KEMI
Kemikalieinspektionen
Swedish Chemicals Agency

REPORT

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Date
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Product Assessment Report of a Biocidal Product Family
Related to product authorisation under Regulation (EU) No 528/2012

Myrr D Family (Deltamethrin DP 0.05 RTU)

Meta level: Myrr D Family – Deltamethrin DP 0.05

Products: Myrr D Deltamethrin DP 0.05

Myrr D

Type of application Authorisation	Product type PT 18 (insecticide)
Authorisation number for family 5356	Date of decision/Entry into force 08 September 2017
Authorisation number for products Myrr D Deltamethrin DP 0.05: [5356-1-1] Myrr D: [5356-1-2]	
Active substance Deltamethrin, 0.05% (w/w)	Date of expiry 07 September 2027
Sweden's R4BP3 reference code BC-GW010779-09 (2013/1117/7060/SE/APPFF/10787)	User category Class 3 - Products that may be used by anyone

v.1.1 2017-10-27. The PAR has been revised with regard to the label claims in the sections specified below.

Version	Date	Section	After correction 2017-10-27
Version 1	2017-09-08		
Version 1.1	2017-10-27	Section 1.5.2.2 (p. 8): Uses authorised by the Reference Member State – Target organisms Section 2.6.1 (p. 21-22): Ref-MS information to reader … Ref -MS concludes, …, that the submitted documentation supports the following claims…: Section 3.1.4 (p. 89): Conclusions from efficacy evaluation and risk assessment of the biocidal product family	Use pattern 1: For kill and control of ants (workers and nests) - General public – Outdoor. Not for kill and control of tropical ants For kill and control of ants (workers and nests), within 2-3 weeks, around houses. Not for control of tropical ants. The efficacy of the product family for control of workers and nests of garden ants (not tropical ants)…

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1 GENERAL INFORMATION ABOUT THE PRODUCT FAMILY APPLICATION

1.1 APPLICANT

Company Name:	Bayer S.A.S.
Address:	16 rue Jean-Marie Leclair CS 90106
City:	Lyon Cedex 09
Postal Code:	F-69266
Country:	France
Telephone:	[redacted]
E-mail address:	[redacted]

1.1.1 Person authorised for communication on behalf of the applicant

Name:	[redacted]
Function:	[redacted]
Address:	16 rue Jean-Marie Leclair, CS 90106
City:	Lyon
Postal Code:	F-69266 Cedex 09
Country:	France
Telephone:	[redacted]
E-mail address:	[redacted]

1.2 CURRENT AUTHORISATION HOLDER

Company Name:	Bayer AB
Address:	Arne Jacobsens Allé 13
City:	Köpenhamn S
Postal Code:	2300
Country:	Denmark
Telephone:	[redacted]
E-mail address:	[redacted]

Letter of appointment for the applicant to represent the authorisation holder provided (yes/no):	Not applicable

1.3 PROPOSED AUTHORISATION HOLDER

Company Name:	Bayer AB
Address:	Arne Jacobsens Allé 13
City:	Köpenhamn S
Postal Code:	2300
Country:	Denmark
Telephone:	[redacted]
E-mail address:	[redacted]
Letter of appointment for the applicant to represent the authorisation holder provided (yes/no):	No

1.3.1 Person authorised for communication on behalf of the proposed authorisation holder

Name:	[redacted]
Function:	[redacted]
Address:	Arne Jacobsens Allé 13
City:	Köpenhamn S
Postal Code:	2300
Country:	Denmark
Telephone:	[redacted]
E-mail address:	[redacted]

1.4 INFORMATION ABOUT THE PRODUCT FAMILY APPLICATION

Application received:	29th of August 2013
Application reported complete:	20th of December 2013
Type of application:	New authorisation

Further information:	Applicant has indicated submission of application for mutual recognition in [redacted] The application was submitted as the frame formulation Myrr D under Directive 98/8/EC and is transformed to an application for biocidal product family with one meta family and two family members products (products), in accordance with the Biocidal Products Regulation (EU) No 528/2012 and the transitional measures in Article 91. The two biocidal products included in the biocidal product family, Myrr D Deltamethrin DP 0.05 and Myrr D, differ as there is a variation in the concentration of a non-active substance. The detailed information on product composition is presented in a separate confidential annex.

1.5 INFORMATION ABOUT THE BIOCIDAL PRODUCT FAMILY

1.5.1 General information

Family name:	Myrr D Family
Meta (second information level):	Myrr D Family – Deltamethrin DP 0.05
Trade name of individual products (third information level):	Myrr D Deltamethrin DP 0.05 and Myrr D
Manufacturer's development code number(s), if appropriate:	Specification No.: 102000002570-03 Supply Chain No.: UVP05938872 Older code : AE F032640 00 DP01 A3 Specification No.: 102000020443-02 Supply Chain No.: UVP79400446
Product type:	PT18
Composition of the product (identity and content of active substance(s) and substances of concern; full composition see confidential annex):	Deltamethrin: 0.5 g/kg, (0.05 % (w/w))
Formulation type:	Dustable powder (DP)
Ready to use product (yes/no):	Yes
Is the product the very same (identity and content) to another product already authorised under the regime of directive 98/8/EC (yes/no); If yes: authorisation/registration no. and product name: or	The product was submitted as a frame formulation and has under the BPR been handled as a biocidal product family with two members. Myrr D Deltamethrin DP 0.05 is identical to the representative product and Myrr D is very similar to the representative product evaluated in connection with the approval for listing of active substance(s) on to Annex I to directive 98/8/EC.

Has the product the same identity and composition like the product evaluated in connection with the approval for listing of active substance(s) on to Annex I to directive 98/8/EC (yes/no):	

1.5.2 Information on the intended use(s)

1.5.2.1 Uses claimed by the applicant

Overall use pattern (manner and area of use):	Dust ant nest and insect harbourages in the protected outdoors. Around houses.
Target organisms:	Black Ant *(Lasius niger*) and other commonly found garden ants. Other crawling insects, e.g. german cockroaches, silverfish, wood louse or pill bug, in protected outdoor locations.
Category of users:	Consumers
Directions for use including minimum and maximum application rates, application rates per time unit (e.g. number of treatments per day), typical size of application area:	**Ant control** Use not more than 2 g per nest entrance, (equal to three bottle inversions), per ant nest. Scatter directly into nest entrance and/or crack & crevices where ants are visible. If ants appear from multiple entrance holes, treat all of them by evenly distributing the 2 g dust into all nest entries. **Control of crawling insects in localised protected outdoor locations:** Scatter 2 g, equal to 2 mL, of dust per 100 cm^2 in insect harbourages in the protected outdoor. Do not exceed 4 g of product per harbourage.
Potential for release into the environment (yes/no):	Conclusions regarding fate properties are presented for the active substance deltamethrin in Doc IIA. It is considered that the formulation of Myrr D Deltamethrin DP 0.05 and Myrr D will not significantly influence the environmental fate and behaviour of the active substance.
Potential for contamination of food/feedingstuff (yes/no)	No
Proposed Label:	See IIIB9
Use Restrictions:	Detailed on proposed label

1.5.2.2 Uses authorised by the Reference Member State

Overall use pattern (manner and area of use):	1. Spreading outdoors for kill and control of workers and nests of garden ants, at a maximum dose of 2 g per ant nest or 2 g per 100 cm^2 insect harbourage. Do not exceed 4 g per harbourage. 2. Spreading in small confined and protected locations (e.g. underneath flowerpots, floor boards, garden appliances etc) around houses for control of crawling insects and woodlice
Target organisms:	~~Use pattern 1: For kill and control of garden ants (Lasius niger) workers and nests - General public - Outdoor~~ Use pattern 1: For kill and control of ants (workers and nests) - General public – Outdoor. Not for kill and control of tropical ants (*v1.1_2017-10-27*) Use pattern 2: For direct and fast kill, and control, of crawling insects and woodlice – General public – in small confined protected spaces around buildings
Category of users:	General public However, please note: According to the Swedish public policy on suitable measures to reduce the risks and avoid development of pest populations resistant towards the active biocide substance, only professionals should be allowed to treat infestations of cockroaches in Sweden. Since this product is intended for non-professional users, KemI proposes to make a derogation in accordance with Art. 37(1b) of the BPR at the MR stage, and adjust the terms and conditions of the authorisation and SPC so that the use against cockroaches is not included in the authorised uses on the Swedish market.

For details of the uses authorised by the Reference Member State, please see the Summary of biocidal Product Family Characteristics (SPFC), were both the products Myrr D Deltamethrin DP 0.05 and Myrr D are included in one meta-SPC (second information level of the SPFC).

1.5.3 Information on active substance

Active substance chemical name:	Deltamethrin
CAS No:	52918-63-5
EC No:	258-256-6
Purity (minimum, g/kg or g/l):	98.5 % (w/w)

Inclusion directive:	Commission Directive 2011/81/EU
Date of inclusion:	October 1st, 2013
Is the active substance equivalent to the active substance listed in Annex I to 98/8/EC (yes/no):	Yes
Manufacturer of active substance(s) used in the biocidal product:	See the Summary of biocidal Product Family Characteristics

1.6 DOCUMENTATION

1.6.1 Data submitted in relation to product family application

Relevant data on the product family have been submitted for physical, chemical and technical properties; methods of identification and analysis; efficacy; toxicity.

All data were produced in studies of acceptable quality. The studies are listed in Annex 1 (Reference List).

No new data is submitted in relation to the active substance. Summaries of studies to determine the acute toxicity (oral and dermal toxicity, skin and eye irritation and dermal sensitisation potential) are presented in Doc IIIB.

Table 1.6.1-1 Summary of product family toxicity studies

Route	Method Guideline	Species Strain/ Sex no/group/ vehicle	Dose levels duration of exposure	Value LD_{50}/LC_{50} (mg /kg bw or mg /l)	Remarks	Reference in Doc III-B section 6
Oral	US EPA OECD 401	OFA Sprague-Dawley rat 5M+5F Vehicle: distilled water	5000 mg/kg bw	LD_{50}: > 5000 mg/kg bw (M&F)	Not classified	[redacted] 1989a (6.1.1/01)
Dermal	US EPA OECD 402	NZW rabbit 5M+5F Vehicle: none	2000 mg/kg bw	LD_{50}: >2000 mg/kg bw (M&F)	Not classified	[redacted] 1989b (6.1.2/01)
Inhalation	US EPA OECD 403	HSD (SD)rat 5M+5F Vehicle: none	7.75 mg a.s./l air	LC_{50} (4 hrs, aerosol): >7.75 mg a.s./l air (M&F)	Not classified	[redacted] (6.1.3/01)

Route	Method Guideline	Species Strain/ Sex no/group/ vehicle	Dose levels duration of exposure	Value LD_{50}/LC_{50} (mg /kg bw or mg /l)	Remarks	Reference in Doc III-B section 6
Dermal Irritation	US EPA OECD 404	New Zealand Albino rabbit	0.5 mL	Highest erythema score = 0 Highest oedema score = 0 Reversibility – NA, no irritation	Not a skin irritant	[redacted] 1989c (6.2.1/01)
Eye Irritation	OECD 405	New Zealand Albino rabbit	0.1 mL	Transient slight ocular irritation after neat unrinsed application. Reversible within 72 hr. Reactions in rinsed eyes were less severe.	Not an eye irritant	[redacted] 1989d (6.2.2/01)
Dermal sensit isation	Buehler OECD 406	Albino Hartley Guinea pig	No dilution	0/10 sensitised	Not a sensitiser	[redacted] (6.3/01)

1.6.2 Access to documentation

The applicant, Bayer S.A.S., owns the data on the active substance deltamethrin supporting this product family authorization, therefore there is no need for a Letter of Access. The applicant was also the notifying company for Annex I inclusion of the active substance (Directive 2011/81/EU) in directive 98/8/EC.

2 SUMMARY OF THE PRODUCT FAMILY ASSESSMENT

2.1 INFORMATION TO THE READER FROM THE REF-MS

Ref-MS information to the reader:	The following section (Section 2) of the Product Assessment Report for the biocidal product family consists of the applicant's text and tables from Documents IIB and IIC of the product dossier. The format of the documents, such as section and table numbering or the layout, has been altered to conform to the formatting of this Product Assessment Report. As a general rule, the contents of this section have not been amended by the Ref-MS, unless otherwise stated (see below). However, minor alterations, such as removing references considered redundant for the understanding of the risk assessment, for example cross-references referring to other parts of the product dossier (for example Document III) or the dossier for Annex I-inclusion, have been made by the Ref-MS. In this section, the Ref-MS's comments, clarifications, and conclusions are presented in shaded tables or boxes like this one, inserted in the document where considered necessary. In some cases, the applicant´s text has been shaded in grey and marked with an asterisk (*) referring to the adjacent Ref-MS's commenting box. Where values have been re-calculated by the Ref-MS, these values are shown in shaded tables or boxes placed at the end of the relevant sections. For the assessment of the application, the Ref-MS has focused on the elements which are crucial for risk assessment and decision-making; hence, minor errors in the applicant's text or discrepancies from the view of the Ref-MS of no importance for the overall conclusion, or the specific phrasing of the text, are not amended or commented upon. This approach applies mainly to Section 2 of this Product Assessment Report. Further information: Please note that while the application was submitted as a frame formulation under Directive 98/8/EC, it has been transformed to an application for biocidal product family with two family members (products), in accordance with the Biocidal Products Regulation (EU) No 528/2012 and the transitional measures in Article 91. The two family members, Myrr D Deltamethrin DP 0.05 and Myrr D, differ slightly in the composition (see confidential annex). Throughout the assessment report, the product family name Deltamethrin DP 0.05 RTU is used by ref-MS while referring to data that are valid for both formulations, as the family name was changed to Myrr D Family very late in the process. In the applicant's text, both formulations are referred to as a single product. In some places in Section 2, the alternative product name *Deltamethrin DP 0.05* is occurring in the applicant's text and tables, also referring to both formulations. In addition, read-across from related deltamethrin products is also occurring.

2.2 IDENTITY RELATED ISSUES

2.2.1 Identity of ingredients of the biocidal product

See confidential part (Business Confidential Information document).

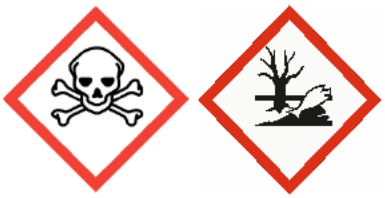
2.2.2 Information on the substance(s) of concern

There are no substances of concern in the biocidal product.

2.3 CLASSIFICATION, LABELLING AND PACKAGING

Ref-MS information to the reader:	This section (2.3.1-2.3.2) is amended by Ref-MS according to CLP-classification only (Regulation (EC) 1272/2008).

2.3.1 Classification and labelling of the active substance deltamethrin

Classification	Acute Tox. 3; H301 Acute Tox. 3; H331 Aquatic Acute 1; H400 Aquatic Chronic 1; H410
Labelling	
Pictograms	 GHS06 GHS09
Signal word	Danger
Hazard statements	H301: Toxic if swallowed. H331: Toxic if inhaled. H410: Very toxic to aquatic life with long lasting effects. M-factor: 1 000 000

2.3.2 Proposed classification and labelling of the biocidal product

Classification	Aquatic Acute 1; H400 Aquatic Chronic 1; H410
Labelling	
Pictograms	
Signal word	Warning
Hazard statements	H410: Very toxic to aquatic life with long lasting effects.
Precautionary statements	P102: Keep out of reach of children P391: Collect spillage P501: Dispose of contents/container in accordance with local regulation.

2.3.3 Packaging of the biocidal product

Myrr D is sold in HDPE bottle with childproof cap and scattering plastic plate in sizes up to 400 g.

2.4 PHYSICO-CHEMICAL PROPERTIES

Myrr D Deltamethrin DP 0.05 is a dustable powder containing 0.5g/kg deltamethrin. It is a white and odourless powder. The product does not burn, does not undergo spontaneous combustion and does not emit flammable gas when in contact with water. The pH of a 1% dispersion is 8.8. Based on the physical and chemical nature of the components, the product has no explosive, oxidising or flammable properties. The product is stable for at least 3 years at ambient temperature. The test results on the physico-chemical properties for Myrr D Deltamethrin DP 0.05 is also valid for Myrr D since the composition of the two products are almost identical. There are no properties that require the product to be classified for physical or chemical hazard.

Studies were provided for the physical and chemical properties of the biocidal product Myrr D Deltamethrin DP 0.05 and are summarised in Table 2.4-1 below.

Table 2.4-1 Physico-chemical properties of the biocidal product

Physico-chemical property	**Guideline No. and Method used**	**Result/Comment**	**Ref. in Doc III**
Physical state	Visual	Powder	Güldner and Hoppe (2008) (B3.1.1/01)

Physico-chemical property	Guideline No. and Method used	Result/Comment	Ref. in Doc III
Colour	Visual	White	Güldner and Hoppe (2008) (B3.1.2/01)
Odour	Organoleptic	Odourless	Güldner and Hoppe (2008) (B3.1.3/01)
Explosive properties	Theoretical consideration based on the properties of the components of the formulation.	The formulation is not considered to be explosive as none of the components have explosive properties.	Heinz, 2004 (B3.2/01)
Oxidising properties	Theoretical consideration based on the properties of the components of the formulation.	The formulation is not considered to be oxidizing as none of the components have oxidizing properties.	Heinz, 2004 (B3.3/01)
Flash point	Not relevant	Not applicable as the formulation is solid.	-
Flammability	EEC A.10	Not highly flammable	Heinz, 2004 (B3.4/02)
Auto-flammability	EEC A.16	Not auto-flammable	Heinz, 2004 (B3.4/01)
	UN-Bowes-Cameron-Cage-Test according to the UN-Recommendations on the Transport of Dangerous Goods	The product does not undergo spontaneous combustion in the Bowes-Cameron-Cage-test at 140°C	
Flammability in contact with water	EEC A.12	0 L/kg/h gas liberated in two tests of 10 g Deltamethrin DP 0.05 over 420 minutes	Heinz, 2004 (B3.4/02)
Acidity/alkalinity pH	CIPAC MT 75.3	1% in CIPAC D water Initial pH: 8.8 After 2 weeks 54 °C pH: 7.5 After 3 years at ambient temperature pH: 7.5 Not required as the pH of a 1% dispersion is >4 and <10	Güldner and Hoppe (2008) (B3.5/01)
Bulk density	CIPAC MT 186	Pour density: 1.07 g/ml Tap density: 1.33 g/ml	Güldner (2004) (B3.6/01)

Physico-chemical property	Guideline No. and Method used	Result/Comment	Ref. in Doc III
Accelerated storage stability	CIPAC MT 46.3	No significant change in the product properties and the active ingredient contents was shown after storage for 2 weeks at 54 °C in the commercial packaging (HDPE) See Table 2.4-2 below.	Güldner and Hoppe (2008) (B3.7/01)
Shelf life	GIFAP Technical Monograph No.17	No significant change in the product properties and the active ingredient content was shown after storage for three years in HDPE-bottles at ambient temperature. See Table 2.4-2 below.	Güldner and Hoppe, 2008 (B3.7/01)
Wettability/ suspensibility	Not relevant	Not applicable to DP-formulations	-
Dry sieve tests	CIPAC MT 59.1 (dry sieve analysis)	Residue on 75 µm sieve Initial: 1.02% After 2 weeks 54 °C: 1.81% After 3 years at ambient temperature: 1.9%	Güldner and Hoppe, 2008 (B3.8/01)
Emulsifiability,	Not relevant	Not applicable to DP-formulations	-
Disintegration time	Not relevant	Not applicable to DP-formulations	-
Attrition/friability of granules; integrity of tablets	Not relevant	Not applicable to DP-formulations	-
Persistence of foaming	Not relevant	Not applicable to DP-formulations	-
Flowability	Not relevant	Not applicable to DP-formulations	-
Pourability	Not relevant	Not applicable to DP-formulations	-
Dust content	CIPAC MT 171 (optical method)	Optical dust factor: Initial: 154 (dusty) After 2 weeks 54 °C: 148 (dusty) After 2 years at ambient temp: 143 (dusty) After 3 years at ambient temperature: 133 (dusty)	Güldner and Hoppe (2008) (B3.8/02)
Dustability	CIPAC MT 34	No negative effects observed. After the test the substance was in the form of a fine, free-flowing powder. No extraneous matter and	Güldner (2004) (B3.8/03)

