Kemikalieinspektionen
Swedish Chemicals Agency

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

Deltamethrin SC 7.5

Swedish trade name: Myrr till utvattning

Type of application Authorisation	Product type PT 18 (insecticide)
Authorisation number 5210	Date of decision/Entry into force 16 November 2015
Active substance Deltamethrin, 0,74% (w/w)	Date of expiry 15 November 2025
Sweden's R4BP3 reference code BC-WR010429-14 (2013/1117/7016/SE/APPFF/10792)	User category Class 3 - Products that may be used by anyone

CONTENTS

1 GENERAL INFORMATION ABOUT THE PRODUCT 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[1]

Company Name:	Bayer AB
Address:	Kronoslätts Företagsby, Västanvägen
City:	Staffanstorp
Postal Code:	245 42
Country:	Sweden
Telephone:	[redacted]

[1] Applies only to existing authorisations

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:	Kronoslätts Företagsby, Västanvägen
City:	Staffanstorp
Postal Code:	245 42
Country:	Sweden
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:	Kronoslätts Företagsby, Västanvägen
City:	Staffanstorp
Postal Code:	245 42
Country:	Sweden
Telephone:	[redacted]
E-mail address:	[redacted]

1.4 INFORMATION ABOUT THE PRODUCT 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]

1.5 INFORMATION ABOUT THE BIOCIDAL PRODUCT

1.5.1 General information

Trade name:	Deltamethrin SC 7.5 Swedish trade name: Myrr Till Utvattning
Manufacturer's development code number(s), if appropriate:	06537138 Specification n° 102000012401-03
Product type:	PT18
Composition of the product (identity and content of active substance(s) and substances of concern; full composition see confidential annex):	Deltamethrin: 7.5 g/L (0.73% w/w)
Formulation type:	Suspension Concentrate (SC)
Ready to use product (yes/no):	No
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):	Yes (K-Othrine SC 7.5). Deltamethrin SC 7.5 is the same formulation as K-Othrine SC 7.5, but with another area of use.

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):	Drench application for the control of ant nests around houses
Target organisms:	Black Ant *(Lasius niger*) and other commonly found garden ants
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:	**Drench of ant nests:** Dilute 20 ml of product with water to obtain a total amount of 5 Liters of solution. Use 5 L of solution for 5 m² per ant nest.

	Concentration of deltamethrin in the diluted product: 0.03 g/L (0.003% w/w).
Potential for release into the environment (yes/no):	Conclusions regarding fate properties are presented for the active substance deltamethrin in Doc IIA. It is considered that the formulation of Deltamethrin SC 7.5 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):	Drench application for the control of ant nests around houses.
Target organisms:	Garden ants
Category of users:	General public

For details of the uses authorised by the Reference Member State, please see the SPC (separate document).

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 Summary of Product Characteristics

1.5.4 Information on the substance(s) of concern

There are no substances of concern in the biocidal product.

1.6 DOCUMENTATION

1.6.1 Data submitted in relation to product application

Relevant data on the product 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, dermal and inhalation toxicity, skin and eye irritation and dermal sensitisation potential) are presented in Doc IIIB.

Summary of product 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	OECD 401	OFA Sprague-Dawley rat 5/sex/group Vehicle: none	0, 5000 and 15000 mg/kg bw	LD_{50}: >15000 mg/kg bw	Not classified	[redacted] 1986a (6.1.1/01)
Dermal	OECD 402	NZW rabbit 5/sex/group	0, 10000 mg/kg bw	LD_{50}: >10000 mg/kg bw	Not classified	[redacted] 1986b (6.1.2/01)
Inhalation	OECD 403	Crl: CD® rat 5/sex/group	0, 2.3[1] mg/l air 4h	LC_{50} (4 hrs, aerosol): >2.3 mg/l air	Not classified	[redacted], 1986 (6.1.3/01)
Skin Irritation	OECD 404	New Zealand Albino hybrid rabbit	4h	Transient slight skin irritation reversible within 24 hr.	Not a skin irritant	[redacted] 1986c (6.2.1/01)
Eye Irritation	OECD 405	New Zealand Albino hybrid rabbit	24h	Transient slight ocular irritation reversible within 24 hr.	Not an eye irritant	[redacted] 1986d (6.2.2/01)

Route	Method Guideline	Species Strain/ Sex no/group/ vehicle	Dose levels duration of exposure	Value LD_{50}/LC_{50} (mg /kg bw or mg /l)	Remarks	Reference in Doc III-B section 6
Dermal 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 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 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 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. Some of the comments from other Member States has resulted in amendment of new text from the RMS. This is highlighted in a preceeding information box. 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. Please note that while the application was submitted under Directive 98/8/EC, the product is authorised in accordance with the Biocidal Products Regulation (EU) No 528/2012 and the transitional measures in Article 91.See Section 3 (Proposal for decision) for further details.

2.2 IDENTITY RELATED ISSUES

2.2.1 Identity of ingredients of the biocidal product

See confidential part (Business Confidential Information document).

2.2.1.1 Information on the substance(s) of concern

There are no substances of concern in the biocidal product.

2.3 CLASSIFICATION, LABELLING AND PACKAGING

Ref-MS information to the reader:	This section is amended by Ref-MS according to CLP-classification only.

2.3.1 Classification of the active substance deltamethrin

Table 2.3.1-1 Classification according to Regulation (EC) No.1272/2008

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

2.3.2 Classification of the biocidal product Deltamethrin SC 7.5

Table 2.3.2-1 Classification according to Regulation (EC) No.1272/2008

	Hazard class and category	Code	Hazard statement
Hazard statements	Aquatic acute 1	H400	Very toxic to aquatic life
	Aquatic chronic 1	H410	Very toxic to aquatic life with long lasting effects.
		EUH208	Contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction.
		EUH208	Contains Reaction mass 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one. May produce an allergic reaction
Pictograms			
Signal word	Warning		
Precautionary statements		P391	Collect spillage
		P501	Dispose of contents/container in accordance with local regulation.

2.3.3 Labelling

A copy of the label is provided in Document IIIB9.

2.3.4 Packaging

Deltamethrin SC 7.5 is sold in plastic bottle with easydose system or in plastic bottle and measuring device, up to 250 mL (material HDPE).

2.4 PHYSICO-CHEMICAL PROPERTIES

Ref-MS information to the reader:	Deltamethrin SC 7.5 is a suspension concentrate containing 7.5 g/l deltamethrin. It has a weak mouldy odour. Based on the properties of the components of the formulation, Deltamethrin SC 7.5 is not considered explosive or oxidizing. Furthermore, based on data from a very similar product Deltamethrin SC 7.5 is not considered auto-flammable or to have a flash-point below its boiling point. The pH of the undiluted product is 5.2. The stability studies were performed on two different formulations. The accelerated study was performed on the current formulation while the two year ambient temperature study was performed on the old formulation. However, the differences in composition of the two formulations are small (see Annex Confidential Data and Information for further details) and the results are therefore considered applicable to Deltamethrin SC 7.5. The product Deltamethrin SC 7.5 is considered stable for at least two years at ambient temperature in HDPE packaging.

Deltamethrin SC 7.5 is a suspension concentrate containing 7.5 g/L deltamethrin. It is a light beige liquid with a weak mouldy odour. The product does not burn, undergo spontaneous combustion or emit flammable gas when in contact with water. The pH of a 1% dispersion ranges from 5.4 to 5.5. Based on the structural formula of the active, the product has no explosive, oxidising or flammable properties. Stability in HDPE packaging was shown on a very similar product for two years at ambient temperature. There are no properties that require the product to be classified for physical or chemical hazard.

Acceptable studies were provided for all required physical and chemical properties of the biocidal product Deltamethrin SC 7.5 as summarised in Table 2.2-1 below.

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

Physico-chemical property	Guideline No. and Method used	Result/Comment	Ref. in Doc III
Physical state	Visual	Suspension	Güldner, 2005 (B3.1.1/01)
Colour	Visual	Light beige	Güldner, 2005 (B3.1.2/01)
Odour	Olfactory	Weak mouldy	Güldner, 2005 (B3.1.3/01)
Explosive properties	An evaluation of the explosive properties has been carried out by examining structural formula	Based on content and chemical structure, it was concluded that the formulation was not explosive.	Heinz, 2005 (B3.2/01)

Physico-chemical property	Guideline No. and Method used	Result/Comment	Ref. in Doc III
Oxidising properties	An evaluation of the oxidizing properties has been carried out by examining structural formula of the active substance	Based on content and chemical structure, it was concluded that the formulation was not oxidising	Heinz, 2005 (B3.3/01)
Flash point	EEC A.9	No flash point up to boiling point.	Heinz, 2005 (B3.4)
Auto-Ignition Temperature	EEC A.15	T_2 = 495ºC	Heinz, 2005 (B3.4/01)
Acidity/alkalinity pH of undiluted material	CIPAC MT 75.3	pH undiluted: 5.1 – 5.3 pH 1% dilution: 5.4 – 5.5	Güldner 2005 (B3.5/01)
Relative density	OECD 109	Mean value D_4^{20} = 1.030 Mean value D_4^{40} = 1.020	Güldner 2005 (B3.6/01)
Accelerated storage stability	CIPAC MT 46.3 CIPAC MT 39.3	No effects up to 54ºC for two weeks or 1 week at 0ºC	Güldner 2005 (B3.7/01)
Ambient storage stability	CIPAC MT 46.3	Stable during two years at ambient temperature.	Güldner; Hoppe, (2007) (B3.7/02)
Wettability/ suspensibility	CIPAC MT 184	0.6%: 91 – 94% 1.0%: 92 – 94% 5.0%: 101 – 102%	Güldner 2005 (B3.8/01)
Wet sieve tests	CIPAC MT 185	75 µm sieve <0.01%	Güldner 2005 (B3.8/02)
Emulsifiability,	Not relevant	Not applicable. The product is not an emulsion	Document III-B3.8
Disintegration time	Not relevant	Not applicable. The product is a liquid	Document III-B3.8
Attrition/friability of granules; integrity of tablets	Not relevant	Not applicable. The product is a liquid	Document III-B3.8
Persistence of foaming	CIPAC MT 47.2	1 min: 29 ml	Güldner 2005 (B3.8/03)
Pourability	CIPAC MT 148	Residue: 2.51 – 2.73% Rinsed residue: 0.20 – 0.21%	Güldner 2005 (B3.8/04)
Dustability	Not relevant	Not applicable as the product is a liquid.	Document III-B3.8

<table>
<tr><th>Physico-chemical property</th><th>Guideline No. and Method used</th><th>Result/Comment</th><th>Ref. in Doc III</th></tr>
<tr><td>Physical and chemical compatibility with other products including biocidal products with which its use is to be authorised (IIIB3.9)</td><td>Not relevant</td><td>Not applicable as the product is not intended for mixtures.</td><td>Document III-B3.9</td></tr>
<tr><td>Surface tension</td><td>OECD 115</td><td>32 mN/m at 25ºC</td><td>Güldner 2005 (B3.10/01)</td></tr>
<tr><td>Viscosity</td><td>OECD 114</td><td>
<table>
<tr><th>Temperature</th><th>Shear rate</th><th>Dynamic (η=) (mean)</th><th>Kinematic (ν=) mean</th></tr>
<tr><td>20°C</td><td>20 s^{-1}</td><td>0.371 Pa•S</td><td>3.60E-04m^2/s</td></tr>
<tr><td></td><td>100 s^{-1}</td><td>0.102 Pa•S</td><td>0.99E-04m^2/s</td></tr>
<tr><td>40°C</td><td>20 s^{-1}</td><td>0.335 Pa•S</td><td>3.28E-04m^2/s</td></tr>
<tr><td></td><td>100 s^{-1}</td><td>0.092 Pa•S</td><td>0.90E-04m^2/s</td></tr>
</table>
</td><td>Güldner 2005 (B3.11/01)</td></tr>
<tr><td>Particle size distribution</td><td>Not relevant</td><td>Not applicable as the preparation is not a powder or granules.</td><td>Document III-B3.12</td></tr>
</table>

2.5 ANALYTICAL METHODS FOR DETECTION AND IDENTIFICATION

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

2.5.1 Formulation analysis

Ref-MS information to the reader:	An analytical method for the analysis of deltamethrin in the biocidal product K-Othrine SC 7.5 was evaluated and accepted in the CAR.

Acceptable method was provided for analysis of deltamethrin in formulations (Seidel, 2003). Validation data for Deltamethrin SC 7.5 was accepted in the CAR (Odendahl, 2006).

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

Table 2.5.1-1 Analysis of deltamethrin in Deltamethrin SC 7.5

Method	Linearity (linear range and r^2)	Precision (repeatability) % RSD	Accuracy (mean recovery) %	Specificity	Reference in Doc III
HPLC-UV (external standardization)	2.59-7.37 mg a.s./100 ml solution (50%-150% of the nominal concentration) r^2=0.9995	0.30% (n=6)	Mean: 100.2% Range 98.0-102.2 (%RSD 1.60%, n=6). Tested in the range 2.49-7.27 mg /100 ml solution (50%-150% of the nominal concentration)	No interference from formulants, impurities or solvents (checked by HPLC-DAD).	Seidel, 2003 (method description; B4.1/02a) Odendahl, 2006 (validation data; B4.1/02b)

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 SC 7.5 is intended to be sold to the Consumer user for drench use on terraces, patios, and pathways around private housing. Deltamethrin SC 7.5 acts on harmful organisms by contact and ingestion resulting in death. Deltamethrin expresses both a knock-down effect, and residual action.

A single nest may be concreted on a very small area and have only 1 nest entrance. However, there are many cases where the field situation is completely different. A nest underneath pavements stones may have several (4-6) discrete entrances that may extend over a considerable area.

M-268844-02-1 shows an effective local dose of 60 mg a.s./m² or higher to kill workers. However, 1 m² has been found to be an area too small to effectively treat an ant nest. The treated are was therefore

increased to 5 m² but the dose lowered to 30 mg a.s./m². This dose rate was tested in several field trials and found to be effective.

The recommended dose rate (20 ml product diluted in 5 L of water for 5 m^2, corresponding to 30 mg a.s./ m²) and use patterns have been evaluated in the following studies.

Table 2.6.1 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 SC 7.5	*Lasius niger*	In-house	Laboratory	**Drench application** Reasonable control at 30 mg/ m^2	Nentwig (2004a) M-268844-02-1 B5-10-2/01	K-Othrine 7.5 SC was tested on 50 ants (Lasius niger) placed in glass dishes with humid earth. The application rate was 7.5 , 15, 30, 60, 90 120 and 150 mg a.i./m^2. Cumulativ mortality was recorded after 1, 2, 7 and 14 days. Each dose was tested in 3 replicates and the mean calculated. Water was used as control and tested in 3 replicates. The 30 mg a.i./m^2 dose was repeated (another 3 replicates). Doses of 60-150 mg a.i./m^2 achieved 100% mortality by day 14, The dose of 30 mg a.i./m^2 achieved 54% mortality by day 14 on the first trial and 91% mortality on the second trial. The lower doses (7.5 and 15 mg a.i./m^2) achieved 21 and 44% mortality, respectively, by day 14. The results shows a dose dependent effect and indicates that the effficacy of the 30 mg dose probably was too low at the first trial (54%) and more correct at the second trial (91%). The Ref-MS accepts the study to be used for support of the label claim and agrees to the conclusions made by the applicant. A dose of 30 mg/m^2 results in 91% mortality by day 14. This is considered acceptable for a product intended for use as gneral surface treatment for consumers with the claim for control of workers and nest, not nest kill.

Test substance	Test organisms	Test system / Concentrations applied / exposure time	Test conditions	Test results: effects, mode of action, resistance	Reference	Ref-MS Comments
Deltamethrin SC 7.5	*Lasius niger*	In-house.	Field.	**Drench application** Good control at control at 30 mg/ m^2.	Nentwig (2004b) M-268843-01-1 B5-10-2/02	K-Othrine 7.5 SC was tested as drench application against Lasius niger. The test system consisted of a site with several activ nests. Three nests were used for each dose level and one further nest was treated with water as a control. The application rates were 30, 60 and 120 mg a.i./m^2. The product was diluted and appliced with a watering can on an area not larger than 1 m^2. Colony activity was scored before (on day -28, -16, -7 and 0) and after treatment (1, 2, 5, 8, 14 and 29). *Scoring: 0 No ants visible. 1 Ants rare or only found after manual agitaion of the nest. 2 Low activity, small numbers of ants visible and foraging.* *3 Medium activity; ants common and readily visible.* *4 Very high levels of activity.* No clear dose response was seen, but generally a clear reduction regardless of dose. Of the three nests treated at the label rate of 30 mg/m^2, two nests were given a score of 0, and the remaining nest was given a score of 1 by day 29. The Ref-MS accepts the study to be used for support of the label claim. A clear effect (nest kill) was seen at 30 mg/m^2 in 2 out of 3 nests 1 month after treatment, however in the 3rd nest the activity on day 29 was the same as before start of treatment. The activity in the 3rd nest was very low before start of treatment, and the result is therefore considered inconclusive.

