, 21683 Stade, Germany	
Hungarian Plant Protection Service / Private Institutes		
Plant Health and Soil Conservation Station of Szabolcs-Szatmár-Bereg county	4400 Nyiregyháza	Conducted in 1994
Plant Health and Soil Conservation Station of Somogy county	2660 Kaposvár	Conducted in 1994
Plant Protection and Soil Conservation Service of county Nograd	2660 Balassagyarmat	Conducted in 1994
Polish Plant Protection Service / Private Institutes		
Institut Ochrony Roslin, Poznan	60-318 Poznan	Conducted in 1994
Institut Ziemniaka, IHAR Bonin	76-009 Bonin	No certificate available
Slovakian Plant Protection Service / Private Institutes		
Central Agricultural Inspection and Testing Institute Bratislava (ÚKSÚP)	Matúškova 21, 833 16 Bratislava	Conducted in 1995 and 1996
Swiss Private Institutes		
Siegfried Agro	4800 Zofingen, Switzerland	GEP not required in Switzerland

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

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
MIIIA1 Sec 7	Nisso Chemical Europe GmbH	Draft Registration Report - Part B - Mospilan SG -DE - Section 7 - Efficacy Data and Information - National addenda	2011	258983
MIIIA1 Sec 7	Schalnat, S.	BIOLOGICAL ASSESSMENT DOSSIER for Mospilan SG	2011	258984
MIIIA1 Sec 6	Nisso Chemical Europe GmbH	Draft Registration Report - Part B - Mospilan SG - DE - Section 6 ¿ Ecotoxicology - Core assessment	2011	258985

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 6.1.2	Refardt, M.	Control of Colorado Beetle on Potatoes	2001	NC0029(= 2001 IF-5/53) 258989
KIIIA1 6.1.3	Refardt, M.	Control of Colorado Beetle on Potatoes	2001	NC0029(= 2001 IF-5/53) 258990
KIIIA1 6.1.2	Refardt, M.	Control of Colorado Beetle on Potatoes	2001	NC0030(= 2001 IF-5/54) 258991
KIIIA1 6.1.3	Refardt, M.	Control of Colorado Beetle on Potatoes	2001	NC0030(= 2001 IF-5/54) 258992
KIIIA1 6.1.2	Refardt, M.	Control of Colorado Beetle on Potatoes	2001	Nc0031(= 2001 IF-5/342) 258993
KIIIA1 6.1.3	Refardt, M.	Control of Colorado Beetle on Potatoes	2001	Nc0031(= 2001 IF-5/342) 258994
KIIIA1 6.1.2	Anzeng-ruber, J.	Control of Colorado Beete on Potato	2001	NC0356(= Kwizda 2001-2) 258995

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 6.1.3	Anzeng-ruber, J.	Control of Colorado Beete on Potato	2001	NC0356(= Kwizda 2001-2) 258997
KIIIA1 6.2.1	Anzeng-ruber, J.	Control of Colorado Beete on Potato	2001	NC0356(= Kwizda 2001-2) 258998
KIIIA1 6.1.2	Anzeng-ruber, J.	Control of Colorado Beetle on Potato	2001	NC0357(= Kwizda 2001-3) 258999
KIIIA1 6.1.3	Anzeng-ruber, J.	Control of Colorado Beetle on Potato	2001	NC0357(= Kwizda 2001-3) 259001
KIIIA1 6.2.1	Anzeng-ruber, J.	Control of Colorado Beetle on Potato	2001	NC0357(= Kwizda 2001-3) 259002
KIIIA1 6.1.2	Eisenheld, F.	Control of Colorado Beetle on Potato	2001	NC0358(= Kwizda 2001-4) 259003
KIIIA1 6.1.3	Eisenheld, F.	Control of Colorado Beetle on Potato	2001	NC0358(= Kwizda 2001-4) 259004

