Document II-B

Effects Assessment and Exposure Assessment for the Biocidal Product

Cypermethrin 100 g/L EW

CAS No. a.s. cypermethrin: 52315-07-8

from Arysta LifeScience Benelux sprl, Belgium

for use in Insecticides (Product Type 18)

Contents

Document II-B – Effects Assessment for the Biocidal Product

1 GENERAL PRODUCT INFORMATION

The biocidal product containing the active substance cypermethrin 40:60 cis/trans would be used only by professionals for the control of crawling and flying insect pests in and around domestic and public buildings including farm buildings /animal housing and food processing factories.

Indirect exposure to the general public will be through entering areas that have been treated by the professional.

1.1 IDENTIFICATION OF THE PRODUCT

Table 1.1. Identity of the product.

Trade name	Cypermethrin 100g/l EW	
Manufacturer's development code number(s)	See confidential data and information of CA-Report	
Ingredient of preparation	Function	Content
Cypermethrin cis/trans 40:60	*Active substance (Insecticide)*	*100g/l*
Confidential	*Preservative*	
Confidential	*Surfactant*	
Confidential	*Solvent*	
Confidential	*Antifreeze*	
Confidential	*Antifoaming agent*	
Confidential	*Surfactant*	
Confidential	*Solvent*	
Confidential	*Antioxidant*	
Physical state of preparation	*Liquid*	
Nature of preparation	*Bulk Liquid*	

For further information see confidential data and information of CA-Report.

1.2 IDENTITIY OF INGREDIENTS OF THE BIOCIDAL PRODUCT

The information of this part is presented in Appendix 1 of Document II B "Confidential Data".

1.3 PHYSICO-CHEMICAL PROPERTIES

Parameter	**Result**
Appearance:	Opaque white liquid
Explosive properties:	Not explosive (EEC A.14)
Oxidising properties:	Not oxidising
Flammability:	Not flammable
Acidity/Alkalinity:	pH 4.26 (undiluted), pH 4.84 (1% aqueous solution) (CIPAC MT 75.3)
Density:	0.9785gml at 20°C (CIPAC MT 3.2.1)
Storage stability:	stable at 54°C+/-2°C for 14 days in commercial type package (CIPAC MT 46.3)
Persistence of foaming:	Start <0.5ml (10sec) going to <0.5ml after 12 minutes. (CIPAC MT 47.2)
Surface tension:	37.9 mN/m at 20°C (0.015% v/v) (METTENS, equiv to EEC method A.5) 33.1 mN/m at 20°C (1.0% v/v) 25.6 mN/m at 25°C (undiluted) 24.2 mN/m at 40°C (undiluted)
Viscosity:	64mPa.s to 15mPa.s (10.58 s-1 to 665.0 s-1) at 20°C (METVISCO, equiv to OECD 114) 64mPa.s to 10mPa.s (10.58 s-1 to 665.0 s-1) at 40°C
Flash point (closed cup):	>79°C (CIPAC MT 12.2, equivalent to EEC A.9)
Self-ignition temperature:	385±5°C (EEC A.15)
Emulsion stability:	Stable at 30 ± 2°C at both 0.015%v/v and 1.0 %v/v .(CIPAC MT 173) Stable at 54 ± 2°C at both 0.015%v/v and 1.0 %v/v for 14 days Stable at 0 ± 1°C at both 0.015%v/v and 1.0 %v/v for 7 days
Rinsability- pourability Residue: Rinsed residue:	0.58% at receipt and after 14 days stored at 54 ± 2°C. (CIPAC MT 148) 0.21-0.20% at receipt and after 14 days stored at 54 ± 2°C

1.4 ANALYTICAL METHODS FOR DETECTION AND IDENTIFICATION

An analytical method using HPLC was developed and validated for the determination of Cypermethrin (cis/trans 40:60) in Cypermethrin 100EW (Ryckel,B. 2005, Agricultural research centre, report no. chimac-agriphar/FO 20891/Ch.3174/2004/177).

Linearity	Concentration (RSD)	Accuracy (RSD)	Non-analyte interference	Precision (RSD)
0.998-0.999 (range 0.19-0.56mg/ml)	100g/L	99.5 % (level 8.823% w/w) (RSD=0.5%)	No Interference	10.15% w/w (0.54%)

1.5 CLASSIFICATION, PACKAGING AND LABELLING

1.5.1 Current classification

Classification	as in Directive 1999/45/EEC
Class of danger	Xn, N
R phrases	R22, R38, R43, R50/53
S phrases	S(2), S13, S20/21, S23, S24, S29/35, S36/37, S51, S61

1.5.2 Proposed classification biocidal product

Classification	as proposed by the BE CA (Directive 1999/45/EEC)
Class of danger	Xn, N
R phrases	R22, R38, R43, R50/53
S phrases	S(2), S13, S20/21, S23, S24, S29/35, S36/37, S51, S61

