REPORT

2017-09-08

Our reference

F-2773-B13-00346

Kemikalieinspektionen
Swedish Chemicals Agency

Product Assessment Report of a Biocidal Product Family

Related to product authorisation under Regulation (EU) No 528/2012

Myrr Spray Family (Deltamethrin EW 0.15 RTU)

1st Meta level: Myrr Spray Family - Deltamethrin EW 0.15

Product: Myrr Spray Deltamethrin EW 0.15

2nd Meta level: Myrr Spray Family - Deltamethrin EW 0.15A

Product: Myrr Spray

Type of application Authorisation	Product type PT 18 (insecticide)
Authorisation number for family 5355	Date of decision/Entry into force 08 September 2017
Authorisation number for products Myrr Spray Deltamethrin EW 0.15: [5355-1-1] Myrr Spray: [5355-2-1]	
Active substance Deltamethrin 0.15 g/L (0.015% (w/w))	Date of expiry 07 September 2027
Sweden's R4BP3 reference code BC-KL010431-53 (2013/1117/7044/SE/APPFF/10791)	User category Class 3 - Products that may be used by anyone

Swedish Chemicals Agency

Mailing address	*Visit*	*Invoicing address*	*Phone & fax*	*Internet*	*VAT No*
Box 2 SE-172 13 Sundbyberg Sweden	Esplanaden 3A, Sundbyberg	FE 124 SE-838 80 Hackås Sweden	Phone +46 8 519 41 100 Fax +46 8 735 76 98	www.kemi.se kemi@kemi.se	SE202100388001

CONTENTS

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:	31st of January 2014
Type of application:	New authorisation
Further information:	Applicant has indicated submission of application for mutual recognition in [redacted]. The application was submitted as a frame formulation under Directive 98/8/EC and is 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 Spray Deltamethrin EW 0.15 and Myrr Spray differ slightly in the composition. 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 Spray Family
First meta name (second information level):	Myrr Spray Family - Deltamethrin EW 0.15
Trade name of individual product in meta Myrr Spray Family - Deltamethrin EW 0.15 (third information level):	Myrr Spray Deltamethrin EW 0.15
Second meta name (second information level):	Myrr Spray Family - Deltamethrin EW 0.15A
Trade name of individual product in meta Myrr Spray Family - Deltamethrin EW 0.15A (third information level):	Myrr Spray
Manufacturer's development code number(s), if appropriate:	AE F032640 00 EW 01 A2, AE F032640 00 EW 01 A200, RU4993, Deltamethrin AL 015, AV047, Deltamethrin EW 0.15, Ant Kill plus AL 0.15 Specification: 102000002551 (material number 05938651) Specification: 102000026487 (material number 80487851)
Product type:	PT18
Composition of the product (identity and content of active substance(s) and substances of concern; full composition see confidential annex):	Deltamethrin: 0.15 g/L, (0.015 % w/w)
Formulation type:	Emulsion in water (EW)
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 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):	Deltamethrin EW 0.15 was not one of the representative formulations submitted for EU review according to the biocide directive 98/8/EC.

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):	Spray indoors and in protected outdoor locations to directly kill and also control crawling insects.
Target organisms:	Black Ant *(Lasius niger*) and other commonly found garden ants Other crawling insects, e.g. spiders, 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:	**Direct Spray** Use one trigger action from a distance of 30 cm to kill a broad spectrum of insects **Control of crawling insects indoors and in protected outdoor locations:** Apply to areas where insects hide and walk (crack and crevices, behind boards, under fridges, around window frames etc.) Do not apply onto areas larger than 2 m².
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 formulations of Myrr Spray Deltamethrin EW 0.15 and Myrr Spray 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):	Spray in small confined protected spaces in and around buildings for direct and fast (within 1 h) kill, and control, of crawling insects and woodlice, at a maximum dose rate of 7.5 mg/m^2 (5 mL of product per 32 x 32 cm, i.e.5 pump strokes):
Target organisms:	Crawling insects and woodlice
Category of users:	General public However, please note: According to the Swedish view 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 the products Myrr Spray Deltamethrin EW 0.15 and Myrr Spray are included in separate meta-SPC:s (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	CEE: Journal Officiel des Communautes Europeennes, 19 septembre 1984.	OFA Sprague-Dawley rat 5M+5F Vehicle: distilled water	2000, 3000 and 5000 mg/kg bw	LD_{50}: > 5000 mg/kg bw (M&F)	Not classified	[redacted] 1990a (6.1.1/01)
Dermal	Officiel des Communautes Europeennes, 19 septembre 1984.	Albino hybrid NZ rabbit 5M+5F Vehicle: none	4000 mg/kg bw	LD_{50}: >4000 mg/kg bw (M&F)	Not classified	[redacted] 1990b (6.1.2/01)
Dermal Irritation	Officiel des Communautes Europeennes, 19 septembre 1984.	New Zealand Albino hybrid rabbit	0.5 mL	Highest erythema score = 1 Highest oedema score = 0 Reversible within 72 hr	Not a skin irritant	[redacted] 1990c (6.2.1/01)
Eye Irritation	Officiel des Communautes Europeennes, 19 septembre 1984.	New Zealand Albino hybrid rabbit	0.1 mL	Transient slight ocular irritation reversible within 72 hr.	Not an eye irritant	[redacted] 1990d (6.2.2/01)
Dermal sensit isation	OECD 429 "Skin Sensitisation: Local Lymph Node Assay"	CBA/J Rj mice	Neat, 50 and 25% dilutions	0/12 sensitised SI values <3.0 in each group	Not a sensitiser	[redacted] 2013 (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 with the name Myrr Spray 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 Spray Deltamethrin EW 0.15 and Myrr Spray, differ slightly in the composition (see confidential annex). Throughout the assessment report, the product family name Deltamethrin EW 0.15 RTU is used by ref-MS while referring to data that are valid for both formulations, as the family name was changed to Myrr Spray Family very late in the process. In the applicant's text, both formulations are referred to as a single product and the product name Myrr Spray is used while referring to both formulations. In some places in Section 2 the alternative product name Deltamethrin EW 0.15 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

Ref-MS information to the reader:	One of the products in the biocidal family contains the mixture of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one as a co-formulant, which is an active substance approved 01/07/2017 for PT2, 4, 6, 11, 12 and 13, thus being a potential substance of concern (SoC). Ref-MS has

	therefore considered whether the mixture should be regarded as an actual substance of concern in the current evaluation, and concludes the following: The application was submitted before relevant guidance on identification and assessment of SoC was adopted. New guidance cannot be required to be followed until after a certain period of time. The guidance that has recently become available has not been used for the evaluation of the present biocidal product family. Additionally, the amount of the mentioned substance in the product does not lead to classification of the product. For these reasons, the mixture of 3(2H)-isothiazolone, 5-chloro-2-methyl- and 2-methyl-3(2H)-isothiazolone should not be considered to be a SoC in this case. Ref-MS therefore concludes that there is no need to further evaluate the potential substances of concern in the biocidal products.

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 (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 Myrr Spray

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. EUH208: Contains Reaction mass 5-chloro-2-methyl-2H-isothiazol-3-one (CMIT) and 2-methyl-2H-isothiazol-3-one (MIT). May produce an allergic reaction.*
Precautionary statements	P102: Keep out of reach of children. P391: Collect spillage. P501: Dispose of contents/container in accordance with local regulation.

** EUH208 is only applicable to products containing the substance. Total concentration of CMIT/MIT is below the limit of 0.0015% for classification of Skin sensitisation.*

2.3.3 Proposed classification and labelling of Myrr Spray Deltamethrin EW 0.15

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. P273: Avoid release to the environment. P371: Collect spillage. P501: Dispose of contents/container in accordance with local regulation.

2.3.4 Packaging

Myrr Spray is sold in PET, HDPE and COEX/E-VAL trigger bottles from 0.5 L up to 1 L.

2.4 PHYSICO-CHEMICAL PROPERTIES

Myrr Spray is an emulsion in water containing 0.15 g/L deltamethrin. It is a white homogenous emulsion with a weak synthetic odour. 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 4.3. Based on the structural formula of the active substance, the product has no explosive, oxidising or flammable properties. The products Myrr Spray Deltamethrin EW 0.15 and Myrr Spray are considered stable for at least two and three years, respectively, at ambient temperature in HDPE, COEX/EVAL and PET packaging 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 Spray and are summarised in Table 2.2-1 below.

Table 2.2-1 Physico-chemical properties of the biocidal product

Physico-chemical property	Guideline No. and Method used	Result/Comment	Ref. in Doc III
Physical state	Visual	Homogenous Emulsion	Manka, 2014 (B3.1.1/01)
Colour	Visual	White	Manka, 2014 (B3.1.2/01)
Odour	Olfactory	Weak synthetic	Manka, 2014 (B3.1.3/01)
Explosive properties	An evaluation of the explosive properties has been carried out by examining structural formula	From the structural formula it can be concluded that the test substance is not explosive	Heinz, 2005 (B3.2/01)
Oxidising properties	An evaluation of the oxidizing properties has been carried out by examining structural formula of the active substance	From examination of the structural formula it can be concluded that the test substance has no oxidizing properties.	Heinz, 2005 (B3.3/01)
Flash point	EEC A.9	No flash point	Heinz, 2005 (B3.4)
Auto-Ignition Temperature	EEC A.15	No auto-ignition temperature up to 600°C	Heinz, 2005 (B3.4/01)
Acidity/alkalinity pH value	CIPAC MT 75.3	Study performed in PET (1L) and pH measured at 20 °C. Initial pH: 4.3 After 2 weeks 54 °C pH: 3.9 After 2 years pH: 3.7	Manka, 2014 (B3.5/01)

Physico-chemical property	Guideline No. and Method used	Result/Comment	Ref. in Doc III
		Study performed in HDPE (1L): Initial pH: 5.2 After 2 weeks 54 °C pH: 5.7 After 2 years pH: 4.6 1% in CIPAC D water Initial pH: 6.5 After 2 weeks 54 °C pH: 6.4 After 2 years pH: 6.2	Güldner and Hoppe, 2007 M-129049-02-1
Relative density	EC A.3	0.998	Manka, 2014 (B3.6/01)
Accelerated storage stability	CIPAC MT 46.3 CIPAC MT 39.3	No significant change in the product properties and the active ingredient contents was shown after storage for 1 week at 0 °C and 2 weeks at 54 °C, in the commercial packaging (PET, HDPE and COEX/EVAL).	Manka, 2014) (B3.7/01) Güldner and Hoppe, 2007 M-129049-02-1 Güldner and Hoppe, 2007 M-129045-02-1
Ambient storage stability	CIPAC MT 46.3	No significant change in the product properties and the active ingredient contents was shown after storage for 2 years at ambient temperature, in the commercial packaging (PET, COEX/EVAL or HDPE)	Manka, 2014) (B3.7/01) Güldner and Hoppe, 2007 M-129049-02-1 Güldner and Hoppe, 2007 M-129045-02-1
Wettability/ suspensibility	Not relevant	Not applicable to EW-formulations	-
Dry sieve tests	Not relevant	Not applicable to EW-formulations	-
Emulsifiability,	CIPAC MT 36.3	1% in CIPAC A water: Initial emulsification: spontaneous After 30 min: 0 mL After 2 h: 0 mL After 24 h: trace of cream	Güldner and Hoppe, 2007 M-129049-02-1

Physico-chemical property	Guideline No. and Method used	Result/Comment	Ref. in Doc III
		Reemulsification after 24 h: completely After 24.5 h: 0 mL After 2 weeks at 54 °C: Initial emulsification: spontaneous After 30 min: 0 mL After 2 h: 0 mL After 24 h: trace of cream Reemulsification after 24 h: completely After 24.5 h: 0 mL After 2 years ambient temperature: Initial emulsification: spontaneous After 30 min: 0 mL After 2 h: 0 mL After 24 h: trace of cream Reemulsification after 24 h: completely After 24.5 h: 0 mL <u>1% in CIPAC D water</u>: Initial emulsification: spontaneous After 30 min: 0 mL After 2 h: 0 mL After 24 h: trace of cream Reemulsification after 24 h: completely After 24.5 h: 0 mL After 2 weeks at 54 °C: Initial emulsification: spontaneous After 30 min: 0 mL After 2 h: 0 mL After 24 h: trace of cream Reemulsification after 24 h: completely After 24.5 h: 0 mL After 2 years ambient temperature: Initial emulsification: spontaneous After 30 min: 0 mL After 2 h: 0 mL After 24 h: trace of cream	

Physico-chemical property	Guideline No. and Method used	Result/Comment	Ref. in Doc III
		Reemulsification after 24 h: completely After 24.5 h: 0 mL	
Persistence of foaming	CIPAC MT 47.2	1 % prep. In CIPAC D water Initial: After 1 min: 1 mL After 2 weeks at 54 °C: After 1 min: 0 mL After 2 years at ambient temperature: After 1 min: 0 mL	Güldner and Hoppe, 2007 M-129049-02-1
Pourability	CIPAC MT 148	Initial: Residue: 0.14% Rinsed residue: 0.13% After 2 weeks at 54 °C Residue: 0.14% Rinsed residue: 0.12% After 2 years at ambient temperature Residue: 0.11% Rinsed residue: 0.09%	Güldner and Hoppe, 2007 M-129049-02-1
Surface tension	Not relevant	Not applicable to Ready to Use spray formulations	Document III-B3.10
Viscosity	CIPAC MT 192	< 2mPas	Manka, 2014 (B3.11)
Function and discharge volume of trigger pump devices	Sponsor method TFT002	Packaging material: 1 L PET trigger spray **Discharge rate:** Initial: 0.89 g/stroke 0 °C 1 week: 0.95 g/stroke 54 °C 2 weeks: 0.98 g/stroke 20 °C 12 months: 1.06 g/stroke 20 °C 24 months: 1.05 g/stroke 20 °C 36 months: 1.01 g/stroke **Function of device:** Initial: Works as planned 0 °C 1 week: Works as planned	Manka, 2016 M-459556-03-1

Physico-chemical property	Guideline No. and Method used	Result/Comment	Ref. in Doc III
		54 °C 2 weeks: Works as planned 20 °C 12 months: Works as planned 20 °C 24 months: Works as planned 20 °C 36 months: Works as planned	

Table 2.2-2 Results from storage stability studies in HDPE packaging material (Güldner and Hoppe, 2007)

Test item: Myrr Spray DELTAMETHRIN EW 0.15

	Initial	2 weeks 54 °C	2 years ambient temp.
A.I. Content			
deltamethrin	0.013 %	0.013 %	0.012 %
Appearance colour, condition (visual)	whitish emulsion	whitish emulsion	whitish emulsion
odour (olfactory)	weak mouldy	weak mouldy	weak mouldy
Packaging stability HDPE bottle with spraying head	no negative effects observed	no negative effects observed	no negative effects observed
weight change	no determination	no determination	no determination
deformation of packaging	no panelling no ballooning	no panelling no ballooning	no panelling no ballooning
leakage	no leakage	no leakage	no leakage
effect on closure	leak proof	leak proof	leak proof
packaging/preparation interaction	no claying, no sedimentation	no claying, no sedimentation	no claying, no sedimentation
Acidity/Alkalinity*, method: CIPAC MT 31.2	not determined	not determined	not determined
pH-Value, method: CIPAC MT 75.3 (**undiluted** sample)	5.2	5.7	4.6
(**1%** in CIPAC D water)	6.5	6.4	6.2
Pourability, method: CIPAC MT 148			
residue	0.14 %	0.14 %	0.11 %
rinsed residue	0.13 %	0.12 %	0.09 %
Emulsion characteristic, method: CIPAC MT 36.3 1 % in CIPAC A water			
initial emulsification	spontaneously	spontaneously	spontaneously
after 30 min	0 ml	0 ml	0 ml
after 2 h	0 ml	0 ml	0 ml
after 24 h	trace of cream	trace of cream	trace of cream
reemulsification after 24 h	completely	completely	completely
after 24.5h	0 ml	0 ml	0 ml
Emulsion characteristic, method: CIPAC MT 36.3 1 % in CIPAC D water			
initial emulsification	spontaneously	spontaneously	spontaneously
after 30 min	0 ml	0 ml	0 ml
after 2 h	0 ml	0 ml	0 ml
after 24 h	trace of cream	trace of cream	trace of cream
reemulsification after 24 h	completely	completely	completely
after 24.5 h	0 ml	0 ml	0 ml

	Initial	2 weeks 54 °C	2 years ambient temp.
Persistent foaming, method: CIPAC MT 47.2, 1 % prep. in CIPAC D water			
after 10 sec	5 ml	0 ml	0 ml
after 1 min	1 ml	0 ml	0 ml
after 3 min	0 ml	0 ml	0 ml
after 12 min	0 ml	0 ml	0 ml
Particle size distribution, method: CIPAC MT 187			
90 % ≤ x µm	20.28 µm	19.59 µm	19.81 µm
50 % ≤ x µm	7.92 µm	7.60 µm	7.76 µm
10 % ≤ x µm	1.18 µm	1.15 µm	1.22 µm

Low temperature stability, CIPAC MT 39.3, after 7 days at 0 °C
Result: no separated material.