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 6.2.1	Eisenheld, F.	Control of Colorado Beetle on Potato	2001	NC0358(= Kwizda 2001-4) 259005
KIIIA1 6.1.2	Eisenheld, F.	Control of Colorado Beetle on Potato	2002	NC0361(= Kwizda 2002-7) 259006
KIIIA1 6.1.3	Eisenheld, F.	Control of Colorado Beetle on Potato	2002	NC0361(= Kwizda 2002-7) 259007
KIIIA1 6.1.2	Eisenheld, F.	Control of Colorado Beetle on Potato	2002	NC0362(= Kwizda 2002-7) 259008
KIIIA1 6.1.3	Eisenheld, F.	Control of Colorado Beetle on Potato	2002	NC0362(= Kwizda 2002-7) 259009
KIIIA1 6.1.2	Rohde, H.	Control of Colorado Potato Beetle on Potatoes	2004	NC0829(= 04KI107D 52) 259010
KIIIA1 6.1.3	Rohde, H.	Control of Colorado Potato Beetle on Potatoes	2004	NC0829(= 04KI107D 52) 259011

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 6.1.2	Pawinska, M.	Control of Insect Pests in Potatoes	2001	NC1070-NI25(=2/2001) 259012
KIIIA1 6.1.3	Pawinska, M.	Control of Insect Pests in Potatoes	2001	NC1070-NI25(=2/2001) 259013
KIIIA1 6.1.2	Pawinska, M.	Control of Insect Pests in Potatoes	2006	NC1072-NI25(=05/CZAR/006) 259014
KIIIA1 6.1.3	Pawinska, M.	Control of Insect Pests in Potatoes	2006	NC1072-NI25(=05/CZAR/006) 259015
KIIIA1 6.2.1	Pawinska, M.	Control of Insect Pests in Potatoes	2006	NC1072-NI25(=05/CZAR/006) 259016
KIIIA1 6.1.2	Pawinska, M.	Control of Insect Pests in Potatoes	2006	NC1073-NI25(=I/05/BON/006) 259018

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 6.1.3	Pawinska, M.	Control of Insect Pests in Potatoes	2006	NC1073-NI25(=I/05/BON/006) 259019
KIIIA1 6.2.1	Pawinska, M.	Control of Insect Pests in Potatoes	2006	NC1073-NI25(=I/05/BON/006) 259020
KIIIA1 6.1.2	Megvei, N.	Control of Insect Pests in Potato	1994	MC1158-NI25(=67 SZ/94) 259021
KIIIA1 6.1.3	Megvei, N.	Control of Insect Pests in Potato	1994	MC1158-NI25(=67 SZ/94) 259022
KIIIA1 6.2.1	Megvei, N.	Control of Insect Pests in Potato	1994	MC1158-NI25(=67 SZ/94) 259023
KIIIA1 6.1.2	Cziklin, M.	Control of Insect Pests in Potato	1994	NC1159-NI25(=Somogy) 259024
KIIIA1 6.1.3	Cziklin, M.	Control of Insect Pests in Potato	1994	NC1159-NI25(=Somogy) 259026

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 6.1.2	Anony-mous	Control of Insect Pests in Potato	1994	NC1172-NI25(=Poznan) 259030
KIIIA1 6.1.3	Anony-mous	Control of Insect Pests in Potato	1994	NC1172-NI25(=Poznan) 259032
KIIIA1 6.2.1	Anony-mous	Control of Insect Pests in Potato	1994	NC1172-NI25(=Poznan) 259033
KIIIA1 6.1.2	Pawinska, M.	Control of Insect Pests in Potato	1994	NC1173-NI25(=Bonin) 259034
KIIIA1 6.1.3	Pawinska, M.	Control of Insect Pests in Potato	1994	NC1173-NI25(=Bonin) 259035
KIIIA1 6.1.2	Pawinska, M.	Control of Insect Pests in Potato	1995	NC1242-NI25(=Bonin) 259036
KIIIA1 6.1.3	Pawinska, M.	Control of Insect Pests in Potato	1995	NC1242-NI25(=Bonin) 259037

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 6.1.2	Eberhart, A.	Control of Insect Pests in Potatoes	2009	NC1376-NI25(=S08-01028-01a&02) 259039
KIIIA1 6.1.3	Eberhart, A.	Control of Insect Pests in Potatoes	2009	NC1376-NI25(=S08-01028-01a&02) 259040
KIIIA1 6.2.1	Eberhart, A.	Control of Insect Pests in Potatoes	2009	NC1376-NI25(=S08-01028-01a&02) 259041
KIIIA1 6.1.3	Eisenheld, F.	Control of Colorado Beetle on Potato	2001	NC0359(=Kwizda 2001-5) 259042
KIIIA1 6.2.1	Eisenheld, F.	Control of Colorado Beetle on Potato	2001	NC0359(=Kwizda 2001-5) 259043
KIIIA1 6.1.3	Budai, C.	Control of Insect Pests in Potato	1994	NC1160-NI25(=Szabolcs) 259044