Classification	as proposed by the BE CA (Regulation EC No 1272/2008)
GHS pictograms	GHS08 GHS09
Signal Word	Warning
Hazard Class and Category Codes	Acute Tox. (oral) 4 Skin sens 1 STOT RE2 Aquatic acute 1(M= 100) Aquatic chronic 1(M= 1000)
Hazard Statement Codes	H302 Harmful if swallowed H317 May cause an allergic skin reaction H373 May cause damage to organs through prolonged or repeated exposure H400 Very toxic to aquatic life H410 Very toxic to aquatic life with long lasting effects
Precautionary Statement Codes	P260 Do not breathe vapours/spray P262 Do not get in eyes, on skin, or on clothing P314 Get medical advice/attention if you feel unwell

	P501	Dispose of content in accordance with local/national regulation
	P273	Avoid release to the environment
	P391	Collect spillage

Justification for the proposal (according to the criteria iof CLP Regulation EC No 1272/2008)

Based on actual data on the formulation or comparable formulation, Cypermethrin 100 g/L EW must be classified as Acute tox. (oral) 4 and Skin sens. 1.

According to the criteria of CLP Regulation EC No 1272/2008 and based on actual data on the formulation, no classification for skin irritation is justified.

In addition, Cypermethrin 100 g/L EW (10% cypermethrin cis:trans/40:60) must be classified as STOT RE2 derived from the application of the CLP calculation.

Justification STOT RE2 (extract from DocIIA section 1.5): the classification of Cypermethrin cis:trans/40:60 was agreed at the 29th ATP and appears in Annex I of Directive 67/548/EEC containing the list of harmonised classifications and labelling for substances which are legally binding within the EU.

In addition, Cypermethrin cis:trans/40:60 has a harmonised classification as listed in Annex VI table 3.1. to Regulation (EC) No 1272/2008, which is also understood to be a legally binding inclusion.

No new scientific information/data is available that may affect the classification of the active substance. Nevertheless, in CLP-Regulation (EC) No 1272/2008 the guidance values are modified for 'specific target organ toxicity following repeated exposure'. Because of the change in guidance values, the clinical effects of neurotoxicity observed in both animals and humans, and the liver toxicity observed in animals, **classification/labelling of the active substance 'cypermethrin cis:trans/40:60' for repeated-dose toxicity,** according to the criteria (modified guidance values) in CLP-Regulation (EC) No 1272/2008 2nd ATP **is justified: STOT RE2; H373. May cause damage to organs through prolonged or repeated exposure.**

JUSTIFICATION ECOTOX

For the environment part of the classification, M-factor has been introduced as part of the classification and are needed in order to classify mixture or products. No M-factor exist in current harmonized classification and these need to be set. The above proposed M factor results from the data set available for the CLH proposal which include in addition to the data available for the CAR, data belonging to other industry to which Arysta Life Science has no access and are not part of this CAR. In the CLH proposal , the lowest EC50 values for Cypermethrin are between > 0.001 < 0.01 mg/L for fish (0.00283 mg/L); > 0.001 < 0.01 for crustacean (0.0047 mg/L) and > 0.01 < 0.1 mg/L for algae (>0.033 mg/L), chronic NOEC values between >0.0001<0.001 for fish (0.00025 mg/L), > 0.00001 < 0.0001 mg/L for crustacean (0.00004 mg/L) and > 0.01 mg/L for algae (≥0.033mg/L). A mesocosm study produces values NOAEC > 0.00001< 0.0001mg/L for macrozoobenthos community and periphyton .

Based on the lowest LC_{50} (fish), cypermethrin should be classified as **Aquatic Acute Category 1 and an M factor of 100 is proposed.**

NOEC values for cypermethrin are available for all trophic levels. The lowest acceptable NOEC is -0.00004 mg/L (obtained for invertebrates). Cypermethrin fulfils criteria for classification as **Aquatic Chronic Category 1.**

The lowest NOEC is between 0.00001 mg/l and 0.0001 mg/l and Cypermethrin is considered not rapidly degradable, therefore an M factor of 1000 for chronic toxicity is proposed.

2 EFFICACY

2.1 FUNCTION

CYPERMETHRIN is an insecticide for use in pest control (product type 18 of the EU Biocidal Products Directive).

2.2 FIELD OF USE ENVISAGED

Products containing CYPERMETHRIN (in spray formulations) are intended to be used indoor & outdoor by professionals (Pest Control Operators) as a broad spectrum insecticide against crawling and flying insects.

However, in the context of a decision on the approval of CYPERMETHRIN, only efficacy tests (for indoor use – on hard surfaces) against house flies, cockroaches, cat fleas and garden ants have been submitted. Finally, efficacy has been only demonstrated against cat fleas and German cockroaches.