Table 2.2-3 Results from storage stability studies in COEX/EVAL packaging material (Güldner and Hoppe, 2007)

Test item: Myrr Spray DELTAMETHRIN EW 0.15

	Initial	2 weeks 54 °C	2 years ambient temp.
A.I. Content			
deltamethrin	0.013 %	0.013 %	0.013 %
Appearance colour, condition (visual)	whitish emulsion	whitish emulsion	whitish emulsion
odour (olfactory)	weak mouldy	weak mouldy	weak mouldy
Packaging stability COEX/E-VAL	no negative effects observed	no negative effects observed	no negative effects observed
weight change	no determination	no determination	no determination
deformation of packaging	no panelling no ballooning	no panelling no ballooning	panelling: 12-13 mm
leakage	no leakage	no leakage	no leakage
effect on closure	leak proof	leak proof	leak proof
packaging/preparation interaction	no claying, no sedimentation	no claying, no sedimentation	no claying, no sedimentation
Acidity/Alkalinity*, method: CIPAC MT 31.2	not determined	not determined	not determined
pH-Value, method: CIPAC MT 75.3 (**undiluted** sample)	5.2	6.5	6.0
(1% in CIPAC D water)	6.5	6.5	6.4
Pourability, method: CIPAC MT 148			
residue	0.14 %	0.14 %	0.15 %
rinsed residue	0.13 %	0.14 %	0.11 %
Emulsion characteristic, method: CIPAC MT 36.3 1 % in CIPAC A water			
initial emulsification	spontaneously	spontaneously	spontaneously
after 30 min	0 ml	0 ml	0 ml
after 2 h	0 ml	0 ml	0 ml
after 24 h	trace of cream	trace of cream	trace of cream
reemulsification after 24 h	completely	completely	completely
after 24.5h	0 ml	0 ml	0 ml
Emulsion characteristic, method: CIPAC MT 36.3 1 % in CIPAC D water			
initial emulsification	spontaneously	spontaneously	spontaneously
after 30 min	0 ml	0 ml	0 ml
after 2 h	0 ml	0 ml	0 ml
after 24 h	trace of cream	trace of cream	trace of cream
reemulsification after 24 h	completely	completely	completely
after 24.5 h	0 ml	0 ml	0 ml

	Initial	2 weeks 54 °C	2 years ambient temp.
Persistent foaming, method: CIPAC MT 47.2, 1 % prep. in CIPAC D water			
after 10 sec	5 ml	0 ml	0 ml
after 1 min	1 ml	0 ml	0 ml
after 3 min	0 ml	0 ml	0 ml
after 12 min	0 ml	0 ml	0 ml
Particle size distribution, method: CIPAC MT 187			
90 % ≤ x µm	20.28 µm	21.83 µm	19.11 µm
50 % ≤ x µm	7.92 µm	8.98 µm	6.99 µm
10 % ≤ x µm	1.18 µm	1.26 µm	1.13 µm

Low temperature stability, CIPAC MT 39.3, after 7 days at 0 °C
Result: no separated material.

Table 2.2-4 Results from storage stability studies (1 week at 0 °C and 2 weeks at 54 °C) in PET packaging material (Manka, 2016)

Test item: Myrr Spray

Parameter	Initial Sample	1 Week at 0 °C	2 Weeks at 54 °C
Active Substance Content (according to method 2001-0054801 HPLC/ESTD) Deltamethrin :	0.140 g/L	n.d.	0.150 g/L
Appearance	White homogeneous emulsion with weak synthetic odor	White homogeneous emulsion with weak synthetic odor	White homogeneous emulsion with synthetic odor
Stability of Packaging	Test Item in sound condition, sealed and without leakages Dimensionally stable	Test Item in sound condition, sealed and without leakages Dimensionally stable	Test Item in sound condition, sealed and without leakages Dimensionally stable
Weight Loss	Not applicable	0.01 to 0.02 %	0.41 to 0.42 %
Relative Density (according to EC440/2008 A.3) 20 °C :	0.998	0.998	0.998
pH-Value Undiluted (according to CIPAC MT 75.3)	4.3	4.3	3.9

Parameter	Initial Sample	1 Week at 0 °C	2 Weeks at 54 °C
Viscosity (according to CIPAC MT 192) 20 °C :	< 2 mPas	< 2 mPas	< 2 mPas
Evaluation of Function and Discharge Volume of Trigger Pump Devices (according to Sponsor method TFT002)			
Discharge rate:	0.89 g/stroke	0.95 g/stroke	0.98 g/stroke
Function of Device:	Works as planned	Works as planned	Works as planned

Table 2.2-5 Results from ambient temperature stability study in PET packaging material (Manka, 2016)

Test item: Myrr Spray

Parameter	12 Months at 20 °C	24 Months at 20 °C	36 Months at 20 °C
Active Substance Content (according to method 2001-0054801 HPLC/ESTD) Deltamethrin :	0.139 g/L	0.131 g/L	0.154 g/L
Appearance	White homogeneous emulsion with weak synthetic odor	White homogeneous emulsion with weak synthetic odor	White homogeneous emulsion with weak synthetic odor
Stability of Packaging	Test Item in sound condition, sealed and without leakages Dimensionally stable	Test Item in sound condition, sealed and without leakages Dimensionally stable	Test Item in sound condition, sealed and without leakages Dimensionally stable
Weight Loss	0.56 to 0.59 %	1.14 to 1.20 %	1.75 to 1.80 %
Relative Density (according to EC440/2008 A.3) 20 °C :	0.998	0.998	0.998
pH-Value Undiluted (according to CIPAC MT 75.3)	3.7	3.7	3.4

Parameter	12 Months at 20 °C	24 Months at 20 °C	36 Months at 20 °C
Viscosity (according to CIPAC MT 192) 20 °C :	< 2 mPas	< 2 mPas	< 2 mPas
Evaluation of Function and Discharge Volume of Trigger Pump Devices (according to Sponsor method TFT002)			
Discharge rate:	1.06 g/stroke	1.05 g/stroke	1.01 g/stroke
Function of Device:	Works as planned	Works as planned	Works as planned

Ref-MS information to the reader:	Products belonging to the biocidal product family Deltamethrin EW 0.15 RTU are oil in water emulsions (EW) containing 0.15 g/L deltamethrin. The oil has a weak synthetic odour. Based on the properties of the components of the formulation, the products are not considered to be explosive or oxidizing. The initial pH of the undiluted product is 4.3 for the formulation containing preservative and 5.2 for the formulation without preservative. Acceptable ambient temperature storage stability studies are available for the formulation with and without preservative. The products Myrr Spray Deltamethrin EW 0.15 and Myrr Spray are considered stable for at least two and three years, respectively, at ambient temperature in HDPE, COEX/EVAL and PET packaging

2.5 ANALYTICAL METHODS FOR DETECTION AND IDENTIFICATION

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

2.5.1 Formulation analysis

Acceptable validation data was provided for the analysis of deltamethrin in an OD-formulation containing 1% deltamethrin and 10% thiacloprid (Odendahl, 2003). In addition to this data to prove the specificity of the method for the biocidal product Myrr Spray was provided (Odendahl, 2004).

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 2.3.1-1 Analysis of deltamethrin in formulations

Method	Linearity (linear range and r^2)	Precision (repeatability) % RSD	Accuracy (mean recovery) %	Specificity	Reference in Doc III
HPLC-UV	1.30-4.08 mg a.s./100 ml solution (use	0.56% (n=6) (tested for a 2.5 mg a.s./100 ml	Mean: 100.86% Range 99.5-	No interference from	Seidel, 2003 (method description;

	concentration for formulations according to the method is 2.5 mg deltamethrin./100 ml) r^2>0.999	solution which is relevant for the representative formulation)	101.6 (RSD 0.69%, n=6). Tested in the range 1.27-4.15 mg a.s./100 ml solution	formulants, impurities or solvents.	CAR DocIII-B4.1/01) Odendahl, 2003 (validation data for OD-formulation, CAR DocIII-B4.1/03); Odendahl, 2004 (specificity data for Myrr Spray)

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). Specificity for the formulation Myrr Spray was shown in Odendahl 2004.

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 EW 0.15 is for the direct kill of arthropods including insects in and around buildings. It contains 0.15g/L of deltamethrin in an emulsion in water formulation (EW). Deltamethrin EW 0.15 acts on harmful organisms by direct spray contact or contact to treated surfaces resulting in death. Deltamethrin expresses both a knock-down effect, and residual action. Deltamethrin EW 0.15 is a ready to use spray treatment for immediate use and is supplied in a container with a trigger spray. The maximum dose rate of 5 mL of product per 32 x 32 cm (5 pump strokes) and 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 are sumarised as follows. 1) Direct kill of insects within 1 hour 2) Control of crawling insects and other arthropods (e.g. black ant and other commony found garden ants, spider, German cockroach, silverfish, wood louse or pill bug) in small confined locations, at a maximum dose rate of 5 mL of product per 32 x 32 cm (5 pump strokes). 3) Residual effect for at least 6 weeks. Products in the biocidal products family Deltamethrin EW 0.15 RTU are intended for consumers and is to be used in and around houses. Requirements according to TNsG for PT18: • For a general claim of direct kill of insects, efficacy studies on a "few relevant species of significant importance" is required. • To show efficacy against crawling insects, as a general claim, information on efficacy shown in both laboratory and simulated-use/field study normally against both one small and one large species of cockroach is required. • To show efficacy against arthropods "information on efficacy in organisms relevant for the intended use" is required. A fied study should be provided or a good justification why this is not appropriate. • "For products with general claims the performance criteria per tested organism are the same as those for products with a specific claim for the test species." The Ref-MS evaluation of the submitted studies (see Table 2.7.1-1) concludes the following for the individual species claimed for: **Direct kill of insects**: Studies to support the claim of direct kill of insects are laboratory studies on garden ant (*Lasius niger*), German cockroach (*Blattella*

	germanica), Oriental cockroach (*Blatta orientalis*), silverfish (*Lepisma saccharina*), wood louse (*Porcellio scaber*) and house fly (*Musca domestica*). The insect species are considered relevant and significant for the intended use of products in the family Deltamethrin EW 0.15 RTU. It is concluded that the laboratory studies support the efficacy of the product, at the recommended dose, as fast kill (within 1 hour) of insects and wood louse at direct application. **Crawling insects/Cockroaches**: Efficacy against German cockroach is supported as shown in both laboratory studies and in a simulated-use study, which is regarded as sufficient for a consumer product. However, efficacy against a large cockroach species (Oriental cockroach) is only shown in a laboratory study. Consequently the general claim against crawling insects is not supported. **Black ant and other commonly found garden ants**: Efficacy aginst black ant (*Lasius niger*) is only shown in a laboratory study but is not supported by a simulated-use or field study. Consequently the claim against ants is not supported. **Arthropods/Silverfish and wood louse or pill bug**: Efficacy against silverfish (*Lepisma saccharina*) and wood louse (*Porcellio scaber*) is supported as shown in both a laboratory study and in a simulated-use study. There is no field study included in the documentation but the intended use is simulated in an appropriate way which is considered to show the efficacy in a field situation. **Spiders**: A field study on webbing spiders (*Araneae*) is submitted to support efficacy against spiders. However, the specific claim of control against spiders is not considered supported by the documentation provided. The available TNsG do not give any information on how to assess efficacy of spiders. However, it is the opinion of the Ref-MS that the submitted data is not enough to support the label claim to control spiders. As spiders belong to another class among the arthropods than insects, efficacy should also be demonstrated with laboratory data confirming mortality. The following arguments were provided by the applicant in February 2016 following a request from the Ref-MS for clarifications. *Bayer: Indeed there is no information on spiders in the current TNsG. In the light of no information given, Bayer decided to test the efficacy in field trials which we regard as the highest tier test protocol. If the insect and use pattern allow the conduct of field trials, then a positive outcome should make any other trial redundant. Additionally, we believe that spiders are a very complex group of arthropods. Most likely most PCOs are not able to identify the correct species they are asked to treat. Therefore, a natural mix of spiders inhabiting a natural habitat will give a more realistic view on the performance of a product. We ask Kemi to allow the claim for control of spiders based on a controlled valid field trial we submitted.* The arguments provided by the applicant has not changed the Ref-MS opinion. The specific claim of control against spiders is therefore not considered supported. During the authorization process questions were raised from cMS that were not resolved. Questions were formally referred to the Coordination Group. During this process the applicant submitted additional studies. After discussions at the CG-23 and a conference call held on 23 May 2017 CG members agreed by consensus. The agreement is reflected in the conclusion below. Ref-MS concludes that the submitted documentation supports the following claims regarding efficacy of the biocidal product family Deltamethrin EW 0.15

	RTU, at the recommended maximum dose of 7.5 mg a.s./m^2 and according to the directions for use (in small confined and protected locations, max 5 mL of product per 32 x 32 cm (5 pump strokes): • Direct and fast kill (within 1 hour), and control of crawling insects and woodlice in small confined and protected spaces, in and around buildings, up to 6 weeks. The residual life will however depend on the nature of the treated surface. Reduced residual efficacy can be expected on for instance PVC.

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

Test substance	Test organisms	Test system / Concentrations applied / exposure time	Test conditions	Test results: effects, mode of action, resistance	Reference	Ref-MS Comments
Deltamethrin EW 0.15	*Lasius niger*	Direct spraying onto organisms and residual efficacy after 1 day, 3 weeks and 6 weeks on different surfaces.	Laboratory	Fast action after direct spraying (100% mortality after 15 minutes). Residual efficacy out to 6 weeks post treatment on unglazed tiles and wood. No residual efficacy on PVC at 6 weeks.	Nentwig, G. (2005) M-268842-01-1 B5-10-2/01	<u>Direct spraying against ants</u> Deltamethrin EW 0.15 was tested on 20 ants (Lasius niger) placed in glass dishes. The ready to use product was sprayed by hand according to label. After 15 minutes, 30 minutes, 60 minutes, 2 hours, 3 hours, 4 hours, 6 hours and 24 hours the mortality was determined. The test consisted of three replicates of which the mean percentage mortality values were calculated. The untreated controls consisted of one replicate. After spraying with Deltamethrin EW 0.15 100% mortality was seen after 15 minutes. No mortality of the control was seen after 6 h, but was 75% after 24 h. **The Ref-MS accepts the study to be used for support of the label claim for fast kill at direct application of crawling insects within 1 hour.** <u>Residual test against ants</u> The ready to use product was sprayed by hand with a dose corresponding to the label. The surfaces tested were unglazed tiles, wood and PVC aged up to 6 weeks.