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 6.1.3	Lauen-stein, G.	Control of Colorado Beetle on Potatoes	2005	NC0912(=HR2I05STS008) 259045
KIIIA1 6.1.3	Rohde, H.	Control of Colorado Beetle on Potatoes	2005	NC0913(=05KI105D39) 259046
KIIIA1 6.2.1	Anony-mous	Control of Insect Pests in Potato	1995	NC1256-NI25(=35/ZV/1995) 259047
KIIIA1 6.2.1	Gallo, P.	Control of Insect Pests in Potato	1996	NC1326-NI25(=51/ZV/1996) 259048
KIIIA1 6.2.1	Gallo, P.	Control of Insect Pests in Potato	1996	NC1327-NI25(=59/ZV/1996) 259049
KIIIA1 6.2.5	Skoulakis, G.	Germination of Potato Tubers	2003	NC0957(=03GTP03) 259050
KIIIA1 6.2.5	Skoulakis, G.	Germination of Potato Tubers	2004	NC0958(=03GTP04) 259051

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 6.2.8	Thieme, T	Relative susceptibility of field collected populations of the Colorado Potato Beetle (Leptinotarsa decemlineata) to the insecticides Mospilan 20 SP, Biscaya and Karate Zeon	2007	NC1348 259052
KIIIA1 10.5.1	Candolfi, M.P.	EXP 60707A - Laboratory acute toxicity test with the parasitic wasp Aphidius rhopslosiphi (Hymenoptera: Braconidae) based on the method of Mead-Briggs (1992) and the IOBC approves method of Polgar (1988)	1997	RD-00020 259063
KIIIA1 10.5.1	Candolfi, M.P.	EXP 60707A - Laboratory contact toxicity test with the predacious mite Typhlodromus pyri Scheuten (Acari: Phytoseiidae) based on the IOBC approved method of Overmeer (1988)	1997	RD-00021 259064
KIIIA1 10.5.1	Candolfi, M.P.	EXP 60707A - Laboratory acute toxicity test with the ground beetle Poecilus cupreus L. (Coleoptera: Carabidae) based on the IOBC approved method of Heimbach (1992)	1997	RD-00019 259065
KIIIA1 10.5.1	Candolfi, M.P.	EXP 60707A - Laboratory contact toxicity test with the seven spotted Lady bettlec, Coccinella septempunctata L. (Coleoptera: Coccinellidae)based on the IOBC approved method of Pinsdorf (1989)	1997	RD-00022 259066
KIIIA1 10.5.2	Moll, M.	Effects of EXP 60707B on the parasitoid Aphidius rhopalosiphi (Hymenoptera, Aphidiidae) - Extended laboratory study	1999	C008456 259067
KIIIA1 10.5.2	Lührs, U.	Effects of EXP 60707B on the predatory mite Typhlodromus pyri Scheuten (Acari, Phytoseiidae) - Extended laboratory study	1999	C008457 259068
KIIIA1 10.5.2	Schuld, M.	EXP 60707A: Toxicity to the aphid parasitoid Aphidius rhopalosiphi DeStefani-Perez (Hymenoptera, Braconidae) using an extended laboratory test with freshly applied and aged residues following a single application at rates of 13 or 100 g a.i./ha	2001	RD-II 02083 259069