Physico-chemical property	Guideline No. and Method used	Result/Comment	Ref. in Doc III
		hard lumps were observed (no compaction).	
Physical and chemical compatibility with other products including biocidal products with which its use is to be authorised (IIIB3.9)	Not relevant	Not relevant as the product is not intended for mixtures with any other products	-
Surface tension	Not relevant	Not applicable as the product is a solid formulation which is not diluted in water.	-
Viscosity	Not relevant	Not applicable as the product is a solid formulation	-
Particle size distribution	CIPAC MT 187 (dispersion in water using a small amount of surfactant)	Initial: 90% ≤ 17.96 µm 50% ≤ 5.58 µm 10% ≤ 0.92 µm After 3 years: 90% ≤ 21.51 µm 50% ≤ 6.35 µm 10% ≤ 0.97 µm	Güldner and Hoppe (2008) (B3.11/01)

Table 2.4-2 Storage Stability and Shelf Life of Myrr D Deltamethrin DP 0.05 (Güldner and Hoppe (2008))

	Initial	2 weeks 54 °C	2 years ambient temperature	3 years ambient temperature
A.I. Content deltamethrin	0.046 %	0.046%	0.044%	0.042%
Appearance, method: visual	white powder	white powder	white powder	white powder
Odour method: olfactory	odourless	odourless	odourless	odourless
Packaging stability HDPE	no negative effects observed	no negative effects observed	no negative effects observed	no negative effects observed
weight change	not determined	not determined	not determined	not determined
deformation of packaging	no panelling no ballooning	no panelling no ballooning	no panelling no ballooning	no panelling no ballooning
leakage	no leakage	no leakage	no leakage	no leakage
effect on closure	leak proof	leak proof	leak proof	leak proof
packaging/preparation interaction	no compaction free-flowing powder, free from extraneous matter and hard lumps	no compaction free-flowing powder, free from extraneous matter and hard lumps	no compaction free-flowing powder, free from extraneous matter and hard lumps	no compaction free-flowing powder, free from extraneous matter and hard lumps
Acidity/Alkalinity *, method: CIPAC MT 31,	not determined	not determined	not determined	not determined
pH-value, method: CIPAC MT 75.3 1 % in CIPAC D water	8.8	7.5	9.3	7.5
Dustiness, method: CIPAC MT 171, optical dust factor	154 dusty	148 dusty	143 dusty	133 dusty
Dry sieving, method CIPAC MT 59.1 residue on a 75 µm sieve	1.02 %	1.81 %	0.28 %	1.9 %
Particle size distribution, method: CIPAC MT 187				
90 % ≤ x µm	17.96 µm	16.61 µm	16.24 µm	21.51 µm
50 % ≤ x µm	5.58 µm	4.98 µm	4.17 µm	6.35 µm
10 % ≤ x µm	0.92 µm	0.87 µm	0.81 µm	0.97 µm

*only if pH < 4 or pH >10,

Ref-MS information to the reader:	The biocidal product family is a dustable powder containing 0.5 g/kg deltamethrin. The physical chemical properties were tested using the representative formulation K-Othrine DP 0.05. The formulation is a white odourless powder. It is neither highly flammable nor auto-flammable. Based on the properties of the components of the formulation, Myrr D Deltamethrin DP 0.05 and Myrr D are not considered to be explosive or oxidising. The initial pH of a 1% dispersion is 8.8. Products in the family Deltamethrin DP 0.05 RTU are stable for at least 3 years at ambient temperature in HDPE packaging.

2.5 ANALYTICAL METHODS FOR DETECTION AND IDENTIFICATION

The identification and quantification of deltamethrin as manufactured is summarised in the Assessment Report for Deltamethrin (PT18).

2.5.1 Analytical methods for the determination of deltamethrin in the biocidal product

Acceptable validation data was provided for the analysis of deltamethrin in an OD-formulation containing 1% deltamethrin and 10% thiacloprid (Odendahl, 2003). In addition, data to prove the specificity of the method for the representative biocidal product Myrr D Deltamethrin DP 0.05 was provided (Odendahl, 2004). As the validation data covers the concentration at which the method will be used for Myrr D (2.5 mg a.s./100 ml) the method and the derived validation data are considered acceptable also for Myrr D.

None of the components of the formulation are considered to be of toxicological, environmental or eco-toxicological concern and therefore no further methods are required for the formulation.

Table 2.5.1-1 Analytical methods

Method	Linearity (linear range and r^2)	Precision (repeatability) % RSD	Accuracy (mean recovery) %	Specificity	Reference in Doc III
HPLC-UV (external standardization)	1.30-4.08 mg a.s./100 ml solution (use concentration for formulations according to the method is 2.5 mg deltamethrin./100 ml) r^2>0.999	0.56% (n=6) (tested for a 2.5 mg a.s./100 ml solution which is relevant for the representative formulation)	Mean: 100.86% Range 99.5-101.6 (RSD 0.69%, n=6). Tested in the range 1.27-4.15 mg a.s./100 ml solution	No interference from formulants, impurities or solvents. Additional chromatograms for Myrr D are available that confirm the absence of interference from the embittering agent.	Seidel, 2003 (method description; CAR DocIII B2 4.1/01) Odendahl, 2003 (validation data for OD-formulation; CAR DocIII B2 4.1/03); Odendahl, 2004 (specificity data for the K-Othrine DP 0.05, (Myrr D Deltamethrin DP 0.05) B4.1/02)

Ref-MS information to the reader:	Acceptable validation data was provided for the analysis of deltamethrin in an OD-formulation containing 1% deltamethrin and 10% thiacloprid (Odendahl, 2003). The method has not been validated for the family Deltamethrin DP 0.05 RTU . However the validation data is acceptable and covers the concentration at which the method will be used for the family. Moreover, the specificity of the method has been shown for Myrr D Deltamethrin DP 0.05 and Myrr D. The method is therefore considered acceptable.

2.5.2 Analytical methods for residues

Ref-MS information to the reader:	Analytical methods for determination of deltamethrin residues in relevant environmental matrices (as well as methods for the determination of residues in animal and human body fluids and in/on food or feedstuffs) are already evaluated and accepted for the active substance in the CAR. However, methods are not fully validated according to the current guideline. Confirmatory methods should be required for the determination of deltamethrin residue in soil, surface water and body fluids. These data should be requested at the active substance renewal.

2.6 EFFICACY

2.6.1 Effects on target organisms and efficacy

Deltamethrin DP 0.05 is for the control of workers and nests of the Black Ant (*Lasius niger*) and other commonly found garden ants; plus other crawling insects and arthropods, e.g. German cockroaches, silverfish, wood louse or pill bug, in small confined and protected locations (e.g. underneath flowerpots, floor boards, garden appliances, etc.) around buildings.

Deltamethrin DP 0.05 acts on harmful organisms by contact and ingestion resulting in death. Deltamethrin expresses both a knock-down effect, and residual action. The maximum dose rate of 2 g of product per nest or 100 cm^2 insect harbourage and uses in accordance with the recommended use patterns have been evaluated in the following studies.

Ref-MS information to the reader:	The Ref-MS has evaluated the submitted documentation for efficacy in accordance with the available guidance document (TNsG for PT18/19, http://echa.europa.eu/documents/10162/16960215/bpd_guid_tnsg_efficacy_pt18-19_final_en.pdf). Label claims identified by the Ref-MS in the provided documentation is summarized as follows. 1) Control of workers and nests of garden ants at a dose of 2 g of dust per ant nest. Nest control may take 1 to 2 weeks. If control is not achieved repeat application once. 2) Control of crawling insects and arthropodes (German cockroaches, silverfish, woodlouse or pill bug), in small confined and protected locations, at a dose of 2 g/100 cm^2. Knockdown within 1 hour. Undisturbed dust will prevent re-infestation for at least 6 weeks. The products are intended for consumers and are to be scattered around houses. Requirements according to TNsG for PT18: • To show efficacy against workers and nests of **garden ants** laboratory and field studies on *Lasius niger* and its nests are needed. • To show efficacy against **crawling insects**, as a general claim, both a laboratory and a simulated-use/field study is normally needed on two species of cockroaches (one small and one large). • To show efficacy against **arthropods** "information on organisms relevant for the intended use" is required. A field study should be provided or a good justification why this is not appropriate. The Ref-MS evaluation of the submitted studies (see Table 2.6.1-1) concludes the following for the individual species claimed for: **Garden ants and nests**: Effect on ants (*Lasius niger*) is shown in a laboratory study, in which a dose of 2 g/m^2 resulted in a mortality of 93% 14 days after treatment, which is acceptable for a product intended for use as general surface treatment for consumers. In the submitted field studies, for 12 of 16 treated nests

	(75%) the treatment resulted in no ant activity. For the rest of the treated nests a reduction of ants was seen and the effect therefore only temporary. However, the efficacy is probably much dependent on the success in treating all the entrences to the nest. If the right area is treated the efficacy of the product has shown to be very good. Ref-MS concludes that the claim against workers of garden ants is supported but the claim of control of nests is not supported. **Crawling insects/Cockroaches**: Efficacy against German cockroach (*Blattella germanica*) is supported as shown a laboratory/simulated use study, in which a dose of 2 g resulted in a mortality of 100 % within 24 hours, both directly after application and at the end of the residual period (6 weeks), which is acceptable for a product intended for use as general surface treatment for consumers. However, the general claim against crawling insects is not supported as only one small cockroach species is tested. **Arthropods/Silverfish and wood louse or pill bug**: Efficacy against silverfish (*Lepisma saccharina*) and wood louse (*Porcellio scaber*) is supported as shown in a laboratory/simulated-use study in which a dose of 2 g resulted in a mortality of 100 % within 24 hours, both directly after application and at the end of the residual period (6 weeks), which is acceptable for a product intended for use as general surface treatment for consumers. Some questions could not be resolved between ref-MS and cMS and was referred to the Coordination Group under Article 35 of the BPR. The applicant submitted further studies to support the label claims for crawling insects (see Table 2.6.1-1). The matter was discussed at CG-23 and a teleconference held on 23 May 2017 and the CG members agreed by consensus on the issues that were addressed. The conclusion below reflects the outcome of the referral. Ref -MS concludes, after referral to the CG, that the submitted documentation supports the following claims regarding efficacy of the biocidal product family Deltamethrin DP 0.05 RTU, at the recommended maximum dose of 2 g per ant nest or 100 cm^2 insect harbourage and according to the directions for use (in small confined and protected locations; e.g. underneath flowerpots, floor boards, garden appliances etc) around buildings: • ~~For kill and control of garden ants (*Lasius niger*) workers and nests, within 2-3 weeks, around houses. If control is not achieved repeat application once.~~ • For kill and control of ants (workers and nests), within 2-3 weeks, around houses. Not for control of tropical ants. If control is not achieved repeat application once. (*v1.1_2017-10-27*) • For direct and fast kill, and control, of crawling insects and woodlice, in small confined protected spaces around buildings, up to 6 weeks. The residual life of the deposit will however depend on the nature of the treated surface. • Effect by contact and ingestion resulting in death. Both a knock-down (within 1 hour) and residual action.

Table 2.6.1-1 Efficacy of the active substance from its use in the biocidal product family

Test substance	Test organisms	Test system / Concentrations applied / exposure time	Test conditions	Test results: effects, mode of action, resistance	Reference	Ref-MS Comments
Deltamethrin DP 0.05	*Lasius niger*	2g of product applied per arena. Three replicates. Percentage mortality recorded on days 1, 3, 7 and 14 post application of product.	Laboratory	Deltamethrin DP 0.05 had 93% mean mortality after 14 days.	Nentwig, D. (2007). M-433180-01-1 B5.10.2/01	A plastic container was fitted with an external harbourage (a glass tube closed with cork at the outer end, and linked via an entrance to the test unit) and a feeding source. One day before the trial started 20 worker ants were released inside the test unit. One day later, most ants were inside the glass-tube, the feeding source and the formulation to be tested was applied and the percentage of mortality was recorded after 1, 3, 7 and 14 days (cumulatively). The product was scattered at a dose rate of 2 g/m^2 onto the sand. Each trial consisted of three replicates of which the mean values were calculated. One untreated control was used, in which 5% mortality was reported at each observation. Deltamethrin DP 0.05 resulted in 93% mortality after 14 days. The study do not fulfil the requirements of a simulated-use study (as stated by the applicant) in order to investigate the efficacy of the product for nest kill but supports the efficacy of the product against worker ant at the recommended dose. The prolonged mortality may indicate that the ants live long enough to bring the product to the nest. **The Ref-MS accepts the study to be used in support of the label claim control of worker ants within 2 weeks.**

Deltamethrin DP 0.05	*Blattella germanica* *Lepisma saccharina,* *Porcellio scaber*	The population of insects was allowed to settle for 24 to 48 hours. The harbourage was lifted, dusted with 2 g of product and closed again. The percentage of mortality was recorded after 30 minutes, 1, 2, 4 and 24 hours.	Laboratory /Simulated use study	Direct treatment with Deltamethrin DP 0.05, delivered by dusting of 2 g of product directly into harbourages led to 97% mortality of *Blattella germanica* within 1 h. Efficacy against *Porcellio scaber* and *Lepisma saccarina* within 1 h was 87 and 82%, respectively.	Gutsmann, V. (2012) M-444123-01-1 B5.10.2/02	A laminated cardboard box was equipped with a plastic ring, a rectangular piece of compressed peat, a food and drinking source in form of a wet sponge. The plastic ring was introduced to lift the harbourage slightly from the bottom to give more space for the insects. Food was placed on top of the peat to establish the population firmly into this area. The population of insects (20 male adults of *B.germanica*, 20 adults of *L.saccharina* or 20 middle stages of *P.scaber*) was allowed to settle for 24 to 48 hours. The harbourage was lifted, dusted with 2 g of product and closed again. The percentage of mortality was recorded after 30 minutes, 1, 2, 4 and 24 hours. **The Ref-MS accepts this part of the study as a laboratory study to support mortality of the tested organisms at the recommended dose.** Six weeks after the first treatment, the dead insects were removed and a new test was set up (both food and insects were introduced on top of the peat) to assess if re-infestation is prevented by a single earlier treatment. **The Ref-MS accepts this part of the study as a simulated use study to support mortality and residual effect.** For *Blattella germanica* the efficacy of Deltamethrin DP 0.05 was 97% within one hour of application and 100% within one hour of the re-infestation test. For *Porcellio scaber*, the efficacy was 87% within one hour and 100 % within 2 hours of application and 100% within one hour of the re-infestation test.

Test substance	Test organisms	Test system / Concentrations applied / exposure time	Test conditions	Test results: effects, mode of action, resistance	Reference	Ref-MS Comments
						For *Lepisma saccharina*, the efficacy was 82% within one hour and 95% within 2 hours of application and 100% within one hour of the re-infestation test. According to the study report, all trials were run in triplicate and none of the negative controls conducted in untreated containers (all insects, all time points) showed any mortality. However, raw data is not shown which is a shortcoming of the study. **As this study is designed to mimic the real treatment situation for the intended use of the product (in small confined and protected locations) the Ref-MS accepts this study as a laboratory and simulated-use study for supporting the specific label claim of control of these three organism groups and with some residual effect preventing re-infestation in small confined locations.**

Test substance	Test organisms	Test system / Concentrations applied / exposure time	Test conditions	Test results: effects, mode of action, resistance	Reference	Ref-MS Comments
Deltamethrin DP 0.05	*Lasius niger*	2g of product applied per arena. Four replicates. Exposure of four hours, after which the insects are removed and observed for mortality at 24 and 96 hours.	Laboratory	Deltamethrin DP 0.05 achieved 100% knock down within 5 minutes on ceramic tiles, concrete and plywood. Knockdown was slower on treated soil, increasing from 15 minutes on fresh deposits (day 0) to 60 minutes on 60 day-old deposits for 100% effect.	Serrano, B. (2004a). M-433180-01-1 B5.10.2/03	Four different substrates were evaluated – ceramic tiles, plywood, concrete and earth ("vegetal ground") – and treated at a deposit rate of 2g product/m2. Surfaces that had been aged for 0, 7, 14, 30 and 60 days were tested. Ants were exposed for four hours and then removed and held for mortality counts at 24 and 96 hours Worker ants (*Lasius niger*) were all (100%) knocked down within 5 minutes of exposure to deposits on ceramic tiles, concrete and plywood and 100% mortality was recorded. Knockdown was slower when exposed to treated soil, increasing from 15 minutes exposure on fresh deposits (day 0) to 60 minutes on 60 day-old deposits for 100% effect. According to the study, the mortality of untreated control were lower enough to validate the trial (data not shown). **The Ref-MS accepts the study to be used in support of the label claim of control of worker ants.**

Deltamethrin DP 0.05	*Lasius niger* L.	1-2g of product applied per nest according to label instructions. Six nests treated. Ant activity monitored post treatment for 27 days.	Field	No ant activity achieved by day 21 in 5 out of 6 nests treated.	Brooks, M.D. (2011). M-426050-01-1 B5.10.2/04	This was a field study in The Netherlands. The test site was a row of 5 terraced houses in approximately 1000m^2 grounds. Six test locations and one control location were located within the site (gardens). The powder was applied directly out of the ready to use 100 g container/dispenser. Between 1 g and a maximum of 2 g powder was applied, scattered in and around the nest openings at each of the test locations depending on the number of nest openings and the ant activity observed during the initial activity inspections. Ant activity was estimated on days 4, 7, 14, 21 and 27 days post treatment. No ant activity was acheived for 5 of the 6 nests treated. It is possible that the treatments were insufficient for the remaining nest because of its size and the location of the nest openings. The nest opening used mostly by the ants was between the paving stone against the house wall. Ants leaving the opening did so via the wall and did not have to walk over the treated area around the openings. **The Ref-MS accepts the study to support the efficacy of the product against *Lasius niger* at the recommended dose rates of 2 g/nest with a claim for control of workers.** According to available guidance, it has to be shown that the queen(s) in the test nests is killed when a mortality lower than 100% is observed. However, inspection of brood and queen mortality was not performed when this was the case. This is a shortcoming of the study.

Test substance	Test organisms	Test system / Concentrations applied / exposure time	Test conditions	Test results: effects, mode of action, resistance	Reference	Ref-MS Comments
Deltamethrin DP 0.05	*Lasius niger* L.	1-2g of product applied per nest according to label instructions. Five nests treated. Ant activity monitored post treatment for 27 days.	Field	No ant activity achieved by day 15 in 3 out of 5 nests treated. Two nests re-treated on day 15 and achieved >90% efficacy by day 27 (after first treatment)	Schoelitsz, B. (2011). M-426110-01-1 B5.10.2/05	This was a field study in The Netherlands. The test site was grounds around a business complex. Five test locations and one control location were located within the site. The powder was applied directly out of the ready to use 100 g container. Between 1 g and a maximum of 2 g powder was applied, scattered in and around the nest openings at each of the test locations depending on the number of nest openings and the ant activity observed during the initial activity inspections. Ant activity was estimated on days 5, 7, 15, 18, 21 and 27 days post treatment. Deltamethrin DP 0.05 showed successfully control (100% efficacy) of 3 colonies of the black garden ant. Two nests required a re-treatment at day 15 which resulted in an efficacy of > 90% by day 27. **The Ref-MS accepts the study to support the efficacy of the product against *Lasius niger* at the recommended dose rates of 2 g/nest with a claim for control of workers.** According to available guidance, it has to be shown that the queen(s) in the test nests is killed when a mortality lower than 100% is observed. However, inspection of brood and queen mortality was not performed when this was the case. This is a shortcoming of the study.