						The test insects were anesthetized with CO2 and 20 individuals placed onto each treated surface. After 15 minutes, 30 minutes, 60 minutes, 2 hours, 3 hours, 4 hours, 6 hours and 24 hours the mortality was determined. The test was repeated at different times to evaluate the residual efficacy. Deltamethrin EW 0.15 showed good residual efficacy on unglazed tiles (100% mortality at 1 h post exposure on one day, 3 w and 6 w old tiles) and wood (100% mortality at 1 h post exposure on one day old tiles and 100 % mortality at 2 h post exposure on 3 w and 6 w old tiles) for up to 6 weeks post treatment but poor residual efficacy on PVC (93% mortality on one day old tiles at 24h post exposure, falling to 3% at 6 weeks post treatment). No mortality of controls, on all surfaces, was seen up to 6 h and was <15% at 24 h. For the poor residual efficacy on PVC the applicant has argumented that the PVC in the study was unsealed while modern PVC usually is sealed. **The Ref-MS accepts the study in support of residual efficacy up to 6 weeks.** However, it should be clarified on the label that the residual effect will depend on the surface and reduced residual efficacy can be expected on for instance PVC.
Deltamethrin EW 0.15	*Blattella germanica*	Sprayed to create a barrier. Percentage mortality after 30	Laboratory	Good control by 30 minutes exposure (≥80%),	Gutsmann, V. (2012a)	An arena, a laminated card board box, containing a raised harbourage was used for this study. The food source was placed

		min, 1h, 2h, 4h and 24h. Residual efficacy tested at 6 and 10 weeks.		100%mortality by 1-2 hours post exposure. Good residual efficacy at 10 weeks post application	M-444120-02-1 B5-10-2/02	at the opposite end of the arena to the harbourage and the product sprayed in a 10cm wide strip between them, ensuring that the cockroaches (20 male adults) had to cross it to gain access to the food. The product was applied with 1-2 pump actions, corresponding to 3.125-6.25mg/m^2. The effect on the population was assessed after regular intervals (30 min, 1h, 2h, 4h and 24h). Further tests were conducted with new insects at six and ten weeks after intitial treatment. 100% mortality was achieved in 1-2 hours post application. The residual efficacy remained for at least 10 weeks. All controls revealed no mortality. According to the relevant guidance, simulated use studies should be designed to give insects a choice to be in contact with the treated surface, that is, the food should not have been placed on the opposite side. This means that this study can not be regarded as a simulated use study. However the results show a very high efficacy of the product, and the **Ref-MS accepts the overall quality of the study and consider it as laboratory efficacy data in support of the claim for fast kill at direct application of crawling insects within 1 hour, for control of german cockroach and for the claim that treated undisturbed surfaces will prevent reinvasion.** However the residual

						efficacy will depend on the surface and this needs to be clarified on the label.
Deltamethrin EW 0.15	*Blattella germanica* *Lepisma saccharina* *Porcellio scaber*	Sprayed directly into harbourages. Percentage mortality after 30 min, 1h, 2h, 4h and 24h. Residual efficacy tested at 6 weeks post application on re-introduced organisms.	Laboratory /simulated-use	93-100% mortality after 30 minutes. 100% mortality in 1 hour post application for all three test populations. 6 weeks residual efficacy against re-introduced organisms.	Gutsmann, V. (2012b) M-444121-02-1 B5-10-2/03	An arena, a laminated card board box, containing a raised harbourage (compressed peat) was used for this study. A food and drinking source (in the form of a wet sponge) was placed on top of the harbourage. The test population was allowed to settle for 24 to 48 hours. At this stage, as a simulation of a consumer treatment, the harbourage was lifted and sprayed with one to two pump actions per harbourage were applied (corresponding to 3.125-6.25mg/m^2). The harbourage was then closed again. The effect on the population was assessed after regular intervals (30 min, 1h, 2h, 4h and 24h). After 30 min, 100% mortality was achieved for *B.germanica* and *L.saccharina* and 93% for *P.scaber*. 100% mortality was achieved after 1 h for all species. **The Ref-MS accepts this part of the study as a laboratory study to support mortality of the tested organisms at the recommended dose.** Further tests were conducted with new insects at six and ten weeks after intitial treatment (both food and insects were introduced on top of the peat). This part of the trial assessed the period in which 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. 100% mortality was achieved in 1 hours post application for all three organism types tested. The residual efficacy remained for at least 6 weeks. All controls revealed no mortality. **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 claim of fast kill at direct application of crawling insects and wood louse within 1 hour and for control of german cockroach, silverfish and wood louse with residual effect up to 6 weeks.** However the residual efficacy will depend on the surface and this needs to be clarified on the label.
Deltamethrin EW 0.15	*Lasius niger*, *Musca domestica*, *Blattella germanica*, *Blatta orientalis* *Lepisma saccharina*,	Organisms directly sprayed with 0.5ml of product. Percentage mortality after 30 min, 1h, 2h, 4h and 24h.	Laboratory	100% mortality by 30 minutes for *Lasius niger, Musca domestica, Blattella germanica*, and *Blatta orientalis*. 100% mortality for *Porcellio scaber* by 1 hour post treatment and *Lepisma saccharina* by 2 hours post treatment.	Nentwig, G. (2012a) M-444122-02-1 B5-10-2/04	Ten organisms (cockroaches: five) were introduced into a glass ring (10 cm diameter, 5 cm high) on filter paper, inner walls treated with talcum. The product was applied with a funnel glass nozzle for better reproducibility. A quantity of 0.5 ml product (corresponding to 7.5 mg/m^2) was introduced into the funnel and sprayed onto the organisms in the glass ring. Knock down was evaluated after 30', 1h, 2h and 4h mortality after 24 h. Each test consisted of three replicates of which the

	Porcellio scaber					mean values were calculated. The product was fast acting with 100% mortality by 30 minutes post treatment for *Lasius niger, Blattella germanica*, and *Blatta orientalis* and by 2 hours for *Lepisma saccharina* and *Porcellio scaber.* **The Ref-MS accepts this study for supporting the claim of fast kill at direct application of crawling insects within 1 hour and wood louse within 2 hours.**
Deltamethrin EW 0.15	Webbing spiders Order *Araneae*	Organisms and surrounding location sprayed directly with 30ml product ($0.6m^2$). Area monitored on , 3, 8, 16, 24, 26 and 32 days post treatment.	Field	Spray treatment of Deltamethrin EW 0.15 resulted in fast knockdown. No spiders were evident 1 day post treatment. No spider webs were detected in the treated area by 32 days post treatment.	Gutsmann, V. (2012c)M-442353-01-1 B5-10-2/05	A wooden carport showing a heavy infestation of webbing spiders was used for this trial. At the start of the trial, all webbing on both sides of the carport was removed with a broom. The North-east facing side of the carport was sprayed with Deltamethrin EW 0.15. About 30 trigger strokes, delivering 30 ml of product was used on an area approximating $0.6m^2$. This corresponded to a dose rate of 7.5 mg Deltamethrin/m^2. The South-west facing side of the carport was left untreated and served as negative control. Re-build of webbing, indicating presence of live spiders, was recorded on days 1, 3, 8, 16, 24, 26 and 32 days post treatment. No spiders were evident 1 day post treatment. No spider webs were detected in the treated area by 32 days post treatment. On the un-treated side, several newly built webs were visable already after three days.

						In the Ref-MS opinion this study is not enough to support a label claim of controlling spiders. A major shortcoming of the study is the lack of monitoring of the number of spiders living at the carport before treatment (to have an idea of the base level of infestation). In addition, the test does not conclude on mortality but only on re-infestation into the treated area. Laboratory studies and/or simulated use studies should also have been submitted supporting the mortality of the product on spiders. The applicant has been given the opportunity to comment on this, please see the Ref-MS commenting box above table.
Deltamethrin EW 0.15	Oriental cockroach (Blatta orientalis)	1-2 pump strokes sprayed directly into harbourages. Percentage mortality after 30 min, 1h, 2h, and 24h.	Simulated-use study	Direct treatment with Deltamethrin EW 0.15, delivered by 1-2 pump strokes of product directly into harbourages led to 100% knockdown within 30 min.	Gutsmann, V. (2017a) M-585699-01-1	A laminated card board box was equipped with plastic rings, a food and drinking source. A rectangular piece of compressed peat was placed onto the plastic rings to give more space for the relatively large cockroach species. The insects were allowed to settle for 24 hours. At this stage, as simulation of a consumer treatment, 1-2 pump strokes of product were directed under the harbourage where all insects congregated. The effect on the population was assessed after regular intervals (30 min, 1h, 2h, and 24h). **The Ref-MS accepts this study for supporting the claim of fast kill of *Blatta orientalis* after direct spray treatment within 1 hour.**

Deltamethrin EW 0.15	Blattella germanica, Periplaneta americana, Lepisma saccharina, Porcellio scaber and Lasius niger	0.5ml of undiluted RTU Deltamethrin EW 0.15 was sprayed with a glass nozzle from a height of 15 cm to cover a radial area of 100 cm^2. This corresponds to a loading of 7.5 mg Deltamethrin /m^2. Before spraying, a glass ring was positioned in the center of the sprayed area. Insects were introduced to the glass ring. Then spray was applied. Insects were set aside for observation. Knock down is recorded after 0.5h, 1h, and 2h. Mortality is confirmed after 24h. For P. scaber, L.niger and L. saccharina, 20 insects were used and three replicates were conducted. For B. germanica and P. americana, 10	Laboratory	Blattella germanica, Periplaneta americana, L. saccharina and Lasius niger are reliably killed within 30 min. Knockdown of Porcellio scaber reaches 58% after 30 minutes, 98% after 1h and 100% after 2h. No recovery was observed at 24h.	Gutsmann, V. (2017b) M-585752-01-1	0.5ml of undiluted RTU Deltamethrin EW 0.15 was sprayed with a glass nozzle from a height of 15 cm to cover a radial area of 100 cm^2. This corresponds to a loading of 7.5 mg Deltamethrin /m^2. Before spraying, a glass ring was positioned in the center of the sprayed area. Insects were introduced to the glass ring. Then spray was applied. Insects were set aside for observation. Knock down is recorded after 0.5h, 1h, and 2h. Mortality is confirmed after 24h. 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. **The Ref-MS accepts this laboratory study to support mortality of the tested organisms at the recommended dose.**

		insects were used in 6 replicates.				
Deltamethrin EW 0.15	Oriental cockroach (Blatta orientalis)	1-2 pump strokes sprayed directly into harbourages. Percentage mortality after 30 min, 1h, 2h, and 24h. Residual efficacy tested at 6 weeks post application on re-introduced organisms. Procentage mortality measured after 30 min, 1h, 2h, 4h and 24h.	Simulated-use study	Direct treatment with Deltamethrin EW 0.15, delivered by 1-2 pump strokes of product directly into harbourages led to 100% knockdown within 30 min. Residual activity tested after 6 weeks led to 67 % mortality after 30 min, and 100% knockdown within 1h.	Gutsmann, V. (2017c) M-585699-02-1	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 insects and other arthropods 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:	Efficacy of products in the family Deltamethrin EW 0.15 RTU 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 and the risk of spread of the pest rather than kill 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 Spray. 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 strategy, in acordance with the TNsG for PT 18/19, is to avoid resistance as cockroaches are very difficult to control and as it can not be expected that non-professionals have enough knowledge of the resistance problem.

2.7 EXPOSURE ASSESSMENT

2.7.1 Description of the intended use(s)

MG/PT	Field of uses envisaged	Likely concentrations at which a.s. will be used
MG 03 PT18	Public Health (Hygiene) Deltamethrin EW 0.15 is intended for use in and around buildings (Around houses treated area must be protected from rain) for direct kill of insects or control of crawling insects and other arthropods in small confined locations.	Direct Spray Use one trigger action from a distance of 30 cm to kill a broad spectrum of insects Control of crawling insects in confined locations: For control of crawling insects in small confined locations, apply product into areas where insect hide and walk (crack and crevices, behind boards, under fridges, around window frames etc.). Do not apply onto areas larger than 2 m^2. Max dose rate: 5 mL Deltamethrin EW 0.15 per 32 x 32 cm (5 pump stokes)

Ref-MS Information to the reader:	Please see also section 1.5.2.1 and 1.5.2.2 for description of the usage.

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 pets and domestic animals are exposed to deltamethrin during or after non-professional use of this 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 should be extended to 'Exclude animals and children during application and prevent access to treated areas until dry.'

	The possible exposure and risk of consumers due to residues in food through the non-professional use of the products has neither been assessed. Therefore, the following risk mitigation measures should be applied: "The product should be applied so that children, pets, food or feedstuffs do not come in contact with the product", "Do not apply directly to surfaces on which food or feed is stored, prepared or eaten".

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	Not 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 EW 0.15, a ready-to-use spray, is intended for use by consumers only.

2.7.2.3 Non-professional exposure

The product is intended for the amateur user.

Deltamethrin EW 0.15 is an insecticide which used for the control of ants and other crawling insects in a residential environment. The product is formulated as a ready-to-use solution packaged in bottles equipped with a hand triggered pump sprayer and contains the active substance (a.s.) deltamethrin (0.15g/L). The highest recommended application rate is 5 mL Deltamethrin EW per 32x32cm applied via spot type application to surfaces with high transit of the insects or to areas where insects hide. The product will be only used by amateurs.

The product will be only used by amateurs.

<u>Consideration on dermal absorption</u>

Deltamethrin EW 0.15 was not one of the representative formulations submitted for EU review according to the biocide directive 98/8/EC. However, for the representative formulations submitted for EU review, i.e. K-Othrine WG 250, K-Othrine SC 7.5, K-Othrine SC 26.25 and K-Othrine DP 0.5 a value of 2% dermal absorption was considered appropriate for the concentrate as well as for the in use dilution of the respective product[1]. The value was established based on data generated using an organic solvent based

formulation, i.e. deltamethrin formulated as Deltamethrin EC 25. Hence, the 2% value is considered as well adequate conservative for Deltamethrin EW 0.15 and therefore will be considered in this evaluation.

Ref-MS information to the reader:	No study has been conducted on products in the family Deltamethrin EW 0.15 RTU. However, Ref-MS agrees with the conclusion of the Applicant that the data generated for the value of 2%, using an organic solvent based formulation, is considered to be adequately conservative for products in the family Deltamethrin EW 0.15 RTU.

Consideration on estimation of primary- and secondary exposure

Deltamethrin EW 0.15 was not one of the representative formulations submitted for EU review according to the biocide directive 98/8/EC. The product is formulated as a read-to-use solution packaged in bottles equipped with a hand triggered pump sprayer. For primary exposure the direct spraying (spot treatment or crack and crevice application) is considered to be the worse case situation. Corresponding exposure calculations are performed using the Consumer exposure model (ConsExpo, Version 4.1) as proposed in the technical notes for guidance (TNsG, 2007)[1].

For secondary exposure it is concluded that re-entry of a toddler into a treated room represents a worse case and therefore will be assessed. Corresponding exposure estimated are performed following the approach proposed in the CAR for K-Othrine WG 250: "*Document II B1 Effects and Exposure Assessment for K-OTHRINE* WG *250 of the non public CAR, final June 2011*".

Persons may be exposed to Deltamethrin EW 0.15 via primary-, secondary- and/or combined routes of exposure. Accordingly, the corresponding exposure scenarios were assessed.

Primary exposure – application phase

As previously outlined, Deltamethrin EW 0.15 was not one of the representative formulations submitted for EU review according to the biocide directive 98/8/EC. The product is formulated as a ready-to-use solution packaged in bottles equipped with a hand triggered pump sprayer. Hence, no mixing and loading of the formulation into the application equipment is required. Furthermore, cleaning/maintenance of the application equipment can be regarded as not relevant. Accordingly, in terms of primary exposure actual spraying is considered to be a worse case situation. As proposed in the technical notes for guidance (TNsG, 2007)[2] corresponding exposure calculations are performed using the consumer exposure model (ConsExpo, Version 4.1) developed by the Netherlands National institute for Public Health and the Environment[3].

[1] Human exposure to biocidal products, Technical Notes for Guidance; June 2007. Available at: http://ihcp.jrc.ec.europa.eu/our_activities/public-health/risk_assessment_of_Biocides/guidance-documents

[2] Human exposure to biocidal products, Technical Notes for Guidance; June 2007. Available at: http://ihcp.jrc.ec.europa.eu/our_activities/public-health/risk_assessment_of_Biocides/guidance-documents

[3] Consumer Exposure model, available at: http://www rivm.nl/en/Topics/Topics/C/ConsExpo

Inhalation exposure:

The product is an emulsion with water that is directly sprayed on target pests or for control of crawling insects. During application, exposure via inhalation from aerosol particles may therefore occur. The assessment of inhalation exposure is assessed using the consumer model (ConsExpo, Version 4.1) developed by the Netherlands National institute for Public Health and the Environment[4] for the scenario pest control products sprays, targeted spot , application (trigger spray).