Test substance	Test organisms	Test system / Concentrations applied / exposure time	Test conditions	Test results: effects, mode of action, resistance	Reference	Ref-MS Comments
Deltamethrin SC 7.5	*Lasius niger*	In-house.	Field.	**Drench application** Good control at control at 30 mg/ m^2. Residual control up to 35 days.	Brooks (2008) M-399604-01-1 B5-10-2/03	K Othrine SC 7.5 was tested as drench application applied outdoors against *Lasius niger* (application rate 30 mg a.i./m^2). The test system consisted of a site with several active nests. Six nests were used for the trial and one further nest was treated with water as a control. The insecticide was applied by first mixing in a watering can and then by drenching the paving stones in close proximity to each nest. The nests were observed on two separate occasions prior to the onset of the trial and on seven further occasions during the 35 day period in which the trial was running. Insecticidal effect was measured by counting ants and by scoring their general activity. These counts and scores were compared to the pre-treatment measurements. At a dose of 30 mg/ m^2 4 out of 6 nests were eradicated within 3 days. The 2 nests unaffected were most likely large nests only partly treated with the drench treatment. The Ref-MS accepts the study to be used for support of the label claim. The study supports the efficacy of the product against Lasius niger at the recommended dose rates of 30 mg/m^2 . It is however concluded that it is vital that the whole nest is treated to get an eradication of the nest.

Test substance	Test organisms	Test system / Concentrations applied / exposure time	Test conditions	Test results: effects, mode of action, resistance	Reference	Ref-MS Comments
Deltamethrin SC 7.5	*Lasius niger*	In-house.	Field.	**Drench application** Good control at control at 30 mg/ m^2. Residual control up to 17 days.	Knorr *et al.*, (2009) M-399629-01-1 B5-10-2/04	K Othrine SC 7.5 was tested as drench application applied outdoors against *Lasius niger* (application rate 30 mg a.i./m^2), and compared with a pyrethrum drench treatment (AquaPy EW 30). A total of eighteen separate nests were observed on three separate sites. Six nests were assigned to each of the two products tested and six were treated with water to act as controls. A scoring system was employed to evaluate the actual ant activity. Observations were both "incited" by using honey bait, and "untouched", where no baiting was used. A dose of 30 mg/ m^2 resulted in a general decline of activity as compared to the control nests until two weeks after treatment. On day 3 after treatment no activity was seen in 5 out of the 6 treated nests and in the last one only low activity (score 1) was seen. The Ref-MS accepts the study to be used for support of the label claim. The study supports the efficacy of the product against Lasius niger at the recommended dose rates of 30 mg/m^2. It has to be noted that the test was performed late in summer and the weather made the ant activity decrease also in the control nests towards the end oft he observation period. The initial effect oft he treatment was however clear.

Test substance	Test organisms	Test system / Concentrations applied / exposure time	Test conditions	Test results: effects, mode of action, resistance	Reference	Ref-MS Comments
Deltamethrin SC 7.5	*Lasius niger*	In-house.	Field.	**Drench application** Good control at control at 30 mg/ m^2. Residual control up to 35 days.	Brooks *et al.*, (2008) M-399638-01-1 B5-10-2/05	K Othrine SC 7.5 was tested as drench treatment outdoors against Lasius niger (application rate 30 mg a.i./m2) to evaluate the efficacy The test system consisted of a site with several active Lasius niger nests. Six nests were used for the trial and two further nests were treated with water as a control. The insecticide was applied by first mixing in a watering can and then by drenching the paving stones in close proximity to each nest. The nests were observed on two separate occasions prior to the onset of the trial and on seven further occasions during the 35 day period in which the trial was running. Insecticidal effect was measured by both counting ants at a bait and by scoring their general activity. These bait counts and scores were compared to the pre treatment measurements. Following the treatment five out of six nests showed no further activity. One of the nests showed a small return to activity 28 and 35 days post treatment. Some evidence of new nest openings were recorded for one nest. The Ref-MS accepts the study to be used for support of the label claim. The study supports the efficacy of the product against Lasius niger at the recommended dose rates of 30 mg/m^2 with a claim for control of workers and nest.

Ref-MS information to the reader:	The efficacy of the product for control of workers and nests of garden ant (*Lasius niger)*, at a dose of 30 mg/m^2 and according to the directions for use, is considered to be acceptable. Effect on ants (Lasius niger) is shown in a laboratory study, in which a dose of 30 mg/m2 resulted in a mortality of 91%, 14 days after treatment, which is acceptable for a product intended for use as general surface treatment for consumers. A higher mortality and a quicker onset would have been to prefer, but field studies verified that the dose is sufficient to control workers and nests. In 16 of 21 treated nests (76%) the treatement resulted in a complete nest kill. For the rest of the treated nests a reduction of ants was seen but the nest kill was incomplete and the effect therefore only temporary. The efficacy was much dependent on the success in treating all the entrences to the nest. If the right area was treated the efficacy of the product has shown to be very good. The studies shows limitations in efficacy and for the approval of the product the information on how the product works and additional instructions have to be added to label and dirctions for use. 1. The time from treatment to visible effect should be clarified on the label and directions for use. 2. An interval to a possible re-treatment of a nest should also be stated and a limit on number of treatments performed during a season. 3. The time frame for residual control is dependent on the weather conditions. In the case of rain the residual control can be lost within a few days. This is also important to include in the directions for use.

2.6.2 Mode of action including time delay

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

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

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

2.6.3 Occurrence of resistance

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

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

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

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

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

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

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

Ref-MS information to the reader:	It is not likely that resistence will build up in ants nest with a queen who lay eggs for a long period. However, the product will affect other organisms in the treated area, and since resistance to deltamethrin is known in other insects the product should be used with care.

2.7 EXPOSURE ASSESSMENT

Ref-MS Information to the reader:	**Exposure and risk assessment for pets** Exposure and risk assessment for 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 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 (lethal) intoxications by pyrethroids are very common. Thus, the access of cats to areas, where an application is or was performed, must be excluded by an appropriate labelling. Therefore the riks mitigation measure is extended to 'Exclude animals and children during application and prevent access to treated areas until dry.'

2.7.1 Human exposure assessment

Ref-MS Information to the reader:	In the TNsG on Human exposure (2007) there is a model scenario for professional mixing and loading by watering can. It is suggested to use the parameter for exposure of hands from this scenario as a worst case. The estimated exposure using ConsExpo is derived to be less than 1% of AEL; using the TNsG on Human exposure (2007) model scenario for professional mixing and loading by watering can the estimated exposure is derived to be approximately 3.3% of the AEL. Thus, the exposure assessment of users result in a value significantly below the AEL. Ref-MS therefore concludes that the risk for users is acceptable. Ref-MS concludes that the secondary exposure assessment of children is based on worst case assumption and still results in a margin to the AEL. However, as indicated in the CAR, due to the uncertainties with regard to developmental neurotoxicity, precautions should be taken regarding exposure of children. It is therefore suggested that the product is labelled with phrases that warn and inform users so that measures can be taken to minimise the exposure of children.

2.7.1.1 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 as the product is intended for non-professional use.	Primary and secondary exposure	Indirect exposure only

Dermal	Relevant for direct exposure	Not relevant as the product is intended for non-professional use.	Primary and secondary exposure	Indirect exposure only
Oral	Not relevant for direct exposure	Not relevant as the product is intended for non-professional use.	Primary and secondary 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.

2.7.1.2 Professional exposure

Not relevant for Deltamethrin SC 7.5 uses.

2.7.1.3 Non-professional exposure

Data on exposure

Drench application

Deltamethrin SC 7.5 is an insecticide which is foreseen for the control of ants in a residential environment (e.g. terraces). The product is formulated as a suspension concentrate (SC) and contains the active substance (a.s.) deltamethrin (7.5 g/L). Before application Deltamethrin SC 7.5 has to be diluted with water to a final concentration of 0.03 g deltamethrin/L (= 20 mL Deltamethrin SC 7.5 per 5L of water). The application solution is applied into and around the entrances of an ant nest using e.g. a watering can or comparable application equipment. The maximum application rate is 5 L of the drench solution per 5 m^2 per ant nest. The product will be used by amateurs.

Consideration on estimation of primary- and secondary exposure

Ref-MS Information to the reader:	The Applicant refers to the evaluation of K-Othrine SC 7.5 and K-Othrine DP 0.05 in connection with the approval for listing of deltamethrin on Annex I to directive 98/8/EC (see text below). However, it should be noted that the former formulation (although identical in composition to Deltamethrin SC 7.5) was assessed for spray applications indoor by professionals only. The latter formulation albeit assessed for the relevant use and user group, was a ready-to-use dry dustable powder. Hence, the exposure assessment for primary exposure is not directly comparable to the one in question. Ref-MS has added a suggestion for a worst-case scenario for Primary exposure below using a model scenario for professional mixing and loading by watering can.

With regard to the intended professional use of the product Deltamethrin SC 7.5 was one of the representative formulations submitted for EU review according to the biocide directive 98/8/EC. Hence, where applicable this evaluation will follow the approaches as agreed on EU level and presented in: "*Document II B4 Effects and Exposure Assessment for K-OTHRINE SC 7.5 of the non public CAR, final June 2011*". Furthermore, approaches presented in the CAR for K-Othrine DP 0.05 (*Document II B3*

Effects and Exposure Assessment for K-OTHRINE DP 0.05 of the non public CAR, final June 2011) – a product used as well by amateurs to control ants – are taken into consideration.

Persons (adults and/or children) may be potentially exposed to Deltamethrin SC 7.5 via primary-, secondary- and/or combined routes of exposure. Accordingly, the corresponding exposure scenarios will be assessed in the following.

Primary exposure

Main routes of operator exposure to Deltamethrin SC 7.5 during the use phase are via inhalation and by the dermal route. Primary exposure to amateur operators may also occur during the post-application phase (cleaning and maintenance).

Hence both situations will be assessed in this evaluation.

Primary exposure during mixing/loading and application

Ref-MS Information to the reader:

In the TNsG on Human exposure (2007) there is a model scenario for professional mixing and loading by watering can. It is suggested to use the parameter for exposure of hands from this scenario as a worst case.

Mixing and loading of the b.p. into a watering can and application of the diluted product to ant nests

Data base for exposure estimation		
Parameter	Value	Reference
AEL_{acute}	0.0075 mg/kg bw	CAR/PAR
$AEL_{medium-term}$	0.0075 mg/kg bw/d	CAR/PAR
$AEL_{long-term}$	0.0075 mg/kg bw/d	CAR/PAR
Oral absorption	75%	CAR/PAR
Dermal absorption	2%	CAR/PAR
Inhalation absorption	100%	CAR/PAR
Inhalation rate adult	1.25 m^3/h	Default, TNsG on Human Exposure (2007)
Body weight adult	60 kg	HEEG opinion 'Default human factor values for use in exposure assessments for biocidal products' (2013)
Body weight toddler	10 kg	HEEG opinion 'Default human factor values for use in exposure assessments for biocidal products' (2013)
Clothing penetration	100%	Default, worst case
Parameter for Scenario 'Mixing and loading of the b.p. into a watering can and application of the diluted product to ant nests'		
Indicative value exposure hands (in gloves)	48.80 mg b.p. /min	TNsG on Human Exposure (2007) Professional mixing and loading and treating soil by watering can
Indicative value exposure hands (on gloves)	4880 mg b.p. /min	MOTA, version 6, section 4.2.10 2
Indicative value exposure rest of body (on gloves)	38.2 mg b.p. /min	TNsG on Human Exposure (2007) Professional mixing and loading and treating soil by watering can
Indicative value inhalation exposure	4.15 mg/m^3	TNsG on Human Exposure (2007) Professional mixing and loading and treating soil by watering can
Task duration	5 min	Expert judgement

To treat an ant nest, it is estimated that mixing/loading and application could take up to 5 minutes. Data from the model for professional mixing and loading and treating soil by watering can [TNsG on human exposure, 2007, page 68] have been used to assess exposure during mixing/loading and application. The indicative data are for application of a liquid in-use formulation to soil. After application, user should rinse the watering can with water and empty the rinsings on the treated area. The indicative exposure value for hand exposure in this model is based on exposure data in gloves. In accordance to the Manual of Technical Agreements (MOTA, version 6, section 4.2.10.2) the actual hand exposure (in gloves) is converted to the potential hand exposure by a multiplication factor of 100.

	Systemic (dermal) exposure	= *[indicative value hands (no gloves) + indicative value rest of body (on clothing)] x task duration x concentration a.s.in dilution x dermal absorption / body weight*
	Systemic (inhal.) exposure	= *indicative value inhalation x task duration x inhalation rate x concentration a.s.in dilution x inhal. absorption / body weight*
	Systemic dermal exposure:	**2.46×10^{-4} mg/kg bw/d**
	Systemic inhalation exposure:	**2.16×10^{-7} mg/kg bw/d**
	Total systemic exposure:	**2.46×10^{-4} mg/kg bw/d**

Application of the treatment solution is typically performed using a watering can. For this tape of application it can be concluded that "spray drift" which could be a source for primary exposure does not occur. Accordingly, significant exposure during application of the treatment solution is not expected. Taking furthermore into account that the treatment solution is highly diluted (i.e. 20 mL of product in 5 L of water*), it is concluded that the risk for primary exposure during application is negligible as compared to mixing and loading of the treatment solution, i.e. handling of the concentrate. Primary exposure during mixing and loading is calculated using the consumer exposure model (ConsExpo, Version 4.1) developed by the Netherlands National institute for Public Health and the Environment[3].

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

Default databases: Pest control products

Product categories: Mixing and loading

Default products: Mixing and loading

Scenario: Mixing and loading, liquid

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, mixing and loading, liquids

ConsExpo 4.1 report

file name:

Report date: 17.06.2013

Product

Compound

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

General Exposure Data

exposure frequency	6	1/year
body weight	60	kilogram

Inhalation model: Exposure to vapour : evaporation

weight fraction compound	0.75	%
exposure duration	1.33	minute
room volume	1	m^3
ventilation rate	0.6	1/hr
applied amount	500	gram
release area	20	cm^2
application duration	1.33	minute
mol weight matrix	3000	g/mol
mass transfer rate	1.68E3	m/min

Uptake model: Fraction

uptake fraction	100	%
inhalation rate	32.9	m^3/day

Dermal model: Direct dermal contact with product : instant application

weight fraction compound	0.75	%
exposed area	820	cm^2
applied amount	0.01	gram

Uptake model: fraction

uptake fraction	2	%

Outpout

Inhalation (point estimates)

inhalation mean event concentration :	0.0000000844	mg/m^3
inhalation mean concentration on day of exposure:	0.0000000000779	mg/m^3
inhalation air concentration year average :	0.00000000000128	mg/m^3/day
inhalation acute (internal) dose :	0.0000000000428	mg/kg
inhalation chronic (internal) dose :	0.000000000000702	mg/kg/day

Dermal : point estimates

dermal load :	0.0000915	mg/cm^2
dermal external dose :	0.00125	mg/kg
dermal acute (internal) dose :	0.000025	mg/kg
dermal chronic (internal) dose :	0.000000411	mg/kg/day

Integrated (point estimates)

total external dose:	0.00125	mg/kg
total acute dose (internal):	**0.000025**	**mg/kg**
total chronic dose (internal):	0.000000411	mg/kg/day

Operator exposure during cleaning of the application equipment

Usually cleaning is performed by filling clean water in the application device, in this case a watering can. It is obvious that during this procedure the unavoidable small amount of the treatment solution remaining in the sprayer after application gets highly diluted. Furthermore, as for application there is no significant risk expected for the operator to come into contact with the cleaning solution during disposal of the solution. Therefore, it is reasonable to conclude that exposure during cleaning is negligible as compared to the situation when the concentrate is handled during mixing and loading.

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

Drench application

Persons (adults and/or children) may be secondarily exposed to Deltamethrin SC 7.5 when re-entering area where the product has been applied. From the perspective of persons re-entering a treated area re-entry by a child – or in the context of the assumed body weight of 10 kg better characterised as toddler – is considered to represent the worst case exposure scenario and is therefore addressed in the following.

A. Exposure of a toddler to deltamethrin when re-entering area where the product has been applied.

Ref-MS Information to the reader:	The Applicant states below that with the assumed exposure conditions, only 50% of the total surface is treated. This is not correct, if the terrace is assumed to be 30 m^2 and 5 m^2 is treated this is 17% of the total area. Five m^2 corresponds to the maximum application rate (5L of the drench solution per 5 m^2 per ant nest).

In line with the CAR prepared for deltamethrin regarding the representative formulation K-Othrine DP 0.05 – being as well a product used by amateurs to control ants – calculation of secondary exposure will be performed considering the worst case scenario: "A toddler re-enters a terrace where Deltamethrin SC 7.5 has been applied". Furthermore, according to the CAR it is assumed that one ant nest has been treated using the maximum application rate. Accordingly for Deltamethrin SC 7.5 the calculations consider an application rate of 1 L treatment solution per m^2 (= 30 mg a.s./m^2) and 5 m^2 are treated. According to: OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 18, EMISSION SCENARIO DOCUMENT FOR INSECTICIDES, ACARICIDES AND PRODUCTS TO CONTROL OTHER ARTHROPODS FOR HOUSEHOLD AND PROFESSIONAL USES (ENV/JM/MONO(2008)14), 17-Jul-2008), the size of the terrace is assumed to be 30 m^2. The transfer coefficient (TC) is assumed to be 6000 cm2/day. It has to be noted that this transfer coefficient reflects the situation where the toddler permanently plays on treated surface. However, with the assumed exposure conditions only 50% of the total surface is treated. Hence, to reflect this situation and to be in line with the proposed TC the average surface loading is taken into account for the exposure calculations. The same approach was selected in the CAR for K-Othrine DP 0.05. Regarding the transfer of residues to the skin a 30% transfer was considered in the CAR for K-Othrine DP 0.05 being formulated as a ready to use powder. However, for Deltamethrin SC 7.5 being applied as a water solution a 10% transfer is assumed as tier I as proposed in the CAR for K-Othrine SC 7.5.