Test substance	Test organisms	Test system / Concentrations applied / exposure time	Test conditions	Test results: effects, mode of action, resistance	Reference	Ref-MS Comments
Deltamethrin DP 0.05	*Lasius niger*	2g of product applied per arena. Five replicates. Exposure up to 21 days after the product was applied. Three weeks after treatment the nests were opened to verify if live ants and brood were still present.	Field	Deltamethrin DP 0.05 achieved 80% reduction of ant activity in a week. Most ant activity around the nest entrances had ceased completely, by 2 weeks after treatment. When the nests were opened for inspection zero adults and no brood were seen in 4 of the 5 treated nests. The 5th nest contained 11 adults and 61 larvae/cocoons.	Serrano, B. (2004b). M-268539-01-1 B5.10.2/06	Deltamethrin DP 0.05 was applied to the immediate vicinity of entrances to black ant (*Lasius niger*) nests at a rate of 2g product per nest. Ant activity was determined by counting the number of ants moving in a defined area around the nest entrances one day before and up to 21 days after the product was applied. Three weeks after treatment, the nests were opened to verify if live ants and brood were still present. Within a week of treatment, the dust product was associated with an 80% reduction of ant activity. In 4 of the 5 nests, ant activity around the nest entrances had ceased, completely, by 2 weeks after treatment, and a reduction in activity of > 99% was also apparent in the 5th nest by 3 weeks post-treatment. of that recorded 1 day prior to treatment. In the untreated controls (three replicates), the ant activity was reduced by 16% after 3 weeks. When the nests were opened for inspection, > 1000 workers and brood were visible within untreated nests, compared with zero adults and no brood in 4 of the 5 treated nests. The 5th nest contained just 11 adults and 61 larvae/cocoons. **The Ref-MS accepts the study to support the efficacy of the product against *Lasius niger* at the recommended dose rates of 2 g/nest with a claim for control of workers.**

Test substance	Test organisms	Test system / Concentrations applied / exposure time	Test conditions	Test results: effects, mode of action, resistance	Reference	Ref-MS Comments
Deltamethrin DP 0.05%,	Oriental cockroach (Blatta orientalis)	2 g dust per harbourage (1 mg of deltamethrin per harbourage) 3 Replicates Exposure up to 24 hours Effect assessed after 30 min, 1 h, 2 h and 24 h.	Simulated-use study	60% knockdown after 30 min. 100% mortality within 1h. Negative controls showed no mortality during the trial (24 h).	Gutsmann, V. (2017a). M-585706-01-1	*Study submitted during referral to CG.* A laminated cardboard box was equipped with a plastic ring, a rectangular piece of compressed peat, a food and drinking source. The plastic ring was introduced to lift the harbourage slightly from the bottom to give more space for the insects. The population of insects (10 male adults of B. orientalis) was allowed to settle for 24 hours. The harbourage was lifted, dusted with 2 g of product and closed again. The percentage of mortality was recorded after 30 minutes, 1, 2, 4 and 24 hours. **The Ref-MS accepts this laboratory study to support mortality of the tested organisms at the recommended dose.**

Deltamethrin DP 0.05%	*Blattella germanica,* *Periplaneta americana, Lepisma saccharina, Porcellio scaber and Lasius niger*	Application: 1 g product per 100 cm2. For P. scaber, L.niger and L. saccharina, 20 insects were used and three replicates were conducted. For B. germanica and P. americana, 10 insects were used in 6 replicates. 1 g of Deltamethrin DP 0.05% was applied to an area of 100 cm^2. A glass ring was positioned in the center of the treated area. Insects	Laboratory	Blattella germanica, Periplaneta americana, L. saccharina and Lasius niger were shown to be completely knockdown within 30 min. Knockdown of Porcellio scaber reaches 23% after 30 minutes, 97% after 1h and 100% after 2h. Pests did not recover and were confirmed dead after 24h. Negative controls showed no mortality during the trial (24 h).	Gutsmann, V. (2017b). M-585768-01-1	*Study submitted during referral to CG.* 1 g of Deltamethrin DP 0.05% was applied to an area of 100 cm^2. A glass ring was positioned in the center of the treated area. Insects were introduced to the treated area. Effect on insect groups were recorded as % knock down after 0. 5h, 1h, and 2h and mortality was confirmed after 24h. **The Ref-MS accepts this laboratory study to support mortality of the tested organisms at the recommended dose.**

Test substance	Test organisms	Test system / Concentrations applied / exposure time	Test conditions	Test results: effects, mode of action, resistance	Reference	Ref-MS Comments
		were introduced to the glass ring. Knock down is recorded after 0.5h, 1h, and 2h. Mortality is confirmed after 24h.				

Test substance	Test organisms	Test system / Concentrations applied / exposure time	Test conditions	Test results: effects, mode of action, resistance	Reference	Ref-MS Comments
Deltamethrin DP 0.05%	Oriental cockroach (Blatta orientalis)	2 g dust per harbourage, effect assessed after 30 min, 1 h, 2 h and 24 h. Residual efficacy tested at 6 weeks post application on re-introduced organisms. Procentage mortality measured after 30 min, 1h, 2h, and 24h.	Simulated-use study	Treatment lead to 60% knockdown after 30 min. 100% mortality within 1h. Residual activity tested after 6 weeks led to 83% mortality within 30 minutes, 100% mortality within 1h.	Gutsmann, V. (2017c). M-585706-02-01	The study is the same as Gutsmann, V. (2017a), but with the addition of a residual effect test. After removal of the dead insects and a waiting period of 6 weeks, a new population of insects was released into the testing arena. The new insects moved into the artificial harbourage where they were killed by the residual action of the previous insecticide treatment. **The Ref-MS accepts this study for supporting the claim of fast kill of Blatta orientalis after direct spray treatment within 1 hour, and with a residual action up to 6 weeks.**

2.6.2 Mode of action including time delay

Deltamethrin is a synthetic pyrethroid which acts on ants by contact and ingestion resulting in death. Deltamethrin expresses a strong knock-down effect.

Pyrethroids impair ion transport through the membrane of nerve axons, causing muscular paralysis in the insect; death seems to follow a nervous system impairment that occurs a few minutes to several hours after biocidal absorption.

The primary site of activity of deltamethrin is the voltage sensitive sodium channel in nerve membrane. Deltamethrin prolongs the opening of the sodium channels (i.e. the channels directly responsible for generating nerve action potentials) leading to neuronal hyperexcitability.

2.6.3 Occurrence of resistance

Deltamethrin is a pyrethroid insecticide. Some resistance to pyrethroids has been found to varying degrees, depending on the pest species and location (Anon, 1987). In Europe the main problems have occurred in some areas with pests of agricultural significance. Laboratory tests on resistant strains have shown, for *Myzus persicae*, a resistance factor of 200 (to control the resistant strain requires 200 times the dose required to control a sensitive strain).

A review by the WHO of Vector Resistance to Pesticides (Anon, 1992) identified no reports of resistance to synthetic pyrethroids in mosquitoes and other sucking insects in Europe. However, resistance among some species of flies and cockroach populations was more evident. Resistance to synthetic pyrethroids among European agricultural pest species, where insecticide use is more intensive, may be more widespread (Anon, 2000).

Cross-resistance of pest species to the group of synthetic pyrethroids is to be anticipated due to a common mode of action (Staetz, 2004), and instances of cross-resistance (or multiple resistance) between pyrethroids and organochlorine insecticides have been reported (Brogdon & McAllister, 1998).

Because resistance is well known to be a potential problem, strategies to avoid resistance are normal practice. For example, the use of alternating sequences, mixtures and avoidance of frequent repeated use are standard.

General advice is provided by IRAC (Anon, 1987).

The principles of strategies for managing the development of resistance are similar for deltamethrin as they are for other synthetic pyrethroids;

- where possible, application treatments should be recommended to be combined with non-chemical measures
- products should always be used in accordance with label recommendations
- applications should always be made against the most susceptible stages in the pest life cycle
- where an extended period of control is required, treatments should be alternated with products with different modes of action
- levels of effectiveness should be monitored, and instances of reduced effectiveness should be investigated for possible evidence of resistance, noting that sanitary conditions and proximity of untreated refuges can contribute to the risk of re-infestation.
- in cases where label rates, correctly applied, fail to give the expected level of control and resistance is demonstrated, use of any product containing the same class of chemistry should cease

Ref-MS information to the reader:	It is not likely that resistence will build up in ants nest with a queen who lay eggs for a long period. However, products in the family Deltamethrin DP 0.05 RTU will affect other organisms in the treated area, and since resistance to deltamethrin is known in other insects the product should be used with care. For information, concerning cockroaches, several mechanisms are involved in resistance to pyrethroids[1]. Resistant populations of German cockroaches have been identified in the entire world (Asia, Europe, and America). The Oriental cockroach has developed little resistance. Efficacy of the product against cockroaches is supported by the submitted documentation. However, in Ref-MS (Sweden) the use of the products against cockroaches will be restricted to professionals (with reference to Article 37:1b of the BPR). Based on the risk for development of resistance (see text above) and the risk of spreading of the pest rather than killing by an incorrect use of the products, and as cockroaches (and also bedbugs) are difficult to control, Sweden applies a practice that these organisms should not be controlled by non-professionals. The risk mitigation measure "Not for control of cockroaches and bedbugs" applies to all insecticides to be used by non-professionals against crawling insects in Sweden and should consequently apply also on Myrr D. The products could through mutual recognition be authorized against cockroaches in other European countries. However, Ref-MS suggests the following risk mitigation measure should be added to the label: "When the product is not used according to the label resistance of cockroaches might occur. When an infestation persists contact a professional". This is a strategy, in accordance with the TNsG for PT 18/19, to avoid resistance as cockroaches are very difficult to control and it can not be expected that non-professionals have enough knowledge of the resistance problem. [1] Wei Y., Appel A.G., Moar W. J, Liu N., Pyrethroid resistance and cross resistance in the german cockroach, *Blattella germanica* (L), Pest manag Sci 57 :1055-1059, (2001).

2.7 EXPOSURE ASSESSMENT

2.7.1 Intended uses

MG/PT	Field of uses envisaged	Likely concentrations at which a.s. will be used
MG 03 PT18	Public Health (Hygiene) Deltamethrin DP 0.05 is intended for use around buildings for the control of: - workers and nests of the Black Ant (Lasius niger) and other commonly found garden ants - crawling insects or other arthropods, e.g. German cockroaches, silverfish, wood louse or pill bug, in small confined locations.	2 g of dust per ant nest, (approx. 2g equivalent to 3 dispensing actions) 2g per 100 cm^2 in insect harbourages. Maximum 4g of product per harbourage.

2.7.2 Human exposure assessment

Ref-MS Information to the reader:	The exposure assessment by the applicant is acceptable.

Ref-MS Information to the reader:	Exposure and risk assessment of pets and domestic animals has not been performed. For the private area it can be expected that they are exposed to deltamethrin during or after non-professional use of these biocidal products. As a worst case it can be assumed that the health risk for these animals (except cats) is comparable to those of toddlers and children. Therefore, the risk mitigation measure 'Exclude animals and children during application' must be followed. Cats are more sensitive against pyrethroids due to a slower metabolisation. Thus, the access of cats to areas where an application is or has been performed, should be restricted by an appropriate labelling. Therefore the risk mitigation measure is extended to 'Exclude animals and children during application and prevent access to treated areas.' The possible exposure and risk of consumers due to residues in food (from edible plants) through the non-professional use of the products has neither been assessed. Therefore, the following risk mitigation measures should be applied: "Do not apply the product below or close to edible plants or in growing area for edible plants." "Exclude animals and children during application and prevent access to treated areas."

2.7.2.1 Identification of main paths of human exposure towards active substance from its use in biocidal product

Exposure path	Industrial use	Professional use	General public	*via* the environment
Inhalation	Relevant for direct exposure*	Not relevant for direct exposure	Relevant for direct exposure	Indirect exposure only
Dermal	Relevant for direct exposure*	Not relevant for direct exposure	Relevant for direct exposure	Indirect exposure only
Oral	Not relevant for direct exposure*	Not relevant for direct exposure	Relevant for direct exposure	Indirect exposure only

*Exposure during the manufacture of the biocidal product is covered under separate legislation and is subject to national worker protection legislation.

2.7.2.2 Professional exposure

Not applicable. Deltamethrin DP 0.05 is intended for use by consumers only.

2.7.2.3 Non-professional exposure

The product is intended for the amateur user.

Potential exposure via inhalation, dermal or oral uptake during the primary exposure (applying product to ant nests) or during the worst case secondary exposure scenario identified – child crawling over treated area – are both summarised in the following table:

Intended use (MG/PT)	Exposure scenario	Inhalational uptake	Dermal uptake	Oral uptake
		Total systemic exposure concentration (mg a.s./kg bw/day)	**Exposure concentration (mg a.s./kg bw/day)**	
MG 03 PT18	Primary exposure: Application to ant nest	0.000000312	0.00000083	*NA*
MG 03 PT18	Secondary exposure: Re-entry- Crawling over treated areas	*NA*	*0.0000119*	*0.0000446*

Deltamethrin DP 0.05 is an insecticide used for the control of ants in a residential environment (consumer/non-professional use).

Deltamethrin DP 0.05 can also be used to control other crawling insects , e.g. German cockroaches, silverfish, wood louse or pill bug, in localised protected areas (for example, underneath flowerpots, floor boards or garden appliances).

The product is formulated as a ready to use dry powder (DP) and contains the active substance (a.s.) deltamethrin (0.5 g/kg). The treatment powder is applied onto the entrances of ant nests on terraces, patios and pathways, or on the harbourage area (nesting/resting area) of the pest crawling insect. The highest

recommended application rate for the control of ants is 0.5 g Deltamethrin DP 0.05/entrance and no more than 2 g product per ant nest. For the control of other crawling insects an application rate of 2g per 100 cm^2 in harbourage is recommended and the treatment should not exceed 4g of product per harbourage.

Ref-MS information to the reader:	According to the products claim and to the label, 1 dispensing action is recommended per nest entrance and a maximum of 3 dispensing actions per nest. Three dispensing actions equals approximately 2 g and therefore 1 dispensing action result in more than 0.5 g (eg. 0.67 g).

The product will be used by non-professionals/consumers only.

Consideration on dermal absorption

Deltamethrin DP 0.05 was not one of the representative formulations submitted for EU review according to the biocide directive 98/8/EC. A value of 2% dermal absorption was considered appropriate for K-Othrine DP 0.05, a similar product[1]. The value of 2% represented a worst case, with measured values for various deltamethrin containing products all providing absorption values of less than 2%. For assessment of exposure to Deltamethrin DP 0.05, the 2% value was considered adequately conservative for use in this evaluation.

Ref-MS information to the reader:	No study has been conducted on products in the family Deltamethrin DP 0.05 RTU. However, the value of 2% dermal absorption is considered acceptable, since the argumentation for accepting read across from the tested EC and EW formulations to K-Othrine DP 0.05 in the Competent Authority Report of deltamethrin (final CAR, Doc IIB3) also are valid for Deltamethrin DP 0.05. Ref-MS agrees that the dermal absorption value based on results from the EC formulation may be considered to be a worst case compared to Deltamethrin DP 0.05. For the powder formulation of deltamethrin, a lower dermal absorption is expected since water and certain solvents favour dermal uptake.

Consideration on estimation of primary- and secondary exposure

Deltamethrin DP 0.05 is a product family consisting of product composition variants very similar to K-Othrine DP 0.05 which was one of the representative formulations submitted for EU review according to the biocide directive 98/8/EC. Hence this evaluation of the Deltamethrin DP 0.05 will follow the approaches as agreed on EU level and presented in: "*Document II B3 Effects and Exposure Assessment for K-Othrine DP 0.05 of the non public CAR, final June 2011*".

Ref-MS information to the reader:	The representative dustable powder formulation (K-Othrine DP 0.05/Deltamethrin DP 0.05) has the same content of deltamethrin as the products applied for in the current application, 0.5 g/kg. However, the acute toxicology studies were performed on more concentrated formulations. Whereas, dermal absorption where tested with both a more concentrated formulation (25 g/L) and lower concentrated formulation (0.118 g/L).

[1] Document II B3 Effects and Exposure Assessment for K-OTHRINE DP 0.05 of the non public CAR, final June 2011

Primary exposure – application phase

Inhalation exposure:

The product is a dry powder that is scattered on the floor. During application, exposure via inhalation may therefore occur. The assessment of inhalation exposure is based on the exposure model when using a hand-held duster *(TNsG; Technical notes for guidance; Human exposure to biocidal products, Guidance on exposure estimation, June 2002; consumer product spraying and dusting: model 2, Hand-held dusting applicator pack for crack and crevice*).

Ref-MS information to the reader:	In the description above it is stated that the dry powder is scattered on the floor. However, in the product claim (3.1 Intended uses) it is stated that the powder will be used around buildings.

Dermal exposure:

The product is a ready-to-use dry powder that is scattered on the floor. During application, exposure via dermal exposure may occur. The assessment of dermal exposure is based on the exposure model when using a hand-held duster *(TNsG; Technical notes for guidance; Human exposure to biocidal products, Guidance on exposure estimation, June 2002; consumer product spraying and dusting: model 2, Hand-held dusting applicator pack for crack and crevice*). The model considers potential exposure of hand and forearm, legs, feet and face.

For the representative use supported during EU review (application to control ants in a residential environment, the risk assessment presented in the CAR considered the treatment of one ant nest with four entrances at the maximum application rate of 2 g product/nest). The same scenario is evaluated for Deltamethrin DP 0.05. For this residential scenario the consumer exposure duration was assumed to be 1 minute. The CAR indicated this to be a conservative assumption since treatment would actually take only a few seconds.

For the intended use to control other crawling insects an application rate of 2g per 100 cm^2 in harbourage is recommended with a maximum 4g of product being applied per harbourage. Consequently although the maximum application rate is higher than for ant control, the absolute amounts of product that have to be applied in both scenarios are still low. The inclusion of the extended, conservative, exposure duration of 1 minute as proposed by the EU, ensures the ant nest treatment scenario also covers the treatment performed to control other crawling insects.

The risk assessment presented in the CAR concluded that since the product is formulated as a ready-to-use dry powder no mixing/loading is required and no disposal of the applied powder is performed. Deltamethrin DP 0.05 is similarly a ready-to-use dry powder packed in a sealed shaker container, that precludes any cleaning or maintenance activities and when the product has been used, the empty container is simply disposed of in normal household rubbish. Therefore, there is no post-application cleaning or maintenance exposure.

Primary exposure is therefore confined to the application phase. Product specific exposure figures are not available to estimate primary exposure during application. Therefore, exposure figures for consumer hand held dusting applicator pack for crack and crevice applications (*TNsG; Technical notes for guidance; Human exposure to biocidal products, Guidance on exposure estimation, June 2002; consumer product spraying and dusting: model 2, Hand-held dusting applicator pack for crack and crevice*) are used as reasonable worst case surrogates.

Assumptions/requirements to calculate primary exposure during application:

Exposure duration:	1 minute*
Dermal absorption	2%
Inhalation absorption:	100%
Standard operator body weight:	60 kg

The following table shows the estimation of primary exposure to Deltamethrin DP 0.05 during application.

Table 2.7.2.3-1 Estimated primary exposure to Deltamethrin DP 0.05 during application

Exposure description	**Exposure estimate** ***(75th percentile#)***
Hand and forearm	
indicative value (rate of deposition of product : mg in-use product/min)	***2.83***
task duration (default value = 1 min/day)	1
product on hands and forearm(mg/day)	2.83
Legs, feet and face	
indicative value (rate of deposition of product : mg in-use product/min)	***2.15***
task duration (default value = 1 min/day)	1
product on legs, feet and face (mg/day)	2.15
total dermal exposure to product (mg/day)	4.98
total dermal exposure to a.s. (mg) *[in-use product contains 0.0005 mg a.s/mg]*	0.00249
dermal absorption	2%
Total systemic exposure to a.s. via dermal exposure (mg a.s./person/day)	**0.0000498**
Total systemic exposure to a.s. via dermal exposure for a 60 kg adult (mg a.s./kg bw/day)	**0.00000083**
Inhalation exposure	
indicative value (exposure to product via inhalation : mg in-use product/m^3)	**1.78**
breathing rate (default value = 1.25 m^3/h):	1.25
task duration (default value = 1 min/day)	1
volume of air inhaled over task duration (m^3)	0.021

amount of product inhaled during task (mg)	0.0374
Total systemic exposure to a.s. via inhalation = amount of a.s. inhaled (mg a.s.) *[in-use product contains 0.0005 mg a.s/mg]*	**0.0000187**
Total systemic exposure to a.s. via inhalation = amount of a.s. inhaled for a 60 kg adult (mg a.s./kg bw/day)	**0.000000312**
Total systemic exposure via dermal and inhalation exposure to a.s. (mg a.s./person/day)	**0.00006852**
Total systemic exposure to a.s. for a 60 kg adult (mg a.s./kg bw/day)	**0.000001142**

#The calculations presented above are based on a number of worst-case assumptions, but also use 75th percentile data for the indicative values. TNsG from 2007 indicate different values for the 90th percentile - Hands/forearm: 2.73 mg/min; Legs/feet/face: 2.74 mg/min; Inhalation: 2.47 mg/m^3. Use of the 90th percentile values is not considered likely to significantly affect the primary exposure conclusions.