Dermal exposure:

The product is a ready-to-use liquid that directly sprayed on target pests or for control of crawling insects. During application, exposure via dermal exposure may occur. The assessment of dermal exposure is assessed using the consumer model (ConsExpo, Version 4.1) developed by the Netherlands National institute for Public Health and the Environment[5] for the scenario pest control products sprays, targeted spot , application (trigger spray).

The model approach selected for calculating operator exposure is presented below:

Default databases:	Pest control products
Product categories:	Sprays
Default products:	Targeted spot
Scenario:	Application (trigger spray)

Corresponding model proposed default assumptions as well as product specific data used for the calculations and the resulting exposure estimates are summarised in the following table presenting the ConsExpo 4.1 report.

Exposure calculations using ConsExpo 4.1 with the scenario pest control products, sprays, targeted spot, application (trigger spray)

ConsExpo 4.1 report

file name:

Report date: 19.06.2013

Product

Compound

Compound name :	deltamethrin	
CAS number :		
molecular weight	505.2	g/mol
vapour pressure	0.0000000124	Pascal
KOW		linear

[4] Consumer Exposure model, available at: http://www rivm.nl/en/Topics/Topics/C/ConsExpo

[5] Consumer Exposure model, available at: http://www rivm.nl/en/Topics/Topics/C/ConsExpo

General Exposure Data

exposure frequency	9	1/year
body weight	60	kilogram

Inhalation model: Exposure to spray

weight fraction compound	0.015	%
exposure duration	240	minute
room volume	20	m^3
ventilation rate	0.6	1/hr
mass generation rate	0.4	g/sec
spray duration	6	minute
airborn fraction	0.008	fraction
weight fraction non-volatile	0.015	%
density non-volatile	1.8	g/cm^3
room height	2.5	meter
inhalation cut-off diameter	15	micrometer
non-respirable uptake fraction	0.75	fraction
Spraying away from exposed person		

Uptake model: Fraction

uptake fraction	1	fraction
inhalation rate	32.9	m^3/day

Dermal model: Direct dermal contact with product : constant rate

weight fraction compound	0.015	%
exposed area	10000	cm^2
contact rate	46	mg/min
release duration	360	second

Uptake model: fraction

uptake fraction	2	%

Output

Inhalation (point estimates)

inhalation mean event concentration :	0.000891	mg/m^3
inhalation mean concentration on day of exposure:	0.000149	mg/m^3
inhalation air concentration year average :	0.00000366	mg/m^3/day
inhalation acute (internal) dose :	0.0000815	mg/kg
inhalation chronic (internal) dose :	0.00000201	mg/kg/day

Dermal : point estimates

dermal load :	0.00000414	mg/cm^2

dermal external dose :	0.00069	mg/kg
dermal acute (internal) dose :	0.0000138	mg/kg
dermal chronic (internal) dose :	0.00000034	mg/kg/day

Oral non-respirable: point estimates

oral external dose :	0.000000883	mg/kg
oral acute (internal) dose :	0.000000883	mg/kg
oral chronic (internal) dose :	0.0000000217	mg/kg/day

Integrated (point estimates)

total external dose:	0.000773	mg/kg
total acute dose (internal):	**0.0000962**	**mg/kg**
total chronic dose (internal):	0.00000237	mg/kg/day

Ref-MS information to the reader:	The scenario could not be re-created due to that ConsExpo has been updated (version 5.0). However, the exposure is found to be in the same range as shown by the applicant. Some input values (mass generation rate and airborn fraction) are from the document "New default values for the spray model." National Institute for Public Health and the Environment (RIVM), dated March 2010.

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

It might be assumed that persons (adults and/or children) are secondarily exposed to Deltamethrin EW 0.15 when re-entering area where the product has been applied.

Exposure of young children (toddlers) re-entering an area where the product has been applied and crawling over sprayed areas (with consequent hand to mouth transfer of potential residues) is considered to represent the worst case in terms of secondary exposure.

Exposure of a person (child or adult) when re-entering an area where Deltamethrin EW 0.15 has been applied.

Secondary exposure as a result of use of deltamethrin may occur via the dermal route (transfer of surface bound residues to the skin) and by inhalation (while aerosol particles settle during the acute phase of the secondary exposure). For inhalation exposure (during the period of aerosol particles settling), the exposure calculations using ConsExpo 4.1 already take into account a post application phase of about 4 hours. The corresponding exposure estimate including exposure due to spraying amounts to only 0.0000962 mg/kg bw/day (=1.2% of the AEL). Furthermore, the vapour pressure of deltamethrin is low (1.24×10^{-8} Pa; 25ºC; according to Council Directive 1999/13/EC, a substance should be considered volatile when the vapour pressure is >0.01 kPa at 20ºC). Therefore, inhalation secondary exposure can be regarded as negligible.

Secondary exposure to deltamethrin is therefore considered predominantly via the dermal route (transfer of surface bound residues to the skin). For a young child (or with the assumed body weight of 10 kg better characterized as a toddler) one might in addition consider oral exposure via hand to mouth transfer. Hence, in terms of secondary exposure it is reasonable to conclude that re-entry by a toddler represents the worst case scenario.

When assessing exposure of the re-entering toddler it has to be noted that the spray is applied to surfaces only with high transit of insects or where insects hide. Thus a spot type application can be considered. The exposure calculations are performed for Deltamethrin EW 0.15 following the approach as outlined in the CAR for K-Othrine WG 250 (spot type application).

The assumptions/considerations for calculating secondary exposure of a toddler to Deltamethrin EW 0.15 are summarised in the following table.

Assumptions to calculate secondary exposure

Scenario:	**Secondary exposure to a toddler after spot type application indoors.**
Maximum application rate:	50 mL Deltamethrin EW 0.15/m^2 (7.5mg a.s./m^2)
Area treated: - **Spot type application (usual case):**	10% of the area the toddler plays on during the relevant exposure period
Surface residues (SR): - Spot type application:	0.000075 mg a.s./cm^2 (= 7.5 mg/m^2/10)*
Surface Transferable Residues (TR): Hard surfaces:	10% of the residues present on the surface**
Transfer Coefficient (TC):	6000 cm^2 per day
Dermal absorption:	2%
Inhalation absorption:	100%
Oral absorption:	75%
Body weight of the toddler:	10 kg

***** To be consistent with the proposed transfer coefficient, in a conservative approach it is assumed that "virtually" the residues present in the spots are distributed to the whole surface the toddler can play on.

****** For deltamethrin a study has been conducted to determine the amount of surface transferable residues when being applied to carpets: "Determination of Dislodgeable Residues of Deltamethrin following a Broadcast Application of Suspend SC Speciality Insecticide, Maxey S.W., Murphey P.G., and Berbrick D.H.; February, 1996". Based on this study the CAR considered a value of 2.5% dislodgeability appropriate for deltamethrin residues present on carpets. A value of 10% dislodgeability was used in the CAR to assess transfer from hard surfaces. The 10% value was used in the CAR regarding the spot type application.

Corresponding exposure calculations are presented in the following table.

Estimated systemic secondary exposure when re-entering an area where Deltamethrin EW 0.15 has been applied.

	Toddler
Dermal exposure (D) of the toddler is calculated as follows: **D = SR x TR x TC**	
Surface Residue (SR) (mg a.s./cm²):	0.000075
Surface Transferable Residue (TR):	0.1
Transfer Coefficient (TC) (cm²/day):	6000
Dermal exposure (D) (mg a.s./toddler/day):	**0.045**
Taking into account the dermal absorption of 2 % systemic exposure by the dermal route (S_{dermal}) is calculated as follows: **S_{dermal} = D x Dermal absorption ÷ Body weight**	
D (mg a.s./toddler/day):	0.045
Dermal absorption:	0.02
Body weight (kg bw):	10
S_{dermal} (mg a.s./kg bw/day):	**0.000090**
For the toddler one might in addition consider oral exposure via hand to mouth transfer. The TNsG propose to assume in a tier 1 approach that essentially 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 (= 20% of dermal exposure ends up on the hands and subsequent oral exposure by hand to mouth transfer amounts to 50% of hand exposure). Considering furthermore oral absorption of 75% the systemic exposure by the oral route (S_{oral}) is calculated as follows: **S_{oral} = D x Fraction on hands x Hand to mouth transfer x Oral absorption ÷ Body weight**	

D (mg a.s./toddler/day):	0.045
Fraction of D on hands:	0.2
Hand to mouth transfer:	0.5
Oral absorption:	0.75
Body weight (kg bw):	10
S_{oral}(mg a.s./kg bw/day):	**0.000338**
Total systemic exposure (S_{total}) by the dermal route and hand to mouth transfer is calculated as follows: $$S_{total} = S_{dermal} + S_{oral}$$	
S_{dermal} (mg a.s./kg bw/day:)	0.000090
S_{oral} (mg a.s./kg bw/day):	0.000338
S_{total} (mg a.s./kg bw/day):	**0.000428**

Combined exposure

The CAR prepared for deltamethrin by the competent authority considers the possibility of combined exposure (i.e. the professional user of the product might be exposed via secondary routes of exposure when re-entering a treated area). With respect to the amateur-use products, combined exposure was not assessed in the CAR indicating that at least for this type of product and intended use (spray formulation applied to crawling insect nests or hiding places) combined exposure is not relevant.

For Deltamethrin EW 0.15 it can be concluded that the consumer/non-professional user of the product is aware of the surfaces being treated and accordingly would avoid contact with those surfaces. Thus incidental/accidental contact can be considered negligible in terms of combined exposure.

2.7.3 Environmental exposure assessment

2.7.3.1 Fate and distribution in the environment

Deltamethrin EW 0.15 is a ready to use emulsion of deltamethrin in water which contains the active substance deltamethrin at a concentration of 0.15 g/L. Deltamethrin EW 0.15 is used for the control of insects in and around buildings. The product may be used to directly kill insects or to control crawling insects and other arthropods (e.g. black ant and other commonly found garden ants, spider, German cockroaches, silverfish, wood louse or pill bug) in small confined locations (e.g. underneath flowerpots, floor boards, garden appliances, etc…).

The product is applied by trigger spray at a maximum concentration of 5 mL of product per 32x32cm. The spray is not applied to areas larger than $2m^2$. Deltamethrin is a contact poison that is picked up by the insects via direct spray contact or contact with treated surfaces. Undisturbed residual spray will prevent re-infestation of indoor or protected confined locations for a minimum of six weeks.

The environmental exposure assessment has been performed in accordance with the Emission Scenario Document for Insecticides, acaricides and products to control arthropods (PT18) for household and professional use (OECD, 2008) and was based on information relating to the use patterns of Deltamethrin EW 0.15.

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 EW 0.15 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 EW 0.15 product life cycle.

Deltamethrin EW 0.15 is packaged in ready-to-use spray bottles containing the active substance as an emulsion in water. Hence, 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).

In accordance with the PT18 ESD (dated 17th July 2008), possible receiving compartments include the STP, surface waters and sediments, soils, and to a lesser extent to air.

The co-formulants in the product are not expected to influence the environmental fate and behaviour of deltamethrin, and as such it is considered that no additional information on the fate and behaviour of the product is necessary.

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), where K -Othrine SC 7.5 is a representative product.

1.1.1.1.1 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.

1.1.1.1.2 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.

1.1.1.1.3 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.

1.1.1.1.4 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:	As several risk management measures is added to prevent the product from entering the sewage water system, no exposure calculations from the urban environment are included. Please note that according to the efficacy evaluation in section 2.6.1 the residual life was assessed to up to 6 weeks, instead of three months.

Losses of the product to the STP, and consequently to surface water may occur from indoor and outdoor (around houses, urban) uses of spray insecticides according to the PT18 ESD.

For indoor uses of Deltamethrin EW 0.15, it is assumed that losses to the STP will occur due to cleaning of treated surfaces. As the product is intended for consumer uses in and around households, larger industrial buildings are not considered for this risk assessment. It is considered that the product will only be used for crack and crevice treatments through spot application.

For the purposes of this assessment a worst-case scenario is assumed in which 100% of the surfaces that the product is applied to are washable. The cleaning efficiency ($F_{cleaning\ efficiency} = F_{CE}$) for crack and crevice treatment was considered to be the ESD default factor of 0.25. As the label states that no more than $2m^2$ should be supplied at a single site, it is considered that the area treated will not exceed this per house.

In calculating the PEC_{STP} the simultaneity factor for indoor treatments was calculated to be 0.81%. This value was obtained using the approach presented on p. 39 of the ESD No 18, but considering the frequencies of use which are relevant for the uses of deltamethrin products which exhibit sustained residual activity where residues remain undisturbed, up to three months. It is considered that the product will be used at most three to eleven times per year. Based on the use frequency tables in the PT18 ESD, the simultaneity factor was calculated as follows:

$$Indoor\ simultaneity\ factor\ = \frac{(32.15\ \times 1.9) + \ (37.82 \times 0.54)}{100} = 0.81\%$$

The PEC_{STP} has been calculated as follows:

$PEC_{STP} = Clocal_{eff} = Clocal_{inf}$ x $Fstp_{water}$

where:

$Fstp_{water}$ = fraction of emission directed to water by STP = 0.096

The fraction of the emission directed to water by the STP was derived from the SimpleTreat Model (Struijs *et al.*, 2003) as was presented in the CAR for another Deltamethrin product, Deltamethrin SC 26.25 (named K-Othrine SC 26.25 in the CAR published June 2011). As neither of the formulations are expected to effect the fate and behaviour of deltamethrin in the STP, it is considered appropriate to use this $Fstp_{water}$ value for the risk assessment for Deltamethrin EW 0.15. The distribution of deltamethrin in the STP, as determined by SimpleTreat 3.1 using the average Koc for deltamethrin of 408250 L/kg, is presented in the table below.

Table 2.7.3.2-1. Distribution of deltamethrin within the STP as calculated in SimpleTreat 3.1

Fate	**% of residue**
To air	0.0
To water	9.6
To sludge	90.4
Degraded	0.0
Total	100.0

The amount of deltamethrin available for emission from a single household was based on the maximum application rate stated on the label for the product. Deltamethrin EW 0.15 will be applied at a maximum rate of 5mL per 32x32 cm (equivalent 50mL/$m^{2)}$ and the maximum area that shall be treated is $2m^2$. The concentration of deltamethrin in the product is 0.15 g/L. As a worst case it is assumed that all of the product applied will be available for cleaning. As such, the amount of deltamethrin available for emission to the STP per site is calculated as:

$E_{app,\ treated\ surface}$ = 0.05 x 0.15 x 2 = 0.015 g

In order to calculate the emission from treated surfaces the appropriate cleaning efficiencies for crack and crevice treatment as outlined in the PT18 ESD was applied. Hence, the amount of deltamethrin emitted from a single household from crack and crevice treatments was calculated as follows:

Crack and crevice treatment $E_{treated,\ ww}$ = 0.015 x 0.25 = 0.00375 g/d

From this the local emission rates to water during emission episodes ($Elocal_{water}$) were calculated as:

$Elocal_{water}$ = N x s x A

Where:

N = Number of houses in STP catchment = 4000 (from ESD)

s = simultaneity factor = 0.81%

A = amount of active sent to STP from cleaning

Therefore the local emission rate from crack and crevice cleaning is:

$Elocal_{water}$ = 4000 x 0.0081 x 0.00375 = 0.1215 g/d

Considering the default STP volume the concentration in untreated wastewater ($Clocal_{inf}$) was calculated as:

$Clocal_{inf}$ = ($Elocal_{water}$ x 10^3)/$Effluent_{STP}$

Where:

$Effluent_{STP}$ = 2000000 l/d (default, TGD)

Using the appropriate values the concentration in wastewater resulting from crack and crevice treatments is:

$Clocal_{inf}$ = (0.1215 x10^{3})/2000000 = 6.075 x10^{-5} mg/L

In order to calculate the concentration in effluent ($Clocal_{eff}$) the fraction of emission directed to surface water by the STP ($Fstp_{water}$) was considered:

$Clocal_{eff}$ = $Clocal_{inf}$ x $Fstp_{water}$

Thus, resulting concentration is:

$Clocal_{eff}$ = 6.075 x10^{-5} x 0.096 = 5.83 x10^{-6} mg/L

The $Clocal_{eff}$ is equal to the PEC_{STP}. The PEC_{STP} values are presented below in the table below.