Assumptions/considerations to calculate secondary exposure of a child to Deltamethrin SC 7.5 are summarised in the following table:

Assumptions to calculate secondary exposure

Scenario:	**Secondary exposure to a toddler when re-entering a terrace where Deltamethrin SC 7.5**
Maximum application rate:	4 mL Deltamethrin SC 7.5/m2 (30 mg a.s./m2)
Surface residues (SR):	5 mg a.s./m2 = 0.0005 mg a.s./cm2 (considers total size of the terrace of 30 m2 with 5 m2 being treated)
Surface Transferable Residues (TR): Hard surfaces:	10% of the residues present on the surface**
Transfer Coefficient (TC):	6000 cm2 per day
Dermal absorption:	2% (as given in the CAR)
Inhalation absorption:	100% (as given in the CAR)
Oral absorption:	75% (as given in the CAR)
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.

** [redacted] A value of 10% dislodgeability was used in the CAR to assess transfer from hard surfaces.

Corresponding exposure calculations are presented below.

Dermal exposure (D) of the toddler is calculated as follows: **D = SR x TR x TC**	
SR (mg a.s./cm²):	0.0005
TR:	0.1
TC (cm²/day):	6000
D (mg a.s./toddler/day):	**0.30**
Taking into account the dermal absorption of 2 % systemic exposure by the dermal route (Sdermal) is calculated as follows: **Sdermal = D x Dermal absorption ÷ body weight**	
D (mg a.s./toddler/day):	0.30
Dermal absorption:	0.02
Body weight (kg bw):	10
Sdermal (mg a.s./kg bw/day):	**0.00060**
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). The systemic exposure by the oral route (Soral) is calculated as follows: **Soral = D x Fraction on hands x Hand to mouth transfer x Oral absorption ÷ Body weight**	
D (mg a.s./toddler/day):	0.30
Fraction of D on hands:	0.2
Hand to mouth transfer:	0.5
Oral absorption:	0.75
Body weight (kg bw):	10
Soral (mg a.s./kg bw/day):	**0.00225**
Total systemic exposure (Stotal) by the dermal route and hand to mouth transfer is calculated as follows: **Stotal = S dermal + S oral**	
Sdermal (mg a.s./kg bw/day:)	0.00060
Soral (mg a.s./kg bw/day):	0.00225

Stotal (mg a.s./kg bw/day):	**0.00285**

2.7.2 Environmental exposure assessment

Ref-MS Information to the reader:	The exposure assessment by the applicant is acceptable. Section 2.7.2.1 *Fate and distribution in the environment* is cut and paste with slight editorial changes from the deltamethrin CAR.

2.7.2.1 Fate and distribution in the environment

2.7.2.1.1 Abiotic degradation

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

2.7.2.1.2 Biodegradation

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

2.7.2.1.3 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 Deltamethrin 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 Deltamethrin 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 (preparation step) of Deltamethrin 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 use around domestic house. Where pertinent, the characterstics, e.g. Henry's Law's constant and partitioning coefficient, of Br_2CA has been incorporated in the calculations.

2.7.2.1.4 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.

For further details of the assessment of the environmental fate and behaviour of the active substance contained in biocidal product(s), refer to the chapter on Fate and distribution in the environment Doc. II-A in the CAR.

2.7.2.2 Emmission pathways

Deltamethrin SC 7.5 (*Myrr till utvattning*) is an insecticide (biocidal product type 18) intended for use by consumers on terraces, patios and pathways around private housing. It is used for the control of workers and nests of the Black Ant (*Lasius niger*), and other commonly found garden ants.

Deltamethrin SC 7.5 is a suspension concentrate formulation containing the active substance, deltamethrin, at a concentration of 7.5 $g.L^{-1}$. Following dilution of the product in water, the treatment solution may be applied directly to ant nests and surrounding areas as a drench treatment, at an active substance dose rate of 30 $mg.m^{-2}$. Treatment typically takes place over an area of 5 m^2 per nest. The treatments described above are best represented by the outdoor "spot application" pattern described in the Emission Scenario Document (ESD) for insecticides for household and professional uses (PT 18; OECD, 2008).

Various life-cycle stages can be distinguished in the environmental exposure assessment. The manufacture of the active ingredient, deltamethrin, does not take place in the EU, and is thus not further discussed. The formulation of Deltamethrin SC 7.5 takes place at manufacturing plants that are strictly regulated. These 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 adhere 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 therefore proposed that no unacceptable emissions will occur during the formulation stage of the product life cycle.

Potential emissions to the environment are possible during both the preparation step and the application step of the product life cycle. These emissions are considered in the following sections. The potential for environmental exposure has been evaluated with specific reference to the local environmental scale. Due to the nature of the product preparation and application procedure, it would be expected that, in most cases, any environmental exposure would be localised in nature. It is therefore assumed that any contribution from the regional scale would be so low that it could be considered negligible.

For the waste disposal stage of the product life cycle, it is considered that exposure to the wastewater compartment by washing application equipment, or by illegal disposal, should not occur. It should be noted that disposal of insecticide residues to wastewater is not recognised as a potential exposure pathway in the ESD for household and professional uses of insecticides (PT18; OECD, 2008). In addition, It is not expected that the disposal of empty product packaging to landfill will contribute significantly to the overall environmental exposure in comparison to the emissions from other parts of the life-cycle of the substance (e.g. preparation and application stages). Therefore, based upon the recommendations made in the Technical Guidance Document (European Commission, 2003) it is proposed that waste considerations can be excluded from the assessment process, since general risk management measures based on EU waste legislation should be sufficient.

2.7.2.2.1 Estimated environmental emissions during the preparation step

Ref-MS Information to the reader:	Please note that fraction emitted product to floor ($F_{prep,floor}$) in the equation below also relates to emission to ground.

Deltamethrin SC 7.5 is packaged in HDPE bottles. A preparation step is required prior to the use of the product, involving pouring of the required quantity of product into the contents of a watering can. The resultant treatment solution will then be directly applied to the treated area.

The ESD for insecticides used in household and professional situations (PT 18; OECD, 2008) recommends that emissions from the mixing/loading event should be considered for both 'rural' and 'urban' exposure scenarios. In the rural scenario emissions are directed to soil, while the urban scenario assumes emission of the active substance to a sewage treatment plant (STP).

The ESD for PT18 provides default emission fractions for releases to the ground during outdoor mixing/loading events. The potential emission of the active substance to the ground during the mixing/loading step was calculated as follows:

$$E_{prep,floor} = Q_{prod,prep} \times F_{AI} \times N_{prep} \times F_{prep,floor} \times 10^{-3}$$

Where:

Variable/parameter (units)	Symbol	Unit	Default	Source
Quantity of commercial product used for the preparation	$Q_{prod,prep}$	[mL]	4, 20 or	Input
Concentration of active substance in the commercial product	F_{AI}	[g mL^{-1}]	0.0075	Input
Number of preparations per day	N_{prep}	[d^{-1}]	1	Default
Fraction emitted to ground during preparation step [-]	$F_{prep,floor}$	-	0.001	Pick-list
Emission to ground during preparation step	$E_{prep,floor}$	[kg.d^{-1}]	-	Output

The number of preparations per day was set at the default value of 1. The volume of product used to prepare the treatment solution, $Q_{prod,prep}$, was calculated based on the treatment of a single ant nest ($Q_{prod,prep}$ = 4 mL for a 1 m^2 treatment area, or 20 mL for a 5 m^2 treatment area). In each case, the fraction of the active substance lost to the ground ($F_{prep,floor}$) was taken as 0.001, based on the default figure specified for use of non-specific containers up to 1 litre in size by the general public (worst case). The resulting estimated releases during the preparation step ($E_{prep,floor}$) are presented in the table below.

Table 2.7.2.2.1-1 Estimated emissions to the ground associated with the mixing/loading stage for Deltamethrin SC 7.5

Substance	Treatment type	$E_{prep,floor}$ [kg.d^{-1}]
Deltamethrin	Ant nest treatment – 1 m^2	3.00E-08
	Ant nest treatment – 5 m^2	1.50E-07

For the rural scenario, it is assumed that the emissions from the preparation step remain in soil. Calculations of the resulting exposure for the soil and groundwater compartments are presented in Section 2.7.2.7 and 2.7.2.5 respectively.

In urban areas, any active substance released to the ground from the preparation step is assumed to be washed off by rainwater to the municipal wastewater system. For local-scale assessments, the Technical Guidance Document (European Commission, 2003) assumes that wastewater will pass through a municipal Sewage Treatment Plant (STP) before being discharged into the environment. It is possible that multiple emissions may occur simultaneously within a STP catchment. In order to take account of this possibility, a factor – $F_{simultaneity}$ – is defined, which represents the proportion of buildings, at the catchment scale, in or around which the insecticide might be simultaneously applied.

In the ESD for PT18, reference is made to a French survey on the frequency of insecticide use by the general public. In this survey, the general public was questioned on their use of insecticide, and positive answers were split into bands of usage frequency. The results of the survey are presented in the table below.

Table 2.7.2.2.1-2 Responses to French survey of insecticide use by the general public (PT18; OECD, 2008)

Frequency of use	Number of positive answers (%)	% of houses treated per day
One time per day	2.77	100
One time per week	9.51	14.3
One time per month	17.74	3.22
Three to eleven times per year	32.15	1.9
One to two times per year	37.82	0.54

In accordance with the ESD (OECD, 2008), and conservatively assuming that 100% of the domestic households within the catchment are treated with insecticides at least once a year, the percentage of simultaneous use can be estimated using the following equation:

$$F_{simultaneity} = \frac{100 \times 2.77 + 14.3 \times 9.51 + 3.22 \times 17.74 + 1.9 \times 32.15 + 0.54 \times 37.82}{100} = 5.52\%$$

However, in the case of *Deltamethrin SC 7.5*, it is known that the product will not be used on a daily, weekly or monthly basis. The product exhibits sustained residual activity (up to three months) where residues remain undisturbed, and repeat treatments are only carried out as necessary (e.g. every three months, or longer, if target pests re-infest). Thus, the numbers relating to these frequencies can be removed from the $F_{simultaneity}$ calculation. The revised calculation of $F_{simultaneity}$ is performed as follows:

$$F_{simultaneity} = \frac{1.9 \times 32.15 + 0.54 \times 37.82}{100} = 0.815\%$$

In accordance with the Minutes of the Biocides Technical Meeting 15-19 February 2010, a total of 2500 houses in the STP catchment is assumed for outdoor uses. Assuming a simultaneity factor of 0.815% among these households, the following daily emissions to STP were estimated for the urban scenario, across the whole catchment:

$$Elocal_{water} = E_{wastewater} \times F_{sim} \times N_{Buildings}$$

Estimated daily emissions to STP resulting from product preparation are given in the table below.

Table 2.7.2.2.1-3 Estimated emission to STP from product preparation for parent and metabolite Br_2CA (assuming 100% formation of the metabolite before emission to STP)

Substance	$Elocal_{water}$ [kg.d^{-1}]
Ant nest treatment – 1 m^2	
Deltamethrin	6.11E-07
Br_2CA	3.61E-07
Ant nest treatment – 5 m^2	
Deltamethrin	3.06E-06
Br_2CA	1.80E-06

2.7.2.2.2 Estimated environmental emissions during the application step

The scenario for powder applications to ant nests presented in the ESD for insecticides for household and professional uses (PT 18; OECD, 2008) has been used as a basis for estimating emissions during the application step. The ESD indicates that this powder scenario is also applicable where products are solubilized and applied using a watering can, as is the case for *Deltamethrin SC 7.5*. It is therefore proposed that drench treatments using *Deltamethrin SC 7.5* are sufficiently addressed using the powder scenario. The environmental compartments considered relevant for emissions during the application step are presented in the table below.

Table 2.7.2.2.2-1 Environmental compartments potentially exposed during the application of *Deltamethrin SC 7.5*; source: ESD No. 18 (OECD, 2008)

Main scenario	Sub-scenario	Environmental compartments/protected target exposed					Secondary poisoning
		Air	STP/rainwater	Soil	Surface water	Groundwater	
Powder	Ant nest (rural/urban)	(+)		++		+	+

++ Compartment primarily exposed

\+ Compartment secondarily exposed

(+) Compartment potentially exposed

In accordance with the ESD, the possible receiving compartments are the soil and, to a lesser extent, the air. Release to the air is expected to be negligible, however, due to the low vapour pressure of the active substance (1.24×10^{-8} Pa; Yoder, 1991a).

2.7.2.2.3 Environmental emissions during ant nest treatment

Ant nests are treated at a product dose rate of 4 mL.m^{-2} (active substance dose rate 30 mg.m-^{2}), with treatment taking place over an area ranging from 1 m^2 to 5 m^2. Emissions have therefore been calculated for treated areas of two sizes: 1 m^2 and 5 m^2.

The default emission fraction to soil for powders is 90%. However, as a worst-case, it has been assumed that 100% of the applied product will reach the soil. The direct emission to soil was calculated as follows:

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

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

Where:

Variable/parameter (unit)	Symbol	Unit	Value	Source
Treated area	$AREA_{treated}$	[m^2]	1 or 5	Input
Volume of product applied per m^2	$Dose$	[mL m^{-2}]	4	Input
Quantity of commercial product used for the preparation	Q_{prod}	[mL]	4 or 20	Calculated
Concentration of active substance in the commercial product	F_{AI}	[g mL^{-1}]	0.0075	Input
Number of application sites	N_{sites}	[-]	1	Input
Number of applications	N_{appl}	[-]	1	Input
Fraction emitted to soil during outdoor application on ant nest	$F_{spot\ liquid,\ soil}$	[-]	1	Input*
Direct emission of active substance to soil	$E_{spot,soil}$	[g]	0.03 or 0.15	Output

*Worst-case assumption; default value from ESD PT18 is 0.9 (OECD, 2008)

The calculated emission to soil, $E_{spot,soil}$, as a result of ant nest treatment was therefore 0.03 g for a 1 m^2 area, or 0.15 g for a 5 m^2 area.

2.7.2.3 Estimated environmental exposure during the preparation step

2.7.2.3.1 Soil compartment (preparation step; rural scenario)

Ref-MS Information to the reader:	Concerning the mixing depth of the receiving compartment. Please note that a mixing depth of 50 cm should primarily be considered for PEC calculations. See: TAB from WG II 2015 section 2.4.14 part 2. a soil depth of 50 cm should be applied in restricted areas.

For the rural scenario, it is assumed that emissions from the preparation step remain in soil. Spillage during the preparation of the drench mixture occurs around the application vessel and the user. It is

assumed that this area of ground is separate from the treated area and, hence, the concentration in soil should be calculated distinctly from that of the application step.

A default value of 0.8 m^2 is proposed for the area of the receiving soil compartment (PT 18; OECD, 2008). The volume of this compartment, $V_{spray,outdoor,prep,soil}$, is then calculated as the product of the receiving soil area and the mixing depth. There is some inconsistency in the guidance regarding soil mixing depths. The ESD for insecticides used in household and professional situations (PT 18; OECD, 2008) suggests a default mixing depth of 0.5 m (in-line with that already employed for PT8 assessments). However, the notes from the PT18 workshop of December 2007 (European Commission, 2007) indicate a regulatory preference for shallower mixing depths, with 0.1 m being proposed in the case of no mixing, and 0.2 m in case of mixing. In the absence of clear guidance regarding the level of disturbance in the soil used for mixing and loading, calculations have been performed for all three mixing depths.

The local concentration of the substance in the soil for the rural scenario (in $mg.kg^{-1}$) can be calculated from the emission to soil, $E_{prep,outdoor,soil}$ (in kg), as follows:

$$C_{local,prep,outdoor,soil} = \frac{E_{prep,outdoor,soil}}{V_{spray,outdoor,prep,soil} \times RHOsoil} \times 1000000$$

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 ecosystems, a period of 30 days is taken as a relevant time period with respect to chronic exposure of soil organisms. The ESD for household and professional uses of insecticides (OECD, 2008) also indicates that the instantaneous concentration after 30 days should be calculated. Therefore, predicted concentrations of deltamethrin in soil have been calculated immediately after the mixing/loading event, as a time-weighted average over a 30-day period, and at the end of the 30-day period. These predicted concentrations are given in section 2.7.2.7.

Time-weighted average concentrations in soil are determined as:

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

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

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

Where:

$k = ln2/DT_{50}$ (day^{-1})

t = time period (days)

DT_{50} = half-life of degradation in soil (days)

PEC = Predicted Environmental Concentration

PIEC = Predicted Initial Environmental Concentration

In these calculations t = 30 days. The DT_{50} value for deltamethrin was taken as 48.2 days (geometric mean of DT_{50} values generated in studies on four different soil types, normalised to 12°C and pF2 / field capacity). A description of the soil degradation studies and the normalisation process is provided in Section 1.3 of DocIIA or the CAR.

The degradation of deltamethrin residues in soil may result in the formation of the major metabolite, Br_2CA. Initial concentrations of Br_2CA in soil were estimated using a worst-case assumption that the metabolite is formed in the soil at a quantity equivalent to 100% of the parent compound, adjusted to account for the difference in molecular weight between deltamethrin and Br_2CA. Predicted initial concentrations of deltamethrin in soil were therefore adjusted by a factor of 0.59 (298.0 / 505.2 = 0.59) to provide estimates of exposure for Br_2CA. It should be noted that these PEC values represent extreme worst-case estimates of exposure, since laboratory data indicate that Br_2CA is formed at a maximum of only 23% of the parent compound in aerobic soils after 14 days (Wang, 1991).