2.3 EFFECTS ON TARGET ORGANISMS AND EFFICACY

For the purpose of Annex I entry, the applicant has provided several studies on the efficacy of CYPERMETHRIN against house flies, German and Oriental cockroaches, garden ants and cat fleas. All efficacy studies have been performed in indoor conditions.

The BE CA has evaluated these studies and a summary of the results is presented in Table 2.1.

To assess and to support the efficacy of CYPERMETHRIN, the applicant has submitted four studies only on formulated products containing 10% CYPERMETHRIN : *CyperKill 10* Formulated product – Liquid Emulsifiable Concentrate) and *Exit 100* (Formulated product – oil in water emulsion).

The first study from 1992 is a very old laboratory study and it seems that the composition of the product ***CYPERKILL100*** is not clear enough to take into account this study as a key study. Therefore, this study is to take into account only as a supportive study: tests were performed on porous (plywood) and non-porous (ceramic tiles) surfaces to assess the efficacy of *CyperKill 10* against adult German cockroaches (*Blatella germanica*) and adult house flies (*Musca domestica*). Tests results showed that 100% Knock-down/mortality of flies is achieved in less than 20 min with 16.16 mg a.i./m^2 on both surface types. 100% Knock-down of German cockroaches is achieved in less than 30 min with 33.33 mg a.i./m^2 on both surface types. Considering mortality, it seems that the product is less effective on porous surfaces.

Three studies are efficacy tests using the product Exit 100 in simulated use trials and used as followed:

2,5 mL EXIT 100 / 500 mL /10 m^2
⇔ 250 mg CYPERMETHRIN / 500 mL
/10 m^2 (as the product EXIT 100 does contain 100g CYPERMETHRIN /L)

⇔ 25 mg CYPERMETHRIN /m²
• Product dilution : 0,5%
• CYPERMETHRIN dilution : 0,05% (as the product EXIT 100 does contain 10% CYPERMETHRIN)

5 mL EXIT 100 / 500 mL /10 m²
⇔ 500 mg CYPERMETHRIN / 500 mL
/10 m2 (as the product EXIT 100 does contain 100g CYPERMETHRIN /L)
⇔ 50 mg CYPERMETHRIN /m²
• Product dilution : 1%
• CYPERMETHRIN dilution : 0,1% (as the product EXIT 100 does contain 10% CYPERMETHRIN)

The first study showed that CYPERMETHRIN is effective indoors against mixed age/mixed sex cockroaches (*Blattella germanica* and *Blatta orientalis*) when used at maximum 50 mg a.i./m². Tests were performed on different types of hard surfaces. Test results showed that 100% knock-down was achieved within 24h regardless the cockroach species. 97.7% was achieved within 72h against *Blattella germanica*. However, the submitted data on *Blatta orientalis* show effectiveness too low to be taken into account at this stage.

The second study showed that CYPERMETHRIN is effective indoor against adult cat fleas (*Ctenocephalides felis*) when used at maximum 50 mg a.i./m². Tests were performed on different types of hard surfaces. Test results showed that 100% knock-down was achieved within 24h regardless the product concentration. 100% mortality was achieved within 48h.

Efficacy of CYPERMETHRIN could be claimed against German cockroaches and cat fleas. Efficacy of CYPERMETHRIN-based products (spray formulation) has been demonstrated at the application rate of 50 mg a.i./m² against German cockroaches (Blattella germanica) and at the application rate of 25 mg a.i./m² against cat fleas (Ctenocephalides felis).

Overall, the Belgian CA concludes that the data demonstrated the effectiveness of the products containing CYPERMETHRIN to a sufficient degree for inclusion of the a.i. onto Annex I to be recommended

At the Product Authorisation Stage additional studies will be maybe needed to determine an application rate able to achieve efficacy requirements mentioned in the TNsG “Product evaluation”.

Furthermore, as the claim for an outdoor use is not supported by efficacy data, additional studies will be needed at the Product Authorisation Stage to assess the efficacy of Cypermethrin-based products in outdoor conditions.

2.4 MODE OF ACTION INCLUDING TIME DELAY

CYPERMETHRIN cis:trans/40:60 is a synthetic pyrethroid with contact and stomach action. It acts by preventing the transmission of impulses along the nervous system of the insect. It is thought that this is achieved by blocking the sodium channels in nerve membranes, thus preventing action potentials passing down the nerve axon. Typically, this intoxication results in a rapid "knockdown". The affected insect shows uncoordinated movements and finally dies.

Possible repellent side effect of cypermethrin:

As for other pyrethroid insecticides (such as deltamethrin, esfenvalerate and lamda-cyhalothrin) and known as the "hot-foot effect" for which a repellence effect (after contact) is proven, cypermethrin may also exhibit a repellence effect. This repellent effect may be dose-related and considered as a side effect, since the toxic response of the insect is a delayed kill (insecticidal) effect.