2.7.2.4 Indirect exposure as a result of use of the active substance in biocidal product

Adults or children may be secondarily exposed to Deltamethrin DP 0.05 when re-entering a treated area. In this context a child, or more accurately a toddler, crawling over a treated terrace is considered to represent the worst case exposure scenario. For treated area re-entry by a child, the assumed body weight is 10 kg and dermal contact is assumed to occur over the entire crawling area rather than being limited to the treated nest and its immediate environs.

For the control of ants Deltamethrin DP 0.05 is applied as crack and crevices or directly into the nest entrances. Deltamethrin DP 0.05 can also be used to control other crawling insects, e.g. German cockroaches, silverfish, wood louse or pill bug). With this type of use the product is applied in localised protected areas (e.g. underneath flowerpots, floor boards, garden appliances, etc…). Hence in this case the risk for uninvolved persons to come into contact with the product can be regarded as very low. Accordingly the ant use is considered to represent the worst case and therefore will be considered in the secondary exposure scenario. The exposure assessment considered the worst case scenario of a toddler re-entering a treated terrace where Deltamethrin DP 0.05 has been applied, assuming dermal contact with the product could occur over the entire crawling surface.

Exposure calculations follow the approach presented in the CAR for Deltamethrin.

It can be considered that re-entry exposure is predominantly via the dermal route (transfer of surface bound residues to the skin). The transfer of residues to the skin depends on:

- The intensity of contact with surfaces which can be described by a generic transfer coefficient (cm^2/hour).
- The amount of transferable residues present on the surface (mg a.s./cm^2).
- The exposure duration (hours per day).

The relevant default values given in the Technical Notes for Guidance ("Technical notes for guidance; Human exposure to biocidal products, Guidance on exposure estimation, June 2002; Defaults for non professional use and residential exposure to biocides") are presented below:

Transfer Coefficient:	6000 cm^2/hour[#]
Surface transferable residues:	30 % of the residues present on the surface
Exposure period:	1 hour per day

[#]: It has to be recognised that the proposed transfer coefficient of 6000 cm^2/hour is representative for the situation when the whole surface the toddler plays on is covered with transferable residues. This obviously is not the case for the intended spot type application of Deltamethrin DP 0.05. Hence, for the spot type application where only a fraction of the total surface the toddler can play on is treated it is fair to conclude that the re-entering toddler is mainly in contact with the untreated part of the surface. To mimic this situation and in addition to be consistent with the proposed transfer coefficient, in a conservative approach it can be assumed that "virtually" the residues present in the spots are distributed to the whole surface the toddler can crawl on.

Assumptions/considerations to calculate secondary exposure of a child to Deltamethrin DP 0.05:

Size of the terrace:	30 $m^{2\#}$
Application rate:	2 g* Deltamethrin DP 0.05/ nest (corresponding to 1 mg a.s./nest)
Residues present on the terrace surface:	100% of the application rate*
Nests treated per terrace:	1
Surface residues (SR):	0.0000033 mg a.s./ cm^2*
Surface Transferable Residues (TR):	30% of the residues present on the surface
Transfer Coefficient (TC):	6000 cm^2 per hour
Exposure Period (EP):	1 hour per day
Body weight of the toddler:	10 kg

#: A value of 10 m^2 was assumed in the DAR for deltamethrin. However, a size of a terrace of 30 m^2 is proposed in: OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 18, EMISSION SCENARIO DOCUMENT FOR INSECTICIDES, ACARICIDES AND PRODUCTS TO CONTROL OTHER ARTHROPODS FOR HOUSEHOLD AND PROFESSIONAL USES (ENV/JM/MONO(2008)14), 17-Jul-2008). Hence, this value will be considered in this evaluation.

*: Deltamethrin DP 0.05 is applied as crack & crevices or directly into the nest entrances. With this application pattern it is reasonable to expect the amount of product being accessible for the toddler as negligible. However, to provide a conservative exposure estimate it is assumed that 100% of the applied product is present on the terrace surface.

Ref-MS information to the reader:	*Even if the maximum dose is the double for harbourage (4g), the estimated exposure is so low that a double dose would still be far from the AEL (0,0075 mg/kg bw/day), thus Ref-MS have accepted the applicants calculations.

Ref-MS information to the reader:	In the CAR the size of the terrace is assumed to be $10m^2$, which is considered a reasonable worst case scenario. In such a worst case, the surface residue would be 3 times higher, eg. 0.000010 mg a.s./cm^2.

Based on these assumptions/considerations dermal exposure (D) of the child is calculated as follows:

D = SR x TR x TC x EP

= 0.0000033 mg a.s./cm^2 x 0.3 x 6000 cm^2/hour x 1 hour/day

= 0.00594 mg deltamethrin/toddler/day

Taking into account the dermal absorption of 2% systemic exposure by the dermal route (S_{dermal}) is calculated to be:

S_{dermal} = D x Dermal absorption ÷ Body weight

= 0.00594 mg/toddler/day x 0.02 ÷ 10 kg

= 0.0000119 mg/kg bw/day

For the toddler one might in addition consider oral exposure by hand to mouth transfer. The TNsG propose to assume in a tier 1 approach that 10 % of the total amount of product that ends up on the skin of the toddler is taken in orally by hand to mouth contact ("Technical notes for guidance; Human exposure to biocidal products, Guidance on exposure estimation, June 2002; Defaults for non professional use and residential exposure to biocides").

S_{oral} = D x 0.1 x Oral absorption ÷ Body weight

= 0.00594 mg/toddler/day x 0.1 x 0.75 ÷ 10 kg

= 0.0000446 mg/kg bw/day

Based on this conservative approach total systemic exposure of the toddler is estimated to be about 0.0000565 mg/kg bw/day (0.0000119+0.0000446).

Ref-MS information to the reader:	Using the scenario in the CAR as a worst case results in a systemic exposure by the dermal route of 0.0180 mg/day and 0.000036 mg/kg bw/day in a toddler with a bw of 10 kg. Exposure by the oral route would be 0.000135 mg/kg bw/day and a total exposure 0.000171 mg/kg bw/day (2 % AEL).

2.7.3 Environmental exposure assessment

2.7.3.1 Fate and distribution in the environment

Deltamethrin DP 0.05 is a ready to use, dustable powder formulation which contains the active substance deltamethrin at a concentration of 0.05 %. The main use of Deltamethrin DP 0.05 is as an outdoor application to control ants (e.g. the black ant, *Lasius niger*). Deltamethrin DP 0.05 can also be used to control other crawling insects , e.g. German cockroaches, silverfish, wood louse or pill bug, in localised protected areas (e.g. underneath flowerpots, floor boards, garden appliances, etc.).

The treatment powder is applied onto the entrances of ant nests on terraces, patios and pathways, or on the harbourage area (nesting/resting area) of the pest crawling insect, at a product application rate respectively of 2g per ant nest and 2g per 100 cm^2 in harbourage. For the treatment of ant nests, to treat the nest, entrances are locally treated at a dose of 2 g per ant nest, with no more than 0.5 g sufficient to treat a single entrance. In the case of the treatment of crawling insects in protected outdoor locations (e.g. underneath flowerpots, floor boards, garden appliances, etc.), the dose of 2 g per 100 cm^2 applies, for the localised treatment of the nesting and resting area of the pest insect.

Treatment is best represented by the typical outdoor “spot application” pattern, as described in the Emission Scenario Document for insecticides for household and professional uses (OECD, 2008).

The residual life of the applied product will vary depending upon the nature of the surface to which it is applied, and the extent to which the residue remains undisturbed. Deltamethrin products exhibits sustained residual activity (up to 3 months) where residues remain undisturbed. Repeat treatments may be carried out as necessary, if target pests re-infest.

As deltamethrin is manufactured outside the EU, in accordance with the risk assessment framework presented in the Technical Guidance Document (European Commission, 2003), it is not necessary to specifically quantify the potential for environmental exposure associated with the production stage of the product life cycle.

In addition to this the manufacturing plants where Deltamethrin DP 0.05 is formulated are strictly regulated. The plants have been audited by BCS IOP and have demonstrated compliance with BCS production guidelines. In addition, the formulation plants are ISO 9001 certified, and adheres to the ICPE legislation (Installation Classified for the Protection of the Environment). All wastewater produced during formulation and cleaning of manufacturing equipment is collected and incinerated. Emission limits govern the release of dust from the plants. Since all hazardous wastes are eliminated in incineration facilities it is proposed that no unacceptable emissions will occur during the formulation stage of the Deltamethrin DP 0.05 product life cycle.

The potential for environmental exposure associated with the private/consumer use stage of the Deltamethrin DP 0.05 product life cycle has been evaluated with specific reference to the local environmental scale. Due to the nature of the product use and application procedure it would be expected that, in most cases, environmental exposure that may occur would be localised in nature, therefore, it is assumed that any contribution from the regional scale would be so low that it could be considered negligible.

Deltamethrin DP 0.05 is packaged in 0.5 litre ready-to-use bottles containing the active substance in a powder formulation. There is no preparation step required prior to the use of the product, which can be directly applied to the treated area; therefore, emissions from the preparation step are not considered in this risk assessment. This is consistent with general guidance presented in the Emission Scenario Document for insecticides, acaricides and products to control other arthropods (PT 18) for household and professional uses, which indicates that mixing and loading should not be considered for ready to use products (RTU).

Deltamethrin DP 0.05 is applied by consumers in outdoor premises to control infestations by pest insects. In accordance with the PT18 ESD (dated 17th July 2008), the possible receiving compartments are the soil and to a lesser extent, the air. Release to the air is considered negligible. The default emission to soil for powders is 90%. No emission to the STP or to surface waters is expected to occur from use in control of ants or crawling insects.

Conclusions regarding fate properties are presented for the active substance deltamethrin in Doc IIA. It is considered that the formulation of Deltamethrin DP 0.05 will not significantly influence the environmental fate and behaviour of the active substance. As such, no additional information is available or is required.

Ref-MS Information to the reader:	The following sections with data on the active substance deltamethrin are cut and pasted from the Assessment Report (2011).

2.7.3.1.1 Abiotic degradation

The hydrolysis of deltamethrin was shown to be insignificant at pH 5 and 7. At pH 9, however, the hydrolysis was significant with a half-life of 2.5 days (25°C), normalised to 7 days (12°C). At pH 8, half-life was 31 days (23°C), normalised to 75 days (12°C). Direct photochemical reactions do notoccur at a rate that makes this a significant route of degradation of deltamethrin under natural conditions in water. In soil, direct and indirect photochemical reactions may contribute to the degradation of deltamethrin, but other routes of transformation account for the major loss of parent compound.

2.7.3.1.2 Biodegradation

Deltamethrin was not readily biodegradable in laboratory tests. In aquatic environments, deltamethrin will very rapidly partition to the sediment, to suspended organic matter and to biota. In the laboratory about 60% of the applied radioactivity was found in the sediments immediately after application. In water/sediment systems, the degradation DT_{50} was estimated to 45 and 141 days in two different systems at 20°C (85 and 267 days as normalised to 12°C) and the dissipation DT_{50} in sediment to 55 and 133 days at 20ºC (104 and 253 days as normalised to 12°C). The pH of the aqueous phase of these systems were 8.0-9.1 and hydrolysis may have contributed to the degradation observed. pH of the sediments were lower (7.1/7.5). The difference in degradation rate between the two systems probably reflects difference in amount of fine-textured material and amount of organic matter. In soil, first order DT_{50} values for deltamethrin were 11-27 days and short-lived metabolites were formed. When normalised to 12ºC, the DT_{50} was 31-74 days, with a geometric mean of 48 days. The pH of the four soils used were 5.8, 5.9, 7.5 and 8.1 and hydrolysis was probably an insignificant route of degradation in the soils. The DT_{50}s of the major metabolite of deltamethrin, Br_2CA, has been calculated to 0.7-11.6 days in three soils with a geometric mean of 2.0 days (normalised to 25°C and field capacity). When normalised to 12°C and field capacity the DT_{50}s for Br_2CA were 2.1-32.3 days, geometric mean 5.6 days.

2.7.3.1.3 Distribution

Deltamethrin is very strongly adsorbed to soil and other organic matter, with a K_{oc} value ranging from 204 000 to 577 000 L/kg. The arithmetic mean K_{oc} value was 408 250 L/kg. The metabolites are more mobile with a arithmetic mean K_{oc} of 25.6 L/kg for Br_2CA and 115 L/kg for mPBacid. Due to its low vapour pressure, deltamethrin is not expected to volatilise to air from plants and soil at significant levels, which was confirmed in a wind tunnel study. However, the calculated Henry's law constant is 1.252×10^{-3}

$Pa.m^3.mole^{-1}$, indicating that deltamethrin has a tendency to volatilise from water. If present in air, the data on indirect photo-oxidation indicate a rapid degradation when reacting with hydroxyl radicals.

It is recognised that degradation of the deltamethrin residue may result in the formation of a quantity of the major metabolite Br_2CA. No data are available concerning the formation of Br_2CA from residual deposits of deltamethrin in areas treated with K-Othrine SC 7.5. Similarly, little data are available to reliably estimate the potential formation of the compound in the different environmental compartments of relevance. Furthermore, it is difficult to predict the actual quantity of metabolite Br_2CA present in different environmental compartments following use of K-Othrine SC 7.5, since the parent will potentially have been subject to transformation either in situ or in the STP under very different environmental conditions. Therefore, in order to estimate potential exposure of the major metabolite Br_2CA, associated with losses to the wastewater compartment during the service life of K-Othrine SC 7.5, it has been assumed that the metabolite is formed in the environmental compartment in question at a quantity equivalent to 100% of the parent (adjusted to take into account the molecular weights of the compounds). The parent compound has a molecular mass of 505.2 $g.mol^{-1}$, whilst the metabolite Br_2CA has a molecular mass of 298.0 $g.mol^{-1}$. Therefore, the estimate of potential local exposure of the parent substance has been adjusted by a factor of 0.59 (i.e. 298.0 / 505.2) to provide an estimate of exposure to the metabolite Br_2CA following suggested use. Where pertinent, the characterstics, e.g. Henry's Law's constant and partitioning coefficient, of Br_2CA has been incorporated in the calculations.

2.7.3.1.4 Accumulation

The bioaccumulation of ^{14}C-deltamethrin was investigated in bluegill sunfish (*Lepomis macrochirus*). The BCF values obtained were 310, 2800 and 1400 for edible, non-edible and whole body tissue, respectively. After the 14-day depuration period 70, 75 and 76% of the ^{14}C-residues had been eliminated from the edible, non-edible and whole body tissue, respectively. The biological half-life was 4.3 days for whole body tissue. The potential for bioconcentration of deltamethrin in earthworms was estimated by modelling the hydrophobic partitioning between soil pore water and the phases inside the organism, in accordance with equation 82d in the TGD. Using the Kow of 40 200 for deltamethrin, the $BCF_{earthworm}$ was 483. Assessments of the potential for secondary poisoning via terrestrial and aquatic food chain indicate that there is no unacceptable risk for earthworm- and fish-eating birds and small mammals.

2.7.3.2 PEC in surface water, sediment, STP and ground water

Ref-MS Information to the reader:	The calculation for PEC groundwater is based on 30 d TWA values for PEC soil, presented in the section PEC soil, below. For clarification, the equation below for the air water partition coefficient gives Kair-water = 5.28x10-7.

Deltamethrin DP 0.05 is applied by consumers in outdoor premises to control infestations by pest insects. In accordance with the PT18 Emission Scenario Document for insecticides for household and professional uses (OECD, 2008), it is considered that there is no significant potential for emissions to the STP or surface water. As such, risk to the STP, surface water, and sediment are not considered further in this risk assessment.

It is recognized that there may be some potential for residues of deltamethrin and the major metabolite Br2CA in soil to be transported via leaching to groundwater. In accordance with the guidance presented in the Technical Guidance Document (European Commission, 2003), the concentration in soil porewater has been calculated to provide an indication for potential groundwater contamination risk. This approach is recognized as a suitable first-tier method of estimating groundwater exposure. It should be noted that this is a worst-case assumption, neglecting transformation, sorption and dilution.

In order to estimate the concentration in pore water of soil a number of partition coefficients are derived:

Air water partition coefficient [-]

$$Kair - water = \frac{HENRY}{R \times TEMP}$$

Soil water partition coefficient ($L.kg^{-1}$):

$Kp_{soil} = Koc \times Foc$

Soil-water equilibrium partition distribution coefficient ($m^3.m^{-3}$)

$$Ksoil - water = Fair \times Kai - water + Fwater + Fsoil \times \frac{Kpsoil}{1000} \times RHOsolid$$

Where:

Variable/parameter (unit)	Symbol	Unit	Value	Source*
Henry's law constant	HENRY	[$Pa.m^3\ mol^{-1}$]	1.252E-03	Input
Gas constant	R	[$Pa\ m^3\ mol^{-1}.k^{-1}$]	8.314	Default
Temperature at the air-water interface	TEMP	[K]	285	Default
Air-water partitioning coefficient	$K_{air\text{-}water}$	[-]	-	Output
Partition coefficient organic carbon-water	K_{oc}	[$L\ kg^{-1}$]	-	Input
Fraction organic carbon in the soil	F_{oc}	[-]	0.02	Default
Soil water partition coefficient	Kp_{soil}	[$L\ kg^{-1}$]		Output
Fraction air in soil	F_{water}	[-]	0.2	Default
Fraction water in soil	F_{solid}	[-]	0.6	Default
Fraction solid in soil	F_{solid}	[-]	0.6	Default
Bulk density of solids	RHO_{solid}	[$kg.m^{-3}$]	2500	Default

Soil-water equilibrium partition distribution coefficient	$K_{soil\text{-}water}$	[m3 m^{-3}]	-	Output

*All default values were taken from the Technical Guidance Document (European Commission, 2003)

Therefore:

Air water partition coefficient [-]:

$$Kair - water = \frac{1.25 \times 10^{-3}}{8.314 \times 285}$$

Soil water partition coefficient ($L.kg^{-1}$):

Kp_{soil} = 408250 x 0.02 = 8165

Soil-water equilibrium partition distribution coefficient ($m^3.m^{-3}$):

$$Ksoil - water = 0.2 \times 5.28 \times 10^{-7} + 0.2 + 0.6 \times \frac{8165}{1000} \times 2500 = 12247.7$$

The equation for deriving the concentration in porewater is:

$$PEClocal_{soil,porew} = \frac{PEClocal\ soil \times RHOsoil}{Ksoil{-}water \times 1000}$$

Where:

Variable/parameter (unit)	Symbol	Unit	Value	Source
Predicted environmental concentration in soil	$PEC_{localsoil}$	[mg kg^{-1}]	-	Input
Soil-water partitioning coefficient	$K_{soil\text{-}water}$	[$mg.L^{-1}$]	12247.7	Calculated
Bulk density of wet soil	RHO_{soil}	[kg m^{-3}]	1700	Default
Predicted environmental concentration in porewater	$PEC_{localsoil,porew}$	[$mg.L^{-1}$]	-	Output

The resulting predicted environmental concentrations for deltamethrin in soil porewater associated with soil exposure during the application and subsequent service-life are presented in Table 2.7.3.2-1 and Table 2.7.3.2-2.

Table 2.7.3.2-1: Predicted concentrations of deltamethrin in local soil porewater associated with the application/service life stage for Deltamethrin DP 0.05, for the treatment of ant nest, assuming a range of soil mixing depths

Substance	Soil mixing depth (m)	Predicted concentration in porewater (based on 30-day time-weighted average conc. in soil) ($mg.L^{-1}$)
Deltamethrin	0.1	2.39E-06
	0.2	1.19E-06
	0.5	4.77E-07

Table 2.7.3.2-2: Predicted concentrations of deltamethrin in local soil porewater associated with the application/service life stage for Deltamethrin DP 0.05, for the treatment of crawling insects, assuming a range of soil mixing depths

Substance	Soil mixing depth (m)	Predicted concentration in porewater (based on 30-day time-weighted average conc. in soil) ($mg.L^{-1}$)
Deltamethrin	0.1	7.50E-06
	0.2	3.75E-06
	0.5	1.50E-06

In order to assess the leaching potential of the major metabolite Br_2CA, first-tier pore water calculations have been carried out using the predicted 30-day average concentration in local soil (PEC_{soil}) presented in Table 2.7.3.2-3 and Table 2.7.3.2-5.