The PEC_{STP} (=$Clocal_{eff}$) of deltamethrin following household use

Facility and type of treatment	**PEC_{STP} (mg/L)**
Domestic house, crack and crevice	5.83 x10^{-6}

Due to the pattern of use of Deltamethrin EW 0.15 it is considered unlikely that there will be any direct emission to surface waters from indoor use of this product. Exposure to water will only occur via the STP. Consequently, the local concentration in surface waters arising from indirect emission through the STP has been calculated to further take into account the dilution and removal to suspended sediments (TGD, page 76, equation 45).

$$Clocal_{water} = \frac{Clocal_{eff}}{(1 + Kp_{susp} \times SUSP_{water} \times 10^{-6}) \times DILUTION}$$

Where:

$Clocal_{water}$ = $PEC_{surface\ water}$ = local concentration in surface water during emission episode (mg/l)

$Clocal_{eff}$ = concentration of substance in the STP effluent (mg/L) = PEC_{STP}

Kp_{susp} = solids-water partitioning coefficient of suspended matter = Foc_{susp} x Koc = 40825 L/kg

$SUSP_{water}$ = concentration of suspended matter in the river (default: 15 mg/l)

DILUTION = dilution factor (default: 10)

Based on this, the $PEC_{surface\ water}$ from crack and crevice uses is:

$PEC_{surface\ water} = 5.83 \times 10^{-6} \div [(1 + 40825 \times 15 \times 10^{-6}) \times 10] = 3.61 \times 10^{-7}$ mg/L

THE $PEC_{surface\ water}$ are summarised below in the table below.

The $PEC_{surface\ water}$ of deltamethrin following household use

Facility and type of treatment	**$PEC_{surface\ water}$ (mg/L)**
Domestic house, crack and crevice	3.61×10^{-7}

The degradation of the deltamethrin residue may result in the formation of a quantity of the major metabolite Br_2CA. Data are not available concerning the formation of Br_2CA in treated areas or in the STP. Therefore, the concentration of Br_2CA in surface water has been estimated assuming that the quantity of metabolite formed is equivalent to 100% of the parent, adjusted to consider the molecular weights of the compounds. Deltamethrin has a molecular mass of 505.2 $g.mol^{-1}$, whilst the metabolite Br_2CA has a molecular mass of 298 $g.mol^{-1}$ Hence, the $PEC_{surface\ water}$(*) of the parent was adjusted by a factor of 0.59 (i.e. 298.0/505.2) in order to estimate the $PEC_{surface\ water}$ for Br_2CA.

Ref-MS information to the reader:	* Below, the $PEC_{surface\ water}$ for Br_2CA has been calculated from the Clocaleff for deltamethrin (5.83E-6). The text above states that the PECsurface water for deltamethrin was used, it should state Clocaleff.

Therefore the $PEC_{surface\ water}$ for Br_2CA resulting from crack and crevice treatment is:

$PEC_{surface\ water} = (5.83 \times 10^{-6} \times 0.59) \div 10 = 3.43 \times 10^{-7}$ mg/L

The $PEC_{surface\ water}$ values for Br_2CA are summarised below in the table below.

The $PEC_{surface\ water}$ of Br_2CA following household use

Facility and type of treatment	**$PEC_{surface\ water}$ (mg/L)**
Domestic house, crack and crevice	3.43×10^{-7}

PECs in sediment were calculated from the $PEC_{surface\ water}$ values using the equilibrium partitioning method in accordance with the TGD (EC, 2003). The equation used was:

$$PECsed = \frac{K_{susp-water}}{RHO_{susp}} \times PECsw \times 1000$$

Where:

RHO_{susp} = 1150

$K_{susp\text{-}water} = F_{water} + [F_{solid} \text{ x } (Kp_{susp} /1000) \text{ x } RHO_{solid}]$ = 10207.15

where:

F_{water} = 0.9

F_{solid} = 0.1

Kp_{susp} = 40825 L/kg

RHO_{solid} = 2500 kg/m^3

The $PEC_{sediment}$ values for deltamethrin were calculated using this equation and are presented in the table below.

The $PEC_{sediment}$ for deltamethrin following household use

Facility and type of treatment	**$PEC_{sediment}$ (mg/kg ww)**
Domestic house, crack and crevice	3.2 x10^{-3}

The $PEC_{sediment}$ for the metabolite Br_2CA has also been calculated using this method. However, a $K_{susp\text{-}water}$ value of 1.54 has been calculated for Br_2CA. The $PEC_{sediment}$ values for Br_2CA are presented below in the table below.

The $PEC_{sediment}$ for Br_2CA following household use

Facility and type of treatment	**$PEC_{sediment}$ (mg/kg ww)**
Domestic house, crack and crevice	4.59 x10^{-7}

Concentration in Groundwater

Ref-MS Information to the reader:	To clarify for the reader, information about PEC soils is important for understanding the PECgw calculations and can be found in section 2.7.3.4 below.

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 ($m^3.m^{-3}$)

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

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)

Ref-MS Information to the reader:	**Fair ***Fwater In the table above the abbrevations (in the second column "Symbol") F_{air} and F_{water} is incorrectly labeled F_{water} and F_{solid}, respectively. For clarification the Kair – water below is calculated to 5.28E-06.

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

Ref-MS Information to the reader:	The PEClocalsoil used are CsludgeSoil, Local and agricultural soil: 2.28E-4 and grassland: 9.1E-5. These values are presented in table Table 2.7.3.4-2, and the caluclations are available in section 2.7.3.4.

Deltamethrin and the metabolite Br_2CA exposure in soil may occur by direct means or indirect means. The product may be applied directly to soil, or exposure may occur when deltamethrin is washed down the drain to the STP and the sludge from the STP is spread to soil. For the sake of completeness the concentrations in groundwater were calculated for all possible scenarios and are presented in the tables below.

Table 2.7.3.2-2. Concentrations of deltamethrin in groundwater resulting from use of Deltamethrin EW 0.15 for crack and crevice treatment

Substance	Soil type	Concentration in groundwater (mg/L)
	Local soil	3.1×10^{-8}
	Agricultural soil	$3.1x\ 10^{-8}$
	Grassland soil	1.2×10^{-8}

Table 2.7.3.2-3. Predicted concentrations of deltamethrin in groundwater associated with the direct application of Deltamethrin EW 0.15 to soil

Substance	Soil mixing depth (m)	Predicted concentration in porewater (based on 30-day time-weighted average conc. in soil) ($mg.L^{-1}$)
	0.1	$4.97\ x10^{-6}$
	0.2	$2.48\ x10^{-6}$
	0.5	$9.93\ x10^{-7}$

Ref-MS Information to the reader:	Clarification regarding factors used for the calculation of Br_2CA in groundwater: The same calculations and factors as for delthametrin has been used (please see the table on page 58). The only exceptions to the table are: • Henry's Law constant for the metabolite Br_2CA is 4.04E-2 [Pa.m3.mol-1] according to the CAR for deltamethrin. The applicant has written 4.04E-3 in their porewater calculation below, but as this factor only has a very minor effect on the calculations it does not affect the reported PECvalue. Additionally, as the applicant has provided FOCUS-pearl simulation results for Br_2CA that are well below the regulatory limit of 0.1µg/l this has no impact on the conclusion of the risk assessment. • Koc for the metabolite Br_2CA is 25.6 The groundwater PEC (mg/L) for Br_2CA is based on the Csludgesoil: agricultural and local soil: 1.34E-4, and Grassland 5.37E-05

In order to assess the leaching potential of the major metabolite Br_2CA, first-tier pore water calculations have been carried out for all relevant scenarios.

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 the tables below. 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 2.7.3.2-4. Concentrations of Br_2CA in groundwater resulting from use of Deltamethrin EW 0.15 for crack and crevice treatment

Substance	Soil type	Concentration in groundwater (mg/L)
	Local soil	2.35×10^{-4}
	Agricultural soil	2.35×10^{-4}
	Grassland soil	9.43×10^{-5}

Table 2.7.3.2-5. Predicted concentrations of Br_2CA in groundwater associated with the direct application of Deltamethrin EW 0.15 to soil

Substance	Soil mixing depth (m)	Predicted concentration in porewater (based on 30-day time-weighted average conc. in soil) ($mg.L^{-1}$)
	0.1	0.0119
	0.2	5.98×10^{-3}
	0.5	2.40×10^{-3}

The results of the porewater calculation for the metabolite Br2CA exceed the 0.1 $\mu g.L^{-1}$ regulatory threshold for the direct application to soil scenario. 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 4.4.4. 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. [redacted]

[redacted] 5.245 g/ha

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 5.5 g a.i. ha^{-1} (total: 16.5 g a.i. ha^{-1}). For Br_2CA as a worst case calculations were carried out as if this amount had been applied directly to soil. Since these total application rates are higher than the maximum rate calculated for outdoor applications of Deltamethrin EW 0.15, 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 $\mu g.L^{-1}$ in all scenarios. See table below.

Table 2.7.3.2-6. 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

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

Exposure of soil from use of Deltamethrin EW 0.15 may occur by direct and indirect means. No direct emissions to soil are expected from indoor use of the product; however, as there is emission to the STP soil may be exposed through spreading of sludge.

For outdoor uses of the product may be applied directly to soil, and as such a separate risk assessment has been conducted to cover direct exposure.

Concentrations in soil resulting from direct and indirect emissions are considered separately as there will be no overlap between these emission pathways. Sludge from the STP will only be spread to agricultural and grassland soils and consequently indirect emissions of deltamethrin will only occur for these soils. Direct emissions will only occur in soils surrounding households as this is the specified use for the product. Household soils will not have sludge spread upon them. Therefore no soils will be exposed to both direct and indirect emissions.

Exposure of agricultural and grassland soils via sewage sludge

Ref-MS Information to the reader:	According to the TGD $Elocal_{water}$ needs to expressed in kg/day for the C_{sludge} calculation to be correct. It should be noted that $Elocal_{water}$ is calculated in g/day in section 2.8.3.2 above.

As a significant proportion of deltamethrin entering the STP is expected to partition to sludge, consideration has been given to the potential exposure of agricultural and grassland soils via the spreading of sewage sludge on land. The estimates presented here have been calculated in accordance with the TGD (EC, 2003).

The concentration in sewage sludge was calculated based on the emission rate to water (see section 2.8.3.2), the fraction of deltamethrin sorbed to sludge, and the rate of sewage sludge production. The equation used was as follows:

$$C_{sludge} = \frac{Fstp_{sludge} \times Elocal_{water} \times 10^6}{SLUDGERATE}$$

Where:

$Elocal_{water}$ = local emission rate during episodes

$Fstp_{sludge}$ =fraction of emission directed to sludge by the STP = 0.904 (calculated by SimpleTreat 3.1)

Sludgerate = (2/3 x 0.45 x 2000) + (0.011 x 10000) = 710 kg/d (calculated according to TGD based on default values)

Ref-MS Information to the reader:	The calculated value of concentration in sludge, Csludge, is 0.1547.

The initial concentration in soil after one year was calculated as follows:

$$Csludge_{soil1}(0) = \frac{C_{sludge} \times APPL_{sludge}}{DEPTH_{soil} \times RHO_{soil}}$$

Where:

C_{sludge} = concentration in sludge

$APPL_{sludge}$ = application rate of sludge = variable (see table below)

$DEPTH_{soil}$ = depth of soil considered = variable (see table below)

RHO_{soil} = 1700 kg/m^3

It is suggested in the TGD that PECs be generated for three different soils. Hence, PECs have been derived for local soils, agricultural soils, and grassland soils. The sludge application rates and mixing depth in these soils varies. The default values for these parameters are summarised below in Table 2.7.3.4-1.

Table 2.7.3.4-1. Default values for calculation of soil concentrations via sludge spreading

Soil	Depth of soil (m)	Averaging time (days)	$APPL_{sludge}$ (kg_{dwt} $m^2.yr^{-1}$)
Local soil	0.20	30	0.50
Agricultural soil	0.20	180	0.50
Grassland soil	0.10	180	0.10

Using these equations estimations of concentrations in soil were calculated for all three soil types for crack and crevice. Results are presented in the table below.

Table 2.7.3.4-2. Concentrations of deltamethrin in soils following one application of sludge ($Csludge_{soil}$ (0)) resulting from use of Deltamethrin EW 0.15 for crack and crevice treatment

Soil type	Concentration in soil after one application (mg/kg ww)
Local soil	2.28×10^{-4}
Agricultural soil	2.28×10^{-4}
Grassland soil	9.12×10^{-5}

The CAR another deltamethrin product, Deltamethrin SC 26.25 (named K-Othrine SC 26.25 in the CAR published June 2011), indicates that following annual applications of sludge, concentrations of deltamethrin in soil quickly reach a steady state. As the half-life of deltamethrin is relatively short the predicted maximum concentrations were not significantly different to the PIECs. As such, it is considered that the PIECs calculated for use of Deltamethrin EW 0.15 can be considered to be the maximum values that will occur in soil.

Degradation of deltamethrin in soil may lead to the formation of the major metabolite Br_2CA. As a worst-case it is assumed that Br_2CA is formed in sludge at a quantity equivalent to 100% of the parent (adjusted to consider the molecular weights of the compounds). Hence, the estimates of soil exposure presented for deltamethrin were adjusted by a factor of 0.59 (298.0/505.2) in order to estimate potential concentrations of Br_2CA.

The PEC_{soil} values for Br_2CA are presented below in the table below.

Table 2.7.3.4-3. Concentrations of Br_2CA in soils resulting from use of Deltamethrin EW 0.15 for crack and crevice treatment

Soil type	Concentration in soil (mg/kg ww)
Local soil	1.34×10^{-4}
Agricultural soil	1.34×10^{-4}
Grassland soil	5.38×10^{-5}

It should be noted that the soil PECs for Br_2CA are considered to represent a worst-case scenario, as laboratory data indicates that Br_2CA is formed at a maximum of 23% of the parent in aerobic soils after 14 days. The metabolite Br_2CA is less persistent than deltamethrin, and as such it is not considered necessary to calculate the potential for persistence between sludge applications.

Exposure of soils surrounding households via direct application

Deltamethrin EW 0.5 may be directly applied to soil in order to control crawling insects. For control of crawling insects it is likely that the product will be applied to harbourage areas to efficiently treat the infestation. The label for Deltamethrin EW 0.15 states that the product has a maximum application rate of 50 mL/m^2 and should not be applied to areas greater than 2 m^2. As such, the area treated ($AREA_{treated}$) is considered to be the worst-case value of 2 m^2, and the application rate is considered to be the worst-case value of 50 mL. Hence, the quantity of product used (Q_{prod}) is:

$$Q_{prod} = AREA_{treated} \times Dose = 2 \times 0.05 = 0.1 \text{ L}$$

As a worst case it is assumed that all of the applied product used will be emitted to soil. As the product is applied up to a maximum area of 2 m^2 it is assumed as a worst case that this occurs at a single application site. The total emission of deltamethrin to soil was derived using the following equation:

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

Where:

Variable/parameter (unit)	Symbol	Unit	Value	Source
Nesting/resting area of the target pest	$AREA_{treated}$	[m^2]	2	Input
Treatment dose	Dose	[L/m^2]	0.05	Input
Amount of product applied per harbourage	Q_{prod}	[L]	0.1	Calculated
Fraction active substance in the product	F_{AI}	[g/L]	0.15	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	$F_{spot,\ soil}$	[-]	1	Worst-case assumption
Output				

Direct emission rate of active substance to soil	$E_{spot,soil}$	[g]	0.015	Output

From this the concentration in soil is calculated using the equation:

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

Where:

Variable/parameter (unit)	Symbol	Unit	Value	Source
Local direct emission rate of active substance to soil	$E_{spot,soil}$	[g]	0.015	Input
Area directly exposed to insecticide	$AREA_{exposed}$	[m²]	2	Stated maximum area to which the product is to be applied
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

Ref-MS Information to the reader:	This issue has been resolved after the submission of the application. The applicant has chosen to calculate PEC soil for several soil depths. This issue has been resolved after the submission of the application. 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.

The predicted initial concentrations of deltamethrin in soil are presented in the table below.

Table 2.7.3.4-4. Initial predicted concentrations of deltamethrin in household soils from direct application of Deltamethrin EW 0.15

Substance	Soil mixing depth (m)	Predicted initial concentration in soil ($mg.kg^{-1}$)
	0.1	0.0441
	0.2	0.0221
	0.5	8.82×10^{-3}

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).