According to the literature, it seems that the repellence effect does mainly concern zeta- and alpha-cypermethrin, not cypermethrin.

The applicant has no data concerning repellent effects of cypermethrin, by the time the CAR was finalised.

Please note that cypermethrin is an insecticide, only notified for PT18 and not for PT19. As a consequence, the insecticidal effect (KD and mortality) of cypermethrin-based products must be demonstrated for each claimed target species. Furthermore, products that show this repellent side-effect in the efficacy tests must be rejected at product authorisation because it doesn't fit in PT18.

2.5 OCCURRENCE OF RESISTANCE

Resistance to pyrethroid insecticides has been reported for a number of pests both in agriculture and public health. Strategies such as alteration of insecticides with different modes of action and avoidance of over frequent use are standard practises in agriculture and should be applied also to biocidal uses of cypermethrin *cis:trans*/40:60.

As all efficacy studies seem to have performed in UK, if the applicant wants to use the product in other countries, it is necessary to give new information on the effect of product on a local population of insects.

Table 2.1. Efficacy of the active substance from its use in the biocidal product

Table 2.1: Summary table of experimental data on the effectiveness of Cypermethrin against target organisms. Generally, the substance functions as an insecticide (PT 18) and the envisaged field of use is pest control (MG 03).

Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference
Cyperkill10 containing 10% Cypermethrin (CYP/E243)	***Musca domestica*** (2-4 days old, ♀+♂) ***Blatella germanica*** (adults, ♂♂)	Treated surfaces: 10 × 10 cm tiles made of Plywood (porous) or glazed ceramic (non porous) Application rate with the product: Flies: 25ml/5l/150m² **⇔ 16.66 mg a.i./m²** **⇔ 0.05% a.i.** Cockroaches: 50ml/5l/150m² **⇔ 33.33 mg a.i./m²** **⇔ 0.1% a.i.** The treated surfaces were left dry for 24h before the tests with insects	Temperature: +24 °C ± +1°C Rel. humidity: 50 % ± 5% Light regime: On 16h/day	**Flies on plywood:** KD (1d)= 100% within 15 min => Mortality $_{24h}$ = 100% KD (1month)= 100% within 15 min => Mortality $_{24h}$ = 100% KD (3 months)= 100% within 20 min => Mortality $_{24h}$ = 100% **Flies on tiles:** KD (1d)= 100% within 10 min => Mortality $_{24h}$ = 100% KD (1month)= 100% within 15 min => Mortality $_{24h}$ = 100% KD (3 months)= 100% within 15 min => Mortality $_{24h}$ = 100% **=> Cyperkill 10 is effective to control flies using 16.66 mg cypermethrin/m² on both surfaces types (porous or non-porous surfaces) and is still effective after 3 months.** **Cockroaches on plywood:** KD (1d)= 100% within 30 min => Mortality $_{24h}$ = 92% KD (1month)= 100% within 30 min => Mortality $_{48h}$ = 94% KD (3 months)= 100% within 60 min => Mortality $_{48h}$ = 92% **Cockroaches on tiles:** KD (1d)= 100% within 15min => Mortality $_{24h}$ = 100% KD (1month)= 100% within 15 min => Mortality $_{24h}$ = 100% KD (3 months)= 100% within 30 min => Mortality $_{24h}$ = 100% **=> Cyperkill 10 is effective to control cockroaches using 33.33 mg cypermethrin/m² on non-porous surfaces (tiles) and is still effective after 3 months.** **On porous surfaces (such as plywood), the product seems to be less effective (no qualified explanation given by the applicant).**	Doc^t B5.10(01) MCT 85/921204 JH Cole (1992) **Supportive study** **Justification :** **It seems that the composition of the product CYPERKILL100 is not clear enough to take into account this study as a key study.**

Table 2.1: Summary table of experimental data on the effectiveness of Cypermethrin against target organisms. Generally, the substance functions as an insecticide (PT 18) and the envisaged field of use is pest control (MG 03).

Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference
Exit 100 (oil in water emulsion) (containing 10% w/w Cypermethrin)	***Blatella germanica*** and ***Blatta orientalis*** Mixed age and mixed Sex: With 100 insetcs (30♂,30 non gravid ♀, 20 large nymphs, 20 small nymphs)	<u>Treated</u> Hard surfaces (Vinyl, ceramic, varnished wood, painted wood floor tiles) <u>Application rate with the product:</u> 2.5ml/0.5l/10m² ⇔ 25 mg a.i./m² or 5ml/0.5l/10m² ⇔ 50 mg a.i./m²	Test in simulated use conditions <u>Temperature:</u> +20 - 28 °C <u>Rel. humidity:</u> 20 - 50% <u>Light regime</u>: 12/12	**Exit 100** with 25 mg a.i./m² ***Blatella germanica*** $KD_{30\ min}$ = 91.1% - KD_{24h}= 100% - $Mortality_{72h}$= 98.4% ***Blatta orientalis*** $KD_{30\ min}$ = 66.3% - KD_{24h}= 100% - $Mortality_{72h}$= 78.9% **Exit 100** with 50 mg a.i./m² ***Blatella germanica*** $KD_{30\ min}$ = 85.8% - KD_{24h}= 100% - $Mortality_{72h}$= 97.7% ***Blatta orientalis*** $KD_{30\ min}$ = 57.6% - KD_{24h}= 100% - $Mortality_{72h}$= 83.8% Untreated surfaces ***Blatella germanica*** KD_{24h}= 0% - $Mortality_{72h}$≤ 7.5% ***Blatta orientalis*** KD_{24h}= 0% - $Mortality_{72h}$≤ 6% **=> Data seem to demonstrate the efficacy of the biocidal product EXIT 100 (using both application rates) on hard surfaces against *Blattella germanica*.** **For *Blatta orientalis*, the product seems to be less effective and it could be explained by the higher chinine content in this cockroach species.**	Doc^t B5.10(02) Study 06/04 L. Senior (2006) **Key study** ***Blattella germanica*** **Supportive study only** ***/ Blatta orientalis*** Justification : Submitted data show effectiveness too low to be taken into account at this stage

Table 2.1: Summary table of experimental data on the effectiveness of Cypermethrin against target organisms. Generally, the substance functions as an insecticide (PT 18) and the envisaged field of use is pest control (MG 03).

Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference
Exit 100 as oil in water emulsion (containing 10% w/v Cypermethrin)	***Ctenocephalides felis*** Mixed age and mixed Sex.	Treated surfaces: Hard surfaces (Vinyl, ceramic, varnished wood, painted wood floor tiles) Application rate with the product: **Exit 100 (oil in water emulsion)** 2.5ml/0.5l/10m^2 ⇔ 25 mg a.i./m^2 or 5ml/0.5l/10m^2 ⇔ 50 mg a.i./m^2	Test in simulated use conditions Temperature: +22 – 28.5 °C Rel. humidity: 30 - 52% Light regime: 16/8	**Exit 100 with 25 mg a.i./m^2** **$KD_{30\ min}$ = 93.8% - KD_{24h}= 100%** **$Mortality_{48h}$= 99.5% - $Mortality_{72h}$= 100%** **KD_{50} ≤ 30 min** **Exit 100 with 50 mg a.i./m^2** **$KD_{30\ min}$ = 94.8% - KD_{24h}= 97.9%** **$Mortality_{48h}$= 100%** **KD_{50} ≤ 30 min** **Untreated surfaces** **$KD_{30\ min}$ = 0% - KD_{24h}= 0%** **$Mortality_{72h}$≤ 5%** **=> Both formulations proved to be significantly effective for the control of cat fleas on hard surfaces.** **Within 24h, almost 100% KD is achieved with both application rates. Furthermore, almost 100% mortality can be achieved within 48h.** **Application of Exit 100 at 50 mg ai/m^2 resulted in significantly higher efficacy compared with the other treatment.**	Doc^t B5.10(03) Study 06/03 L Senior (2006) **Key study**

Table 2.1: Summary table of experimental data on the effectiveness of Cypermethrin against target organisms. Generally, the substance functions as an insecticide (PT 18) and the envisaged field of use is pest control (MG 03).

Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference
Exit 100 as oil in water emulsion (containing 10% w/v Cypermethrin)	***Lasius niger*** Only workers	Treated surfaces: Hard surfaces (Vinyl, ceramic, varnished wood, painted wood floor tiles) Application rate with the product: 2.5ml/0.5l/10m^2 ⇔ 25 mg a.i./m^2 or 5ml/0.5l/10m^2 ⇔ 50 mg a.i./m^2	Test in simulated use conditions With 4 replicates per treatment Temperature: +22 - +28 °C Rel. humidity: 20 - 58% Light regime: 16/8	**Exit 100** with 25 mg a.i./m^2 $KD_{30\ min}$ = 30.4% - $Mortality_{196\ h}$ = 88.1% KD_{50} = 2h **Exit 100** with 50 mg a.i./m^2 $KD_{30\ min}$ = 40.8% - $Mortality_{196\ h}$ = 81.2% KD_{50} = 1h **Untreated surfaces** $KD_{30\ min}$ = 1.23% - $Mortality_{196\ h}$ = 7.1% KD_{50} ≥≥ 196h **=> Cypermethrin possesses a good but not optimal level of efficacy to control garden ants. Both treatments were considerably more effective than no treatment. However, for both treatments, 100% mortality can't be achieved within 192h.** **Results were variable, and appeared to be linked to the behaviour of the ants.**	Doc^t B5.10(04) Study 06/02 L Senior (2006) **For information only (for a purpose of clarity) :** efficacy on ants not demonstrated enough because submitted data show effectiveness too low to be taken into account at this stage

3 EXPOSURE ASSESSMENT

3.1 INTENDED USES

An overview of intended use for cypermethrin - insecticide, with the respective in-use concentrations in the treatment solutions is given in table 3.1.1 and table 3.1.2.