The porewater calculations were carried out according to the framework established for the parent deltamethrin above. Therefore:

Air water partition coefficient [-]:

$$Kair - water = \frac{4.04E-03}{8.314 \times 285} = 1.71E-06$$

Soil water partition coefficient ($L.kg^{-1}$): In this calculation the mean Koc for Br_2CA of 25.6 $mL.g^{-1}$ was used as the input parameter.

Kp_{soil} = 25.6 x 0.02 = 0.512

Soil-water equilibrium partition distribution coefficient ($m^3.m^{-3}$):

$$Ksoil - water = 0.2 \times 1.71 \times 10^{-6} + 0.2 + 0.6 \times \frac{0.512}{1000} \times 2500 = 0.97$$

The resulting predicted environmental concentrations in soil porewater for the metabolite Br_2CA are summarised in Table 2.6.3.2-3 and Table 2.6.3.2-4. It should be noted that these PEC_{gw} values for Br_2CA were calculated on the basis of PEC_{soil} values that were calculated on the unrealistically worst-case assumption that 100 % of the parent compound is transformed to Br_2CA (corrected for molecular weight). The higher concentrations predicted for Br_2CA, compared to those for deltamethrin, are consistent with the high mobility of the compound.

Table 2.7.3.2-3: Predicted concentrations of the metabolite Br2CA in porewater of local soil associated with the application/service life stage for Deltamethrin DP 0.05, for the treatment of ant nests, assuming a range of soil mixing depths

Substance	Soil mixing depth (m)	Predicted concentration in porewater (based on 30-day time-weighted average conc. in soil) (mg.L-1)
Br_2CA	0.1	5.76E-03
	0.2	2.88E-03
	0.5	1.15E-03

Table 2.7.3.2-4: Predicted concentrations of the metabolite Br2CA in porewater of local soil associated with the application/service life stage for Deltamethrin DP 0.05, for the treatment of crawling insects, assuming a range of soil mixing depths

Substance	Soil mixing depth (m)	Predicted concentration in porewater (based on 30-day time-weighted average conc. in soil) (mg.L-1)
Br_2CA	0.1	1.81E-02
	0.2	9.05E-03
	0.5	3.62E-03

Ref-MS Information to the reader:

Below, the applicant describes the results from a higher-tier assessment of the potential for groundwater contamination associated with soil applications of deltamethrin using the simulation model FOCUS-PEARL 2.2.2.

This table (below) provides an overview of the simulated concentrations in groundwater for deltamethrin and its metabolite Br_2CA for each FOCUS scenario:

FOCUS predicted groundwater concentrations of deltamethrin and the major metabolite Br_2CA via direct application to soil

Scenario	80th percentile annual average concentration (µg/L)	
	Deltamethrin	Br_2CA
\direct soil application (1 Jan, 1 May and 1 Oct) for PT 18		
Châteaudun (C)	<0.001	<0.001
Hamburg (H)	<0.001	<0.001
Jokioinen (J)	<0.001	<0.001
Kremsmünster (K)	<0.001	<0.001
Okehampton (N)	<0.001	<0.001
Piacenza (P)	<0.001	<0.001
Porto (O)	<0.001	<0.001
Sevilla (S)	<0.001	<0.001
Thiva (T)	<0.001	<0.001

The results of the porewater calculation for the metabolite Br2CA exceed the 0.1 µg.L^{-1} criteria stipulated for agricultural pesticides under EEC 91/414. Therefore first-tier porewater calculations indicate a potential risk of leaching. However, it should be noted that the porewater calculation method is a necessarily simplistic approach neglecting transformation and dilution in deeper soil layers. Furthermore, it should be noted that emissions to soil will be highly localised, meaning that there is significant potential for spatial dilution. A more realistic, higher-tier assessment of the potential for groundwater contamination associated with soil applications of deltamethrin has also been carried out using the simulation model FOCUS-PEARL 2.2.2 (Schafer, 2004, Appendix 1). In order to establish the applicability of the results of the study, it is necessary to calculate an application rate for deltamethrin used in outdoor insect control treatments on a per-hectare basis.

The resulting equivalent per-hectare application rate is 2.05 g.ha^{-1}.

The modelling investigation carried out to assess the leaching behaviour of deltamethrin and Br_2CA simulated applications of deltamethrin according to agricultural use patterns, with three treatment events per year, each of either 7.5 g a.i. ha^{-1} (total: 22.5 g a.i. ha^{-1}) (typical of use in arable crops) or 12.5 g a.i. ha^{-1} (typical of use on fruit or vegetable crops). Since both of these total application rates are higher than the maximum rate calculated for outdoor applications of Deltamethrin DP 0.05, it is proposed that the results of the investigation provide a suitable evaluation of the potential for groundwater contamination associated with this scenario. Simulations were carried out for scenarios representing a wide range of pedoclimatological conditions in the European Union. The model was parameterised according to the standardised guidance provided by FOCUS (2000). The calculated PEC_{gw} values (80th percentiles of the annual average concentrations in the percolate at 1 m soil depth) of deltamethrin and its metabolites were several orders of magnitude below the groundwater trigger value of 0.1 µg.L^{-1} in all scenarios. It is therefore concluded that neither deltamethrin nor Br_2CA represent a risk to groundwater.

2.7.3.3 PEC in air

Due to the low vapour pressure of the active substance (1.24E-08 Pa at 25°C, Yoder, 1991), it is not expected that any volatile losses of deltamethrin to the air compartment would occur either during or after the application.This is consistent with the guidance presented in the ESD which states that exposure of the

air compartment is limited in time and restricted to the local scale and that F_{air} may be considered to be negligible from an environmental point of view (OECD, 2008).

2.7.3.4 PEC in soil

Release to Soil from Ant Nest Treatment

The potential emission to soil associated with spot treatment of ant nests using Deltamethrin DP 0.05 is estimated using the Spot application scenario provided in the ESD (OECD, 2008):

The direct emission to soil is calculated as follows:

$E_{spot,soil} = Q_{prod} \times F_{AI} \times N_{sites} \times N_{appl} \times F_{spot\ powder,soil}$

Where:

Variable/parameter (unit)	Symbol	Unit	Value	Source
Amount of product applied per nest entrance	Q_{prod}	[g]	0.5	Input
Fraction active substance in the product	F_{AI}	[-]	0.0005	Input
Number of application sites	N_{sites}	[-]	4	Input
Number of applications	N_{appl}	[-]	1	Input
Fraction emitted to soil during outdoor application on ant nest	$F_{spot\ powder,\ soil}$	[-]	0.9	Default*
Output				
Direct emission rate of active substance to soil	$E_{spot,soil}$	[g]	9 x 10-4	Output

*Default value from ESD PT18 (OECD, 2008)

The treated surface area has been assumed to be 0.25 m^2, based upon the default area defined for spot treatments in the ESD (OECD, 2008). Deltamethrin DP 0.05 should be applied at a rate of 0.5g per nest entrance. Conservatively, it has been assumed that 4 nest entrances are comprised within any spot area of 0.25m^2.

The concentration in soil is calculated as follows:

$$Cspot, soil = \frac{Espot, soil}{AREAexposed \times DEPTHsoil \times RHOsoil} \times 1000$$

Where:

Variable/parameter (unit)	Symbol	Unit	Value	Source
Local direct emission rate of active substance to soil	$E_{spot,soil}$	[g]	9 x 10-4	Input
Area directly exposed to insecticide	$AREA_{exposed}$	[m^2]	0.25	Default
Depth of exposed soil	$DEPTH_{soil}$	[m]		Default (see text)
Density of exposed soil RHO	RHO_{soil}	[kg m-3]	1700	Default
Output				
Local concentration in soil due to direct release after a campaign*	$C_{spot,soil}$	[mg kg-1]	–	Output

*around the treated spot

Ref-MS Information to the reader:	The applicant has chosen to calculate PEC soil for several soil depths. According to TAB WGII 2015 2.4.14 part 2 the soil depth that should be used for the risk assessment is 0.5 m.

There is some inconsistency in the guidance regarding soil mixing depths. The ESD for insecticides used in household and professional situations (OECD, 2008) suggests a default mixing depth of 0.5 m (in-line with that already employed for PT8 assessments). However, the notes from PT18 workshop of December 2007 (European Commission, 2007) and results from discussions at the Biocides Technical meetings (TMI 08) indicate a regulatory preference for shallower mixing depths, with 0.1 m being proposed in cases of no mixing and 0.2 m where mixing occurs. In the absence of any clear guidance regarding the level of disturbance on the soil exposed during application, calculations have been performed for all mixing depths.

Table 2.7.3.4-1: Initial predicted concentrations in local soil associated with the application/service life stage for Deltamethrin DP 0.05 for the treatment of ant nests, assuming a range of soil mixing depths

Substance	Soil mixing depth (m)	Predicted initial concentration in soil ($mg.kg^{-1}$)
Deltamethrin	0.1	2.12E-02
	0.2	1.06E-02
	0.5	4.24E-03

The Technical Guidance Document (European Commission, 2003) recommends that for estimating more realistic environmental exposure the time-weighted average concentration in soil should also be calculated. For the ecosystem a period of 30 days is taken as a relevant time period with respect to chronic exposure of soil organisms. The Emission Scenario Document for household and professional uses of insecticides (OECD, 2008) indicates that the concentration after 30 days should be calculated. Therefore, this calculation has also been performed.

The time-weighted average concentration in soil is determined by:

$PEC(t) = PIEC * (1-e^{-kt})/kt$

The concentration in soil at the end of the 30 day period is calculated using:

$PEC(t) = PIEC * e^{-kt}$

where:

k = ln2/DT50 (day -1)

t = time period (days)

DT50 = half-life time of degradation in soil (days)

PEC = Predicted Environmental Concentrations

PIEC = Predicted Initial Environmental Concentrations

In this case, t = 30 days, whilst DT50 has been taken as 48.2 days, which is the geometric mean of DT_{50} values generated in studies on four different soil types, normalised to 12°C and PF2 (field capacity). A description of the soil degradation studies and the normalisation process is provided in Section 2.7.3.1.2.

The resulting estimated 30-day time-weighted average concentrations in soil and concentrations at the end of the 30-day period are presented in Table 2.7.3.4-2.

Table 2.7.3.4-2: Predicted 30-day time-weighted average concentrations in local soil associated with the application/service life stage for Deltamethrin DP 0.05, assuming a range of soil mixing depths

Substance	Soil mixing depth (m)	30-day time-weighted average concentration in soil (mg kg^{-1})	Concentration in soil at the end of 30-day period (mg kg^{-1})
Deltamethrin	0.1	1.72E-02	1.38E-02
	0.2	8.60E-03	6.88E-03

Substance	Soil mixing depth (m)	30-day time-weighted average concentration in soil (mg kg^{-1})	Concentration in soil at the end of 30-day period (mg kg^{-1})
	0.5	3.44E-03	2.75E-03

Degradation of the deltamethrin residue may result in the formation of a quantity of the major metabolite Br2CA in soil. Initial concentrations of Br2CA in soil were estimated on the worst-case assumption that the metabolite is formed in the soil at a quantity equivalent to 100% of the parent (adjusted to take into account the molecular weights of the compounds). The estimates of potential initial local soil exposure presented in Table 2.7.3.4-2 have been adjusted by a factor of 0.59 (298.0 / 505.2 = 0.59) to provide estimates of exposure to the metabolite Br2CA. It should be noted that these PEC values represent extreme worst-case estimates of exposure to soil, since laboratory data indicate that Br2CA is formed at a maximum of 23 % for the parent deltamethrin in aerobic soils after 14 days (Wang, 1991a). Based on the worst-case assumption of 100 % transformation of parent deltamethrin to Br2CA, estimated time-weighted average concentrations of the compound in soil have also been presented. These calculations have been carried out using the geometric mean DT50 for the metabolite Br2CA of 5.6 days taken from the three soils normalised to 12°C and PF2 (field capacity). It is recognised that, in reality, the formation and degradation of the metabolite Br2CA is a more complex process, giving rise to much lower, more steady state concentrations in soil. However, the estimates of time weighted average concentrations have been included to provide worst case values for risk assessment purposes.

Table 2.7.3.4-3: Predicted Br2CA exposure to the soil compartment resulting from the application/service life stage for Deltamethrin DP 0.05, assuming a range of soil mixing depths

Substance	Soil mixing depth (m)	Predicted initial concentration in soil (mg.kg^{-1})	30-day time weighted average concentration in soil (mg kg^{-1})	Concentration in soil at the end of 30-day period (mg kg^{-1})
Br_2CA	0.1	1.25E-02	3.28E-03	3.05E-04
	0.2	6.25E-03	1.64E-03	1.52E-04
	0.5	2.50E-03	6.56E-04	6.10E-05

Release to Soil from Crawling Insects Nesting/Resting Area Treatment

Crawling insect pests will typically return to a “harbourage” area to rest and nest. It is proposed to locally treat this nesting/resting area in order to efficiently treat the infestation.

The potential emission to soil associated with spot treatment of crawling insect nests and resting areas using Deltamethrin DP 0.05 has been estimated using the spot application scenario provided in the ESD (OECD, 2008). As a worst-case, treatment of the area under a pot with a base of 20 cm diameter, within the typical spot application area (0.5m x 0.5m = 0.25m^2), has been considered. Treated sheltering areas

should be localized in size and would not typically exceed 200 cm^2, however, as a worst-case, treatment of the integrality of the 20 cm diameter area (314 cm^2) at the dose of 2 g per 100 cm^2 is considered.

The direct emission to soil is calculated as follows:

$AREA_{treated} = \pi \times Radius^2$

$Q_{prod} = AREA_{treated} \times Dose$

$E_{spot,\ soil} = Q_{prod} \times F_{AI} \times N_{sites} \times N_{appl} \times F_{spot\ powder,\ soil}$

Where:

Variable/parameter (unit)	Symbol	Unit	Value	Source
Nesting/resting area of the target pest	$AREA_{treated}$	[cm^2]	314.16	Input
Treatment dose	Dose	[$g.cm^2$-1]	0.02	Input
Amount of product applied per Harbourage	Q_{prod}	[g]	6.28	Calculated
Fraction active substance in the product	F_{AI}	[-]	0.0005	Input
Number of application sites	N_{sites}	[-]	1	Input
Number of applications Nappl	N_{appl}	[-]	1	Input
Fraction emitted to soil during outdoor application on ant nest	$F_{spot\ powder,\ soil}$	[-]	0.9	Default*
Output				
Direct emission rate of active substance to soil	$E_{spot,soil}$	[g]	2.83E-03	Output

*Default value for powders from ESD PT18 (OECD, 2008)

Ref-MS Information to the reader:	The correct Espot, soil used for Cspot, soil is 2.83x 10-03, and not 9x10-4 as is indicated in the table below.

The treated surface area has been assumed to be 0.25 m2, based upon the default area defined for spot treatments in the ESD (OECD, 2008).

The concentration in soil is calculated as follows:

$$Cspot, soil = \frac{Espot, soil}{AREAexposed \times DEPTHsoil \times RHOsoil} \times 1000$$

Where:

Variable/parameter (unit)	Symbol	Unit	Value	Source
Local direct emission rate of active substance to soil	$E_{spot,soil}$	[g]	9 x 10-4	Input
Area directly exposed to insecticide	$AREA_{exposed}$	[m²]	0.25	Default
Depth of exposed soil	$DEPTH_{soil}$	[m]		Default**
Density of exposed soil RHO	RHO_{soil}	[kg m-3]	1700	Default
Output				
Local concentration in soil due to direct release after a campaign*	$C_{spot,soil}$	[mg kg-1]	–	Output

*around the treated spot

**see discussion in section 2 3.3.4

Calculation of the Time-Weighted Average values and calculations for the metabolite has been carried out as described in section 2.6.3.4, for the ant nest treatment. The resulting estimated initial concentrations in soil, 30-day time-weighted average concentrations in soil and concentrations at the end of the 30-day period are presented in Table 2.7.3.4-4 and Table 2.7.3.4-5.

Table 2.7.3.4-4: Predicted Deltamethrin exposure to the soil compartment resulting from the application/service life stage of Deltamethrin DP 0.05, for the treatment of crawling insects, assuming a range of soil mixing depths

Substance	Soil mixing depth (m)	Predicted initial concentration in soil (mg kg^{-1})	30-day time-weighted average concentration in soil (mg kg^{-1})	Concentration in soil at the end of 30-day period (mg.kg^{-1})
Deltamethrin	0.1	6.65E-02	5.40E-02	4.32E-02

	0.2	3.33E-02	2.70E-02	2.16E-02
	0.5	1.33E-02	1.08E-02	8.64E-03

Ref-MS Information to the reader:	In similar way as for 'Release to Soil from Ant Nest Treatment', the estimates of potential initial local soil exposure presented in Table 2.7.3.4-5 have been adjusted by a factor of 0.59 (298.0 / 505.2 = 0.59) to provide estimates of exposure to the metabolite Br2CA.

Table 2.7.3.4-5: Predicted Br2CA exposure to the soil compartment resulting from the application/service life stage of Deltamethrin DP 0.05, for the treatment of crawling insects, assuming a range of soil mixing depths

Substance	Soil mixing depth (m)	Predicted initial concentration in soil (mg kg^{-1})	30-day time-weighted average concentration in soil (mg kg^{-1})	Concentration in soil at the end of 30-day period (mg.kg^{-1})
Br_2CA	0.1	3.92E-02	1.03E-02	9.57E-04
	0.2	1.96E-02	5.16E-03	4.79E-04
	0.5	7.85E-03	2.06E-03	1.91E-04

2.7.3.5 Non-compartmental-specific exposure relevant to the food chain (secondary poisoning)

Accordingly with the ESD (OECD, 2008), the general rules for assessment of secondary poisoning, as presented in section 3.8 of the EU-TGD, have been followed in this risk assessment.

The first step in an assessment of secondary poisoning risk is to consider whether a chemical has the potential to bioaccumulate. The potential for bioaccumulation can be estimated from the value of the n-Octanol/water partition coefficient, log Kow. It is accepted that values of log Kow greater than or equal to 3 indicate that the substance may bioaccumulate. Since, deltamethrin has a log Kow of 4.6 (Yoder, 1991), the potential for bioaccumulation should be considered. A bioaccumulation study in *Lepomis m.* has been carried out with radio labelled deltamethrin (98.1%) under flow through conditions (28 days, plus a 14 day depuration period). Based on the results of this study, the Bioconcentration Factors (BCF) are 310, 2800 & 1400 for edible, nonedible & whole body tissue, respectively. The clearance time was 4.3 days (Fackler *et al.*, 1990).

Ref-MS Information to the reader:	(*) In the following section, RMS has amended the text with classification according to CLP. The second step in any assessment of secondary poisoning risk is to consider whether the substance has the potential to cause toxic effects if accumulated in higher organisms. This assessment is based on classifications on the basis of mammalian toxicity data (i.e. the classification Fatal (Acute Tox. 1 or Acute Tox. 2) or Toxic (Acute Tox. 3) or Harmful (Acute Tox. 4) with at least one of the

	hazard phrases Causes damage to organs through prolonged or repeated exposure (STOT RE 1) or May cause damage to organs through prolonged or repeated exposure (STOT RE2), May damage fertility (Repr. 1A or Repr), May damage the unborn child (Repr. 1A or Repr), Suspected of damaging fertility (Repr. 2), Suspected of damaging the unborn child (Repr. 2), May cause harm to breast-fed children (Lact.). Here, it is assumed that the available mammalian toxicity data can give an indication of the possible risks of the chemical to higher organisms in the environment. Based upon mammalian toxicity data, deltamethrin has been classified as being Toxic (Acute Tox. 3) with the Hazard Phrases Toxic if inhaled (H331) and Toxic if swallowed (H301). In accordance with the guidance presented in the Technical Guidance Document (European Commission, 2003), neither of these risk phrases trigger the criteria for further consideration of secondary poisoning risk. Therefore, it has been concluded that deltamethrin does not present a risk of secondary poisoning in the environment.