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

Table 2.7.3.4-5. Predicted 30-day time-weighted average concentrations in local soil associated with the application/service life stage for Deltamethrin EW 0.15, 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})
	0.1	0.0358	0.0286
	0.2	0.0179	0.0143
	0.5	7.16 $x10^{-3}$	5.73 $x10^{-3}$

As degradation of deltamethrin may result in the formation of the major metabolite Br_2CA, potential concentrations of Br_2CA in soil have been calculated assuming that the metabolite is formed in a quantity equivalent to 100% of the parent (adjusted for the molecular weights of the compounds). Hence, the estimates of soil exposure presented for deltamethrin were adjusted by a factor of 0.59 (298.0/505.2) in order to estimate potential concentrations of Br_2CA.

The PEC_{soil} values for Br_2CA are presented below.

Table 2.7.3.4-6. Initial predicted concentrations of Br_2CA in household soils from direct application of Deltamethrin EW 0.15

Substance	Soil mixing depth (m)	Predicted initial concentration in soil (mg.kg^{-1})
	0.1	0.0260
	0.2	0.0130
	0.5	5.2 $x10^{-3}$

The 30-day time-weighted average concentrations and the concentrations in soil after 30 days were calculated using the geometric mean DT50 for the Br2CA of 5.6 days taken from the three soils normalised to 12°C and PF2 (field capacity). Results are presented in the table below.

Table 2.7.3.4-7. Predicted 30-day time-weighted average concentrations of Br_2CA in local soil associated with the application/service life stage for Deltamethrin EW 0.15, 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})
	0.1	6.83×10^{-3}	6.34×10^{-4}
	0.2	3.42×10^{-3}	3.17×10^{-4}
	0.5	1.37×10^{-3}	1.27×10^{-4}

It should be noted that the soil PECs for Br_2CA are considered to represent a worst-case scenario, as laboratory data indicates that Br_2CA is formed at a maximum of 23% of the parent in aerobic soils after 14 days. The metabolite Br_2CA is less persistent than deltamethrin, and as such it is not considered necessary to calculate the potential for persistence between sludge applications.

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, non-edible & 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.

It should be noted 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. Concentrations of deltamethrin in porewater following sludge application resulting from use of Deltamethrin EW 0.15 for crack and crevice treatment

Soil type	Predicted concentration in porewater (based on initial conc. in soil) (mg/L)
Local soil	3.1×10^{-8}
Agricultural soil	3.1×10^{-8}
Grassland soil	1.2×10^{-8}

Table 2.7.3.5-2. Initial predicted concentrations of deltamethrin in porewater from direct application of Deltamethrin EW 0.15

Substance	Soil mixing depth (m)	Predicted concentration in porewater (based on initial conc. in soil) (mg/L)
	0.1	6.12×10^{-6}
	0.2	3.07×10^{-6}
	0.5	1.22×10^{-6}

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 coefficient	*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:

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

It should also be noted 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 the tables below.

Table 2.7.3.5-3. Predicted Environmental Concentrations of Deltamethrin in secondary consumers' diet (crack and crevice treatment)

Soil type	Concentration in earthworm (Cearthworm) (mg.kg wet Earthworm^{-1})	Predicted concentration in predator diet (mg.kg diet^{-1})
Local soil	3.6 x 10^{-5}	1.8 x 10^{-5}
Agricultural soil	3.6 x 10^{-5}	1.8 x 10^{-5}
Grassland soil	1.45 x 10^{-5}	7.25 x 10^{-6}

Table 2.7.3.5-4. Predicted Environmental Concentrations of Deltamethrin in secondary consumers' diet (direct soil applications, household use)

Substance	Soil mixing depth (m)	Concentration in earthworm (Cearthworm) (mg kg wet Earthworm^{-1})	Predicted concentration in predator diet (mg kg diet^{-1})
	0.1	7.14 x10^{-3}	3.57 x10^{-3}
	0.2	3.58 x10^{-3}	1.79 x10^{-3}
	0.5	1.43 x10^{-3}	7.15 x10^{-4}

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 EW 0.15. 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

Deltamethrin EW 0.15 was not one of the representative formulations submitted for EU review according to the biocide directive 98/8/EC. However, for the representative formulations submitted for EU review, i.e. K-Othrine WG 250, K-Othrine SC 7.5, K-Othrine SC 26.25 and K-Othrine DP 0.5 a value of 2% dermal absorption was considered appropriate for the concentrate as well as for the in use dilution of the respective product[1]. The value was established based on data generated using an organic solvent based formulation, i.e. deltamethrin formulated as Deltamethrin EC 25. Hence, the 2% value is considered as well adequate conservative for Deltamethrin EW 0.15.

Therefore, taking into account a dermal absorption of **2%** for the purpose of human exposure risk assessment for Deltamethrin EW 0.15 has to be regarded as a worst case approach.

Ref-MS information to the reader:	No study has been conducted on Deltamethrin EW 0.15. However, Ref-MS agrees with the conclusion of the Applicant that the data generated for the value of 2%, using an organic solvent based formulation, is considered to be adequately conservative for Deltamethrin EW 0.15.

2.8.1.2 Acute toxicity

Acute toxicity studies have been conducted with the deltamethrin-based formulation DETRANS 4150 S. Details of the comparison of the two formulations (Document M-261278-02-1) are enclosed in the confidential appendix to this document*. In order to avoid unnecessary testing on animals, the acute toxicity information on DETRANS 4150 S is included in this dossier. The classification of the Deltamethrin EW 0.15 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 EW 0.15 RTU, Ref-MS accepts the read across arguments and agrees with the conclusion that the products does not require a classification regarding acute toxicity. *Details of the two formulations are found in the confidential documents (DocIVB-Conf).

Table 2.8.1.2-1 Summary of acute toxicity data in DETRANS 4150 S

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	CEE: Journal Officiel des Communautes Europeennes, 19 septembre 1984.	OFA Sprague-Dawley rat 5M+5F Vehicle: distilled water	2000, 3000 and 5000 mg/kg bw	LD_{50}: > 5000 mg/kg bw (M&F)	Not classified	[redacted] 1990a (6.1.1/01)
Dermal	Officiel des Communautes Europeennes, 19 septembre 1984.	Albino hybrid NZ rabbit 5M+5F Vehicle: none	4000 mg/kg bw (4 mL/kg bw)	LD_{50}: >4000 mg/kg bw (M&F)	Not classified	[redacted] 1990b (6.1.2/01)
Inhalation	NA	NA	NA	NA	Waived – see comment below	

M – male; F- female

DETRANS 4150 S is of low acute toxicity. Based on these data Deltamethrin EW 0.15 is considered to be of low acute toxicity, and does not require EU classification with regard to acute toxicity. No inhalation study was conducted or considered necessary for evaluation of Detrans 4150 S. Similarly, Deltamethrin EW 0.15 is a ready-to-use product applied using hand held spray guns, the exposure by inhalation route is considered to be very unlikely and negligible compared to other possible exposure routes. Therefore an acute inhalation study was not considered to be necessary or relevant and was not conducted. Furthermore, in the improbable case of exposure via this route, no unacceptable risk is anticipated since Deltamethrin EW 0.15 is a highly diluted product.

Ref-MS information to the reader:	Ref-MS accept the arguments of the applicant not to include an acute inhalation toxicity study supported by the fact that the product is applied by trigger spray in combination with the low vapour pressure of the active substance (1.24E-08 Pa at 25°C).

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 Albino hybrid rabbit	Officiel des Communautes Europeennes, 19 septembre 1984.	1	0	Yes within 72 hours.	Not a skin irritant	[redacted] 1990c (6.2.1/01)

DETRANS 4150 is not irritating to skin of rabbits. Based on this data Deltamethrin EW 0.15 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 Albino hybrid rabbit	Officiel des Communautes Europeennes, 19 septembre 1984.	The test material applied neat by the ocular route in the male rabbit, produced slight transient irritation of the eye. 72 hours after application of the test substance, no sign of irritation persisted. 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] *L.*, 1990d (6.2.2/01)

Under the conditions of this study and based on the EU criteria for classification, DETRANS 4150 is considered not irritating to eyes. Based on this data Deltamethrin EW 0.15 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 Deltamethrin EW 0.15 to elicit a specific sensitisation response was assessed in mice using the Local Lymph Node Assay.

Species	Method	Number of animals sensitized/total number of animals	Result	Reference in Doc III
CBA/J Rj mice	OECD 429 "Skin Sensitisation: Local Lymph Node Assay"	0/12 25, 50 % w/v dilutions and neat product – SI values 1.9; 1.7 and 1.4 respectively	Not a sensitiser	[redacted] (6.3/01)

Ref-MS information to the reader:	The sensitisation test Local Lymph Node Assay was performed with Deltamethrin EW 0.15 with in-can preservative (CMIT and MIT) in a total concentration under the limit for classification of skin sensitisation (0.0015%). Thus, Ref-MS accepts the applicant´s conclusion that this product is not a sensitiser.

2.8.2 Environmental effects assessment

Ref-MS information to the reader:	A complimentary summary and evaluation of effect data with relevance to the environment can be found in Document II-A in section 4.2 of the CAR. The summaries of the studies on the ecotoxicity of the active substance and the most relevant metabolite are provided in Doc III-A, Section 7 of the CAR for deltamethrin.

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

In order to assess the risk associated with potential deltamethrin concentrations in surface waters, 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 aquatic toxicity endpoints to derive a PNEC (Predicted No Effect Concentration) endpoint for comparison with the PEC values in surface waters. The selection of an appropriate AF is dependent upon the amount of data available and the type of exposure (European Commission, 2003). The aquatic toxicity data that has been used in the assessment is summarised in the table below.

Table 2.8.2.1-1. Summary of aquatic endpoints for Deltamethrin

Study reference	Trophic level	Species	Guideline	Duration	Test material	Endpoint [µg a i. L^{-1}]
Acute endpoints						
Giddings, 1990	Algae	*Selenastrum capricornutum*	OECD 201	96 h	Deltamethrin 99.2%, static	E_rC_{50} > 9100 (measured)
Hoberg, 1992	Algae	*Chlorella vulgaris*	Brazilian method D 4.1	96 h	Deltamethrin 98.7%, static	E_rC_{50} > 470 (measured)
Putt, 2000b	Crustacean	*Gammarus fasciatus*	US EPA	96 h	Formulation 25 $g.L^{-1}$, 1 pulse (water sediment)	LC_{50} > 0.043 (nominal) 0.0047 (estimated)
Putt, 2000a	Crustacean	*Gammarus fasciatus*	US EPA	96 h	Formulation 25 $g.L^{-1}$, flowthrough, (water only)	LC_{50} = 0.0032 (nominal) LC_{50} = 0.0003 (measured)
Gries and van der Kolk, 2001	Crustacean	*Asellus aquaticus*	US EPA	96 h	14C-deltamethrin as formulation 25 $g.L^{-1}$, semi-static (water only)	EC_{50} = 0.00035 (nominal)
Putt, 1999	Crustacean	*Daphnia magna*	OECD 202	48h	14C-deltamethrin > 95%, flow through	EC_{50} 48h = 0.56 (measured)
[redacted], 1986	Fish	*Salmo gairdneri*	US EPA	96 h	Deltamethrin 99.3 %, static, no concentration check	LC_{50} = 0.91 (nominal)
[redacted]1990a	Fish	*Oncorhynchus mykiss*	US EPA 72-1 OECD 203	96 h	Formulation 25 $g.L^{-1}$ flow	LC_{50} = 0.26 (measured)

Study reference	Trophic level	Species	Guideline	Duration	Test material	Endpoint [µg a i. L^{-1}]
					through, concentration measured	
Chronic Endpoints						
McNamara, 1991	Crustacean	*Daphnia magna*	US EPA 72-4 OECD 202 (1984) OECD 211 (1998)	21d	Deltamethrin > 95%, flow through	NOEC = 0.0041
[redacted] 1990b	Fish	*Salmo gairdneri*	OECD 204	28d	Deltamethrin 99.2 %, flow through	NOEC 28d < 0.032 (measured)
[redacted] 1991	Fish	*Pimephales p*	US EPA 72-4	36d	Deltamethrin > 95% Early life stage, flow through	NOEC 0.022 (measured)
[redacted] 1993	Fish	*Pimephales p*	US EPA 72-5	260d	14C-deltamethrin > 95%, Life-cycle	NOEC (growth, survival or reprod°) 0.017

Ref-MS information to the reader:

Please note that the chronic (28d) Chironumus study used in the risk characterisation for the aquatic compartment is missing in the summarising table. It has been included below to enhance the overview:

Study reference	Trophic level	Species	Guideline	Duration	Study type	Endpoint
Chronic						
Heusel et al., 1998	Sediment Dwelling Invertebrate	Chironomus riparius	BBA 1995	28d	Emergence, Development	NOEC = 0.0035 µg.L-1 31 µg/kgww sediment

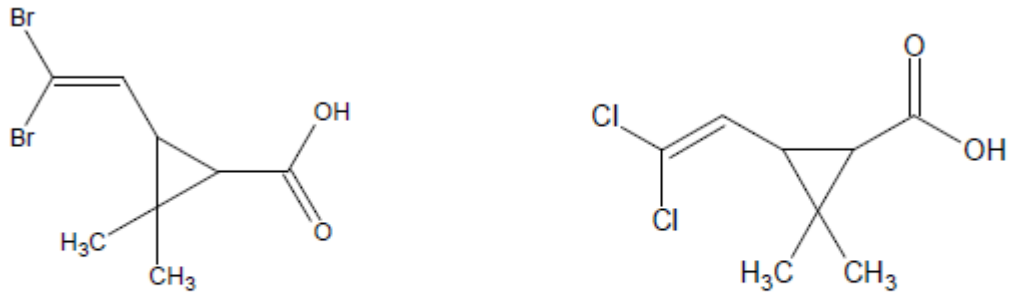
Aquatic Toxicity of the Major Metabolite Br_2CA

Measured effect data of the toxicity of the only major metabolite of deltamethrin, Br_2CA are not available. However, the module ECOSAR of the QSAR programme EPI Suite™ V 3.12, which was developed by the US EPA, QSAR (http://www.epa.gov/opptintr/exposure/docs/episuite.htm), allows a prediction of the toxicity of a compound on the basis of its chemical structure. For pyrethroid metabolites, it has been shown that reliable extrapolations of toxicity figures are possible by means of this programme, for example, for the cyfluthrin metabolite DCVA (See table below).

Table 2.8.2.1-2. Comparison of toxicity of DCVA to aquatic organisms predicted by QSAR vs. experimentally determined ones

Test organism	Endpoint	Value predicted by QSAR calculation [$mg.L^{-1}$]	Experimentally determined value [$mg.L^{-1}$]	Reference
Fish	LC_{50} (96 h)	5.4	14.7	[redacted], 1984
Daphnia	EC_{50} (48 h)	34.0	25-130	Forbis, 1984 Hill, 1989
Green algae	EC_{50} (96 h)	36.8	> 10	Hill, 1989

As can be seen in the table above, by comparing the QSAR estimation with the experimentally determined toxicity, the toxicity of the cyfluthrin metabolite DCVA to aquatic organisms can be reliably predicted by means of a QSAR calculation. The metabolite DCVA has a very similar chemical structure to the major metabolite of deltamethrin (Br_2CA), differing only in the substitution of the vinyl group, Cl versus Br (see figure below).



Br_2CA **DCVA**

Chemical structures of the deltamethrin metabolite (Br_2CA) and the cyfluthrin metabolite (DCVA)

It is, therefore, justified to use this QSAR approach also for an estimation of the toxicity of Br_2CA to aquatic organisms. A summary of acute toxicity data predicted for Br_2CA on the basis of QSAR is presented in the table below. From this table, it can be seen that the predicted toxicity of Br_2CA is orders of magnitude lower than the toxicity of the parent deltamethrin. In addition, the relationship of toxicity between parent compound and metabolite is very similar to that displayed by DCVA and cyfluthrin.