Table 3.1.1. Identification of the product

Product type	Field of use envisaged.	Likely concentration at which the active substance will be used
18.01: Insecticide	Professional use only. Control of insects in and around domestic and public buildings and food processing factories (as initially requested by applicant).	0.1 % w/v

Table 3.1.2. Detailed information on cypermethrin application

Treatment	Treatment duration	Quantity of diluted solution used	Concentration of a.s. in diluted solution	Area of spraying	Quantity of a.s. per m^2 of surface (mg/m^2)
Spraying over surfaces	120 min*	5 liters	0.1% w/v	100 m^2	50.0

*Considering that a knapsack sprayer (usually 5L) sprays with a spray rate of 0.5 L/min and considering an area of 100 m^2 (according to information provided by applicant's customers), the treatment duration would be **10 min.** However, as worst case, BE has assessed the human exposure considering the highest value for band spraying from Biocides Human Health Exposure Methodology (version 1, Oct 2015): **120 min.**

3.2 HUMAN EXPOSURE ASSESSMENT

The human exposure assessment considers the production of the active substance and the production of biocidal product (industrial use). In addition, it considers professional workers spraying over surfaces (primary exposure) as insecticide (PT18.01). Finally, this assessment estimates the potential exposure of residents following pest-control measures (secondary exposure).

The food and feed residues assessment was not considered following the expected use of the substance (see 3.2.5).

The modelling of exposures and risk assessment/risk characterisation during production and formulation of cypermethrin should be addressed under other EU legislation (eg: Directive 98/24/EC) and not repeated under Directive 98/8/EC agreed at the Technical Meeting TMI06 and endorsed at the Competent Authority meeting in September 2006, unless the active substance was totally new to the EU market and manufactured in the EU. This is not the case for cypermethrin which is an existing biocidal active substance within the EU. It was agreed that these data should not be considered routinely as core data requirement for the purposes of Annex I inclusion.

However, a description of the tasks and processes involved in production and formulation is provided here for information and, an assessment of the worker exposures via inhalation and dermal routes has been carried out by the applicant for each activity.

Exposure of professionals during spraying over surfaces has been estimated. The estimation includes a contribution from mixing and loading operations and covered both indoor and outdoor uses.

Secondary exposure could occur in the residential environment following pest-control measures. These exposures include inhalation of volatilized residues and dermal contact of contaminated surfaces. Hand-to-mouth contact might apply to infants and toddlers playing on the floor. Adults may be subject to inhalation exposure only, whereas children may be exposed by inhalation and dermal contact (playing on the floor). Toddlers and infants may be additionally exposed via oral ingestion (hand-to-mouth contact).

Table 3.2.1. Identification of main paths of human exposure towards active substance from its use in biocidal product

Exposure path	Industrial use	Professional use	Non professional use	Secondary exposure
Inhalation	Yes	Yes	No	Yes
Dermal	Yes	Yes	No	Yes
Oral	No	No	No	Yes

General remarks

The estimation of exposures is based on modelling and follows the recommendations of the Technical Notes for Guidance (TNsG) - Human Exposure to Biocidal Products (2002) as revised by User Guidance version 1 (EC, 2002a). These models are based to a great extent on data from UK HSE surveys. In the model calculations, it is assumed that the 75th percentile from the measured data given in the TNsG represents a reasonable scenario for risk assessment purposes. Tier 1 estimates do not take account of personal protective equipment (PPE).

To estimate dermal exposure, a clothing penetration of 10% (User Guidance p.42) was assumed for professionals. The dermal penetration of the water-based formulation has been found to be **13%** ([redacted]: for further discussion see docIIB section 4.4.1). The total internal dose is calculated with values for inhalative absorption of 100 % and for oral absorption of **57%** ([redacted]: conservative approach, for further discussion see docIIA section 3.1).

The default value for body weight of an exposed adult, child, toddler and infant are respectively assumed to be 60 kg, 23.9 kg, 10 kg and 8 kg (Biocides Human Health Exposure Methodology, Oct. 2015).