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 10.5.2	Adelberger, I.	EXP 60707A: Toxicity to the predatory mite Typhlodromus pyri Scheuten (Acari: Phytoseiidae) using an extended laboratory test with freshly applied and aged residues following a single application at rates of 13 or 100 g a.i./ha	2001	RD-II 02082 259070
KIIIA1 10.5.2	Hirth, N.	EXP 60707A: Toxicity to the green lacewing Chrysoperla carnea Steph. (Neuroptera, Chrysopidae) using an extended laboratory test with freshly applied and aged residues following a single application at rates of 13 or 100 g a.i./ha	2001	RD-II 02084 259071
KIIIA1 10.5.2	Hirth, N.	EXP 60707A: Toxicity to the ladybird Coccinella septempunctata L. (Coleoptera, Coccinellidae) using an extended laboratory test with freshly applied and aged residues following a single application at rates of 13 or 100 g a.i./ha	2002	RD-II 02081 259073
KIIIA1 10.6.2	Suteau, P.	EXP 60707A - Acute toxicity (14-day) to earthworms (Eisenia foetida)	1996	RD-00023 259075
KIIIA1 10.6.2	Lührs, U.	Acute toxicity (14 days) of IM-1-2 to the earthworm Eisenia fetida in artificial soil	2002	B004154 259078
KIIIA1 10.6.2	Rodgers, M.	IM-1-5: Acute toxicity (LC50) to the earthworm	2002	RD-II 02451 259080
KIIIA1 10.6.3	Goßmann, A.	EXP 60707B - Effects on reproduction and growth of earthworms (Eisenia foetida) in artificial soil	1997	RD-00024 259082
KIIIA1 10.6.3	Lührs, U.	Effects of IM-1-5 on reproduction and growth of earthworms Eisenia fetida in artificial soil	2003	C029229 259084

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 10.6.6	Klein, S.	Effects of IM-1-5 on reproduction of the collembola Folsomia candida in artificial soil	2003	RD-03058 259085
KIIIA1 10.6.6	Schmitzer, St.	Effects of IM-1-5 on the reproduction of rove beetles Aleochara bilineata in the laboratory	2003	RD-03101 259087

Appendix 2: GAP table

GAP rev. 1, date: 2012-05-29

PPP (product name/code) **Mospilan SG**
active substance 1 **Acetamiprid**

Formulation:
Type: **SG**
Conc. of as 1: **200 g/kg**

Applicant: **Nisso Chemical Europe GmbH** **professional use** ☒ **non professional use** ☐
Zone(s): **central**

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		
1	BE, CZ, DE: IE. LU, HU, NL, AT, PL, RO, SI, SK, UK	(SOLTU) potato	F	(LEPTDE) colorado potato beetle	spraying	spring to summer	a) 1 b) 2	a) 0,125 g b) 0,250 g	a) 25 g b) 50 g	300 - 600		

Remarks:
(a) In case of group of crops the Codex classification should be used
(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
(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
(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

Reporting table

Active substance: **Acetamiprid**
Trade name/Formulation type: **Mospilan SG 005655-00/16**
Rapporteur: **Germany**
Applicant: **Nisso Chemical Europe GmbH**

Annex III point	Member State/ Applicant	Comment	Reply ZRMS
dRR - overall GENERAL COMMENTS			
dRR – Part A			
Page 16	DE	In header 3.1.6.4: **Macro**-organisms (not Marco)	**done**
dRR – Part B			
Section 3 – Mammalian Toxicology			
		Section not available	**This is an extension therefore section 3 still valid**
Section 5 – Environmental Fate			
Page 12	Core	Reference for Table 5.4-7 in text destroyed ("Fehler ! …)	**done**
Page 16	Cor	Formatting error for Header 5.4.3	**done**
Page 25	Addendum DE	There is a significant formatting error on the page, possibly an artefact from pdf print	**No formatting error visible in the doc. format**
Section 6 - Ecotoxicology			
Point 6.2.1.1	Core	Confidential information (Authors of vertebrate studies) in Table 6.2-1 on page 9 (xxx) **and in text below the Table** on the same page **– please delete / blacken out**	**done**
Point 6.3.1.1	Core	Confidential information (Authors of vertebrate studies) in Table 6.3-1 on page 16/17 (xxx) **and in text above the Table** on page 16 **– please delete / blacken out**	**done**
Point 6.4.1.1	Core	Confidential information (Authors of vertebrate studies) in Table 6.4-1 on page 23 (xxx) **– please delete / blacken out**	**done**
Section 7 – Efficacy			

Annex III point	Member State/ Applicant	Comment	Reply ZRMS
Page 25		There is a significant formatting error on the page, possibly an artefact from pdf print	**No formatting error visible in the doc. format**