Table 2.8.2.1-3. Acute toxicity data predicted for Br2CA on the basis of QSAR

Test organism	Endpoint	Value predicted by QSAR calculation [mg.L-1]
Fish	LC_{50} (96 h)	10.4
Daphnia	EC_{50} (48 h)	84.9
Green algae	EC_{50} (96 h)	74.1

Toxicity to Sewage Treatment Plant micro-organisms

Since chemicals may cause adverse effects on microbial activity in STPs it is necessary to derive a *PNECmicroorganisms*. The *PNECmicroorganisms* is used for the calculation of the PEC/PNEC ratio concerning microbial activity in STPs. For deltamethrin, the results of a standard activated sludge respiration test (OECD guideline 209) give an EC50 (3h) >300 $Cg.L^{-1}$ and a NOEC of 300 $Cg.L^{-1}$ Based upon guidance provided within the Technical Guidance Document (European Commission, 2003), it is appropriate to apply an assessment factor of 10 to the NOEC endpoint. The resulting *PNECmicroorganisms* is 30 $Cg.L^{-1}$. No data are available concerning the specific effect of the major metabolite on microorganisms. However, based on the QSAR modelling performed (Grau and Maus, 2006) for other aquatic organisms, it can be concluded that Br2CA is considerably less toxic than the parent substance. Therefore, it has been assumed that a *PNECmicroorganisms* of 30 $Cg.L^{-1}$ is suitably protective for exposure to Br_2CA.

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

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 the table below.

Table 2.8.2.3-1. Summary of terrestrial endpoints 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%	LC_{50} > 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 the Major Metabolite Br_2CA

In a study conducted on *Hypoaspis aculeifer* with Br_2CA applied to LUFA 2.1 soil (Moser, 2005), an overall NOEC of 10 $mg.kg^{-1}$ (dry weight soil) was found (see table below).

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;	NOEC Mortality 10 $mg.kg^{-1}$(dw) NOEC Reproduction >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 family Deltamethrin EW 0.15 RTU is not considered to be explosive and based on the properties of the components of the formulation it is not considered to be oxidizing. Furthermore, Deltamethrin EW 0.15 RTU is not considered auto-flammable or to have a flash-point below its boiling point. No hazards based on the physico-chemical properties of the formulation are expected.

2.10 RISK CHARACTERISATION FOR HUMAN HEALTH

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 the 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 until dry.'

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 EW 0.15 is intended for use in and around buildings for direct kill of insects or control of crawling insects and other arthropods in small confined locations.	**Direct Spray** Use one trigger action from a distance of 30 cm to kill a broad spectrum of insects **Control of crawling insects indoors and in protected outdoor locations:** For control of crawling insects in small confined locations, apply product into areas where insect hide and walk (crack and crevices, behind boards, under fridges, around window frames etc.). Do not apply onto areas larger than 2 m^2. Max dose rate: 5 mL Deltamethrin EW 0.15 per 32 x 32 cm (5 pump stokes)

Deltamethrin EW 0.15 is an insecticide which is foreseen for direct kill of insects or control of crawling insects and other arthropods in small confined locations in the residential/domestic environment.

The product is formulated as a ready to use solution (EW – emulsion in water) in bottles equipped with a hand triggered pump sprayer and contains the active substance (a.s.) deltamethrin (0.15 g/L). The highest recommended application rate is 5 mL Deltamethrin EW 0.15 per 32x32 cm and not more than $2m^2$ surface area treated. The product is sprayed as a spot or crack and crevice treatment in areas of high insect transit or areas where insects hide.

The product will be used by amateurs.

2.10.2 Professional Users

Risk characterisation is not required for professional users since the product, Deltamethrin EW 0.15, 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.

2.10.2.1.1 Critical endpoint(s)

Not applicable.

2.10.2.1.2 Relevant exposure paths

Not applicable.

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

Not applicable.

2.10.2.2 Application Product Type 18

The manufacturing plants where Deltamethrin EW 0.15 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 EW 0.15 product life cycle.

2.10.2.2.1 Critical endpoint(s)

Not applicable.

2.10.2.2.2 Relevant exposure paths

Not applicable.

2.10.2.2.3 Risk characterization for Product Type 18

Not applicable.

2.10.2.3 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 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.

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.

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.

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.

Dermal absorption:

Deltamethrin EW 0.15 was not one of the representative formulations submitted for EU review according to the biocide directive 98/8/EC. However, for the various representative formulations submitted for EU review a value of 2% dermal absorption was considered appropriate for the concentrate as well as for the in-use dilution of the respective product1. The value was established based on data generated using an organic solvent based formulation, i.e. deltamethrin formulated as Deltamethrin EC 25. Hence, the 2% value is considered equally appropriate and adequately conservative for the solvent-based, emulsion in water formulation of Deltamethrin EW 0.15. Calculations in this evaluation used the worst case dermal absorption value of 2%.

2.10.3.2 Relevant exposure paths

Deltamethrin EW 0.15 is formulated as a ready-to-use trigger spray and is intended for non-professional users. No mixing/loading is required. In addition no disposal of the spray dilution is performed and no cleaning or maintenance exposures are anticipated. Waste product can be disposed with the bottle through normal domestic refuse disposal with no consumer exposure. Therefore, primary exposure is confined to the application phase of the product. Oral exposure is not considered a possible route of primary exposure for non-professionals applying spot or crack and crevice treatments.

The spray is applied directly from the ready-to-use bottle with recommendations that single direct spray applications (one trigger movement) are made to nests/insects or hiding areas. An additional restriction is the recommendation not to spray over $2m^2$ in a single treatment. Inhalation of the aerosol and dermal contact with spray are the likely routes of consumer exposure Oral ingestion, for example through food contamination, is addressed by the evaluation of hand-to-mouth transfer for small children – adult consumers can avoid oral exposure by following normal use recommendations not to use in the vicinity of open foodstuffs.

Deltamethrin EW 0.15 was not one of the representative formulations submitted for EU review according to the biocide directive 98/8/EC. However, with regard to primary exposure it has to be noted that the product is formulated as a ready to use solution packaged in bottles equipped with a hand triggered pump sprayer. Hence, no mixing and loading of the formulation into the application equipment is required. Furthermore, cleaning/maintenance of the application equipment can be regarded as not relevant. Accordingly, regarding primary exposure actual spraying is considered to be the worse case situation. Corresponding exposure calculations are performed using the Consumer exposure model (ConsExpo, Version 4.1) as proposed in the technical notes for guidance (TNsG, 2007)[6]

2.10.3.3 Risk characterisation – Primary exposure

Exposure scenario may involve exposure to deltamethrin through dermal contact and inhalation exposure during the spot application of Deltamethrin EW 0.15 using the hand-held trigger spray. No mixing/loading or refilling occurs.

The model approach in ConsExpo 4.1 selected for calculating operator exposure is presented below:

Default databases: Pest control products

Product categories: Sprays

Default products: Targeted spot

Scenario: Application (trigger spray)

Table 2.10.3.3-1 Risk Characterisation following the Use of Deltamethrin EW 0.15 by Non Professional Users using hand-held trigger spray.

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**
		Dermal[a]	None	0.0000815	1.09	9020
		Inhalation[a]	None	0.0000138	0.18	54347
		Oral (non-respirable)	None	0.000000883	0.01	849377
	Total	-	None	0.0000962	1.28	7796

[6] Human exposure to biocidal products, Technical Notes for Guidance; June 2007. Available at: http://ihcp.jrc.ec.europa.eu/our_activities/public-health/risk_assessment_of_Biocides/guidance-documents

* 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 of 100).

** systemic NOAEL= NOAEL of 1 mg/kg bw/day corrected for oral absorption of 75%= 0.75 mg/kg bw/day.

[a] See Ref-MS note below.

Ref-MS information to the reader:	The applicant has erraneously swopped the figures for inhalation and dermal exposure (dermal exposure should be 0.0000138 and inhalation 0.0000815).

The estimated systemic primary exposure of the amateur user accounts for slightly more than 1% of the AEL (1.3%).

Accordingly, there is based on this result no unacceptable risk anticipated for the amateur operator with the intended use of Deltamethrin EW 0.15. This conclusion is in line with the results presented in the CAR for other deltamethrin formulations with similar consumer uses.

2.10.3.4 Risk characterisation – Secondary exposure

Indirect exposure as a result of use

For the intended use of Deltamethrin EW 0.15 the applied product can be assumed to be accessible for persons (children/adults) re-entering the treated areas and this represents the worst-case for secondary exposure (this approach is consistent with the evaluation presented in the CAR for K-Othrine WG 250 - when it might be assumed that persons (adults and/or children) are secondarily exposed to Deltamethrin when re-entering an area where the product has been applied). A calculation of secondary exposure was performed considering the worst case scenario of a child/toddler re-entering a treated area assuming that 100% of the applied product is available for transfer of surface bound residues.

Secondary exposure as a result of use of deltamethrin may occur via the dermal route (transfer of surface bound residues to the skin) and by inhalation (while aerosol particles settle during the acute phase of the secondary exposure). With respect to inhalation exposure while aerosol particles settle it has to be noted that the exposure calculations using ConsExpo 4.1 already take into account a post application phase of about 4 hours. The corresponding exposure estimate including exposure due to spraying amounts to only 0.0000962 mg/kg bw/day (=1.2% of the AEL). Furthermore, the vapour pressure of deltamethrin is low (1.24×10^{-8} Pa; 25°C; according to Council Directive 1999/13/EC, a substance should be considered volatile when the vapour pressure is >0.01 kPa at 20°C). Therefore, inhalation secondary exposure can be regarded as negligible.

Oral exposure is considered in the worst case secondary exposure to toddlers crawling over treated areas and being exposed by hand to mouth transfer. This assessment is considered sufficiently protective for any oral exposure experienced by adult consumers during application of the product. To estimate primary exposure, via inhalation and dermal routes, during application of the product, specific exposure figures are not available.

For the intended use of Deltamethrin EW 0.15 the applied product can be assumed to be accessible for persons (children/adults) re-entering the treated area (i.e. toddler crawling over treated areas) and the following scenarios were considered:

(1) Dermal contact due to transfer of surface bound residues to the skin

(2) Oral (hand-to-mouth) contact with the treated area

It is considered as a worst case scenario that a child will not ingest more than once the product from the treated area.

Table 2.10.3.4-1 Risk Characterisation following the Secondary Exposure to Deltamethrin EW 0.15

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 EW 0.15	Dermal	0.000090	1.2	8333
Toddler - Oral (hand-to-mouth) contact with Deltamethrin EW 0.15	Oral	0.000338	4.51	2219
Total	Oral + dermal	0.000428	5.71	1752

* 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 read % of AEL.

The results of the calculations show that the estimated systemic exposure of children is below the proposed systemic AEL. For the re-entering toddler – as reasonable worse case situation – the estimated systemic exposure accounts for only about 6% of the AEL.

Based on these results there is no unacceptable risk anticipated with the intended uses of Deltamethrin EW 0.15 for persons being exposed to the product via secondary routes of exposure.

2.10.3.5 Risk characterisation – 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. This is more probable where professional users may be exposed subsequently in a domestic scenario.

However, considering the intended uses of Deltamethrin EW 0.15 the risk of combined exposure can be regarded as negligible. The risk assessment conducted for the representative products of Type 18 use in the CAR also did not assume combined exposure for consumers/non-professional users.

For Deltamethrin EW 0.15 again it can be concluded that the user of the product is aware of the surfaces being treated and accordingly would avoid contact with those surfaces. Thus incidental/accidental contact can be considered in terms of combined exposure. In that context one should note that even for the toddler re-entering a treated area the estimated exposure by the dermal route (0.000090 mg/kg bw/day) accounts for about 1% of the AEL. With respect to inhalation exposure the exposure calculations for primary exposure using ConsExpo take into account a post application exposure duration of about 4 hours. Hence, essentially considering combined exposure. The overall exposure still accounts for only about 2.5% of the AEL.

Based on these results there is no unacceptable risk anticipated with the intended use of Deltamethrin EW 0.15 for persons being exposed to the product via primary and secondary routes of exposure.

Therefore, with the intended consumer uses of Deltamethrin EW 0.15 the risk for combined exposure is considered to be negligible.

Ref-MS Information to the reader:	Ref-MS considers the risk of combined exposure to be acceptable.

2.11 RISK CHARACTERISATION FOR THE ENVIRONMENT

2.11.1 Aquatic compartment (incl. sediments)

Several acute and chronic studies are available for the aquatic compartment. Despite higher tier ecotoxicology data being available from a mesocosm study, this information has not been used as a direct basis for the $PNEC_{surface\ water}$. This is because of concerns of the regulatory authorities regarding exposure patterns in this higher tier study compared to biocidal use of insecticides, as well as the fact that effects were observed at the lowest test concentrations in the mesocosm.

Due to the large number of species tested, it was agreed that the available data supported a lower assessment factor. The lowest effect values were obtained in acute studies with *Gammarus* sp. and *Asellus* sp.. However, for these species there were further data indicating that under more realistic field conditions the effect concentrations were higher ($NOEC_{mortality}$ *ca.* 10 $ng.L^{-1}$). Based on these observations, the most sensitive species tested was *Chironomus*, with a chronic NOEC of 3.5 $ng.L^{-1}$ in a water-spiked test.

Taking all of the studies available on the effects of deltamethrin to aquatic organisms into consideration, there is a thorough database available. It has been shown that arthropods are the most sensitive organisms to deltamethrin and thus several arthropods have been tested in laboratory and bioassays, and even more species were included in the mesocosm study with more realistic conditions. The RMS proposed to use an AF of 5 to the lowest chronic laboratory NOEC to account for any remaining uncertainties. Thus, the $PNEC_{surface\ water}$ for deltamethrin is 3.5 $ng.L^{-1}$ / 5 = 0.7 $ng.L^{-1}$, which is used in the risk assessment.

Substances that are potentially capable of depositing on or sorbing to sediments to a significant extent should be assessed for toxicity to sediment-dwelling organisms (European Commission, 2003). As with aquatic ecotoxicity data, a Predicted No Effect Concentration in sediment ($PNEC_{sediment}$) is required in order to carry out such an assessment. The Technical Guidance Document indicates that the $PNEC_{sediment}$ should be derived from the lowest available $NOEC/EC_{10}$ obtained in long-term tests for relevant sediment dwelling species. The chronic toxicity of deltamethrin to *Chironomus riparius* was determined, and gave a NOEC for emergence of 0.0035 $\mu g.L^{-1}$ based on estimated actual exposure concentrations in water or 31

μg.kg $_{ww}$ $^{-1}$ sediment. Applying an assessment factor of 5 to this value, in accordance with the PNEC calculations for water, gives a $PNEC_{sediment}$ of 6.2 μg.kg $_{ww}$ $^{-1}$.

Table 2.11.1-1 Summary of relevant endpoints in aquatic sediment for Deltamethrin

Study reference	Trophic level	Species	Guideline	Duration	Study type	Endpoint
Chronic						
Heusel et al., 1998	Sediment Dwelling Invertebrate	*Chironomus riparius*	BBA 1995	28d	Emergence, Development	NOEC = 0.0035 µg.L^{-1} 31 µg/kgww sediment

Measured effect data of the toxicity of the only major metabolite of deltamethrin, Br_2CA are not available. However, the module ECOSAR of the QSAR programme EPI Suite™ V 3.12, which was developed by the US EPA, QSAR (http://www.epa.gov/opptintr/exposure/docs/episuite.htm), allows a prediction of the toxicity of a compound on the basis of its chemical structure. In accordance with the guidance presented in the Technical Guidance Document (European Commission, 2003), a $PNEC_{water}$ was derived from the predicted acute toxicity values for Br_2CA by applying an assessment factor of 1000 to the most sensitive endpoint of 10.4 mg.L^{-1}. With an assessment factor of 1000 applied this gives a $PNEC_{water}$ for Br_2CA of 10.4 µg.L^{-1}.

Using the equilibrium partitioning method, a $PNEC_{sediment}$ of 1.39 x 10^{-2} mg.kg wwt^{-1} is obtained, for Br_2CA.

Risk Characterisation Ratios for surface water and sediment

No direct exposure of surface water is expected. However, it is considered that exposure of surface water via the STP may occur due to wet cleaning of treated surfaces. As such, PECs have been generated for the surface water and sediment. The risk characterisation ratios for deltamethrin and the most relevant metabolite are presented in the tables below.