The default value for inhalation rate of an exposed adult, child, toddler and infant is respectively assumed to be 1.25 m^3/h, 1.32 m^3/h, 1.26 m^3/h and 0.84 m^3/h (Biocides Human Health Exposure Methodology, Oct. 2015).

3.2.1 INDUSTRIAL EXPOSURE: production and formulation plant

3.2.1.1 Production of active substance

Description of process
Technical cypermethrin is produced in a closed process. The process of production is described in the confidential annex (see doc IIIA 2.6)

Workplace description

The detail of the workplace description contains confidential data. Please refer to the confidential annex of doc.II B.

Inhalation exposure

Pure cypermethrin has a melting point of 41-47°C. Technical grade cypermethrin is a viscous liquid / semi-solid. During sampling and drumming there is a very low probability that inhalable airborne dust particles are formed. Inhalation of vaporised cypermethrin can only occur in the workplace when sampling and drumming neat cypermethrin or during cleaning and maintenance of equipment. The process is a closed system from manufacture to drumming. The EASE model (TGD for Risk Assessment) is used to assess inhalation exposure. Cypermethrin's vapour pressure is 6 x 10^{-7} Pa at 25°C. Also during the manufacture it has a low tendency to become airborne; the process is an enclosed system. Since the vapour pressure is less than 0.001kPa (according to EMEP/EEA emission inventory guidebook 2009) it is classed as having a very low volatility. Being a liquid with very low volatility and no likelihood of aerosol formation, it can be determined that it has a very low tendency to become airborne. It is therefore assigned an inhalation exposure of 0-0.1ppm.

Dermal exposure

Direct dermal contact with cypermethrin is not foreseen. Using the EASE model it can be determined that in the enclosed system used, dermal exposure will be very low. It is therefore not considered further.

3.2.1.2 Formulation of the biocidal product

Description of process

The biocidal product Cypermethrin 100g/L EW is produced from cypermethrin cis:trans/40:60 by dissolving it in a mixture of solvent and various other organic liquids, ultimately diluted with water to give the 10% cypermethrin in solution.

The formulation can be regarded as an aqueous solution.

Workplace description

This product is produced batch-wise in an enclosed system from manufacture to drumming. The amount of cypermethrin 40:60 cis/trans to be used for the production of the EW formulation is not currently known, but expected to be much less than that used in agro-chemicals and will be order-driven. The active substance and the product are only handled by industrial users with adequate training and protective equipment (gloves, boots, Tyvec coveralls and mask with organic-vapour filter.)

Inhalation exposure

Pure cypermethrin has a melting point of 41-47°C. Technical grade cypermethrin is a viscous liquid/semi-solid. Before being used the drums are warmed in an oven to ensure homogeneity and aid transfer. There is a very low probability that inhalable airborne particles are formed. The possibility of particle or aerosol formation is zero once dissolution of the cypermethrin has taken place.

Cypermethrin is transferred to the reactor, via an open manway, using a pneumatic pump from the drum. Therefore inhalation of vaporised cypermethrin could only occur in the workplace when open containers of neat cypermethrin are handled, during the transfer to the vessel or during cleaning and maintenance of equipment.

The concentration in air is limited by vapour pressure and can be calculated from the following equation: $W = (P*V*M) / (R*T)$

Where W is the amount of substance in $1m^3$ air (g)
P is the vapour pressure (6 x 10-7 Pa)
V is the volume of air ($1m^3$)
M is the molecular weight (416 g/mol)
R is the gas constant (8.314 J/mol/K)
T is the temperature (298K)

Using the values listed above, the saturation concentration is calculated to be 1.01×10^{-7} g/m^3 (worst case). Taking into account that the production takes place in a ventilated work area, the concentration is reduced to 1% (TNG part 3, p 50) of the saturation concentration, i.e. 1.01×10^{-9} g/m^3 (normal use). Taking also into account an inhalation rate of 1.25 m^3/h, a working day of 8 hours and an adult body weight of 60kg, this would lead to an inhalation exposure of 1.68×10^{-5} mg cypermethrin/kg bw/day (worst case) and 1.68×10^{-7} mg cypermethrin /kg bw/day (normal use).

Dermal exposure

Direct dermal contact with cypermethrin 40:60 is not foreseen. However, incidental contact is possible during transfer of the substance to the mixing vessel and during cleaning and disposal of the containers. Hands could be incidentally exposed, when the gloves used are contaminated on the inside. In the absence of other guidance the indicative exposure values are taken from model 7 for mixing and loading (corrected from the TNG part 2 p.142) described in the MOTA (HEEG opinion agreed at TMI08).

This model gives a value of 138 mg/min for exposure without gloves and a value of 1.38 mg/min for exposure under clothes and gloves.

Using a general exposure calculator and assuming that the duration of total dermal exposure is 15 min/day, the dermal exposure is estimated to be 2070 mg of formulated product/day without protection and of 207 mg with PPE.