The second step in any assessment of secondary poisoning risk is to consider whether the substance has a potential to cause toxic effects if accumulated in higher organisms. This assessment is based on classifications on the basis of mammalian toxicity data (i.e. the classification Very Toxic (T+) or Toxic (T) or harmful (Xn) with at least one of the risk phrases R48 "Danger of serious damage to health by prolonged exposure", R60 "May impair fertility", R61 "May cause harm to the unborn child", R62 "Possible risk of impaired fertility", R63 "Possible risk of harm to the unborn child", R64 "May cause harm to breastfed babies"). Here, it is assumed that the available mammalian toxicity data can give an indication on the possible risks of the chemical to higher organisms in the environment. Based upon mammalian toxicity data, deltamethrin has been classified as being Toxic (T) with the Risk Phrases R23 Toxic by inhalation and R25 Toxic if swallowed. In accordance with the guidance presented in the Technical Guidance Document (European Commission, 2003), neither of these risk phrases trigger the criteria for further consideration of secondary poisoning risk. Therefore, it has been concluded that deltamethrin does not present a risk of secondary poisoning in the environment.(*)

In 2002 deltamethrin was categorized as having evidence for endocrine disrupting properties (RPS BKH Consultants B.V., 2002). At the same time, deltamethrin was evaluated in scientific panels under EU Directive 91/414 and included in Annex I without raising concerns over potential endocrine disrupting properties and without requiring additional studies in that field (European Commission, 2003). In fact, none of the studies submitted for the toxicological assessment under EU Directive 91/414 provides any evidence that deltamethrin possesses any endocrine disrupting activity (Lautraite, 2006). Accordingly there are no indications that deltamethrin could lead to endocrine disruptive effects via secondary poisoning.

Although it has been concluded that deltamethrin does not present a risk to secondary poisoning, conservatively, the potential for bioaccumulation of deltamethrin in earthworms has been quantitatively estimated in this risk assessment.

Please note that the TGD specifies that for the assessment of biomagnification effects resulting from application of sludge (indirect soil exposure), a time-weighted average period of 180 days can be used. In the absence of clear guidance regarding assessments for the case of direct exposure of biocides to soil, predicted environmental concentration values obtained using the concentration in soil and in soil porewater over a 30-days time-period as well as initial concentrations, have been presented in this risk assessment. Therefore, initial concentrations in porewater have been calculated and are reported below:

Table 2.7.3.5-1: Predicted concentrations of deltamethrin in local soil porewater associated with the application/service life stage for Deltamethrin DP 0.05, assuming a range of soil mixing depths

Substance	Soil mixing depth (m)	Predicted concentration in porewater following ant nest treatment (based on initial conc. in soil) ($mg.L^{-1}$)	Predicted concentration in porewater following crawling insect treatment (based on initial conc. in soil) ($mg.L^{-1}$)
Deltamethrin	0.1	2.94E-06	9.23E-06
	0.2	1.47E-06	4.62E-06
	0.5	5.88E-07	1.85E-06

An estimated BCF value for earthworms of 483 L.kg wet $earthworm^{-1}$ was used for the purpose of the Risk Assessment, calculated using a Kow value of 40200 and the calculation method presented in the TGD, as shown below:

$$BCFearthworm = \frac{0.84 + 0.012 \times Kow}{RHOearthworm}$$

Where:

Variable/parameter (unit)	Symbol	Unit	Value	Source
Earthworm density	*RHOearthworm*	[kgwwt.L-1]	1	Default
Octanol-water partition coefficent	*Kow*	[-]	40200	Input
Bioconcentration factor for earthworms on wet weight basis	*BCFearthworm*	[L kgwet earthworm-1]	483	Output

Calculation of the predicted environmental concentration in food for terrestrial predators has been carried out using the following equations, from the TGD:

$$Cearthworm = \frac{BCFearthworm \times Cporewater \times Wearthworm \times Csoil \times Wgut}{Wearthworm + Wgut}$$

The calculation of the concentration in earthworms can be rewritten using the following equation:

$W_{gut} = W_{earthworm}$ x F_{gut} X $CONV_{soil}$

With:

$$CONVsoil = \frac{RHOsoil}{Fsolid \times RHOsolid}$$

Variable/parameter (unit)	Symbol	Unit	Value	Source
Bioconcentration factor for earthworms on wet weight basis	$BCF_{earthworm}$	[L kgwet earthworm^{-1}]	483	Calculated
Concentration in porewater	$C_{porewater}$	[mg.L^{-1}]	-	Input
Weight of earthworm tissue	$W_{earthworm}$	[kgwwt tissue]	-	Input
Concentration in soil	C_{soil}	[mg.kgwwt^{-1}]	-	Input
Weight of gut contents	W_{gut}	[kgwwt]	-	Input
Fraction of gut loading in worm	F_{gut}	[kgdwt kgwwt^{-1}]	0.1	Default
Conversion factor for soil concentration wet-dry weight soil	$CONV_{soil}$	[kgwwt kgdwt $^{-1}$]	-	Calculated
Bulk density of wet soil	RHO_{soil}	[kgwwt.m^{-3}]	1700	Default
Volume fraction of solids in soil	F_{solid}	[m^3.m^{-3}]	0.6	Default
Density of solid phase	RHO_{solid}	[kgdwt m^{-3}]	2500	Default
Concentration in earthworm on wet weight basis	$C_{earthworm}$	[mg kgwet earthworm^{-1}]	-	Output

Therefore, the resulting calculation is described by the equation below:

$$Cearthworm = \frac{BCFearthworm \times Cporewater + Csoil \times Fgut \times CONVsoil}{1 + Fgut \times CONVsoil}$$

Ref-MS Information to the reader:	Please note, that the assessment of secondary poisoning for insecticides should be based on the approach presented in the ESD PT18 No.18 (2008) considering the estimated theoretical exposure (ETE). However, a risk characterisation for Myrr D based on ETE for large and small insect eating species has been calculated by Ref-MS and leads to no unacceptable risk for the non-target species. The approach in this PAR was also used in the CAR for deltamethrin.

Please also note that the TGD specifies that it would be unrealistic to consider that the totality of an animal diet would be sourced from the release area. Therefore, it is recommended to consider that 50% of the predator diet comes from an area impacted by local release of deltamethrin (referred to as "local area") and the remaining diet would come from an area where regional background concentration can be expected (referred to as "regional area"). In this risk assessment, it is considered that use of the product does not significantly contribute to environmental concentrations at the regional scale. For the purpose of this risk assessment, $PEC_{oral\ predator}$ resulting from 50% of the diet sourced from a local area has been considered.

Therefore, the following equation applies:

$PEC_{oral,\ predator}$ (earthworm) = 0.5 x $C_{earthworm}$

The estimated Predicted Environmental Concentrations of deltamethrin in predator diet for consideration of the risk to secondary poisoning are presented in Table 2.7.3.5-2 and Table 2.7.3.5-3.

Table 2.7.3.5-2: Predicted Environmental Concentrations of Deltamethrin in secondary consumers' diet (ant nest treatment)

Substance	Soil mixing depth (m)	Initial concentrations		30-d TWA	
		Concentration in earthworm (Cearthworm) (mg.kg wet Earthworm^{-1})	Predicted concentration in predator diet (mg kg diet^{-1})	Concentration in earthworm (Cearthworm) (mg.kg wet earthworm^{-1})	Predicted concentration in predator diet (mg kg diet^{-1})
Deltamethrin	0.1	3.43E-03	1.72E-03	2.79E-03	1.39E-03
	0.2	1.72E-03	8.58E-04	1.39E-03	6.97E-04
	0.5	6.86E-04	3.43E-04	5.57E-04	2.79E-04

Table 2.7.3.5-3: Predicted Environmental Concentrations of Deltamethrin in secondary consumers' diet (crawling insects treatment)

Substance	Soil mixing depth (m)	Initial concentrations in soil		30-d TWA concentrations in soil	
		Concentration in earthworm (Cearthworm) (mg.kg wet Earthworm^{-1})	Predicted concentration in predator diet (mg kg diet^{-1})	Concentration in earthworm (Cearthworm) (mg.kg wet earthworm^{-1})	Predicted concentration in predator diet (mg kg diet^{-1})
Deltamethrin	0.1	1.08E-02	5.39E-03	8.75E-03	4.38E-03
	0.2	5.39E-03	2.69E-03	4.38E-03	2.19E-03
	0.5	2.16E-03	1.08E-03	1.75E-03	8.75E-04

2.8 EFFECTS ASSESSMENT

2.8.1 Human health effects assessment

A complete range of acute, irritancy and sensitisation studies are available supporting the classification of Deltamethrin DP 0.05. In addition, data on dermal absorption using different formulations have also been generated. There are no substances of concern in the formulation (see confidential data for details on co-formulants) for which additional testing would be required.

2.8.1.1 Percutaneous absorption

Dermal absorption studies were conducted *in vivo* as well as *in vitro* using different formulations and concentrations of deltamethrin as summarised in the table below.

Table 2.8.1.1-1 Summary of the studies performed to investigate dermal absorption of deltamethrin

Formulation	Study type	Dose levels	Results (absorption rate)	Reference in Doc III
Decis EC25	*In vivo* - Rat	25 g/l	4.82%	[redacted] 2004 (A6.2.2/03)
		0.118 g/l	6.79%	
	In vitro- Rat/human	25 g/l	Human : 6.75% Rat : 27.30% Rat/human ratio : 4	[redacted] 2003 (A6.2.2/02)
		0.118 g/l	Human : 19.22% Rat : 69.08% Rat/human ratio : 3.6	
Decis EW15	*In vitro* - Rat	15 g/l	21.44%	[redacted] 2003 (A6.2.2/01)
		0.12 g/l	38.21%	

In all studies, deltamethrin showed a very poor absorption through the skin independent of the type of formulation. The results indicated that rat skin showed a significantly higher absorption than human skin (the total amount of radioactive material absorbed was 4and 3.6 times greater for rat skin than for human skin at the high and low dose, respectively). Additionally, the absorption was lower for the EW15 than for the EC25 (1.3 and 1.8 fold lower for high and low dose, respectively). Therefore, the extrapolation to an in vivo human scenario from these data is scientifically justified and summarised in the following table.

Table 2.8.1.1-2 Dermal absorption of deltamethrin through human skin (in % of dose)

	High dose	Low dose
EC25		
Rat/human ratio	4	3.6
Dermal absorption	4.82/ 4 = 1.2%	6.79/ 3.6= 1.89%
EW15		
EC25/EW15 ratio	27.30/ 21.44= 1.3	69.08/ 38.21 = 1.8
Dermal absorption	1.2 / 1.3 = 0.9%	1.89/ 1.8= 1.05%

Comparison of the *in-vivo* and *in-vitro* data and corrected for a human *in-vivo* scenario, the dermal absorption in humans is estimated to be about 1.2% and 1.89% for the concentrate and the dilution of the EC25 formulation, respectively, and to be about 0.9% and 1.05% for the concentrate and the dilution of the EW15 formulation, respectively.

No studies were conducted on Deltamethrin DP 0.05 formulation, but the dermal absorption value based on results from the EC formulation may be considered to be a worst case with regard to this formulation. For the powder formulation of deltamethrin a lower dermal absorption is expected since water and certain solvents favour.

Therefore, taking into account a dermal absorption of **2%** for the purpose of human exposure risk assessment for Deltamethrin DP 0.05 has to be regarded as a worst case approach.

Ref-MS information to the reader:	No study has been conducted on products in the family Deltamethrin DP 0.05 RTU. However, the value of 2% dermal absorption is considered acceptable, since the argumentation for accepting read across from the tested EC and EW formulations to K-Othrine DP 0.05 in the Competent Authority Report of deltamethrin (final CAR, Doc IIB3) also are valid for the family Deltamethrin DP 0.05 RTU . Ref-MS agrees that the dermal absorption value based on results from the EC formulation may be considered to be a worst case compared to the family Deltamethrin DP 0.05 RTU . For the powder formulation of deltamethrin, a lower dermal absorption is expected since water and certain solvents favour dermal uptake.

2.8.1.2 Acute toxicity

[redacted] Details of the comparison of the two formulations is enclosed in the confidential appendix to this document. In order to avoid unnecessary testing on animals [redacted]

[redacted], the acute toxicity information on the wettable powder is included in this dossier. The classification of Deltamethrin DP 0.05 formulation can be based on these data.

Ref-MS information to the reader:	Although the studies on acute toxicity are not performed on products in the family Deltamethrin DP 0.05 RTU, Ref-MS accepts the read across arguments and agrees with the conclusion that the products do not require a classification regarding acute toxicity, except for inhalation toxicity* (table 2.8.1.2-1 below), where the tested product mainly consisted of particles above 50 µm whereas in Deltamethrin DP 0.05 RTU most particles (90%) have a size < 50 µm which can be inhaled. Thus, the Ref-MS has calculated acute inhalation toxicity based on the ingredients and can conclude that none of the ingredients are classified / exceeding the concentration for which a classification of acute inhalation toxicity is necessary.

Table 2.8.1.2-1 Summary of acute toxicity data [redacted]

Route	Method Guideline	Species Strain/ Sex no/group/ vehicle	Dose levels duration of exposure	Value LD_{50}/LC_{50} (mg /kg bw or mg /l)	Remarks	Reference in Doc III-B section 6
Oral	US EPA OECD 401	OFA Sprague-Dawley rat 5M+5F Vehicle: distilled water	5000 mg/kg bw	LD_{50}: > 5000 mg/kg bw (M&F)	Not classified	[redacted], 1989a (6.1.1/01)
Dermal	US EPA OECD 402	NZW rabbit 5M+5F Vehicle: none	2000 mg/kg bw	LD_{50}: >2000 mg/kg bw (M&F)	Not classified	[redacted] 1989b (6.1.2/01)
Inhalation *	US EPA OECD 403	HSD (SD)rat 5M+5F Vehicle: none	7.75 mg a.s./l air	LC_{50} (4 hrs, aerosol): >7.75 mg a.s./l air (M&F)	Not classified	[redacted] (6.1.3/01)

M – male; F- female

[redacted] is of low acute toxicity. Based on these data Deltamethrin DP 0.05 is considered to be of low acute toxicity, and does not require EU classification with regard to acute toxicity.

2.8.1.3 Irritation and corrosivity

2.8.1.3.1 Skin irritation

Species	Method	Highest score 24, 72 h, 96h, 120h, 144h, 168h		Reversibility yes/no	Result	Reference in Doc III-B section 6
		Erythema	Oedema			
New Zealand White rabbit	US EPA OECD 404	0	0	Not applicable, as there was no irritation	Not a skin irritant	[redacted] 1989c (6.2.1/01)

[redacted] is not irritating to skin of rabbits. Based on this data Deltamethrin DP 0.05 is considered non-irritating to skin, and does not require EU classification with regard to skin irritation.

2.8.1.3.2 Eye irritation

Species	Method	Results	Reversibility yes/no	Result	Reference in Doc III-B section 6
New Zealand White rabbit	OECD 405	The test material applied neat by the ocular route in the male rabbit, was classified as follows: Slightly irritant – when application of the test substance was not followed by a rinse (irritation index: 11 on a scale with max score 110). Non irritant – when an eye rinse was made four seconds after application. Irritant – when eye rinse was made 30 seconds after application (irritation index: 16 on a scale with max score 110). The irritation noted in the study was not considered significant for a classification of the product as an eye irritant according to EC criteria.	Yes	Not an eye irritant	[redacted] 1989d (6.2.2/01)

Under the conditions of this study and based on the EU criteria for classification, [redacted] is considered not irritating to eyes. Based on this data Deltamethrin DP 0.05 is considered not irritating to eyes, and does not require EU classification with regard to eye irritation.

2.8.1.4 Sensitisation

The potential for [redacted] to elicit a specific sensitisation response was assessed in guinea pig according to the Buehler test.

Species	Method	Number of animals sensitized/total number of animals	Result	Reference in Doc III
Albino Hartley Guinea pig	Buehler (OECD 406)[1]	0/10	Not a sensitiser	[redacted] (6.3/01)

[1] Deviation from the OECD guideline no. 406: Low number of animals used.

Under the conditions of the test and with respect to the evaluation criteria, [redacted] exhibits no skin-sensitisation potential. Based on this data Deltamethrin DP 0.05 is considered not a skin sensitiser according to Buehler Test.

2.8.1.5 Other

The biocidal product, Deltamethrin DP 0.05 contains deltamethrin (0.5 g/kg), together with co-formulants [redacted]. The toxicity of the active substance has been documented in Document III-A. Information on the toxicology of the other components of the product was provided based on the corresponding Material Safety Data Sheets. As the composition of the formulation is confidential, information on the formulants is also confidential as it would allow conclusions concerning the composition of the product. However, no additionally toxicological concerns are raised by the co-formulants according to the Material Safety Data Sheets for which additionally toxicity testing would be required.

Ref-MS information to the reader:	Ref MS agrees with the conclusion made by the applicant regarding the co-formulants in the products. No additional toxicity testing is required.

2.8.2 ENVIRONMENTAL EFFECTS ASSESSMENT

The co-formulants are not expected to affect the fate of deltamethrin in the environment or significantly affect its ecotoxicity. As such the ecotoxicity data provided for the active substance in soil (see Doc IIIA, Section 7) are relevant to assess the toxicity/classification of the product by extrapolation.

2.8.2.1 Aquatic compartment

Ref-MS information to the reader:	The use of the products is limited to only direct application to nests and harbourages. It is considered that these limited uses do not lead to significant exposure to STP, surface water or sediment. Thus these compartments are not considered relevant for the risk assessment. Nevertheless, the applicant has included an effects assessment for aquatic compartment. Ref-MS has decided to omit the effects assessment from this report. Summary and evaluation of effect data with relevance to the aquatic compartment for the active substance can be found in Document II-A in section 4.2.1. of the CAR.

2.8.2.2 Atmosphere

Due to the low vapour pressure of the active substance (1.24E-08 Pa at 25°C, Yoder, 1991), it is not expected that any volatile losses of deltamethrin to the air compartment would occur either during or after the application. This is consistent with the guidance presented in the ESD which states that exposure of the air compartment is limited in time and restricted to the local scale and that F_{air} may be considered to be negligible from an environmental point of view (OECD, 2008). As such, studies on the environmental effects in the atmosphere are not considered necessary.

2.8.2.3 Terrestrial compartment

Summary and evaluation of effect data with relevance to the terrestrial compartment for the active substance can be found in Document II-A in section 4.2.2 of the CAR.

Terrestrial toxicity of deltamethrin

In order to assess the risk associated with potential deltamethrin concentrations in soil, the available toxicity data has been reviewed to select the most appropriate endpoints. In accordance with the guidance presented in the TGD (European Commission, 2003), appropriate Assessment Factors (AF) should be applied to terrestrial toxicity endpoints to derive a PNEC (Predicted No Effect Concentration) for comparison with the Predicted Environmental Concentrations in soil (PEC_{soil}). The selection of an appropriate Assessment Factor is dependent upon the amount of data available and the type of exposure (European Commission, 2003). The terrestrial toxicity data that has been used in the assessment is summarised in Table 2.8.2.3-1.

Table 2.8.2.3-1 Terrestrial toxicity studies for deltamethrin

Study reference	Trophic level	Species	Duration	Test material	Endpoint [mg.kg-1]
Acute					
Hoxter and Smith, 1993	Earthworm	*Eisenia fetida*	14d	Deltamethrin 98%	LC50 > 1290 NOEC 447 mg.kg-1(dw) soil
Chronic					
Luehrs, 2004	Earthworm	*Eisenia fetida*	56 d	Deltamethrin EW15	NOEC 0.78 mg kg-1 ww soil
Lechelt-Kunze, 2004	Springtail	*F. candida*	28 d	Deltamethrin EC25	NOEC 1.25 mg kg-1 dw soil
Lechelt-Kunze, 2005	Predatory mite	*H. aculeifer*	16 d	Deltamethrin EC25	NOEC ≥ 1.78 mg kg-1 dw soil
Frings and Bock, 1994a, 1994b	Microorganisms	*n/a*	28d	Deltamethrin 99.6%, aerobic respiration in 2 soils	NOEC > 0.50 mg kg-1 dw soil

Acute toxicity data for deltamethrin is available from one study with earthworms. No mortality was observed at the highest concentration tested and the 14d-LC_{50} was therefore > 1290 mg/kg dw soil.

Terrestrial toxicity of Br2CA

In a study conducted on Hypoaspis aculeifer with Br2CA applied to LUFA 2.1 soil (Moser, 2005), an overall NOEC of 10 mg.kg-1 (dry weight soil) was found.