Surface water RCRs for deltamethrin following household use

Facility and type of treatment	$PEC_{surface\ water}$ (mg/L)	PNEC (mg/L)	RCR
Domestic house, crack and crevice	3.61 x10^{-7}	7 x10^{-7}	0.516

Sediment RCRs for deltamethrin following household use

Facility and type of treatment	$PEC_{sediment}$ (mg/kg ww)	PNEC (mg/kg ww)	RCR
Domestic house, crack and crevice	3.2 x10^{-3}	6.2 x10^{-3}	0.516

Surface water RCRs for Br_2CA following household use

Facility and type of treatment	$PEC_{surface\ water}$ (mg/L)	PNEC (mg/L)	RCR
Domestic house, crack and crevice	3.43 x10^{-7}	0.0104	<0.01

Sediment RCRs for Br_2CA following household use

Facility and type of treatment	$PEC_{sediment}$ (mg/kg ww)	PNEC (mg/kg ww)	RCR
Domestic house, crack and crevice	4.59×10^{-7}	0.0139	<0.01

Ref-MS Information to the reader:	(*) Ref-MS does not appreciate the wording "no risk" but would rather use "no unacceptable risk". The RCR indicated are in some cases >0.5 and this should be reflected also in the describing text. RMS agrees that deltamethrin has poor water solubility but would like to stress that in wet cleaning it is likely that a detergent is used, which would affect the solubility and cleaning efficacy.

No risk is indicated for crack and crevice treatments using Deltamethrin EW 0.15. This assessment is considered to be conservative as it assumes that the maximum label application amount is applied in all sites in all cases. It should also be noted that deltamethrin is sorbed strongly to organic carbon (geometric mean Koc = 408250 L/kg) and is highly insoluble in water (0.005 mg/L at 20ºC), which would likely mean that the fraction of the substance removed in any cleaning event would be much lower than that estimated for this risk assessment. Hence, the risk assessment is likely to largely overestimate the PECs for surface water and sediment.

As all RCRs for Br_2CA are less than 1 it is considered that there is no risk from the major metabolite of deltamethrin. (*)

Sewage Treatment Plant

Since chemicals may cause adverse effects on microbial activity in STPs it is necessary to derive a *PNECmicroorganisms*. The *PNECmicroorganisms* is used for the calculation of the PEC/PNEC ratio concerning microbial activity in STPs. For deltamethrin, the results of a standard activated sludge respiration test (OECD guideline 209) give an EC50 (3h) >300 Cg.L-1 and a NOEC of 300 Cg.L-1 Based upon guidance provided within the Technical Guidance Document (European Commission, 2003), it is appropriate to apply an assessment factor of 10 to the NOEC endpoint.

The resulting PNECmicroorganisms is 30 µg.L-1. No data are available concerning the specific effect of the major metabolite on microorganisms. However, based on the QSAR modelling performed (Grau and Maus, 2006) for other aquatic organisms, it can be concluded that Br2CA is considerably less toxic than the parent substance. Therefore, it has been assumed that a $PNEC_{microorganisms}$ of 30 µg.L-1 is suitably protective for exposure to Br2CA.

Risk characterisation ratios are summarised below.

Sewage treatment plant micro-organism RCRs for deltamethrin following household use

Facility and type of treatment	PEC_{STP} (mg/L)	PNEC (mg/L)	RCR
Domestic house, crack and crevice	5.83×10^{-6}	0.03	<0.01

As the RCRs are less than 1 it is considered that there is no significant risk to STP microorganism from the use of Deltamethrin EW 0.15 in the control of crawling insects.

Groundwater

The following groundwater concentrations were predicted for deltamethrin and Br2CA using FOCUS PEARL 4.4.4.

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

As all predicted concentrations are lower than the regulatory threshold of 0.1 µg/L it is considered that there is no significant risk to groundwater.

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(*).

Ref-MS Information to the reader:	(*) atmospheric compartment

2.11.3 Terrestrial compartment

Chronic toxicity data are 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 Br2CA 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	$PNEC_{soil\_dwt}$	[mg kg^{-1}]	0.16	Input

(dry weight)				
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:

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

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

Risk Characterisation Ratios

Risk characterisation ratios calculated for soil exposure through direct and indirect pathways. The risk characterisation ratios for soil exposure to deltamethrin through spreading of sewage sludge are presented below in the table below.

Risk characterization ratios for deltamethrin in soil via sludge application (crack and crevice treatment)

Soil type	Concentration in soil (mg/kg ww)	PNEC (mg/kg wwt)	RCR
Local soil	2.28 x 10^{-4}	0.075	<0.01
Agricultural soil	2.28 x 10^{-4}	0.075	<0.01
Grassland soil	9.12 x 10^{-5}	0.075	<0.01

Risk characterization ratios for soil exposure to Br2CA from spreading of sewage sludge are presented the table below.

Risk characterization ratios for Br_2CA in soil via sludge application (crack and crevice treatment)

Soil type	Concentration in soil (mg/kg ww)	PNEC (mg/kg wwt)	RCR
Local soil	1.34 x 10^{-4}	0.14	<0.01

Agricultural soil	1.34×10^{-4}	0.14	<0.01
Grassland soil	5.38×10^{-5}	0.14	<0.01

As soil exposure may also occur due to direct application to soil separate risk characterization ratios have been derived for this pathway. For the sake of completeness both initial concentrations in soil and the 30-day time-weighted average concentrations have been considered. Results are summarized in the tables below.

Risk characterization ratios for initial concentrations of deltamethrin in soil from direct application

Soil mixing depth (m)	Initial concentration in soil (mg/kg ww)	PNEC (mg/kg wwt)	RCR
0.1	0.0441	0.075	0.588
0.2	0.0221	0.075	0.295
0.5	8.82×10^{-3}	0.075	0.118

Risk characterization ratios for 30-day TWA concentrations of deltamethrin in soil from direct application

Soil mixing depth (m)	30-day TWA concentration in soil (mg/kg ww)	PNEC (mg/kg wwt)	RCR
0.1	0.0358	0.075	0.477
0.2	0.0179	0.075	0.227
0.5	7.16×10^{-3}	0.075	0.095

Risk characterization ratios for initial concentrations of Br_2CA in soil from direct application

Soil mixing depth (m)	Initial concentration in soil (mg/kg ww)	PNEC (mg/kg wwt)	RCR
0.1	0.0260	0.14	0.186
0.2	0.0130	0.14	0.093
0.5	5.2×10^{-3}	0.14	0.037

Risk characterization ratios for 30-day TWA concentrations of Br_2CA in soil from direct application

Soil mixing depth (m)	30-day TWA concentration in soil (mg/kg ww)	PNEC (mg/kg wwt)	RCR
0.1	6.83×10^{-3}	0.14	0.049
0.2	3.42×10^{-3}	0.14	0.024

Soil mixing depth (m)	30-day TWA concentration in soil (mg/kg ww)	PNEC (mg/kg wwt)	RCR
0.5	1.37×10^{-3}	0.14	<0.01

As all risk characterization ratios are less than 1 it is considered that there is no significant risk to the soil compartment.

It should be noted that for direct applications to soil the exposure will be highly localized. 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.

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 PNECbird 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 PNECsmall 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 the tables below.

Risk characterisation ratios for deltamethrin in secondary consumers' diet (crack and crevice treatment)

Soil type	Predicted concentration in predator diet (mg.kg $diet^{-1}$)	PNEC (mg kg $food^{-1}$)	RCR
Exposure to small mammals			
Local soil	1.8×10^{-5}	2.67	<0.01
Agricultural soil	1.8×10^{-5}	2.67	<0.01
Grassland soil	7.25×10^{-6}	2.67	<0.01
Exposure to birds			

Local soil	1.8×10^{-5}	15	<0.01
Agricultural soil	1.8×10^{-5}	15	<0.01
Grassland soil	7.25×10^{-6}	15	<0.01

Risk characterisation ratios for deltamethrin in secondary consumers' diet resulting from direct application to soil

Soil mixing depth (m)	Predicted concentration in predator diet (mg.kg diet^{-1})	PNEC (mg.kg food^{-1})	$RCR_{oral, predator}$ (based on 30-d TWA concentrations in soil) (mg.kg diet $^{-1}$)
Exposure to small mammals			
0.1	3.57×10^{-3}	2.67	<0.01
0.2	1.79×10^{-3}	2.67	<0.01
0.5	7.15×10^{-4}	2.67	<0.01
Exposure to birds			
0.1	3.57×10^{-3}	15	<0.01
0.2	1.79×10^{-3}	15	<0.01
0.5	7.15×10^{-4}	15	<0.01

As all risk characterisation ratios are less than 1, it is considered that the use of Deltamethrin EW 0.15 for control of crawling insects poses no significant risk to predators through secondary poisoning.

2.11.5 Conclusions

Exposure of the STP, surface water, sediment, soil, and groundwater may occur due to the use of Deltamethrin EW 0.15 for control of crawling insects. All RCRs for deltamethrin and its metabolite Br2CA are less than 1 for the STP and soil. In addition to this concentrations in groundwater were estimated to be below 0.1 µg/L and so it is considered that there is no risk to this compartment. The RCRs for deltamethrin in all compartments were less than 1, and as such the use of Deltamethrin EW 0.15 poses no significant risk to surface water or sediment.

Ref-MS Information to the reader:	Ref-MS does not support the wording "no risk" but would rather use "no unacceptable risk", even if RCR are below 1. However, Ref-MS considers the risk assessment as submitted by the applicant to be acceptable with minor comments.

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.

Wash hands immediately after application.

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

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, cool and well-ventilated place. Store in original container. Store in a place accessible by authorized persons only. 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

In the event of fire dangerous gases can be released.

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

Use self-contained breathing apparatus for fire fighting.

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

Contain the spread of the fire-fighting media.

High volume water jet is unsuitable for extinguishing/controlling fire

Emergency Measures in Case of an Accident

First-aid measures:

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:	According to MSDS for Myrr Spray the Ref-MS notice that information about contact lenses are missing for first aid measures (eye contact). Thus 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.

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 Spray 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 Spray Family (in communications also called Deltamethrin EW 0.15 RTU family). The two biocidal product family members, Myrr Spray Deltamethrin EW 0.15 and Myrr Spray, 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 Spray has been authorised since 2007.

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

The efficacy of the product family for direct and fast kill and for control of crawling insects and woodlice at a dose of maximum 5 mL of product per 32 x 32 cm and according to the directions for use, is considered acceptable. However, in Ref-MS Sweden the use of the product family 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 Sweden. 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 Myrr Spray Family (Deltamethrin EW 0.15 RTU) that the intended use of the products 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, e.g. through phrases like “keep out of reach of children”, “keep children away during application” and “do not enter treated area until dry”. Furthermore, the health risk assessment does not include direct exposure via food or feedstuff, nor does it include the risk assessment of exposed pets. Instead, this will be handled with risk mitigation measures. The products is proposed to be labelled with the sentence “The product should be applied so that children, pets, food or feedstuffs do not come in contact with the product.”

The environmental risk assessment does not indicate any unacceptable risks for the environment from the use of the products as described by 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 Spray Family and the products in this family, to be used as biocide products. The conditions are outlined in the Summary of biocidal Product Family Characteristics (SPFC), were the products Myrr Spray Deltamethrin EW 0.15 and Myrr Spray are included in separate meta-SPC:s (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 3.7/04 3.7/05 3.11/01	Manka, S	2016	Determination of Physico-Chemical Properties and Storage Stability Test for Deltamethrin EW 0.15A G in PET bottles - 3 years interim report. BioGenius GmBH, Germany Report No: M-459556-03-1 15 March 2016 GLP. Unpublished	Y	Bayer AG
3.7/02	Güldner, W; Hoppe, M	2007	Storage Stability and Shelf Life of Deltamethrin EW 0.15 [Packaging material: COEX/E-VAL]. Bayer CropScience AG, Germany Report No: M-129045-02-1 24 August 2007 GLP. Unpublished	Y	Bayer AG
3.7/03	Güldner, W; Hoppe, M	2007	Storage Stability and Shelf Life of Deltamethrin EW0.15 [Packaging material: HOPE bottle with spraying head]. Bayer CropScience AG, Germany Report No: M-129049-02-1 24 August 2007 GLP. Unpublished	Y	Bayer AG
3.2/01 3.3/01 3.4/01 3.4/02	Heinz, U.	2005	Determination of Safety-Relevant Data of Deltamethrin EW 0.15 Bayer Industry Services GmbH & Co. OHG Report No: M-243716-01-1 21 January 2005 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
4.1/01	Seidel, E.	2003	Determination of deltamethrin in formulations (2001-0054801-03E) Bayer CropScience, Germany Report No: MO-03-000764 17 January 2003 Not GLP. Unpublished.	Y	Bayer AG
4.1/02	Odendahl, A.	2004	Validation of HPLC method 2002-0054801-03 – Determination of Deltamethrin in Formulations Bayer CropScience, Germany Report No: MO-04-009639 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
5.10.2/01	Nentwig, G	2005	BES0337 Ant Kill plus (pbi Home & Garden) in comparison to K-Othrine flow: immediate and residual efficacy against the Black garden ant (*Lasius niger*) Bayer Environmental Science, 40789, Monheim, Germany Report No: M-268842-01-1 26 July 2005 Unpublished	Y	Bayer AG
5.10.2/02	Gutsmann, V.	2012 a	Use of Deltamethrin EW 0.15 for use as a barrier against common household nuisance pests Bayer CropScience, Monheim, Germany Report No: M-444120-02-1 13 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	Gutsmann, V.	2012 b	Use of Deltamethrin EW 0.15 for treatment of hiding places of common household nuisance pests Bayer CropScience, Monheim, Germany Report No: M-444121-02-1 30 November 2012 Unpublished	Y	Bayer AG
5.10.2/04	Nentwig, G.	2012	Efficacy of Deltamethrin EW 0.15 against common household insects in direct spray application Bayer CropScience, Monheim, Germany Report No: M-444122-02-1 30 November 2012 Unpublished	Y	Bayer AG
5.10.2/05	Gutsmann, V.	2012 c	Efficacy of Deltamethrin EW 0.15 against spiders infesting a wooden structure Bayer Environmental Science, 40789, Monheim, Germany Report No: M-442353-01-1 23 November 2012 Unpublished	Y	Bayer AG
Referral discussion	Gutsmann, V.	2017	Efficacy of direct application of Deltamethrin EW 0.15 onto common household insects Bayer AG, Monheim, Germany Report No: M-585752-01-1 13 April 2017 Unpublished	Y	Bayer AG
Referral discussion	Gutsmann, V.	2017	Use of Deltamethrin EW 0.15 in a simulated use trial for treatment of hiding places of the Oriental cockroach (Blatta orientalis) Bayer AG, Monheim, Germany Report No: M-585699-02-1 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
6.1/01	Garcin, J.C., Vinck, K.	2005	Bridging statement from toxicity of [redacted] to Deltamethrin EW 0.15 Bayer CropScience SA Report No: M-261278-02-1 17 November 2005 Not GLP. Unpublished **CONFIDENTIAL (see DocIVB confidential data and information)**	No	Bayer AG
6.1.1/01	[redacted]	1990 a	[redacted] – Acute Oral Toxicity Study in the Rat Division Scientifique Roussel Uclaf, France Report No: A73144 29 June 1990 GLP. Unpublished.	Y	Bayer AG
6.1.2/01	[redacted]	1990 b	[redacted] – Acute Dermal Toxicity Study in the Rabbit Division Scientifique Roussel Uclaf, France Report No: M-173298-01-1, A96670 13 September 1990 GLP. Unpublished.	Y	Bayer AG
6.2.1/01	[redacted]	1990 c	[redacted] – Primary Dermal Irritation Study in the Male Rabbit Division Scientifique Roussel Uclaf, France Report No: M-173296-01-1, A96669 13 September 1990 GLP. Unpublished	Y	Bayer AG
6.2.2/01	[redacted]	1990 d	[redacted] – Primary Eye Irritation Study in the Male Rabbit Division Scientifique Roussel Uclaf, France Report No: A73143 13 September 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
6.3/01	[redacted]	2013	Deltamethrin EW 0.15 g/l – Local Lymph Node Assay in the Mouse [redacted] Report No: M-458797-01-1, TXDAN048 03 July 2013 GLP. Unpublished.	Y	Bayer AG