Estimated time-weighted average concentrations of Br_2CA in soil were also calculated using the procedure described above. The calculated PECs are given in section 2.7.2.7. These calculations were carried out using a geometric mean DT_{50} value for Br_2CA of 5.6 days, based on data from three soils normalised to 12°C and pF2 (field capacity). It is recognised that, in reality, the formation and degradation of the metabolite Br_2CA is a more complex process, giving rise to much lower, more steady state concentrations in soil. However, these estimates of time weighted average concentrations have been included to provide worst-case values for risk assessment purposes.

2.7.2.3.2 Groundwater compartment (preparation step; rural scenario)

It is recognised that there may be some potential for residues of deltamethrin present 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 of each compound in soil porewater has been calculated to provide an indication of the potential groundwater contamination risk. This approach is recognised as a suitable first-tier method of estimating groundwater exposure. It should be noted that this is a worst-case approach, neglecting transformation, sorption and dilution.

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

Air water partition coefficient [-]

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

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

$$Kpsoil = Koc \times Foc$$

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

$$K_{soil-water} = Fair \times K_{air-water} + Fwater + Fsolid \times \frac{Kp_{soil}}{1000} \times RHOsolid$$

Where:

Variable/parameter (unit)	Symbol	Unit	Value	Source*
Henry's Law Constant	*HENRY*	[$Pa.m^3\ mol^{-1}$]	1.25E-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	*Koc*	[L kg^{-1}]	408250	Input
Fraction organic carbon in the soil	*Foc*	[-]	0.02	Default
Soil water partition coefficient	*Kpsoil*	[L kg^{-1}]	-	Output
Fraction air in soil	*Fair*	[-]	0.2	Default
Fraction water in soil	*Fwater*	[-]	0.2	Default
Fraction solid in soil	*Fsolid*	[-]	0.6	Default
Bulk density of solids	*RHOsolid*	[$kg.m^{-3}$]	2500	Default
Soil-water equilibrium partition distribution coefficient	*Ksoil-water*	[$m^3.m^{-3}$]	-	Output

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

Therefore, for deltamethrin:

Air water partition coefficient [-]:

$$Kair-water = \frac{1.25 \times 10^{-03}}{8.314 \times 285} = 5.28 \times 10^{-07}$$

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

$$Kpsoil = 408250 \times 0.02 = 8165$$

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

$$K_{soil-water} = 0.2 \times 5.28 \times 10^{-07} + 0.2 + 0.6 \times \frac{8165}{1000} \times 2500 = 12247.7$$

The equation for deriving the concentration in porewater is:

$$PEClocal_{soil,porew} = \frac{PEClocal_{soil} \times RHOsoil}{K_{soil\text{-}water} \times 1000}$$

Where:

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

Ref-MS Information to the reader:	Input parameter *PEClocal soil* is found in table 2.7.2.7.2-2.

Predicted porewater concentrations of metabolite Br_2CA were calculated in an analogous manner to those of the parent compound, using the following substance-specific parameters:

Variable/parameter (unit)	Symbol	Unit	Value	Source*
Henry's Law Constant	*HENRY*	[$Pa.m^3\ mol^{-1}$]	4.04E-03	Input
Partition coefficient organic carbon -water	*Koc*	[L kg^{-1}]	25.6	Input

Calculated porewater PECs for deltamethrin and Br_2CA for the rural scenario are given in section 2.7.2.5.

2.7.2.3.3 Fate in the sewage treatment plant (preparation step; urban scenario)

Ref-MS Information to the reader:	Upon recommendation from other Member States, the approach in the CAR employing SimpleTreat 3.1 is used to model the fate of deltamethrin in the STP. Hence, applicant's text and approach employing SimpleTreat version 4 is omitted.

In urban areas, any active substance released to the ground from the preparation step is assumed to be washed off in rainwater to the STP. The concentration of deltamethrin in the STP influent (i.e. the untreated wastewater) can be calculated as follows:

$$Clocal_{\text{inf}} = \frac{Elocal_{water} * 10^6}{Effluent_{stp}}$$

Where:

Variable/parameter	Symbol	Unit	Value	Source
Local emission to (waste) water during episode	$Elocal_{water}$	[$kg.d^{-1}$]	-	Input*
Effluent discharge rate of STP	$EFFLUENT_{stp}$	[$L.d^{-1}$]	2000000	Default**
Concentration in untreated waste water	$Clocal_{inf}$	[$mg.L^{-1}$]	-	Output

* See calculated values in table above (Estimated emission to STP from product preparation for parent and metabolite Br2CA (assuming 100% formation of the metabolite before emission to STP).

** Since no specific data are available, $EFFLUENT_{stp}$ has been based on an averaged wastewater flow of 200 L per capita per day for a population of 10,000 inhabitants. This is consistent with guidance provided in the Technical Guidance Document (European Commission, 2003).

The predicted concentration in surface water receiving releases from the STP is dependent upon the fraction directed to effluent. In order to carry out this calculation, it is necessary to consider the fate of deltamethrin within the STP. It is clear that, due to physico-chemical characteristics of the compound (strong affinity for sorption to organic carbon), a considerable portion of the deltamethrin load in wastewater will be removed through partitioning to sludge in the STP. In order to take this into account, estimates of distribution of the compound within STP compartments have been made using the SimpleTreat 3.1 model (Version 14th March 2003) (Struijs *et al*., 2003). This model is a multi-compartment box model, calculating steady-state concentrations in a sewage treatment plant, consisting of a primary settler, an aeration tank and a liquid-solid separator. The use of this model is consistent with guidance presented in the Technical Guidance Document (European Commission, 2003). The model takes into account the Henry's Law Constant and the organic carbon partitioning coefficient (K_{oc}) of the compound to predict partitioning behaviour. In the case of deltamethrin, these values are 1.25×10^{-08} Pa $m^3.mol^{-1}$ at 25°C and 408250 $g.L^{-1}$, respectively. The selection of the appropriate fate characteristics is also dependent upon the biodegradability of the compound.

Distribution of deltamethrin in the STP, as calculated by SimpleTreat 3.1

to air	0.00	%
to water	9.6	%
to sludge	90.4	%
degraded	0.00	%
total	100.00	%

The concentration of deltamethrin in the STP effluent ($Clocal_{eff}$) was calculated using the following equation:

$$Clocal_{eff} = Clocal_{\inf} * Fstp_{water}$$

Where:

Variable/parameter	Symbol	Unit	Value	Source
Concentration in untreated waste water	$Clocal_{inf}$	[mg.L^{-1}]	-	Input
Emission fraction directed to water in STP	$Fstp_{water}$	[-]	0.096	Input
Concentration of substance in the STP effluent	$Clocal_{eff}$	[mg.L^{-1}]	-	Output

The concentration of deltamethrin in dry sewage sludge was calculated from the local emission rate to waste water ($Elocal_{water}$), the fraction of the emission adsorbed to sludge ($Fstp_{sludge}$) and the rate of sewage sludge production:

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

Where:

Variable/parameter	Symbol	Unit	Value	Source*
Emission rate to water during episode	$Elocal_{water}$	[kg.d^{-1}]	-	Input**
Fraction of emission directed to sludge by STP	$Fstp_{sludge}$	[-]	0.904	Input
Rate of sewage sludge production	*SLUDGERATE*	[kg.d^{-1}]	710	Default
Concentration in dry sewage sludge	C_{sludge}	[mg kg^{-1}]	-	Output

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

** See calculated values in table above (Estimated emission to STP from product preparation for parent and metabolite Br2CA (assuming 100% formation of the metabolite before emission to STP)

Whether the STP concentration most relevant to microorganisms is $Clocal_{inf}$ or $Clocal_{eff}$ will depend upon the exposure profile that is likely to occur. As a worst case, it is assumed that microorganisms will be exposed to concentrations equivalent to those present in the untreated wastewater ($Clocal_{inf}$).

Therefore:

$PEC_{stp} = Clocal_{inf}$

Where:

Variable/parameter	Symbol	Unit	Value	Source
Concentration in untreated waste water	$Clocal_{inf}$	[mg.L^{-1}]	-	Input
PEC for micro-organisms in STP	PEC_{stp}	[mg.L^{-1}]	-	Output

Estimated concentrations of deltamethrin and Br_2CA in STP influent, effluent and dry sewage sludge are given in section 2.7.2.5.

2.7.2.3.4 Release to surface water and sediment (preparation step; urban scenario)

In accordance with the guidance provided in the Technical Guidance Document, the local concentration of deltamethrin in the receiving surface water compartment is calculated as follows:

$$Kp_{susp} = FOC_{susp} * Koc$$

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

$$PEClocal_{water} = Clocal_{water}$$

Where:

Variable/parameter	Symbol	Unit	Value	Source
Partition coefficient organic carbon-water	K_{oc}	[L.kg^{-1}]	408250	Input
weight fraction of organic carbon of suspended matter	FOC_{susp}	[kg kg^{-1}]	0.1	Default*
Concentration of substance in the STP effluent	$Clocal_{eff}$	[mg.L^{-1}]	-	Calculated
Solids-water partitioning coefficient of suspended matter	Kp_{susp}	[L.kg^{-1}]	40825	Calculated
Concentration of suspended matter in the river	$SUSP_{water}$	[mg.L^{-1}]	15	Default*
Dilution factor	$DILUTION$	-	10	Default*
Local concentration in surface water during emission episode	$Clocal_{water}$	[mg.L^{-1}]	-	Output

*** Default values taken from the Technical Guidance Document (European Commission, 2003)**

The predicted concentration of deltamethrin in aquatic sediment is calculated according to the guidelines presented in the Technical Guidance Document. In order to estimate the concentration in aquatic sediment for deltamethrin, a number of partition coefficients were derived:

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

$$Kp_{susp} = Koc \times Foc_{susp}$$

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

$$K_{susp-water} = Fwater + Fsolid \times \frac{Kp_{susp}}{1000} \times RHOsolid$$

Where:

Variable/parameter (unit)	Symbol	Unit	Value	Source*
Partition coefficient organic carbon -water	*Koc*	[L kg^{-1}]	408250	Input
Fraction organic carbon in the suspended matter	Foc_{susp}	[-]	0.1	Default
Partition coefficient solid-water in suspended matter	Kp_{susp}	[L kg^{-1}]	40825	Output
Fraction water in suspended matter	*Fwater*	[-]	0.9	Default
Fraction solid in suspended matter	*Fsolid*	[-]	0.1	Default
Bulk density of solid phase	*RHOsolid*	[$kg.m^{-3}$]	2500	Default
Suspended matter-water equilibrium partition distribution coefficient	$K_{susp-water}$	[$m^3.m^{-3}$]		Output

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

Therefore:

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

$$Kp_{susp} = 408250 \times 0.1 = 40825$$

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

$$K_{susp-water} = 0.9 + 0.1 \times \frac{40825}{1000} \times 2500 = 10207.15$$

The concentration in bulk sediment can be derived from the predicted concentration in surface water, assuming a thermodynamic partitioning equilibrium:

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

Where:

Variable/parameter (unit)	Symbol	Unit	Value	Source*
Concentration in surface water during episode	*PECsw*	[mg.L^{-1}]	-	Input
Suspended matter-water partitioning coefficient	$K_{susp\text{-}water}$	[m^3.m^{-3}]	10207.15	Input
Bulk density of suspended matter	*RHOsusp*	[kg.m^{-3}]	1150	Default
Predicted environmental concentration in sediment	*PECsed*	[mg kg^{-1}]	-	Output

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

Concentrations of the major metabolite, Br_2CA, in surface water and sediment were estimated using the same approach as for the parent compound, using a Koc value of 25.6 mL.g^{-1}.

Estimated concentrations of deltamethrin and Br_2CA in surface water and sediment are given in section 2.7.2.5.2.

2.7.2.3.5 Release to soil via sewage sludge application to land (preparation step; urban scenario)

Since a proportion of the deltamethrin load entering an STP will partition into sludge, consideration has been given to the potential fate of these residues following application of sewage sludge to land. In order to do this, estimates of environmental exposure have been calculated according to the framework described in the Technical Guidance Document (European Commission, 2003).

The Technical Guidance Document indicates that, as a realistic worst-case, it should be assumed that sludge application takes place for 10 consecutive years. In order to calculate the potential exposure to soil over this time period, an initial concentration in soil after one year of sludge application needs to be derived. Due to the low volatility of deltamethrin, it is not expected that any emission to the air compartment will occur in the STP. The concentration in soil after the first year of sludge application is therefore given by:

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

Where:

Variable/parameter	Symbol	Unit	Value	Source*
Concentration in dry sewage sludge	C_{sludge}	[mg kg$_{dwt}^{-1}$]	-	Input
Dry sludge application rate	$APPL_{sludge}$	[kg m^{-2}.yr^{-1}]	-	Default**
Mixing depth of soil	$DEPTH_{soil}$	[m]	-	Default**
Bulk density of soil	RHO_{soil}	[kg$_{wwt}$.m^{-3}]	1700	Default
Concentration in soil due to sludge in first year at t = 0	$Csludge_{soil\ 1}(0)$	[mg kg$_{wwt}^{-1}$]	-	Output

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

** Values for mixing depth of soil and dry sludge application rate depend upon the endpoint being considered (see table below)

The Technical Guidance Document suggests that PECs for three different soils should be generated using this equation: a PEC in local soil for comparison against terrestrial ecosystem endpoints, a PEC in agricultural soil for comparison against crop endpoints for human consumption, and a PEC in grassland soil for comparison against endpoints in grass for cattle. Different values for the mixing depth of soil and dry sludge application rate are applicable, depending upon the endpoint being considered. These default values are summarised in the table below.

Table 2.7.2.3.5-1 Characteristics of soil and soil-use for the three different endpoints (taken from the Technical Guidance Document, European Commission, 2003)

Soil	Depth of soil (m)	Averaging time (days)	Rate of sludge application (kg_{dwt} $m^2.yr^{-1}$)	Bulk soil density (kg_{wwt} m^{-3})
Local soil	0.20	30	0.50	1700
Agricultural Soil	0.20	180	0.50	1700
Grassland Soil	0.10	180	0.10	1700

In accordance with the guidance presented in the Technical Guidance Document, worst-case initial PEC values were calculated for local soil, agricultural soil and grassland soil to enable comparison with a range of different endpoints.

Based upon the estimated initial concentrations in soil after one sludge application, the potential persistence of the substance in soil was investigated to establish the plateau maximum concentration in soil. This was carried out using the standard soil degradation equation introduced previously:

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

Where:

PIEC	Initial concentration in soil ($mg.kg^{-1}$)
k	$ln2/DT_{50}$ (day^{-1})
t	time period (days)
DT_{50}	half-life of degradation in soil (days)

Using a soil DT_{50} value for deltamethrin of 48.2 days (geometric mean of DT_{50} values derived from four different soils, normalised to 12°C and pF2 / field capacity), calculations were carried out in a Microsoft Excel spreadsheet to simulate the dissipation of deltamethrin after successive sludge applications, assuming a sludge application interval of one year. The calculations were carried out using a daily time-step. The total concentration present in soil at any one time was calculated as the sum of the residues in soil remaining from each of the annual sludge application events. The resulting pattern of deltamethrin dissipation in soil over a ten year period is summarised in the figure below.

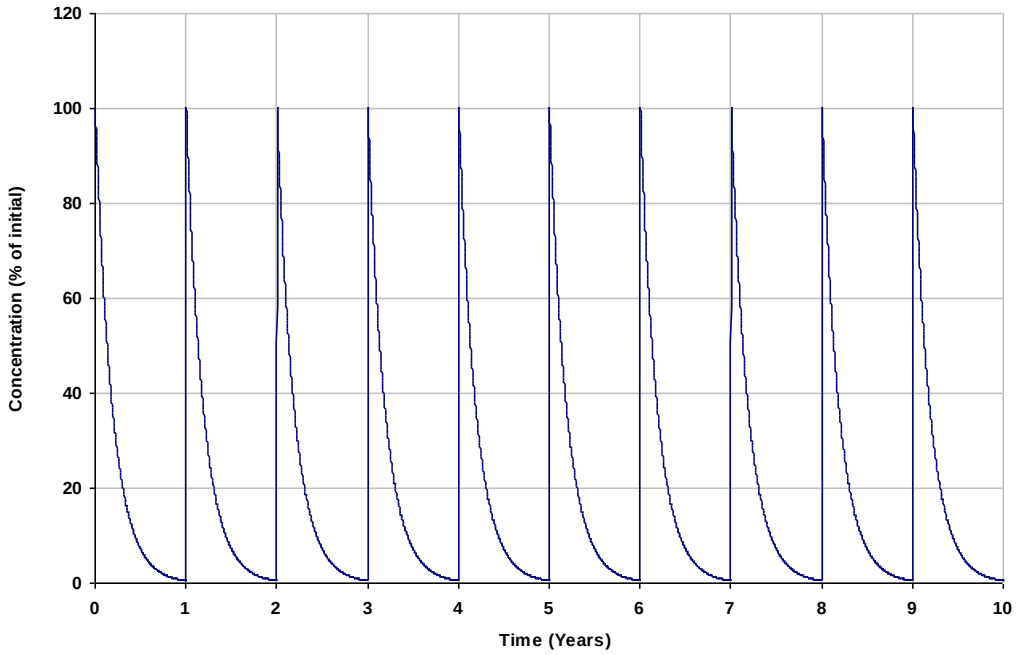

Figure 2.7.2.3.5-1 Potential for accumulation of deltamethrin residues in soil after ten consecutive annual sludge application events

From the figure above it can be seen that, following annual applications of sludge, concentrations of deltamethrin in soil fall quickly into a steady-state pattern. This reflects the relatively short half-life of the compound in soil, and therefore its low levels of carryover. An accumulation factor of 100.53% was calculated, with the maximum plateau concentration predicted to be reached immediately after the fifth annual sludge application. Predicted initial concentrations of deltamethrin in soil were therefore adjusted to take into account this very small potential for carryover; these instantaneous PECs are given in section 2.7.2.7.2.