Table 2.8.2.3-2: Summary of terrestrial endpoints for Br_2CA

Study reference	Trophic Level	Species	Guideline	Duration	Study type	Endpoint [$mg.kg^{-1}$]
Moser, 2005	Secondary consumer	*Hypoaspis aculeifer*	SECOFASE	14d (exposure) 34d (reproduction)	Br_2CA, AE F108565 00 1B99 0001, LUFA 2.1 soil;	NOECMortality 10 $mg.kg^{-1}$(dw) NOECReproduction >1000 $mg.kg^{-1}$(dw)

2.8.2.4 Non-compartment-specific effects relevant to the food chain (secondary poisoning)

Deltamethrin toxicity to higher organisms has been studied for a number of species. For bird species, reproduction studies in bobwhite quail and mallard duck are available and the lowest NOEC obtained exceeds 450 ppm ([redacted], 1991a & b – A97605 and A97604).

For the assessment of toxicity to small mammals, a reproduction study conducted in rats provided a NOAEL of 80 ppm for parents and pups ([redacted], 1992 – A70863).

2.9 HAZARD IDENTIFICATION FOR PHYSICO-CHEMICAL PROPERTIES

Ref-MS information to the reader:	The products in the family Deltamethrin DP 0.05 RTU are not considered to be explosive and based on the properties of the components they is not considered to be oxidizing. Furthermore, the products in Deltamethrin DP 0.05 RTU are not auto-flammable and have no flash-point below their boiling point. Therefore, there are no hazards identified based on the physico-chemical properties of the formulations.

2.10 RISK CHARACTERISATION FOR HUMAN HEALTH

Ref-MS Information to the reader:	The risk characterisation by the applicant is considered acceptable.

2.10.1 General Aspects

MG/PT	Field of use envisaged	Likely concentration at which a.s. will be used
PT 18	Public Health (Hygiene) Deltamethrin DP 0.05 is intended for use around buildings for the control of: - workers and nests of the Black Ant (*Lasius niger*) and other commonly found garden ants - crawling insects or other arthropods, e.g. German cockroaches, silverfish, wood louse or pill bug, in small confined locations.	2 g of dust per ant nest, (approx. 2g equivalent to 3 dispensing actions) 2g per 100 cm^2 in insect harbourages. Maximum 4g of product per harbourage.

Deltamethrin DP 0.05 is an insecticide which is foreseen for the control of ants in a residential environment.

Deltamethrin DP 0.05 can also be used to control other crawling insects , e.g. German cockroaches, silverfish, wood louse or pill bug, in small confined areas (e.g. underneath flowerpots, floor boards, garden

appliances, etc.). The product is formulated as a ready to use dry powder (DP) and contains the active substance (a.s.) deltamethrin (0.5 g/kg). The treatment powder is applied onto the entrances of ant nests on terraces, patios and pathways, or on the harbourage area (nesting/resting area) of the pest crawling insect. The highest recommended application rate for the control of ants is 0.5 g Deltamethrin DP 0.05/entrance and no more than 2 g product per ant nest. For the control of other crawling insects an application rate of 2g per 100 cm^2 in harbourage is recommended. The treatment should not exceed 4g of product per harbourage.

The product will be used by amateurs.

2.10.2 Professional Users

Risk characterisation is not required for professional users since the product, Deltamethrin DP 0.05, is only intended for amateur/consumer use.

2.10.2.1 Production / formulation of the active substance

The active substance is formulated outside the EU and therefore no assessment is required.

2.10.2.2 Critical endpoint(s)

Not applicable.

2.10.2.3 Relevant exposure paths

Not applicable.

2.10.2.4 Risk characterisation for production / formulation of a.s.

Not applicable.

2.10.2.5 Application Product Type 18

The manufacturing plants where Deltamethrin DP 0.05 is formulated are strictly regulated. The plants have been audited by BCS IOP and have demonstrated compliance with BCS production guidelines. In addition, the formulation plants are ISO 9001 certified, and adheres to the ICPE legislation (Installation Classified for the Protection of the Environment). All wastewater produced during formulation and cleaning of manufacturing equipment is collected and incinerated. Emission limits govern the release of dust from the plants. Since all hazardous wastes are eliminated in incineration facilities it is proposed that no unacceptable emissions will occur during the formulation stage of the Deltamethrin DP 0.05 product life cycle.

2.10.2.6 Critical endpoint(s)

Not applicable.

2.10.2.7 Relevant exposure paths

Not applicable.

2.10.2.8 Risk characterization for Product Type 18

Not applicable.

2.10.2.9 Overall assessment of the risk for the use of the active substance in biocidal products

Professional user exposure to the active substance and to various deltamethrin –containing products was assessed in the CAR. As the products are formulated in a closed automated system and packaged in a semi-open system where workers are compelled to use personal protective equipment, personnel can handle the product safely. The estimated primary exposure for the intended use of deltamethrin-containing products is below the proposed systemic AEL with or without PPE. Based on these results there is no unacceptable risk for professional operators anticipated with the intended uses of various deltamethrin formulations.

2.10.3 Non-professional users

2.10.3.1 Application Product Type 18

2.10.3.1.1 Critical endpoints

Information concerning the toxicity of the active substance is summarised in the Annex I Assessment Report for Deltamethrin. Bayer S.A.S. (formerly named Bayer Environmental Science) is the original active substance notifier and therefore has access to these data.

2.10.3.1.2 Acute toxicity:

An AEL of 0.0075 mg/kg bw/day was derived based on the NOAEL (1 mg/kg bw/day) obtained in a 13-week dog study after taking an oral absorption of 75% and a safety factor of 100 into account. In the study neurotoxic effects occurred early after dosing.

2.10.3.1.3 Medium-term toxicity:

An AEL of 0.0075 mg/kg bw/day was derived based on the NOAEL (1 mg/kg bw/day) obtained in the 13-week and 1-year dog studies after taking an oral absorption of 75% and a safety factor of 100 into account.

2.10.3.1.4 Long term toxicity:

An AEL of 0.0075 mg/kg bw/day was derived based on the NOAEL (1 mg/kg bw/day) obtained in the 1-year dog study after taking an oral absorption of 75% and a safety factor of 100 into account.

Based on values determined for the representative formulations submitted for EU review according to the biocide directive 98/8/EC, a value of 2% dermal absorption was considered appropriate for the product[2]. The 2% dermal absorption value was considered an appropriate conservative estimate of absorption for the diluted product assessed in this evaluation.

2.10.3.2 Relevant exposure paths

Deltamethrin DP 0.05 is formulated as a ready-to-use dry powder, and is intended for non-professional users. No mixing/loading is required. In addition no disposal of the applied powder is performed. Therefore, primary exposure is confined to the application phase of the product.

Dermal and inhalation exposure are relevant for Deltamethrin DP 0.05 for non professional users.

Oral exposure is not considered a possible route of primary exposure for non-professionals. The dust is applied through a small piercing in the bottle closure, and nests are dusted with product by a maximum of three inversions of the container. Ingestion of dust is covered by the inhalation assessment and use around

[2] Document II B3 Effects and Exposure Assessment for K-OTHRINE DP 0.05 of the non public CAR, final June 2011

foodstuffs is not indicated on the label and so no oral exposure from contaminated food is considered likely.

Table 2.10.3.2-1: Deltamethrin DP 0.05 Relevant Exposure Pathways for Non-Professional Use

Exposure path	Non-professional use	General public	Via the environment
Inhalation	Yes	No	No
Dermal	Yes	Yes	No
Oral	No	Yes	Negligible

2.10.3.3 Risk characterisation for Product Type 18

Exposure scenarios may involve exposure to deltamethrin through dermal contact and inhalation exposure during the spot application of Deltamethrin DP 0.05 using the small piercing in the bottle closure. No mixing/loading or refilling occurs.

Table 2.10.3.3-1: Risk Characterisation following the Use of Deltamethrin DP 0.05 by Non Professional Users.

Active substance	Scenario	Exposure path	PPE	Exposure estimates [mg/ kg bw/day]	Risk characterisation	
					% of AEL [0.0075 mg/kg bw/day]*	Margin of Safety NOAEL 0.75 mg/kg bw/day**
Deltamethrin	**Application**	Dermal	None	0.00000083	<0.1	903614
		Inhalation	None	0.000000312	<0.1	2403846
	Total	Dermal+Inhalation	None	0.0000011	<0.1	681818

* proposed systemic AEL= 0.0075 mg/kg bw/day (based on a NOAEL of 1 mg/kg bw/day (corrected for oral absorption of 75%, and a safety factor of100). ** systemic NOAEL= NOAEL of 1 mg/kg bw/day corrected for oral absorption of 75%= 0.75 mg/kg bw/day.

The results of the exposure estimates reveal that regarding primary exposure the situation is favourable with the intended use of Deltamethrin DP 0.05.

The estimated systemic primary exposure of the amateur user accounts for less than 0.1% of the AEL.

2.10.3.4 Application Product Type 18

See point 2.5.3.1.

2.10.3.5 Overall assessment of the risk for the use of the active substance in biocidal products

Accordingly, there is based on this result no unacceptable risk anticipated for the amateur operator with the intended use of Deltamethrin DP 0.05. This conclusion is in line with the result presented in the CAR.

2.10.3.6 Indirect exposure as a result of use

Secondary exposure to the general public is unlikely. However, for the intended use of Deltamethrin DP 0.05 the applied product can be assumed to be accessible for persons (children/adults) re-entering the treated terrace (i.e. toddler crawling over treated areas) and the following scenarios were considered:

Dermal contact with the dust

Oral (hand-to-mouth) contact with the dust

The product contains a strong bittering aversive agent and therefore, it is considered as a very worst case scenario that a child will not ingest more than once dust from the bait.

Ref-MS information to the reader:	It is only one of the members in this biocidal product family which contains a bittering agent: Myrr D but not Myrr D Deltamethrin DP 0.05.

Table 2.10.3.6-1: Risk Characterisation following the Secondary Exposure to Deltamethrin DP 0.05

Scenario	Exposure path	Systemic exposure (mg/kg bw/d)	Risk Characterisation	
			¤ Acute AEL 0.0075 mg/kg bw/d	Margin of Safety NOAEL 0.75 mg/kg bw/d
Toddler - Dermal contact with Deltamethrin DP 0.05	Dermal	0.0000119	0.16	63025
Toddler - Oral (hand-to-mouth) contact with Deltamethrin DP 0.05	Oral	0.0000446	0.59	16816
Total	Oral + dermal	0.0000565	<1	13274

* proposed systemic AEL= 0.0075 mg/kg bw/day (based on a NOAEL of 1 mg/kg bw/day (corrected for oral absorption of 75%, and a safety factor of100). ** systemic NOAEL= NOAEL of 1 mg/kg bw/day corrected for oral absorption of 75%= 0.75 mg/kg bw/day.

Ref-MS information to the reader:	¤ Should be % of acute AEL.

Ref-MS information to the reader:	Using the scenario in the CAR with a size of the terrace 10m^2 as a worst case results in that the estimated systemic exposure of the toddler accounts for 2% of the proposed systemic AEL. Based on this calculation, there is no unacceptable risk for persons being exposed to products in the Deltamethrin DP 0.05 RTU family via secondary routes of exposure. It should be noted that the highest application is 4 g/harbourage which is twice the dose that has been used in the exposure assessment. However, as the margin of safety is considerable it can be concluded that the risk will be acceptable also for the highest application.

The results of the calculations show that the estimated systemic exposure of children is below the proposed systemic AEL. Based on these calculations there is no unacceptable risk anticipated for persons being secondary exposed to these four deltamethrin formulations.

Overall assessment of secondary exposure

Based on these results there is no unacceptable risk anticipated with the intended uses of Deltamethrin DP 0.05 for persons being exposed to the product via secondary routes of exposure.

2.10.3.7 Combined exposure

With certain products/use scenarios it might occur that the user of a product being exposed via primary routes of exposure might be also exposed to the product via secondary routes of exposure.

However, considering the intended uses of Deltamethrin DP 0.05 the risk of combined exposure can be regarded as negligible. The risk assessment conducted for the product Deltamethrin DP 0.05 in the CAR also did not assume combined exposure for consumers/non-professional users.

Therefore, with the intended consumer uses of Deltamethrin DP 0.05 the risk for combined exposure is considered to be negligible.

Accordingly based on these results there is no unacceptable risk anticipated with the intended use of Deltamethrin DP 0.05 for persons being exposed to the product via primary or secondary routes. The risk for combined exposure is considered negligible.

Ref-MS information to the reader:	Ref-MS considers that there is no unacceptable risk for combined exposure.

2.11 RISK CHARACTERISATION FOR THE ENVIRONMENT

2.11.1 Aquatic compartment (incl. sediments)

Ref-MS information to the reader:	The use of the products is limited to only direct application to nests and harbourages. It is considered that these limited uses do not lead to significant exposure to STP, surface water or sediment. Thus these compartments are not considered relevant for the risk assessment. Nevertheless, the applicant has included a risk characterisation for aquatic compartment but Ref-MS has decided to omit that section this report.

2.11.2 Atmospheric compartment

Due to the low vapour pressure of the active substance (1.24E-08 Pa at 25°C, Yoder, 1991), it is not expected that any volatile losses of deltamethrin to the air compartment would occur either during or after the application. This is consistent with the guidance presented in the ESD which states that exposure of the air compartment is limited in time and restricted to the local scale and that F_{air} may be considered to be negligible from an environmental point of view (OECD, 2008). Hence, it is considered that the product poses no significant risk to the environment.

2.11.3 Terrestrial compartment

Chronic toxicity data is available for earthworms, springtail, predatory mite and terrestrial microorganisms, representing two trophic levels. However, since deltamethrin is an insecticide used for crop protection and is not phytotoxic, plants are not expected to be more sensitive than terrestrial invertebrates. It could, therefore, be considered that three trophic levels are covered by the available data, and that an assessment factor of 10 can be used to derive the PNEC.

According to the Technical Guidance Document (European Commission, 2003) the PNEC should be based on the lowest long-term toxicity value. In the available data set, the lowest NOEC is that for terrestrial microorganisms, and the next lowest is from earthworms. Since no effects were observed in these tests, and the NOECs were "higher than" values, it is more appropriate to base the PNEC on the next lowest NOEC, from a test where effects were actually observed. Therefore, the test with springtails resulting in a NOEC of 1.25 mg/kg dw soil for effect on reproduction is chosen for PNEC derivation.

It should be noted that the Springtail (*F. candida*) study was conducted with a standardised artificial soil containing 5% organic matter. The Technical Guidance Document recommends normalisation of data by converting results to a standard soil, which is defined as a soil with an organic matter content of 3.4% wherever possible. This is carried out using the following:

$$PNEC(standard) = PNEC(\text{experimental}) \times \frac{Fom(standard)}{Fom(experimental)}$$

Where:

Variable/parameter (unit)	Symbol	Unit	Value	Source
Predicted No effect concentration in soil (dry weight)	$PNEC_{soil\_dwt}$	[mg kg^{-1}]	0.085	Input

Bulk Density of wet soil	$RHO_{soilwwt}$	[mg m^{-3}]	1700	Default*
Volume fraction of solids in soil	F_{solid}	[$m^3.m^{-3}$]	0.6	Default*
Density of solid phase	RHO_{solid}	[mg m^{-3}]	2500	Default*
Predicted No effect concentration in soil (wet weight)	$PNEC_{soilwwt}$	[mg kg^{-1}]		Output

*Default values taken from TGD (European Commission, 2003)

Therefore:

$$PNECsoilwwt = 0.085 \times \frac{0.6 \times 2500}{1700} = 0.075\, mg.kg^{-1}(wet\ weight\ soil)$$

Thus, the $PNEC_{soil}$ for deltamethrin used in this risk assessment was calculated as 0.075 mg.kg^{-1}.

Terrestrial PNEC for major metabolite Br_2CA

The Technical Guidance Document (European Commission, 2003) indicates that where a NOEC is available for a species representing one trophic level, an assessment factor of 100 is appropriate. The resulting $PNEC_{soil}$ for the major metabolite Br_2CA is 0.1 mg.kg^{-1} (dry weight soil).

It should be noted that the study was performed using a natural soil with very low organic matter content (2.12%). The Technical Guidance Document (European Commission, 2003) recommends normalisation of data by converting results to a standard soil, which is defined as a soil with an organic matter content of 3.4% wherever possible. This is carried out using the following:

$$PNEC(standard) = PNEC(\text{experimental}) \times \frac{Fom(standard)}{Fom(experimental)}$$

Where:

Variable/parameter (unit)	Symbol	Unit	Value	Source
PNEC in experiment	*NOEC(exp)*	[mg kg-1]	0.1	Input
Fraction organic matter in experimental soil	*Fom(exp)*	[-]	**0.0212**	Input
Fraction organic matter in standard soil	*Fom(standard)*	[-]	**0.034**	Default*
PNEC in standard soil	*NOEC(standard)*	[mg kg-1]		Output

*Default values taken from TGD (European Commission, 2003)

Therefore:

$$PNEC(standard) = 0.1 \times \frac{0.034}{0.0212} = 0.16\ mg.kg^{-1}$$

Furthermore, Predicted Environmental Concentrations in soil (PECsoil) have been calculated in this assessment on a concentration in wet soil basis. Therefore, to enable comparison between the PNECsoil and PECsoil values, the PNECsoil has been converted to a concentration in wet soil:

$$PNECsoilwwt = PNECsoil_{dwt} \times \frac{Fsolid \times RHOsolid}{RHOsoilwwt}$$

Where:

Variable/parameter (unit)	Symbol	Unit	Value	Source
Predicted No effect concentration in soil (dry weight)	$PNEC_{soil\_dwt}$	[mg kg^{-1}]	0.16	Input
Bulk Density of wet soil	$RHO_{soilwwt}$	[mg m^{-3}]	1700	Default*
Volume fraction of solids in soil	F_{solid}	[$m^3.m^{-3}$]	0.6	Default*
Density of solid phase	RHO_{solid}	[mg m^{-3}]	2500	Default*
Predicted No effect concentration in soil (wet weight)	$PNEC_{soilwwt}$	[mg kg^{-1}]		Output

*Default values taken from TGD (European Commission, 2003)

Therefore:

$$PNECsoilwwt = 0.16 \times \frac{0.6 \times 2500}{1700} = 0.14\ mg.kg^{-1}\ (wet\ weight\ soil)$$

Thus, the $PNEC_{soil}$ for Br_2CA used in this risk assessment was calculated as 0.14 mg.kg-1 (wet weight soil).

Ref-MS information to the reader:	Risk characterisation ratios calculated for local soil covers one application per 30 days. However, for the ant nest treatment it is recommended to repeat application once if control is not achieved within 2-3 weeks, based on the efficiency of the

	product. A simplified calculation (where PECsoil initial is calculated for 2 applications at the same time) shows no unacceptable risks, and Ref-MS has accepted the retreatment after 2-3 weeks.

Risk characterisation ratios calculated for local soil exposure from application of the product for ant nest treatment are presented below in Table 2.11.3-1.

Table 2.11.3-1: Risk characterisation ratios calculated for local soil exposure associated with the ant nest treatment using Deltamethrin DP 0.05, assuming a range of soil mixing depths

Substance	Soil mixing depth (m)	RCR Local soil (initial)	RCR Local PEC soil (30 d TWAC)	RCR Local PEC soil (30 days after application)	RCR Groundwater
Deltamethrin	0.1	2.82E-01	2.29E-01	1.83E-01	No unacceptable risk
	0.2	1.41E-01	1.15E-01	9.17E-02	No unacceptable risk
	0.5	5.65E-02	4.59E-02	3.67E-02	No unacceptable risk
Br_2CA	0.1	8.92E-02	2.34E-02	2.18E-03	No unacceptable risk
	0.2	4.46E-02	1.17E-02	1.09E-03	No unacceptable risk
	0.5	1.78E-02	4.69E-03	4.35E-04	No unacceptable risk

Risk characterization ratios calculated for local soil exposure from application of the product in control of crawling insects is presented below in Table 2.11.3-2.