The Technical Guidance Document (European Commission, 2003) advises that time-weighted average concentrations in soil over specified time periods should be calculated for risk assessment purposes. Different averaging times should be considered for various endpoints: for the ecosystem, a period of 30 days after application of sludge is used, whereas in order to determine biomagnification effects and indirect human exposure, it is more appropriate to use an extended period of 180 days. Time-weighted average concentrations in soil were calculated using the following equation (described earlier), assuming a DT_{50} of 48.2 days for deltamethrin:

$$TWA\ PEC(t) = PIEC \times (1-e^{-kt})/kt$$

In the case of an evaluation for terrestrial ecosystems t = 30 days, whilst t = 180 days for agricultural and grassland soils is more relevant to the assessment of bioaccumulation potential and porewater concentrations as a screening approach for groundwater assessment. The concentration in soil at any time can be calculated using the following equation:

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

Estimated time-weighted average concentrations of deltamethrin in soil following sludge application to land are given in section 2.7.2.7.

Degradation of deltamethrin residues may result in the formation of the major metabolite Br_2CA in soil. It is difficult to predict the quantity of metabolite Br_2CA present in soil after sludge application, since transformation of the parent may have occurred either in soil or in the sludge itself, under very different environmental conditions. Conservatively, it has been assumed that 100% transformation of the parent into Br_2CA takes place within the sludge, prior to application. To provide estimates of exposure for metabolite Br_2CA, predicted instantaneous concentrations of deltamethrin in sludge were therefore adjusted by a factor of 0.59 to account for the difference in molecular weight between the parent and metabolite (298.0 / 505.2). These values are given in section 2.7.2.7. It should be noted that these PEC values represent extreme worst-case estimates of exposure to soil, since laboratory data indicate that Br_2CA is formed at a maximum of only 23% from the parent deltamethrin in aerobic soils after 14 days (Wang, 1991).

There is no persistence potential between successive sludge application events as the metabolite Br_2CA is quickly degraded in soil. Time-weighted average concentrations of Br_2CA in soil were estimated using the same method as for deltamethrin, based on the maximum instantaneous concentration after a single sludge application. These calculations were carried out using a geometric mean DT_{50} for Br_2CA of 5.6 days, taken from the three soils normalised to 12°C and pF2 (field capacity). It is recognised that, in reality, the formation and degradation of the metabolite Br_2CA is a more complex process, giving rise to much lower, more steady state concentrations in soil. However, the included here provide worst case values for risk assessment purposes.

Estimated time-weighted average concentrations of Br_2CA in soil following sludge application to land are given in section 2.7.2.7.

2.7.2.3.6 Groundwater exposure (preparation step; urban scenario)

The concentrations of deltamethrin and Br_2CA in soil porewater were calculated from time-weighted average soil concentrations for agricultural soil over 180 days, in an analogous manner to that described previously for the rural scenario.

Estimated concentrations of deltamethrin and Br_2CA in porewater following sludge application to land are given in section 2.7.2.5.

2.7.2.4 Estimated environmental exposure during the application step

2.7.2.4.1 Soil exposure (application step)

Ref-MS Information to the reader:	Concerning the mixing depth of the receiving compartment. Please note that a mixing depth of 50 cm should primarily be considered for PEC calculations. See: TAB from WG II 2015 section 2.4.14 part 2. a soil depth of 50 cm should be applied in restricted areas.

The scenario for powder applications to ant nests presented in the Emission Scenario Document for insecticides for household and professional uses (PT 18; OECD, 2008) has been used as a basis for exposure estimation during the application step.

The potential emission of deltamethrin to soil during application of *Deltamethrin SC 7.5* was calculated previously in Section 2.7.2.2.3. For the treatment of ant nests, the total emission of the active substance to soil ($E_{spot,soil}$) was calculated to be 0.03 g for a 1 m^2 treatment area, or 0.15 g for a 5 m^2 treatment area.

For the treatment of ant nests, the area of the receiving soil compartment, $AREA_{exposed}$, is assumed to be 1 m^2 or 5 m^2, as appropriate.

The concentration in the soil was calculated for each use pattern as follows:

$$Cspot,soil = \frac{Espot,soil}{AREA\exp osed \times DEPTHsoil \times RHOsoil} \times 1000$$

Where:

Variable/parameter (unit)	Symbol	Unit	Value	Source
Local emission of active substance to soil	$E_{spot,soil}$	[g]	0.03 or 0.15	Input
Area directly exposed to insecticide	$AREA_{exposed}$	[m^2]	1 or 5	Default
Depth of exposed soil	$DEPTH_{soil}$	[m]	0.1, 0.2 or 0.5	Default
Density of exposed soil RHO	*RHOsoil*	[$kg.m^{-3}$]	1700	Default
Local concentration in soil due to direct release	*Cspot,soil*	[$mg.kg^{-1}$]	-	Output

As discussed previously, there is some inconsistency in the guidance regarding the soil mixing depth, with values of 0.5 m, 0.2 m and 0.1 m proposed at various points in the guidance. Calculations have therefore been performed for all three suggested depths.

Calculations of 30-day time-weighted average PECs, and exposure concentrations for metabolite Br_2CA, were performed as described previously for direct soil exposure during the preparation step (rural scenario). Estimated concentrations of deltamethrin and Br_2CA in soil as a result of the application step of the product life cycle are given in section 2.7.2.7.

2.7.2.4.2 Groundwater exposure (application step)

In order to assess the leaching potential of the parent and major metabolite Br_2CA, first-tier pore water calculations have been carried out based on the predicted 30-day average concentrations in local soil described in the previous section. These calculations were performed according to the framework outlined previously for direct soil exposure as a result of the preparation step of the product life cycle.

Estimated concentrations of deltamethrin and Br_2CA in soil porewater as a result of the application step of the product life cycle are given in section 2.7.2.5.

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

2.7.2.5.1 PEC in STP (preparation step; urban scenario)

Estimated concentrations of deltamethrin and Br_2CA in STP influent, effluent and sludge following the preparation step of the product life cycle are given in the table below. Metabolite calculations were performed assuming 100% degradation of the parent prior to emission to STP.

Alternative sludge concentrations for Br_2CA, assuming 100% formation of the metabolite from the parent compound in sludge (used in calculations of PEC_{soil}), are given in the table below.

Table 2.7.2.5.1-1 Predicted concentrations of deltamethrin and Br_2CA in STP influent, effluent and sludge following product preparation (metabolite calculations assume 100% degradation of parent before emission to STP)

Substance	$Clocal_{inf}$ [mg.L^{-1}]	$Clocal_{eff}$ [mg.L^{-1}]	C_{sludge} [mg kg^{-1}]
Ant nest treatment – 1 m^2			
Deltamethrin	3.06E-07	2.93E-08	7.78E-04
Br_2CA	1.81E-07	1.73E-08	4.60E-04
Ant nest treatment – 5 m^2			
Deltamethrin	1.53E-06	1.47E-07	3.90E-03
Br_2CA	9.00E-07	8.64E-08	2.29E-03

2.7.2.5.2 PEC in surface water and sediment (preparation step; urban scenario)

Estimated concentrations of deltamethrin and Br_2CA in surface water and sediment following the preparation step of the product life cycle are given in the table below.

Table 2.7.2.5.2-1 Predicted concentrations of deltamethrin and Br_2CA in surface water and sediment following product preparation (metabolite calculations assume 100% degradation of parent before emission to STP)

Substance	*PECsw* [mg.L^{-1}]	*PECsed* [mg kg$_{wwt}^{-1}$]
Ant nest treatment – 1 m^2		
Deltamethrin	1.82E-09	1.61E-05
Br_2CA	1.73E-09	2.32E-09
Ant nest treatment – 5 m^2		
Deltamethrin	9.10E-09	8.09E-05
Br_2CA	8.64E-09	1.16E-08

2.7.2.5.3 PEC in groundwater (preparation step; *via* sludge application; urban scenario)

Estimated concentrations of deltamethrin and Br_2CA in soil porewater (*via* sewage sludge application to land) following the preparation stage of the product life cycle are given in the table below.

Table 2.7.2.5.3-1 Predicted concentrations of deltamethrin and Br_2CA in soil porewater, *via* sludge application, following product preparation (metabolite calculations assume 100% degradation of parent in sludge)

Substance	Concentration in porewater (agricultural soil) 180d TWA (mg.L^{-1})
Ant nest treatment – 1 m^2	
Deltamethrin	5.70E-11
Br_2CA	5.36E-08
Ant nest treatment – 5 m^2	
Deltamethrin	2.86E-10
Br_2CA	2.67E-07

2.7.2.5.4 PEC in groundwater (preparation step; *via* direct soil exposure; rural scenario)

Estimated concentrations of deltamethrin and Br_2CA in soil porewater (*via* direct soil exposure in the rural scenario) following the preparation stage of the product life cycle are given in the table below.

Table 2.7.2.5.4-1 Predicted concentrations of deltamethrin and Br_2CA in soil porewater, *via* direct soil exposure, following product preparation (range of soil mixing depths)

Substance	Soil mixing depth (m)	Predicted concentration in porewater ($mg.L^{-1}$)	
		Based on initial conc. in soil	Based on 30-day TWA conc. in soil
Ant nest treatment – 1 m^2			
Deltamethrin	0.1	3.06E-08	2.49E-08
	0.2	1.53E-08	1.24E-08
	0.5	6.12E-09	4.97E-09
Br_2CA	0.1	2.29E-04	6.00E-05
	0.2	1.14E-04	3.00E-05
	0.5	4.57E-05	1.20E-05
Ant nest treatment – 5 m^2			
Deltamethrin	0.1	1.53E-07	1.24E-07
	0.2	7.65E-08	6.22E-08
	0.5	3.06E-08	2.49E-08
Br_2CA	0.1	1.14E-03	3.00E-04
	0.2	5.71E-04	1.50E-04
	0.5	2.29E-04	6.00E-05

2.7.2.5.5 PEC in groundwater (application step)

Estimated concentrations of deltamethrin and Br_2CA in soil porewater (*via* direct soil exposure) following the application stage of the product life cycle are given in the table below.

Table 2.7.2.5.5-1 Predicted concentrations of deltamethrin and Br_2CA in soil porewater following product application (range of soil mixing depths)

Substance	Soil mixing depth (m)	Predicted concentration in porewater ($mg.L^{-1}$)	
		Based on initial conc. in soil	Based on 30-day TWA conc. in soil
Ant nest treatment – 1 m^2			
Deltamethrin	0.1	2.45E-05	1.99E-05
	0.2	1.22E-05	9.95E-06
	0.5	4.90E-06	3.98E-06
Br_2CA	0.1	1.83E-01	4.80E-02
	0.2	9.14E-02	2.40E-02
	0.5	3.66E-02	9.61E-03
Ant nest treatment – 5 m^2			
Deltamethrin	0.1	2.45E-05	1.99E-05

	0.2	1.22E-05	9.95E-06
	0.5	4.90E-06	3.98E-06
Br_2CA	0.1	1.83E-01	4.80E-02
	0.2	9.14E-02	2.40E-02
	0.5	3.66E-02	9.61E-03

2.7.2.6 PEC in air

Due to the low vapour pressure of the active substance (1.24×10^{-8} Pa at 25°C, Yoder, 1991a), it is not expected that any volatile losses of deltamethrin to the air compartment would occur during or after the use of *Deltamethrin SC 7.5*.

This is consistent with the guidance presented in the ESD for PT18 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).

2.7.2.7 PEC in soil

2.7.2.7.1 PEC in soil (preparation step; *via* direct soil exposure; rural scenario)

Estimated concentrations of deltamethrin and Br_2CA in soil (*via* direct soil exposure) following the preparation stage of the product life cycle (rural scenario) are given in the table below.

Table 2.7.2.7.1-1 Predicted concentrations of deltamethrin and Br_2CA in soil following product preparation, *via* direct soil exposure (range of soil mixing depths)

Substance	Soil mixing depth (m)	Predicted initial concentration in soil (mg kg^{-1})	30-day time-weighted average concentration in soil (mg kg^{-1})	Concentration in soil at the end of 30-day period (mg.kg^{-1})
Ant nest treatment – 1 m^2				
Deltamethrin	0.1	2.21E-04	1.79E-04	1.43E-04
	0.2	1.10E-04	8.96E-05	7.16E-05
	0.5	4.41E-05	3.58E-05	2.87E-05
Br_2CA	0.1	1.30E-04	3.42E-05	3.17E-06
	0.2	6.51E-05	1.71E-05	1.59E-06
	0.5	2.60E-05	6.84E-06	6.35E-07
Ant nest treatment – 5 m^2				
Deltamethrin	0.1	1.10E-03	8.96E-04	7.16E-04
	0.2	5.51E-04	4.48E-04	3.58E-04
	0.5	2.21E-04	1.79E-04	1.43E-04
Br_2CA	0.1	6.51E-04	1.71E-04	1.59E-05
	0.2	3.25E-04	8.55E-05	7.94E-06

	0.5	1.30E-04	3.42E-05	3.17E-06

2.7.2.7.2 PEC in soil (preparation step; *via* sludge application to land; urban scenario)

Maximum instantaneous concentrations of deltamethrin and Br_2CA in soil (*via* sewage sludge application) following the preparation stage of the product life cycle are given in the table below. For the parent compound, these account for the potential for carryover between successive annual sludge application events (i.e. accumulation factor of 1.0053).

Table 2.7.2.7.2-1 Predicted maximum instantaneous concentrations of deltamethrin and Br_2CA in soil following product preparation, *via* sludge application to land (metabolite calculations assume 100% degradation of parent in sludge; parent calculations include accumulation factor of 1.0053)

Substance	$Csludge_{soil}$ (terrestrial ecosystem; mg kg_{wwt}^{-1})	$Csludge_{soil}$ (agricultural soil; mg kg_{wwt}^{-1})	$Csludge_{soil}$ (grassland soil; mg kg_{wwt}^{-1})
Ant nest treatment – 1 m^2			
Deltamethrin	1.15E-06	1.15E-06	4.60E-07
Br_2CA	6.79E-07	6.79E-07	2.72E-07
Ant nest treatment – 5 m^2			
Deltamethrin	5.76E-06	5.76E-06	2.46E-06
Br_2CA	3.39E-06	3.39E-06	1.36E-06

Table 2.7.2.7.2-2 Predicted time-weighted average concentrations of deltamethrin and Br_2CA in soil following the product preparation step, *via* sludge application to land (metabolite calculations assume 100% degradation of parent in sludge)

Substance	$Csludge_{soil}$ (terrestrial ecosystem) 30d TWA (mg kg_{wwt}^{-1})	$Csludge_{soil}$ (agricultural soil) 180d TWA (mg.kg_{wwt}^{-1})	$Csludge_{soil}$ (grassland soil) 180d TWA (mg kg_{wwt}^{-1})
Ant nest treatment – 1 m^2			
Deltamethrin	9.34E-07	4.10E-07	1.65E-07
Br_2CA	1.79E-07	3.05E-08	1.22E-08
Ant nest treatment – 5 m^2			
Deltamethrin	4.67E-06	2.06E-06	8.78E-07
Br_2CA	8.90E-07	1.52E-07	6.12E-08

2.7.2.7.3 PEC in soil (application step)

Estimated concentrations of deltamethrin and Br_2CA in soil following the application step of the product life cycle are given in the table below.

Table 2.7.2.7.3-1 Predicted concentrations of deltamethrin and Br_2CA in soil following product application (range of mixing depths)

Substance	Soil mixing depth (m)	Predicted initial concentration in soil ($mg.kg^{-1}$)	30-day time-weighted average concentration in soil ($mg\ kg^{-1}$)	Concentration in soil at the end of 30-day period ($mg\ kg^{-1}$)
Ant nest treatment – 1 m^2				
Deltamethrin	0.1	1.76E-01	1.43E-01	1.15E-01
	0.2	8.82E-02	7.17E-02	5.73E-02
	0.5	3.53E-02	2.87E-02	2.29E-02
Br_2CA	0.1	1.04E-01	2.73E-02	2.54E-03
	0.2	5.20E-02	1.37E-02	1.27E-03
	0.5	2.08E-02	5.47E-03	5.08E-04
Ant nest treatment – 5 m^2				
Deltamethrin	0.1	1.76E-01	1.43E-01	1.15E-01
	0.2	8.82E-02	7.17E-02	5.73E-02
	0.5	3.53E-02	2.87E-02	2.29E-02
Br_2CA	0.1	1.04E-01	2.73E-02	2.54E-03
	0.2	5.20E-02	1.37E-02	1.27E-03
	0.5	2.08E-02	5.47E-03	5.08E-04

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

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 K_{ow}. It is accepted that values of log K_{ow} greater than or equal to 3 indicate that the substance may bioaccumulate. Since deltamethrin has a log K_{ow} of 4.6 (Yoder, 1991b), 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 ([redacted] 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.

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, quantitative estimations of the potential for bioaccumulation of deltamethrin from consumption of earthworms and fish are presented in this risk assessment. Calculations have been performed for both the preparation and application steps of the product life-cycle, and for aquatic and terrestrial compartments where appropriate.

2.7.2.8.1 Diet sourced from the aquatic compartment

Secondary poisoning of predators whose diets are sourced from the aquatic compartment has been assessed only for the preparation step of the product life-cycle, where emissions from the urban environment may reach surface water *via* release from the STP.

A BCF of 1400 for whole body tissue [redacted] 1990) has been used in this risk assessment as a representative BCF_{fish} value. The Biomagnification value (BMF) is typically determined based on a measured BCF_{fish} value; if such a value is unavailable, the log K_{ow} should be used. Default BMF values for organic substances are presented in the table below.

Table 2.7.2.8.1-1 Default BMF values for organic substances; souce: TGD (European Commission, 2003)

log K_{ow} of substance	BCF (fish)	BMF
<4.5	< 2,000	1
4.5 - <5	2,000-5,000	2
5 – 8	> 5,000	10
>8 – 9	2,000-5,000	3
>9	< 2,000	1

Based on the measured BCF_{fish}, a BMF of 1 would be suitable, however, as a worst case, a BMF value of 2 has been used.

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 diet comes from an area impacted by local release of deltamethrin (referred to as the "local area") and the remaining diet would come from an area where regional background concentration can be expected (referred to as the "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.

Calculation of the $PEC_{oral\ predator}$ for the aquatic compartment was carried out according to the TGD and includes consideration that 50% of the predator's diet is sourced locally, as follows:

$$PEC_{oral,\ predator}(fish) = 0.5 \times PEC_{water} \times BCF_{fish} \times BMF$$

Where:

Variable/parameter (unit)	Symbol	Unit	Value	Source
Predicted environmental concentration in water	*PECwater*	[$mg.L^{-1}$]	-	Input
Bioconcentration factor for fish on wet weight basis	BCF_{fish}	[l $kg_{wet\ fish}^{-1}$]	1400	Input
Biomagnification factor in fish	*BMF*	[-]	2	Input
Predicted environmental concentration in food	$PEC_{oral,\ predator}$ *(fish)*	[mg $kg_{wet\ fish}^{-1}$]	-	Output

2.7.2.8.2 Diet sourced from the terrestrial compartment

Secondary poisoning of predators whose diets are sourced from the terrestrial compartment has been assessed for both the preparation and application steps of the product life-cycle. For the preparation step, secondary poisoning has been assessed for direct soil exposure in rural environments, and also for indirect exposure *via* land application of sewage sludge.

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 K_{ow} value of 40200 and the calculation method presented in the TGD, as shown below:

$$BCF_{earthworm} = \frac{(0.84 + 0.012 \times Kow)}{RHO_{earthworm}}$$

Where:

Variable/parameter (unit)	Symbol	Unit	Value	Source

Earthworm density	*RHOearthworm*	[$kg_{wwt}.L^{-1}$]	1	Default
Octanol-water partition coefficient	*Kow*	[-]	40200	Input
Bioconcentration factor for earthworms on wet weight basis	*BCFearthworm*	[$L.kg_{wet\ earthworm}^{-1}$]	-	Output

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

$$C_{earthworm} = \frac{BCF_{earthworm} \times C_{porewater} \times W_{earthworm} + C_{soil} \times W_{gut}}{W_{earthworm} + W_{gut}}$$

With:

$$CONV_{soil} = \frac{RHO_{soil}}{F_{solid} \times RHO_{solid}}$$

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

$$W_{gut} = W_{earthworm} \times F_{gut} \times CONV_{soil}$$

Where:

Variable/parameter (unit)	**Symbol**	**Unit**	**Value**	**Source**
Bioconcentration factor for earthworms on wet weight basis	*BCFearthworm*	[$L.kg_{wet\ earthworm}^{-1}$]	483	Input
Concentration in porewater	*Cporewater*	[$mg.L^{-1}$]	-	Input
Weight of earthworm tissue	*Wearthworm*	[$kg_{wwt\ tissue}$]	-	Input
Concentration in soil	*Csoil*	[$mg.kg_{wwt}^{-1}$]	-	Input
Weight of gut contents	*Wgut*	[kg_{wwt}]	-	Input
Fraction of gut loading in worm	*Fgut*	[$kg_{dwt}\ kg_{wwt}^{-1}$]	0.1	Default
Conversion factor for soil concentration wet-dry weight soil	*CONVsoil*	[$kg_{wwt}.kg_{dwt}^{-1}$]	-	Calculated
Bulk density of wet soil	*RHOsoil*	[$kg_{wwt}.m^{-3}$]	1700	Default
Volume fraction of solids in soil	*Fsolid*	[$m^3\ m^{-3}$]	0.6	Default
Density of solid phase	*RHOsolid*	[$kg_{dwt}\ m^{-3}$]	2500	Default
Concentration in earthworm on wet weight basis	*Cearthworm*	[$mg.kg_{wet\ earthworm}^{-1}$]	-	Output

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

$$C_{earthworm} = \frac{BCF_{earthworm} \times C_{porewater} + C_{soil} \times F_{gut} \times CONV_{soil}}{1 + F_{gut} \times CONV_{soil}}$$

As for the aquatic food chain, the TGD specifies that it would be unrealistic to consider that the totality of an animal diet would be sourced from the release area for the terrestrial compartment. Therefore, it is recommended to consider that 50% of the diet comes from an area impacted by local release of deltamethrin (referred to as the "local area") and the remaining diet would come from an area where regional background concentration can be expected (referred to as the "regional area"). In this risk assessment, it is considered that use of the product would not significantly contribute to environmental concentrations at the regional scale. Therefore, the following equation applies:

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

The TGD specifies that, for the assessment of biomagnification effects resulting from indirect soil exposure (i.e. sludge application to land), a time-weighted average period of 180 days can be used. Predicted environmental concentrations in the agricultural soil compartment (section 2.7.2.7), which represents the worst-case compartment for the 180-day time period, were therefore used to assess secondary poisoning for the case that deltamethrin reaches soil *via* sludge application.

For direct soil exposure, *via* product application or preparation in rural environments, the guidance provided is less clear. Two sets of calculations were therefore performed, using either the estimated initial concentrations, or estimated time-weighted average concentrations over a 30-day time-period.

2.7.2.8.3 Summary of predicted environmental concentrations of deltamethrin in predator diets

Estimated concentrations of deltamethrin in predator diets, for consideration of the risk of secondary poisoning, are presented in the tables below.

Table 2.7.2.8.3-1 Predicted concentrations of deltamethrin in secondary consumer diets, following emissions from product preparation (urban scenario)

Substance	$PEC_{oral,\ predator}$ (fish) [$mg.kg_{wet\ fish}^{-1}$]	$PEC_{oral,\ predator}$ (earthworm) [$mg\ kg_{wet\ earthworm}^{-1}$]
Ant nest treatment – 1 m^2		
Deltamethrin	9.05E-07	3.56E-08
Ant nest treatment – 5 m^2		
Deltamethrin	4.52E-06	1.78E-07

Table 2.7.2.8.3-2 Predicted concentrations of deltamethrin in secondary consumer diets, following emissions from product preparation (rural scenario)

Substance		Initial concentrations	30-d TWA

	Soil mixing depth (m)	Concentration in earthworm (Cearthworm) (mg.kg $_{wet\ earthworm}^{-1}$)	Predicted concentration in predator diet (mg kg $_{diet}^{-1}$)	Concentration in earthworm (Cearthworm) (mg.kg $_{wet\ earthworm}^{-1}$)	Predicted concentration in predator diet (mg.kg $_{diet}^{-1}$)
Ant nest treatment – 1 m²					
Deltamethrin	0.1	3.57E-05	1.79E-05	2.90E-05	1.45E-05
	0.2	1.79E-05	8.94E-06	1.45E-05	7.26E-06
	0.5	7.15E-06	3.57E-06	5.81E-06	2.90E-06
Ant nest treatment – 5 m²					
Deltamethrin	0.1	1.79E-04	8.94E-05	1.45E-04	7.26E-05
	0.2	8.94E-05	4.47E-05	7.26E-05	3.63E-05
	0.5	3.57E-05	1.79E-05	2.90E-05	1.45E-05

Table 2.7.2.8.3-3 Predicted concentrations of deltamethrin in secondary consumer diets, following emissions from product application

Substance	Soil mixing depth (m)	Initial concentrations		30-d TWA	
		Concentration in earthworm (Cearthworm) (mg.kg $_{wet\ earthworm}^{-1}$)	Predicted concentration in predator diet (mg kg $_{diet}^{-1}$)	Concentration in earthworm (Cearthworm) (mg.kg $_{wet\ earthworm}^{-1}$)	Predicted concentration in predator diet (mg.kg $_{diet}^{-1}$)
Ant nest treatment – 1 m²					
Deltamethrin	0.1	2.86E-02	1.43E-02	2.32E-02	1.16E-02
	0.2	1.43E-02	7.15E-03	1.16E-02	5.81E-03
	0.5	5.72E-03	2.86E-03	4.65E-03	2.32E-03
Ant nest treatment – 5 m²					
Deltamethrin	0.1	2.86E-02	1.43E-02	2.32E-02	1.16E-02
	0.2	1.43E-02	7.15E-03	1.16E-02	5.81E-03
	0.5	5.72E-03	2.86E-03	4.65E-03	2.32E-03

Ref-MS information to the reader:	Please note, that the assessment of secondary poisoning for insecticides should be based on the approach presented in the ESD PT18 No.18 (2008) considering the estimated theoretical exposure (ETE). However, a risk characterisation for Deltamethrin SC 7.5 based on ETE for insect and worm eating species has been calculated by cMS DE and leads to no unacceptable risk for the non-target species. The approach in this PAR was also used in the CAR for deltamethrin.

2.7.2.9 Product Waste Disposal

Exposure to the wastewater compartment by washing application equipment or illegal disposal should not occur. It should be noted that disposal of insecticide residues to wastewater is not recognised as a potential exposure pathway in the ESD for household and professional uses of insecticides (OECD, 2008).

2.7.2.9.1 Disposal to landfill

It is not expected that disposal of empty product packaging to landfill will contribute significantly to the overall environmental exposure in comparison to the emissions from other parts of the life-cycle of the substance (e.g. use stages). Therefore, based upon the recommendations made in the Technical Guidance Document (European Commission, 2003) it is proposed that waste considerations can be excluded from the assessment process since general risk management measures based on EU waste legislation should be sufficient.

Degradation data produced for deltamethrin in aerobic soils (DT50 30.7-73.7 days at 12°C and pF2) (Section 2.4.2.1, DOCIIA of the CAR) indicate that the parent compound is dissipated relatively quickly in the environment and is therefore unlikely to accumulate in the landfill matrix. Considering this information, as well as the requirement for technical and engineering requirements for aspects such as water control and leachate management, designed to protect soil and water stipulated under Council Directive 1999/31/EC of 26 April 1999, it may be concluded that the disposal of deltamethrin residues in solid waste to landfills would not be expected to present a groundwater contamination risk.

Considering the low vapour pressure of the active substance (1.24E-08 Pa at 25°C, Yoder, 1991a), it is not expected that any volatile losses of deltamethrin would leave the landfill with the produced landfill gas. This is consistent with the guidance presented in the ESD, which proposes that exposure of the air compartment is limited in time and restricted to local scale and that Fair can be considered to be negligible from an environmental point of view (OECD, 2008).

2.8 EFFECTS ASSESSMENT

2.8.1 Human health effects assessment

Acute, irritancy and sensitisation studies are available supporting the classification of Deltamethrin SC 7.5. 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

Ref-MS information to the reader:	No study has been conducted on Deltamethrin SC 7.5. However, the value of 2% dermal absorption is considered acceptable, since Deltamehtrin SC 7.5, which is an aqueous solution, can be expected to have a lower dermal absorption than for the tested organic solvent formulations (EC/EW) investigated in the studies in the Competent Authority Report of deltamethrin (final CAR, Doc IIB4).

Deltamethrin SC 7.5 was one of the representative formulations submitted for EU review according to the biocide directive 98/8/EC. For the representative formulations submitted for EU review, i.e. K-Othrine WG 250, Deltamethrin 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. 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 SC 7.5.

Therefore, taking into account a dermal absorption of **2%** for the purpose of human exposure risk assessment for Deltamethrin SC 7.5 has to be regarded as a worst case approach.

2.8.1.2 Acute toxicity

Ref-MS information to the reader:	Although the studies on acute toxicity are not performed on Deltamethrin SC 7.5, Ref-MS accepts the read across arguments and agrees with the conclusion that the product does not require a classification regarding acute toxicity.

The acute oral, dermal, inhalation and eye and skin irritation studies were run with a suspension concentrate containing [redacted]) instead of Deltamethrin SC 7.5, while the skin sensitisation potential was tested with [redacted] in a LLNA study (2013). A comparison of the formulations has been made and it is concluded that the results from the studies with the flowable formulation [redacted] can be bridged to the suspension concentrate. The comparison is included in the Confidential Appendix I to Document IIIB for this product. Regarding skin sensitisation it is concluded that the result of the study [redacted] can be bridged to Deltamethrin SC 7.5.

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	OECD 401	OFA Sprague-Dawley rat 5/sex/group Vehicle: none	0, 5000 and 15000 mg/kg bw	LD_{50}: >15000 mg/kg bw	Not classified	[redacted] 1986a (6.1.1/01)
Dermal	OECD 402	NZW rabbit 5/sex/group	0, 10000 mg/kg bw	LD_{50}: >10000 mg/kg bw	Not classified	[redacted] 1986b (6.1.2/01)
Inhalation	OECD 403	Crl: CD® rat 5/sex/group	0, 2.3[1] mg/l air	LC_{50} (4 hrs, aerosol): >2.3 mg/l air	Not classified	[redacted], 1986 (6.1.3/01)

[1] Maximum concentration achievable: 2.3 mg/l.

[redacted] is of low acute toxicity. In the acute inhalation toxicity study with [redacted] no mortalities were seen at the highest achievable concentration (2.3 mg/l over 4 hrs). No clinical signs of toxicity were noted following oral or dermal administration. Clinical signs such as wet abdomens, muzzles and fur, brown muzzle and staining and matted fur, hypersensitivity to stimulus and lack of coordination were noted following administration via the inhalation route. Although the 5 mg/l threshold for Hazard classification was not achieved in this study, no classification in the category of danger ("Harmful") was proposed for the product since no mortality was observed at the maximum concentration achievable and the criterion for classification ("Harmful by inhalation") was not met according to concentration limits fixed in Table I of Annex II, Part B to Directive 99/45/EC.

Based on these data (presented above) Deltamethrin SC 7.5 is considered to be of low acute toxicity, and does not require EU classification with regard to acute toxicity.

2.8.1.3 Irritation and corrosivity

2.8.1.3.1 Skin irritation

Species	Method	Highest score 24, 72 h, 96h, 120h, 144h, 168h		Reversibility yes/no	Result	Reference in Doc III-B
		Erythema	Oedema			
NZW rabbit (Male)	OECD 404	0	0	Yes	Not a skin irritant	[redacted] 1986c (6.2.1/01)

Decis 5 Flow is non irritating to skin of rabbits. Based on this data Deltamethrin SC 7.5 is considered non-irritating to skin, and does not require EU classification regarding skin irritation.

2.8.1.3.2 Eye irritation

Species	Method	Results	Reversibility yes/no	Result	Reference in Doc III-B
NZW rabbit (Male)	OECD 405	The eye of one animal out of the 6 tested developed slight chemosis on Day 2 which disappeared the following day. The primary eye irritation score was 2 (on a scale with total maximum 110). The product does not require EU classification with regard to eye irritation.	Yes	Not an eye irritant	[redacted] 1986d (6.2.2/01)

Under the conditions of this study and based on the EU criteria for classification, [redacted] is considered not irritating to eyes of rabbits. Based on this data Deltamethrin SC 7.5 is considered not irritating to eyes, and does not require EU classification regarding eye irritation.

2.8.1.4 Sensitisation

The potential for [redacted] to elicit a specific sensitisation response was assessed in mice according to a Local Lymph Node Assay according to the OECD guideline 429. The results from this study can be bridged to the formulation Deltamethrin SC7.5. Based on this data Deltamethrin SC 7.5 is not a skin sensitizer, and does not require EU classification regarding sensitisation.

2.8.1.5 Other

The biocidal product, Deltamethrin SC 7.5 contains deltamethrin (7.5 g/l), together with co-formulants. The toxicity of the active substance has been documented in Document III-A. Information on the toxicology of the other components of the product was provided based on the corresponding Material

Safety Data Sheets. As the composition of the formulation is confidential, information on the formulants is also confidential as it would allow conclusions concerning the composition of the product. However, no additionally toxicological concerns are raised by the co-formulants according to the Material Safety Data Sheets for which additionally toxicity testing would be required.

2.8.2 Environmental effects assessment

The co-formulants are not expected to affect the fate of deltamethrin in the environment or significantly affect its ecotoxicity.

The ecotoxicity data provided for the active substance (see Doc III-A, Section 7 of the CAR) are relevant to assess the toxicity/classification of the product by extrapolation.