Table 2.11.3-2: Risk characterisation ratios calculated for local soil exposure associated with the crawling insect treatment using Deltamethrin DP 0.05, assuming a range of soil mixing depths

Substance	Soil mixing depth (m)	RCR Local soil (initial)	RCR Local PEC soil (30 d TWAC)	RCR Local PEC soil (30 days after application)	RCR Groundwater
Deltamethrin	0.1	8.87E-01	7.20E-01	5.76E-01	No unacceptable risk
	0.2	4.44E-01	3.60E-01	2.88E-01	No unacceptable risk
	0.5	1.77E-01	1.44E-01	1.15E-01	No unacceptable risk
Br_2CA	0.1	2.80E-01	7.36E-02	6.84E-03	No unacceptable risk
	0.2	1.40E-01	3.68E-02	3.42E-03	No unacceptable risk
	0.5	5.61E-02	1.47E-02	1.37E-03	No unacceptable risk

Exposure to local soil is not expected to result in unacceptable exposure to the soil or groundwater compartment by either deltamethrin or the metabolite Br2CA, for the ant nest treatment and crawling insects treatment scenarios.

It should be noted that soil exposure associated with spot treatment of insect nesting/resting areas is necessarily highly localised. It is therefore proposed that the surrounding soil biota will remain unaffected. It is considered that the presumed affected area is sufficiently small and infrequent in the landscape that recolonisation by soil biota will occur rapidly once residues have declined to an acceptable level, recovering any effect of product use. Further evidence of recolonisation potential is provided by the moderate half life of deltamethrin in soil of 48.2 days (normalised to 12°C and pF 2), i.e., residues would fall to harmless levels well within the life cycle of soil organisms.

In addition, it should be noted that insect nests and resting areas will be randomly distributed throughout the garden, but only a small number of nests and infected areas (those that are identified as a nuisance) will be treated in any one year. Taking account of the distribution and highly localised nature of the nesting areas, it is concluded that the potential for repeat treatment to the same area of soil is very low. As a result, it is considered that deltamethrin will not accumulate in the soil, meaning that recolonisation by soil-dwelling organisms from unaffected areas of soil will not be inhibited. Therefore, it is concluded that highly localised exposure to soil associated with the use of Deltamethrin DP 0.05 will not result in an unacceptable ecological risk to soil organisms.

2.11.4 Non-compartmental specific effects relevant to the food chain (secondary poisoning)

Deltamethrin toxicity to higher organisms has been studied for a number of species. For bird species, reproduction studies in bobwhite quail and mallard duck are available and the lowest NOEC obtained exceeds 450 ppm [redacted] 1991a & b – A97605 and A97604). Based on the Technical Guidance Document (European Commission, 2003), an assessment factor of 30 is appropriate for this endpoint, providing a $PNEC_{bird}$ of 15 mg.kg $food^{-1}$.

For the assessment of toxicity to small mammals, a reproduction study conducted in rats provided a NOAEL of 80 ppm for parents and pups ([redacted] 1992 – A70863). Using an appropriate safety factor of 30, based on the Technical Guidance Document (European Commission, 2003), a $PNEC_{small\ mammal}$ of 2.67 mg.kg $food^{-1}$ is obtained.

Risk characterisation ratios for exposure of predators (small mammals and birds) from use of the product in ant nest treatment and control of crawling insects are presented below in Table 2.11.4-1 and Table 2.11.4-2.

Table 2.11.4-1: Risk characterisation ratios for potential exposure of predators (small mammals and birds) through secondary poisoning (ant nest treatment scenario), assuming a range of soil mixing depths

Substance	Soil mixing depth (m)	$RCR_{oral,\ predator}$ (based on initial concentrations in soil) (mg kg diet $^{-1}$)	$RCR_{oral,\ predator}$ (based on 30-d TWA concentrations in soil) (mg.kg diet $^{-1}$)
Exposure to small mammals			
Deltamethrin	0.1	6.42E-04	5.22E-04
	0.2	3.21E-04	2.61E-04
	0.5	1.28E-04	1.04E-04
Exposure to birds			
Deltamethrin	0.1	1.14E-04	9.29E-05
	0.2	5.72E-05	4.64E-05
	0.5	2.29E-05	1.86E-05

Table 2.11.4-2: Risk characterisation ratios for potential exposure of predators (small mammals and birds) through secondary poisoning (crawling insects treatment scenario), assuming a range of soil mixing depths

Substance	Soil mixing depth (m)	RCRoral, predator (based on initial concentrations in soil) (mg kg diet -1)	RCRoral, predator (based on 30-d TWA concentrations in soil) (mg.kg diet -1)
Exposure to small mammals			
Deltamethrin	0.1	2.02E-03	1.64E-03
	0.2	1.01E-03	8.20E-04
	0.5	4.04E-04	3.28E-04
Exposure to birds			
Deltamethrin	0.1	3.59E-04	2.92E-04
	0.2	1.80E-04	1.46E-04

	0.5	7.19E-05	5.84E-05

As all risk characterisation ratios are less than 1, it is considered that the use of Deltamethrin DP 0.05 for treatment of ant nests and control of crawling insects poses no significant risk to predators through secondary poisoning.

2.11.5 Conclusions

Deltamethrin DP 0.05 may be applied directly to soil for treatment of ant nests and control of other crawling insects. No emission to the STP, surface water, or sediments is expected. A risk assessment conducted for soil indicates that the product poses no significant risk to the terrestrial compartment when used at the specified application rate. In addition to this a risk assessment for secondary poisoning indicated no risk for predators and the predicted concentrations in groundwater were calculated to be below the regulatory threshold value.

Hence, it is considered that there are no significant risks to the environment from use of this product.

Ref-MS Information to the reader:	The RMS considers the risk chracterisation for the environment provided by the applicant to be acceptable.

2.12 MEASURES TO PROTECT MAN, ANIMAL AND THE ENVIRONMENT

Recommended Methods and Precautions Concerning Handling, Storage, Transport or Fire Handling

Hygiene measures

No specific requirements for handling unopened packs/containers.

When using, do not eat, drink or smoke.

Avoid dust formation.

Use only in area provided with appropriate exhaust ventilation

Wash hands immediately after application.

Remove soiled or soaked clothing immediately and clean thoroughly before using again.

Ref-MS Information to the reader:	Since the product is only intended to be used outdoor, the sentence "Use only in area provided with appropriate exhaust ventilation" is not relevant. Moreover, since this is a dusting powder, "….soaked clothing…." is not relevant only "….soiled clothing…".

Personal Protection

For normal use and handling conditions please refer to the label and/or leaflet. In all other cases the following recommendations would apply.

Respiratory Protection: No personal respiratory protective equipment normally required.

Wash hands always before eating, drinking, smoking or using the toilet.

Handling

No specific precautions required when handling unopened packs/containers; follow relevant manual handling advice.

Storage

Requirements for storage areas and containers. Keep containers tightly closed in a dry and well-ventilated place. Store in original container. Store in a place accessible by authorized persons only. Protect from heat sources. Keep away from direct sunlight. Protect against moisture.

Advice on common storage: Keep away from food, drink and animal feedingstuffs.

Stable under normal storage conditions.

No hazardous reactions when stored/handled in accordance with label instructions.

Transport:

According to national and international transport regulations not classified as dangerous goods.

UN number: 3077

Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (DELTAMETHRIN MIXTURE)

Transport hazard class(es): 9

Packing group: III

Environm. Hazardous Mark: YES

ADR/RID/AND: Hazard no.: 90; Tunnel code: E

IMDG: Marine pollutant: YES; IMDG SEGREGATION GROUP 18 - ALKALIS

IATA: As above

Fire:

Fire-fighting measures Deltamethrin DP 0.05

In the event of fire dangerous gases can be released.

In the event of fire and/or explosion do not breathe fumes.

Use breathing apparatus for fire fighting.

Extinguishing media: water spray, carbon dioxide (CO2), dry powder, foam

Contain the spread of the fire-fighting media.

Emergency Measures in Case of an Accident

First-aid measures:

Ref-MS Information to the reader:	These first-aid measures were proposed by the applicant. Ref-MS have added relevant information in a grey comment-box below. The first aid measures agreed by the MS are found in the SPC.

General

Remove contaminated clothing immediately and dispose of safely.

Inhalation: Move the patient to fresh air and keep at rest. Call a physician or poison control centre immediately

Ingestion: Call a physician or poison control centre immediately. Rinse mouth. Do NOT induce vomiting.

Skin contact: Wash off thoroughly with plenty of soap and water for approximately 15 minutes.
Warm water may increase the subjective severity of the irritation/paresthesia. This is not a sign of systemic poisoning. In case of skin irritation, application of oils or lotions containing vitamin E may be considered.
Call a physician if irritation develops and persists.

Eye contact: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.
Warm water may increase the subjective severity of the irritation/paresthesia. This is not a sign of systemic poisoning.
Apply soothing or anaesthetic eye drops if needed. Call a physician if irritation develops and persists.

Ref-MS Information to the reader:	The Ref-MS noticed that information about contact lenses were missing for first aid measures (eye contact). The following first aid instruction should be recommended for eyes: "Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a physician or poison control center immediately."

Notes to physician:

Treat symptomatically.

Monitor: respiratory and cardiac functions.

In case of ingestion gastric lavage should be considered in cases of significant ingestions only within the first 2 hours. However, the application of activated charcoal and sodium sulphate is always advisable.

Keep respiratory tract clear.

Oxygen or artificial respiration if needed.

In case of convulsions, a benzodiazepine (e.g. diazepam) should be given according to standard regimens. If not effective, phenobarbital may be used.

Contraindication: atropine.

Contraindication: derivatives of adrenaline.

There is no specific antidote.

Ref-MS Information to the reader:	In all cases of contacting physician or poison centre, show the label or packaging when possible.

Accidental release measures:

Personal precautions

Avoid contact with spilled product or contaminated surfaces.

Wear personal protective equipment.

Unprotected persons must be kept away.

Environmental Precautions

Do not allow to get into surface water, drains and ground water.

Methods for cleaning up

For decontamination measures following accidental release follow recommended methods and precautions concerning handling, use, storage, transport or fire.

Clean contaminated floors and objects thoroughly, observing environmental regulations.

Keep in suitable, closed containers for disposal

Disposal Considerations.

Collect and dispose of the damaged packaging and contaminated materials according to the current regulations.

In accordance with current regulations and, if necessary, after consultation with the site operator and/or with the responsible authority, the product may be taken to a waste disposal site or incineration plant.

Contaminated packaging: Not completely emptied packaging should be disposed of as hazardous waste.

3 PROPOSAL FOR DECISION

3.1 BACKGROUND TO THE DECISION

3.1.1 General background

The application was submitted as a frame formulation, with the name Myrr D, under Directive 98/8/EC, and was subsequently transformed to an application for biocidal product family with two family members (products), in accordance with the Biocidal Products Regulation (EU) No 528/2012 and the transitional measures in Article 91. The proposed name of this biocidal product family is Myrr D Family (in communications also called Deltamethrin DP 0.05 RTU). The two biocidal product family members, Myrr D Deltamethrin DP 0.05 and Myrr D, differ in formulation regarding non-active substances. See confidential annex for details.

3.1.2 From the Assessment Report of the active substance

The active substance, deltamethrin, was 2013-10-01 included as an active substance in Annex I to directive 98/8/EC. Sweden was the Rapporteur Member State (RMS). According to the Assessment Report, the following specific provisions apply:

-The active substance, deltamethrin, as manufactured, shall have a minimum purity of $\geq$ 98.5% w/w.

- In view of the risks identified for aquatic ecosystems for the indoor barrier treatmens in domestic/larger buildings (resulting in emissions to STP), products shall not be authorised for this use unless it can be demonstrated that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of risk mitigation measures.

- When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, where relevant for the particular product, the populations and environmental compartments that may be exposed to the product and use or exposure scenarios that have not been representatively addressed at the Union level risk assessment.

All the specific provisions do apply.

3.1.3 Previous use and authorisation in Sweden

In Sweden the biocidal product Myrr D has been authorised since 2004.

3.1.4 Conclusions from efficacy evaluation and risk assessment of the biocidal product family

The efficacy of the product family for control of workers and nests of ~~garden~~ ants (not tropical ants) (*v1.1_2017-10-27*) and for control of crawling insects and woodlice at a maximum dose of 2 g per ant nest or 100 cm^2 insect harbourage and according to the directions for use, is considered acceptable. However, in Ref-MS Sweden the use of the products against cockroaches will not be included in the authorised uses on the Swedish market (with reference to Article 37:1b of the BPR). Sweden applies a practice that cockroaches and bedbugs should not be controlled by non-professionals. This is a strategy for managing the development of resistance and the following risk mitigation measure “Not for control of cockroaches and bedbugs” will apply. In case the target species cockroach is included in an authorisation for mutual recognition the following risk mitigation measure should apply “When the product is not used according to the label resistance of insects might occur. When the infestation persists contact a professional”. This is a strategy, in accordance with the TNsG for PT 18/19, to avoid resistance as cockroaches are very difficult to control and it cannot be expected that non-professionals have enough knowledge of the resistance problem.

It is concluded that the risks associated with physico-chemical properties of the biocidal product family such as flammability, explosivity and thermal stability are low.

It is concluded from the health risk assessment of the products that the intended use of the product family Myrr D would not pose unacceptable risk to human health. Risk mitigation reasons suggests that to protect children, the user should be informed that measures should be taken to protect children from exposure, eg. through phrases like “keep out of reach of children”, “keep children away during application” and “do not enter treated area”. Furthermore, the health risk assessment does not include direct exposure via food (edible plants), nor does it include the risk assessment of exposed pets. Instead, this will be handled with risk mitigation measures. The products are proposed to be labelled with the sentence “The product should be applied so that children, pets and edible plants do not come in contact with the product.”

The environmental risk assessment does not indicate any unacceptable risks when the products are used according to the conditions in the SPFC.

3.2 PROPOSAL FOR DECISION

On basis of the Assessment Report of the active substance and the Product Assessment Report, the opinion of Ref-MS Sweden is to authorise the Myrr D biocidal product family, to be used as biocide products. The conditions are outlined in the Summary of biocidal Product Family Characteristics (SPFC) were both the products Myrr D Deltamethrin DP 0.05 and Myrr D are included in one meta-SPC (second information level of the SPFC).

ANNEX 1: REFERENCE LIST

Studies submitted for active substance evaluation by for inclusion in Annex I to directive 98/8/EC is listed in the Competent Authority Report for deltamethrin. Below is a reference list of submitted product studies and other product assessment related reports.

Reference list by Annex point in applicant's dossier

Section No. / Reference No.	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes / No)	Owner
3.1.1/01 3.1.2/01 3.1.3/01 3.5/01 3.6/01 3.7/01 3.7/02 3.8/01 3.8/02 3.8/03 3.11/01	Güldner, W & Hoppe, M.	2008	Storage Stability and shelf-life of Deltamethrin DP 0.05 (Packaging material HDPE) – Final report Bayer CropScience AG Report No: M-237411-03-1 25 March 2008 GLP. Unpublished.	Y	Bayer AG
3.2/01 3.3/01 3.4/01 3.4/02	Heinz, U.	2004	Determination of Safety-Relevant Data of Deltamethrin DP 0.05 Bayer Industry Services GmbH & Co. OHG Report No: M-237699-01-1 16 December 2004 GLP. Unpublished.	Y	Bayer AG
3.8/01	Güldner, W. & Hoppe	2006	Physical, chemical and technical properties of deltamethrin DP 0.05 Amendment n°1 Bayer CropScience AG Report No: M-237645-02-1 28 November 2006 Not GLP. Unpublished.	Y	Bayer AG
4.1/01	Seidel, E.	2003	Determination of deltamethrin in formulations (2001-0054801-03E) Bayer CropScience, Germany Report No: M-075625-01-2 17 January 2003 Not GLP. Unpublished.	Y	Bayer AG

Section No. / Reference No.	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes / No)	Owner
4.1/02	Odendahl, A.	2004	Validation of HPLC method 2002-0054801-03 – Determination of Deltamethrin in Formulations Bayer CropScience, Germany Report No: M-092792-01-1 15 October 2004 Not GLP. Unpublished.	Y	Bayer AG
4.1/03	Odendahl A.	2003	Validation of HPLC-method 2001-0054801-03 – Determination of Deltamethrin in formulations, Report No. VB1-2001-0054801 (basic report) Bayer CropScience, Germany Report No MO-083990-01-1 19 February 2003 Unpublished	Y	Bayer AG
4.1/04	Schulz F.	2017	Supplement chromatograms to Deltamethrin DP 0.05 (102000020443). Bayer AG, Crop Science Division, Germany Report No: not available 13 March 2017 Unpublished	Y	Bayer AG
5.10.2/01	Nentwig, D.	2007	BES 0377: Different scatter formulations in comparison to [redacted] efficacy against the Black garden ant (*Lasius niger*). BCS AG-ES-I-Product Development White Report No: M-433180-01-1 26 February 2007 Unpublished.	Y	Bayer AG
5.10.2/02	Gutsmann, V.	2012	Use of Deltamethrin DP 0.05 for treatment of hiding places of common household nuisance pests. Bayer CropScience, 40789, Monheim, Germany Report No: M-444123-02-1 3 December 2012 Unpublished.	Y	Bayer AG

Section No. / Reference No.	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes / No)	Owner
5.10.2/03	Serrano, B.	2004 a	Laboratory Assessment of the Efficacy of Two Speciality Products to Control Garden Ants – Laboratory Trial Bayer Environmental Science, France Report No: M-268536-01-1 2 November 2004 Unpublished.	Y	Bayer AG
5.10.2/04	Brooks, M.D.	2011	Field efficacy of Deltamethrin DP 0.05 (UVP 5938872) scattered around nest openings of the black garden ant *Lasius niger* L. Kenniscentrum Dierplagen (KAD), Costerweg 5, 6702 EB Wageningen Report No: M-426050-01-1 8 July 2011 Unpublished.	Y	Bayer AG
5.10.2/05	Schoelitsz B.	2011	Field efficacy of Deltamethrin DP 0.05 (UVP 5938872) scattered around nest openings of the black garden ant *Lasius niger* L Kenniscentrum Dierplagen (KAD), Costerweg 5, 6702 EB Wageningen Report No: M-426110-01-1 8 July 2011 Unpublished.	Y	Bayer AG
5.10.2/06	Serrano, B.	2004 b	Laboratory Assessment of the Efficacy of Two Speciality Products to Control Garden Ants – Field Trial Bayer Environmental Science, France Report No: M-268539-01-1 2 November 2004 Unpublished.	Y	Bayer AG
Referral discussion	Gutsmann, V.	2017	Use of Deltamethrin DP 0.05% for treatment of hiding places of the Oriental cockroach (Blatta orientalis Bayer AG, Germany Report No: M-585706-02-1 17 May 2017 Unpublished.	Y	Bayer AG

Section No. / Reference No.	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes / No)	Owner
Referral discussion	Gutsmann, V.	2017	Efficacy of direct application of Deltamethrin DP 0.05% onto common household insects Bayer AG, Germany Report No: M-585768-01-1 13 April 2017 Unpublished.	Y	Bayer AG
6.1/01	Garcin, J.C., Vinck, K.	2005	Bridging statement from toxicity of [redacted] to Deltamethrin DP 0.05 Bayer CropScience SA Report No: M-255680-01-1 11 August 2005 Not GLP. Unpublished **CONFIDENTIAL (see DocIVB confidential data and information)**	No	Bayer AG
6.1.1/01	[redacted]	1989 a	[redacted] – Acute Oral Toxicity Study in the Rat Division Scientifique Roussel Uclaf, France Report No: M-150515-01-1 25 September 1989 GLP. Unpublished.	Y	Bayer AG
6.1.2/01	[redacted]	1989 b	[redacted] Acute Dermal Toxicity Study in the Rabbit Division Scientifique Roussel Uclaf, France Report No: M-150516-01-1 25 September 1989 GLP. Unpublished.	Y	Bayer AG
6.1.3/01	[redacted]	1990	Acute Inhalation Toxicity Study in Rats with [redacted] Report No: M-150522-01-1 19 November 1990 GLP. Unpublished.	Y	Bayer AG

Section No. / Reference No.	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes / No)	Owner
6.2.1/01	[redacted]	1989 c	[redacted] – Primary Dermal Irritation Study in the Male Rabbit Division Scientifique Roussel Uclaf, France Report No: M-150519-01-1 25 September 1989 GLP. Unpublished	Y	Bayer AG
6.2.2/01	[redacted]	1989 d	[redacted] – Primary Eye Irritation Study in the Male Rabbit Division Scientifique Roussel Uclaf, France Report No: M-150517-01-1 25 September 1989 GLP. Unpublished.	Y	Bayer AG
6.3/01	[redacted]	1990	Dermal Sensitization Study in Guinea Pigs with [redacted] Report No: M-150521-01-1 14 November 1990 GLP. Unpublished.	Y	Bayer AG