2.8.2.1 Aquatic compartment

Summary and evaluation of effect data with relevance to the aquatic compartment for the active substance can be found in Document II-A in section 4.2.1. of the CAR

2.8.2.2 Atmosphere

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

2.8.2.3 Terrestrial compartment

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

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

The available toxicity data for deltamethrin are summarised in Doc II-A, Section 3 and 4.2 of the CAR. The risk assessment for non-compartment specific effects of the active substance relevant to the food chain (secondary poisoning) is presented in section 2.11.4. There it was concluded that deltamethrin does not present a risk of secondary poisoning in the environment.

2.9 HAZARD IDENTIFICATION FOR PHYSICO-CHEMICAL PROPERTIES

Based on the properties of the components of the formulation, Deltamethrin SC 7.5 is not considered explosive or oxidizing. Furthermore, based on data from a very similar product Deltamethrin SC 7.5 is not considered auto-flammable or to have a flash-point below its boiling point. The stability studies were performed on two different formulations. The accelerated study was performed on the current formulation, while the two year ambient temperature study was performed on the old formulation. However, the differences in composition between the two formulations are small (see Annex Confidential Data and Information for further details) and the results are therefore considered applicable to Deltamethrin SC 7.5. Deltamethrin SC 7.5 is considered stable upon storage for at least two years at ambient temperature. There are no hazards identified based on the physico-chemical properties of the formulation.

2.10 RISK CHARACTERISATION FOR HUMAN HEALTH

2.10.1 General aspects

MG/PT	Field of use envisaged	Likely concentration at which a.s. will be used
PT 18	Deltamethrin SC 7.5 is intended for amateur use to control ant nest around houses by drench application.	**Ant nest drench application** 20 mL Deltamethrin SC 7.5 per 5L of water 5 L of the drench solution per $5m^2$

Deltamethrin SC 7.5 is an insecticide for the amateur for the control of ant nests in a residential environment (e.g. terraces) by drench application. The product is formulated as a suspension concentrate (SC) and contains the active substance (a.s.) deltamethrin (7.5 g/L).

Before application Deltamethrin SC 7.5 has to be diluted with water to a final concentration of 0.03 g deltamethrin/L (= 20 mL Deltamethrin SC 7.5 per 5L of water). The application solution is applied into and around the entrances of an ant nest using e.g. a watering can or comparable application equipment. The maximum application rate is 5 L of the drench solution per 5 m^2 per ant nest.

The product will be used by amateurs.

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

The manufacturing plants where Deltamethrin SC 7.5 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 SC 7.5 product life cycle.

2.10.3 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.

2.10.4 Non-professional users

2.10.4.1 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.

Deltamethrin SC 7.5 was one of the representative formulations submitted for EU review according to the biocide directive 98/8/EC. A value of 2% dermal absorption was considered appropriate for 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. Calculations in this evaluation used the worst case dermal absorption value of 2%.

2.10.4.2 Risk characterisation - Drench application – Primary exposure

Ref-MS information to the reader:

In the TNsG on Human exposure (2007) there is a model scenario for professional mixing and loading by watering can. It is suggested to use the parameter for exposure of hands from this scenario as a worst case.

Following this exposure estimation, the risk characterization will be as follows:

Primary exposure scenario	Systemic Exposure (mg/kg bw/[d])				Relevant AEL / NOAEL (mg/kg bw [d])	AF / ref. MoE	% AEL	MoE
	inhalation	dermal	oral	total				
Mixing and loading of the b.p. into a watering can and application of the diluted product to ant nests	2.16×10^{-7}	2.46×10^{-4}	-	2.46×10^{-4}	0.0075 mg/kg bw/d / 0.75 mg kg bw/d	100	3.3	3049

The estimated exposure using ConsExpo is derived to be less than 1% of AEL; using the TNsG on Human exposure (2007) model scenario for professional mixing and loading by watering can the estimated exposure is derived to be approximately 3.3% of the AEL. Thus, the exposure assessment of users result in a value significantly below the AEL. Ref-MS therefore concludes that the risk for users is acceptable.

Comparison of the estimated exposure and the AEL

The following table provides a comparison of the estimated systemic primary exposure with the corresponding proposed AEL (in terms of percentage of the AEL).

Table 2.10.4.2-1 Comparison of the estimated systemic primary exposure to deltamethrin [mg/kg bw/day] to the proposed AEL.

Active substance	Scenario	Exposure estimates [mg/ kg bw/day]	% of AEL [0.0075 mg/kg bw/day]
Deltamethrin	Mixing and loading	0.000025	<1

Assessment

The results of the exposure estimates reveal that regarding primary exposure the situation is favourable with the intended use of Deltamethrin SC 7.5.

The estimated systemic primary exposure of the amateur user accounts for less than 1% of the AEL.

Accordingly, there is based on this result no unacceptable risk anticipated for the amateur operator with the intended uses of Deltamethrin SC 7.5.

2.10.4.3 Risk characterisation - Drench application – Secondary exposure

Table 2.10.4.3-1 Secondary exposure of drench application scenario

Active substance	Scenario	Exposure estimates [mg/ kg bw/day]	% of AEL [0.0075 mg/kg bw/day]
Deltamethrin	A toddler re-enters a terrace where Deltamethrin SC 7.5 has been applied	0.00285	38

The estimated systemic exposure of the re-entering toddler amounts to only the AEL 38% of the AEL.

When assessing this result it has to be noted that this estimate still does not take into account that with porous surfaces – typical for stone types used on terraces – significant amounts of the drench solution are soaked up by the surface/stone. Thus the loading on the surface being potentially available for transfer is actually significantly lower than the surface loading considered for the assessment. Further, with an application volume of 1 L/m^2 for non porous surfaces it is obvious to assume some run off into cracks and crevices (e.g. between stone slabs) which again results in a lower actual loading on the surface than considered for the calculations.

Therefore, based on these results there is no unacceptable risk anticipated with the intended use of Deltamethrin SC 7.5 for persons being exposed to the product via secondary routes of exposure.

2.10.5 Combined exposure

Ref-MS information to the reader:	The estimated exposure using ConsExpo is derived to be less than 1% of AEL; using the TNsG on Human exposure (2007) model scenario for professional mixing and loading by watering can the estimated exposure is derived to be approximately 3.3% of the AEL. Thus, the exposure assessment of users result in a value significantly below the AEL. Ref-MS therefore concludes that the risk for users is acceptable. Regarding secondary exposure to infants, it is concluded in the CAR of deltamethrin, Doc I, that: "Multiple exposures of infants may occur in case an infant is exposed during contact with treated areas first at general buildings such as day-care centres and hospitals and then in domestic properties. Due to some uncertainties with regard to developmental neurotoxicity (no data for the most sensitive strain) precautions should be taken regarding exposure of children and pregnant users during the last trimester. The exposure level for children should be carefully considered in order to protect children during the sensitive period of brain development, and Member States may consider attaching conditions on use area, application method, type of formulation etc when granting authorisation of a product." Ref-MS concludes that the secondary exposure assessment of children is based on worst case assumption and still results in a margin to the AEL. However, as indicated in the CAR, due to the uncertainties with regard to developmental neurotoxicity, precautions should be taken regarding exposure of children. It is therefore suggested that the product is labelled with phrases that warn and inform users so that measures can be taken to minimise the exposure of children.

With the CAR prepared for deltamethrin by the competent authority furthermore the possibility of combined exposure was considered and therefore is taken into account in this evaluation as well. In this context it is reasonable to conclude that combined exposure is most relevant for the amateur operator who applies the product and afterwards might be exposed via secondary routes of exposure.

However, considering the intended amateur use of Deltamethrin SC 7.5, i.e. treatment of ant nests, the risk of combined exposure can be regarded as negligible. This conclusion is in line with the CAR prepared for the product K-Othrine DP 0.05 – being as a product used as well by amateurs to control ants – which did not assume combined exposure. Therefore, with the intended use of Deltamethrin SC 7.5 the risk for combined exposure is considered to be negligible.

Accordingly based on these results there is no unacceptable risk anticipated with the intended uses of Deltamethrin SC 7.5 for persons being exposed to the product via primary and secondary routes of exposure.

2.11 RISK CHARACTERISATION FOR THE ENVIRONMENT

Using the ecotoxicity endpoints (PNEC values) and the first-tier estimates of environmental exposure calculated in section 2.7.2, PEC/PNEC or Risk Characterisation Ratio (RCR) calculations have been carried out in order to assess the environmental risk associated with the use of *Deltamethrin SC 7.5*. A PEC/PNEC ratio of <1 indicates no unacceptable risk to the environmental compartment under consideration. An RCR of >1 indicates an unacceptable risk. It should be noted that the PEC values used in these calculations have been derived using simple first-tier calculation methods and incorporate a number of worst-case assumptions regarding environmental fate and exposure. A summary of the toxicity endpoints used in the environmental risk assessment is given in the table below.

Ref-MS information to the reader:	One of the reasons that realistic worst case assumptions are incorporated in exposure models are simply due to the fact that models are simplistic versions of reality, and thus, such exposure estimates will always be associated with great uncertainties. In situations of great uncertainty and variability, precautionary worst case assumptions employed at low tiers with a possibility for refinement, are a natural part of today's risk assessment process.

Table 2.11-1 Summary of toxicity endpoints used in the environmental risk assessment

Compartment	Species	Endpoint	AF*	PNEC
Deltamethrin				
Surface water	*Chironomus riparius*	NOEC = 3.5 ng a.s. L^{-1}	5	0.7 ng a.s. L^{-1}
Sediment	*Chironomus riparius*	NOEC = 3.5 ng a.s. L^{-1}	5	0.7 ng a.s. L^{-1} equivalent to 6.2 µg kg^{-1} (wet weight) in sediment using equilibrium partitioning
Soil	*Folsomia candida*	NOEC = 1.25 mg kg^{-1} (dry weight)	10	75 µg kg^{-1} (wet weight) adjusted for OM content
STP Microorganisms	N/A	NOEC = 300 µg.L^{-1}	10	30 µg.L^{-1}
Secondary poisoning - birds	Colinus virginianus; Anas platyrhynchos	NOEC > 450 ppm	30	15 mg kg $food^{-1}$
Secondary poisoning - mammals	Rattus Norvegicus	NOAEL = 80 ppm	30	2.67 mg kg $food^{-1}$
Br_2CA				
Surface water	Fish	QSAR LC_{50} = 10.4 mg a.s. L^{-1}	1000	10.4 µg a.s. L^{-1}
Sediment	No Data	No Data	No Data	13.9 µg kg^{-1} (wet weight) in sediment using equilibrium partitioning
Soil	*Hypoaspis aculeifer*	NOEC = 10 mg kg^{-1}	100	0.14 mg kg^{-1} (wet weight) adjusted for OM content
STP Microorganisms	No Data	No Data	No Data	30 µg.L^{-1} (deltamethrin) considered protective

*Assessment Factor

2.11.1 Aquatic compartment (incl. sediments)

PEC/PNEC or Risk Characterisation Ratio (RCR) calculations have been carried out in order to assess the environmental risk associated with the use of *Deltamethrin SC 7.5*.

A PEC/PNEC ratio (or RCR) of <1 indicates no unacceptable risk to the environmental compartment under consideration. An RCR of >1 indicates an unacceptable risk.

2.11.1.1 Risk characterisation for groundwater; application step

Ref-MS information to the reader:	Note: RCRs in the table below are based on 30-day TWA estimates of the concentration in soil. For deltamethrin, RCRs based on initial concentration are below 1, and thus, the estimated risk is acceptable.

Calculated RCR values for deltamethrin and Br_2CA in the groundwater compartment following the application step of the product life-cycle are given in the table below.

Table 2.11.1.1-1 Risk characterisation ratios in groundwater associated with the application step of the product life cycle (assuming a range of soil mixing depths)

Substance	Soil mixing depth (m)	RCRgw
Ant nest treatment – 1 m^2		
Deltamethrin	0.1	1.99E-01
	0.2	9.95E-02
	0.5	3.98E-02
Br_2CA	0.1	**4.80E+02**
	0.2	**2.40E+02**
	0.5	**9.61E+01**
Ant nest treatment – 5 m^2		
Deltamethrin	0.1	1.99E-01
	0.2	9.95E-02
	0.5	3.98E-02
Br_2CA	0.1	**4.80E+02**
	0.2	**2.40E+02**
	0.5	**9.61E+01**

All calculated RCRs are below 1 for deltamethrin. For metabolite Br_2CA, however, the calculated RCR values exceed 1, indicating a potential risk of leaching according to the first tier porewater calculations. However, it should be noted that the porewater calculation method is necessarily a simplistic approach, neglecting transformation and dilution in deeper soil layers. Furthermore, emissions to soil as a result of the use of *Deltamethrin SC 7.5* will be highly localised, resulting in significant potential for spatial dilution.

A more realistic, higher-tier assessment of the potential for groundwater contamination associated with deltamethrin residues in soil has been carried out using the simulation model FOCUS-PEARL 2.2.2 (Schäfer, 2004). To establish the applicability of the results of this study to the present assessment, it is necessary to calculate an application rate for deltamethrin on a per-hectare basis for the proposed use patterns of *Deltamethrin SC 7.5*.

The Member States guidance regarding leaching assessments for wood preservatives (PT 8) assumes a default of 35 houses per hectare, giving an equivalent area of 286 m^2 per housing plot (European Commission, Undated). For the control of ants, up to five separate treatments may be carried out throughout the period March - October, with a minimum interval of 1 month between successive

applications (i.e. one application event per month). In a single application to an ant nest over an area of 5 m^2, a total quantity of 150 mg of active substance is emitted to the soil compartment. Although there will be considerable opportunity for the dissipation of residues between successive application events, it has been assumed, as a worst-case, that no degradation takes place. Therefore, the maximum annual soil loading of deltamethrin in a typical garden has been assumed to be equivalent to 5 individual application events for ant nest control carried out simultaneously, giving a total soil loading of 750 mg.

Ref-MS information to the reader:	Please note that the assumed house density of 35 houses per hectare is not in agreement with figure in the TAB from WG II 2015 section 2.4.7 of 16 houses per hectare. The figure of 35 houses per hactare originates from the OECD series on emission scenario documents number 2. Revised emission scenario document for wood preservatives. Since 35 could serve as a conservative assumption of house density for PECgw estimation the approach by the applicant is considered acceptable.

To calculate the equivalent per-hectare application rate, the total quantity of active substance that might be applied (0.750 g) is divided by the total area of the housing plot (286 m^2) and converted to a rate per hectare. The resulting equivalent per-hectare application rate is therefore 5.24 $g.ha^{-1}$, calculated as follows:

$(((150\ mg \times 5) \times 0.001) / 286\ m^2) \times 10000\ m^2 = 26.2\ g.ha^{-1}$

The FOCUS modelling investigation carried out by Schäfer (2004) investigated soil applications of deltamethrin according to agricultural use patterns, with three treatment events simulated per year, each at a rate either of 7.5 g a.i. ha^{-1} (total: 22.5 g a.i. ha^{-1}; typical of use in arable crops) or 12.5 g a.i. ha^{-1} (total: 37.5 g a.i. ha^{-1}; typical of use in fruit or vegetable crops). Since both of these annual soil loadings are in the same range as the maximum effective deltamethrin application rate calculated for the use of *Deltamethrin SC 7.5*, it is proposed that the results of the FOCUS investigation provide a suitable evaluation of the potential for groundwater contamination associated with *Deltamethrin SC 7.5*.

In the study by Schäfer (2004), simulations were carried out using FOCUS-PEARL 2.2.2, with scenarios representing a wide range of pedo-climatological conditions in the European Union. The model was parameterised according to the standardised guidance provided by FOCUS (2000). The calculated PEC_{gw} values for deltamethrin and its metabolites, as represented by the 80th percentile annual average leachate concentrations at 1 m soil depth, were several orders of magnitude below the groundwater trigger value of 0.1 $\mu g.L^{-1}$ in all scenarios. It is therefore concluded that neither deltamethrin nor Br_2CA represent a risk to groundwater for the use of *Deltamethrin SC 7.5*.

2.11.1.2 Risk characterisation for the aquatic compartment; preparation step

Calculated RCR values for deltamethrin and Br_2CA in the STP, surface water, sediment and groundwater compartments following the preparation step of the product life-cycle are given in tables below.

Table 2.11.1.2-1 Risk characterisation ratios in STP, surface water, sediment and groundwater associated with the preparation step of the product life cycle (urban scenario)

Substance	RCRstp	RCRsw	RCRsed	RCRgw
Ant nest treatment – 1 m^2				
Deltamethrin	1.02E-05	2.60E-03	2.60E-03	5.70E-07
Br_2CA	6.01E-06	1.67E-07	1.67E-07	5.36E-04
Ant nest treatment – 5 m^2				
Deltamethrin	5.09E-05	1.30E-02	1.30E-02	2.86E-06
Br_2CA	3.00E-05	8.31E-07	8.32E-07	2.67E-03

Table 2.11.1.2-1 Risk characterisation ratios in groundwater associated with the preparation step of the product life cycle (rural scenario; assuming a range of soil mixing depths)

Substance	Soil mixing depth (m)	RCRgw
Ant nest treatment – 1 m^2		
Deltamethrin	0.1	2.49E-04
	0.2	1.24E-04
	0.5	4.97E-05
Br_2CA	0.1	6.00E-01
	0.2	3.00E-01
	0.5	1.20E-01
Ant nest treatment – 5 m^2		
Deltamethrin	0.1	1.24E-03
	0.2	6.22E-04
	0.5	2.49E-04
Br_2CA	0.1	**3.00E+00**
	0.2	**1.50E+00**
	0.5	6.00E-01

No unacceptable exposure is expected to occur for the STP, surface water and sediment compartments as a result of the preparation step of the product life-cycle. For the groundwater compartment, however, calculated RCR values for metabolite Br_2CA exceed 1 in some cases for the rural scenario (5 m^2 ant nest treatment; 0.1 m or 0.2 m soil mixing depth). As noted in the previous section, however, the porewater calculation method is a simplistic approach which neglects transformation and dilution in deeper soil layers, as well as the significant potential for spatial dilution. The effective soil loading of deltamethrin in the preparation step is much lower than that in the application step, therefore the higher-tier FOCUS groundwater modelling study described previously (Schäfer, 2004) is also applicable to the preparation step. On the basis of this higher-tier FOCUS study, it can therefore be concluded that neither deltamethrin nor Br_2CA poses a risk to groundwater as a result of the preparation step of the product life-cycle.

Ref-MS information to the reader:	Please note, that the higher-tier FOCUS modeling investigation carried out to simulate agricultural applications of the deltamethrin and Br_2CA (Schäfer, 2004) is not an appropriate and concerted approach for groundwater assessment of biocides. However, a recalculation with FOCUS PEARL 4.4.4 by CMS DE leads to no unacceptable risk for groundwater either for deltamethrin and Br2CA.

2.11.2 Atmospheric compartment

Emissions to the atmospheric compartment are considered negligible and therefore no risk characterisation is proposed.

2.11.3 Terrestrial compartment

2.11.3.1 Risk characterisation for the terrestrial compartment; application step

Ref-MS Information to the reader:	Concerning the mixing depth of the receiving compartment. Please note that a mixing depth of 50 cm should primarily be considered for PEC and subsequent RCR calculations. See: TAB from WG II 2015 section 2.4.14 part 2. a soil depth of 50 cm should be applied in restricted areas.

Calculated RCRs for deltamethrin and Br_2CA in the soil compartment following the application step of the product life-cycle are given in the table below.

Table 2.11.1.1-1 Risk characterisation ratios in soil associated with the application step of the product life cycle (assuming a range of mixing depths)

Substance	Soil mixing depth (m)	RCR local soil (initial)	RCR local PEC soil (30 d TWAC)	RCR local PEC soil (30 days after application)
Ant nest treatment – 1 m^2				
Deltamethrin	0.1	**2.35E+00**	**1.91E+00**	**1.53E+00**
	0.2	**1.18E+00**	9.56E-01	7.64E-01
	0.5	4.71E-01	3.82E-01	3.06E-01
Br_2CA	0.1	7.44E-01	1.95E-01	1.81E-02
	0.2	3.72E-01	9.77E-02	9.07E-03
	0.5	1.49E-01	3.91E-02	3.63E-03
Ant nest treatment – 5 m^2				
Deltamethrin	0.1	**2.35E+00**	**1.91E+00**	**1.53E+00**
	0.2	**1.18E+00**	9.56E-01	7.64E-01
	0.5	4.71E-01	3.82E-01	3.06E-01
Br_2CA	0.1	7.44E-01	1.95E-01	1.81E-02
	0.2	3.72E-01	9.77E-02	9.07E-03
	0.5	1.49E-01	3.91E-02	3.63E-03

The results of the first-tier assessment for the terrestrial compartment indicate potentially unacceptable exposure to soil-dwelling organisms for the parent compound, with RCRs exceeding 1 at soil mixing depths of 0.1 m and 0.2 m. Assuming a soil mixing depth of 0.1 m, the RCR based on the initial PEC in soil is 2.35, although this is predicted to drop to 1.53 after 30 days, and concentrations are reduced to an acceptable level within 60 days. Assuming a soil mixing depth of 0.2 m, the RCR based on the initial PEC in soil is 1.18; this is reduced to acceptable levels within 12 days.

It should be noted that soil exposure associated with spot treatment of insect nests is necessarily highly localised. It is therefore proposed that the surrounding soil biota will remain unaffected. It is considered that the 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, mitigating any effect of product use.

Further support for this recolonisation potential is given by the moderate half-life of deltamethrin in soil of 48.2 days (normalised to 12°C and pF 2).

In addition, it should be noted that insect nests will be randomly distributed throughout the garden, but only a small number of nests (those that are identified as a nuisance) will be treated in any one year. Taking account of the distribution and highly localised nature of the nesting areas, it is concluded that the potential for repeat treatment to the same area of soil is low. As a result, it is considered that deltamethrin will not accumulate in the soil, meaning that recolonisation by soil-dwelling organisms from unaffected areas of soil will not be inhibited. Therefore, it is concluded that the highly localised exposure to soil associated with the use of *Deltamethrin SC 7.5* will not result in an unacceptable ecological risk to soil organisms.

Ref-MS information to the reader:	Given a 50 cm soil mixing depth RCRs in soil is below but close to one. Assuming no degradation, RCRs would allow one additional treatment if the first is unsuccessfull. Although RCRs are below 1 (above 1 for lower soil mixing depths), Ref-MS still finds the argumentation of the applicant relevant given the uncertainty of the RCR estimates: The exposure is of a highly localised nature, and thus, the risk of negative effects in the soil compartment community as a whole, will probably be low. Furthermore, the localised nature of exposure increases the possibility for recolonisation of non-target soil dwelling organisms after treatment. RMS concludes that the risk is low for unacceptable effects in the terrestrial compartment following normal use of *Deltamethrin SC 7.5*.

2.11.3.2 Risk characterisation for the terrestrial compartment; preparation step

Ref-MS Information to the reader:	Concerning the mixing depth of the receiving compartment. Please note that a mixing depth of 50 cm should primarily be considered for PEC and subsequent RCR calculations. See: TAB from WG II 2015 section 2.4.14 part 2. a soil depth of 50 cm should be applied in restricted areas.

Calculated RCRs for deltamethrin and Br_2CA in the soil compartment following the preparation step of the product life-cycle are given in the tables below.

Table 2.11.3.2-1 Risk characterisation ratios in soil associated with the preparation step of the product life cycle (urban scenario)

Substance	RCRsoil
Ant nest treatment – 1 m^2	
Deltamethrin	1.53E-05
Br_2CA	4.85E-06
Ant nest treatment – 5 m^2	
Deltamethrin	7.68E-05
Br_2CA	2.42E-05

Table 2.11.3.2-2 Risk characterisation ratios in soil associated with the preparation step of the product life cycle (rural scenario; assuming a range of mixing depths)

Substance	Soil mixing depth (m)	RCR local soil (initial)	RCR local PEC soil (30 d TWAC)	RCR local PEC soil (30 days after application)
Ant nest treatment – 1 m²				
Deltamethrin	0.1	2.94E-03	2.39E-03	1.91E-03
	0.2	1.47E-03	1.19E-03	9.55E-04
	0.5	5.88E-04	4.78E-04	3.82E-04
Br_2CA	0.1	9.29E-04	2.44E-04	2.27E-05
	0.2	4.65E-04	1.22E-04	1.13E-05
	0.5	1.86E-04	4.88E-05	4.53E-06
Ant nest treatment – 5 m²				
Deltamethrin	0.1	1.47E-02	1.19E-02	9.55E-03
	0.2	7.35E-03	5.97E-03	4.78E-03
	0.5	2.94E-03	2.39E-03	1.91E-03
Br_2CA	0.1	4.65E-03	1.22E-03	1.13E-04
	0.2	2.32E-03	6.10E-04	5.67E-05
	0.5	9.29E-04	2.44E-04	2.27E-05

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

2.11.4.1 Risk characterisation for deltamethrin in the diet of secondary consumers; application step

Calculated RCRs for deltamethrin in the diet of secondary consumers following the application step of the product life-cycle are given in the table below. No unacceptable exposure is expected to occur.

Table 2.11.4.1 -1 Risk characterisation ratios for potential exposure of predators to deltamethrin associated with the application step (assuming a range of soil mixing depths)

Substance	Soil mixing depth (m)	RCRoral, predator (based on initial concentrations in soil)	RCRoral, predator (based on 30-d TWA concentrations in soil)
Ant nest treatment – 1 m^2			
Exposure to small mammals			
Deltamethrin	0.1	5.36E-03	4.35E-03
	0.2	2.68E-03	2.17E-03
	0.5	1.07E-03	8.70E-04
Exposure to birds			
Deltamethrin	0.1	9.53E-04	7.74E-04
	0.2	4.77E-04	3.87E-04
	0.5	1.91E-04	1.55E-04
Ant nest treatment – 5 m^2			
Exposure to small mammals			
Deltamethrin	0.1	5.36E-03	4.35E-03
	0.2	2.68E-03	2.17E-03
	0.5	1.07E-03	8.70E-04
Exposure to birds			
Deltamethrin	0.1	9.53E-04	7.74E-04
	0.2	4.77E-04	3.87E-04
	0.5	1.91E-04	1.55E-04

2.11.4.2 Risk characterisation for deltamethrin in the diet of secondary consumers; preparation step

Calculated RCRs for deltamethrin in the diet of secondary consumers following the preparation step of the product life-cycle are given in the tables below. No unacceptable exposure is expected to occur in either case.

Table 2.11.4.2 -1 Risk characterisation ratios for potential exposure of predators to deltamethrin associated with the preparation step (urban scenario)

Treatment	RCRoral, predator (fish)		RCRoral, predator (earthworm)	
	Birds	Small mammals	Birds	Small mammals
Ant nest treatment – 1 m^2	6.03E-08	3.39E-07	2.37E-09	1.33E-08
Ant nest treatment – 5 m^2	3.02E-07	1.69E-06	1.19E-08	6.66E-08

Table 2.11.4.2 -2 Risk characterisation ratios for potential exposure of predators to deltamethrin associated with the preparation step (rural scenario; assuming a range of soil mixing depths)

Substance	Soil mixing depth (m)	RCRoral, predator (based on initial concentrations in soil)	RCRoral, predator (based on 30-d TWA concentrations in soil)
Ant nest treatment – 1 m^2			
Exposure to small mammals			
Deltamethrin	0.1	6.69E-06	5.44E-06
	0.2	3.35E-06	2.72E-06
	0.5	1.34E-06	1.09E-06
Exposure to birds			
Deltamethrin	0.1	1.19E-06	9.68E-07
	0.2	5.96E-07	4.84E-07
	0.5	2.38E-07	1.94E-07
Ant nest treatment – 5 m^2			
Exposure to small mammals			
Deltamethrin	0.1	3.35E-05	2.72E-05
	0.2	1.67E-05	1.36E-05
	0.5	6.69E-06	5.44E-06
Exposure to birds			
Deltamethrin	0.1	5.96E-06	4.84E-06
	0.2	2.98E-06	2.42E-06
	0.5	1.19E-06	9.68E-07

2.11.5 Conclusions

No unacceptable exposure is expected to occur for deltamethrin or its metabolite, Br_2CA, in the STP, surface water, sediment or soil compartments as a result of the preparation step of the product life-cycle.

First-tier porewater calculations carried out for the preparation and application steps of the product life-cycle indicated a potential environmental risk to the groundwater compartment for Br_2CA. However, it was established that the equivalent application rates of the active substance were in the same range as those used in a higher-tier FOCUS modelling investigation carried out to simulate agricultural applications of the compound (Schäfer, 2004). Based on the results of this higher-tier modelling study, it was

concluded that neither deltamethrin nor Br_2CA present any unacceptable risk of leaching to groundwater as a result of the use of *Deltamethrin SC 7.5*.

A potential risk was also indicated to soil-dwelling organisms in some scenarios (scenarios employing 10 and 20 cm soil mixing depth, but not the agreed depth of 50 cm) for the application step of the product life-cycle. However, soil exposure associated with the use of *Deltamethrin SC 7.5* is necessarily localised, and it is proposed that the surrounding soil biota will remain unaffected. The affected area is sufficiently small and infrequent in the landscape that recolonisation by soil biota is expected to occur rapidly once residues have declined to an acceptable level, mitigating any effect of product use. This recolonisation process is expected to occur within 60 days. Furthermore, it is considered that due to the random distribution and highly localised nature of ant nests, the potential for repeat treatment to the same area of soil is low. As a result, it is considered that deltamethrin will not accumulate in the soil, meaning that recolonisation by soil-dwelling organisms from unaffected areas of soil will not be inhibited.

Ref-MS information to the reader:	Although RCRs in soil is close to or clearly above one for some scenarios (10 and 20 cm soil mixing depth), Ref-MS agrees with the argumentation of the applicant and concludes that the risk is low for unacceptable effects in the terrestrial compartment including bees and other beneficial arthropods, following normal use of *Deltamethrin SC 7.5*. The exposure is of a highly localised nature, and thus, the risk of negative effects in the soil compartment community as a whole, will probably be low. Furthermore, the localised nature of exposure increases the possibility for recolonisation of non-target soil dwelling organisms after treatment.

2.12 Measures to protect man, animal and the environment

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

2.12.1.1 Handling

2.12.1.1.1 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.

2.12.1.1.2 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.

2.12.1.1.3 Handling

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

2.12.1.2 Storage

Requirements for storage areas and containers. Keep container tightly closed. Store in original container. Keep away from direct sunlight. Protect from freeze.

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

2.12.1.3 Fire:

Fire-fighting measures Deltamethrin SC 7.5

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

2.12.2 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.
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.

2.12.3 Accidental release measures:

2.12.3.1 Personal precautions

Avoid contact with spilled product or contaminated surfaces.

Wear personal protective equipment.

Unprotected persons must be kept away.

2.12.3.2 Environmental Precautions

Do not apply near ponds and other waterbodies.

Do not use where the biocidal product can be discharged to municipal sewage treatment plant.

Do not discharge the biocidal product nor the diluted solution of the biocidal product into the sewage system.

2.12.3.3 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.

2.12.4 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 From the Assessment Report of the active substance

The active substance, deltamethrin, has previously (2013-10-01) been 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 elements should be taken into account by MSs when authorising products:

- 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, those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment.

- Products shall not be authorised for indoor treatments resulting in sewage treatment plant emissions of the scale for which the Union level risk assessment showed unacceptable risks, unless data are submitted demonstrating that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures.

All the specific provisions do apply.

Requirement for further information:

The evaluation showed that sufficient data had been provided to permit inclusion of deltametrin in Annex I to Directive 98/8/EC.

3.1.2 Previous use and authorisation in Sweden

In Sweden Deltamethrin SC 7.5 (Swedish trade name Myrr till utvattning) has been authorised since 2007. The current authorisation (2011-01-01, Dnr F-2675-B13-00348) is valid until 2016-12-31.

3.1.3 Conclusions from risk assessment of the product

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

The efficacy of the product for the control of ants, workers and nests, by drench treatment at a dose of 30 mg/m^2, when used according to the directions for use, is considered acceptable. But a careful assessment of the nest location before starting treatment is paramount to obtain full effect.

It is concluded from the health risk assessment of Deltamethrin SC 7.5 that the intended use of the product would not pose unacceptable risk to human health. Risk mitigation reasons suggests that to protect children, the user should be informed that measures should be taken to protect children from exposure, eg. through phrases like “keep out of reach of children”, “keep children away during application” and “do not enter treated area until dry”.

The environmental risk assessment identified potential risks to soil dwelling organsism (terrestrial compartment). However, due to the spatially localised nature of the exposure following normal use of the product, these risks are considered acceptable. Since organsims in the surrounding area are considered to be unaffected and the degradation rate is relatively high, there is a high probability that treated areas will be recolonised within a resonable time period.

3.2 PROPOSAL FOR DECISION

With the proposed use, the risk to human health and environment is considered acceptable.

On basis of the Assessment Report and the Product Report the opinion of Ref-MS Sweden is to authorise the use of Deltamethrin SC 7.5 to be used as a biocide product, with the conditions outlined in the product’s SPC (Summary of Product Characteristics).

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
A3.2/01	Yoder S.J	1991 a	Deltamethrin A.I. - Determination of vapour pressure. Report No.: A47916. Dep. Anal. Serv. Ricerca, USA. Bayer CropScience AG. Unpublished	Y	Bayer CropScience AG
A3.9/01	Yoder S.J	1991 b	Deltamethrin A.I. - Determination of Octanol/Water partition coefficient. Report No.: A47915 Dep. Anal. Serv. Ricerca, USA. Bayer CropScience AG. Unpublished	Y	Bayer CropScience AG
5.10.2/01	Nentwig, G.	2004 a	StB-AI0022 [redacted] K-Othrine 07.5 SC: drench test against the Black Garden ant (Lasius niger) in the laboratory. Bayer Environmental Science, 40789, Monheim, Germany. Study number BES-EH-Mo 00798, ID No.: NE-LA040813, M-268844-02-1. 13th August 2004. Unpublished.	Y	Bayer Crop Science AG
5.10.2/02	Nentwig, G.	2004 b	Field efficacy of Deltamethrin 7.5 SC as drench application against L. niger nests in the field. Bayer Environmental Science, 40789, Monheim, Germany. Study number M-268843-01-1, BES-EH-MO ID: 01193. 15 December 2004. Unpublished.	Y	Bayer Crop Science 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	Brooks, M.D.	2008	Field Efficacy of K Othrine (DTM) SC 7.5 drench application against the black garden ant Lasius niger L. Kenniscentrum Dierplagen (KAD), Vadaring 81, 6702 EB Wageningen, The Netherlands. On behalf of: Bayer Environmental Science, 40789, Monheim, Germany. Document M-399604-01-1, KAD/2008/0353, Mo ES 04527. 30 August 2008. Unpublished.	Y	Bayer Crop Science AG
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