The highest exposure is during the dilution step i.e. during the production of the formulation to produce the 100 g/L EW, which contains 10% cypermethrin. Dermal exposure is calculated assuming a worker with a bodyweight of 60 kg. In a tier 1 approach, dermal penetration is assumed to be 100%. The tier 2 approach considers a dermal penetration of 13% ([redacted]).

Using the general exposure calculator:

-Worst case dermal penetration of 100% without gloves (tier 1)
2070 x 0.1/60 = 3.45 mg a.s/kg bw/day
-Worst case dermal penetration of 100% with PPE (tier 2)
207 X 0.1/60 = 0.345 mg a.s/kg bw/day

-Reasonable worst case, dermal penetration 13% without gloves (tier 1)
3.45 x 0.13 = 0.449 mg a.s./kg bw/day
Reasonable worst case, dermal penetration 13% with PPE (tier2)
0.345 x 0.13 = 0.045 mg a.s/kg bw/day

Table 3.2.1.2.1. Primary exposure during formulation of the biocidal product Cypermethrin 100g/L WE containing 10% cypermethrin

Intended use	Scenario	Inhalation uptake (chronic)	Dermal uptake (acute)
PT 18.01	Air concentration = 1% of saturation concentration (8hr day) Normal use.	1.67 x 10^{-7} mg a.s. /kg bw/day	
	Worst case with dermal penetration of 100%		Tier 1: 3.45 mg a.s/kg bw/day Tier 2: 0.345 mg a.s/kg bw/day
	Reasonable worst case with dermal penetration of 13%		Tier 1: 0.449 mg a.s./kg bw/day Tier 2: 0.045 mg a.s/kg bw/day

3.2.2 PROFESSIONAL EXPOSURE from the use of the biocidal product PT18.01

The product is used by professionals by spray. The product must be diluted in order to obtain a concentration in a.s. of 0.1%. Exposure will vary depending on the time of year. Exposure can range from a few minutes to possibly one hour at a time. In summer an operator could be using the product all day. However, this will not be continual and one hour use would be exceptional. For flea control the product would usually be applied through a 5 L knapsack sprayer with a flat fan nozzle at a pressure of 2-3 bar, giving a discharge time of ½ litre per minute. If used against bed-bugs or cockroaches and

applied into cracks and crevices the pressure on the sprayer would be reduced to less than ½ bar with no information on discharge time. PPE during use would be unlikely to be high as for mixing but would be dependent on a COSHH assessment.

For the exposure to a professional, the TNsG provides an appropriate model, Spraying; Model 1, for professional use. For the assessment it is assumed that a sprayer will be doing a job for 2 hours a day, based on the highest exposure time for band spraying (see DocIIB, section 3.1). A tiered modelling approach has considered a user wearing no PPE (Tier 1) and the use of gloves (Tier 2a).

The model includes a contribution to exposure from mixing and loading operations which ensure the spraying aspect of the model over-predicts deposition to a marginal degree. The indoor use is assessed with this model. The outdoor use is considered similar to the indoor use. (NB: according the model SPRAYING MODEL 1, both indoor and outdoor uses are covered).

Table 3.2.2.1. Summary table professional biocidal use

Intended use (PT)	Exposure scenario	Acute /chronic	Dermal Estimated internal exposure [mg/kg bw(/day)]	Inhalation Estimated internal exposure [mg/kg bw(/day)]	Total Estimed internal exposure [mg/kg bw(/day)]
Tier 1: without PPE					
18.01	Spraying	Acute	0.07098	0.0054	0.0764
		Chronic	0.04667	0.0036	0.05024
Tier 2a : with gloves (only) PPE					
18.01	Spraying	Acute	0.02670	0.0054	0.0321
		Chronic	0.01756	0.0036	0.0211

Applied model (see exposure calculation in the annex I)

Spraying, Model 1: Low-pressure spray applications (incl. mixing and loading), TNsG- Human Exposure to Biocidal Products (2002), Part 2, p. 146, (75 percentile from the data base). The application involves low pressure via hand-held compression sprayers
Body weight: 60 kg
Clothing penetration: 100%
Total duration task: 120 minutes
Inhalation rate: 1.25 m^3/h (=0.021 m^3/min), Inhaled uptake: 100%
Dermal penetration: 13%

Exposure controls and personal protection

Safe handling practices, worker training and the use of PPE must be used to prevent exposure to cypermethrin 100 g/L EW (diluted or neat) when it is routinely used.

3.2.3 NON-PROFESSIONAL EXPOSURE from the use of the biocidal product PT18.01

There is no non-professional use of the biocidal product.

3.2.4 INDIRECT EXPOSURE as a result of use of the active substance in biocidal product

3.2.4.1 Potential risk to residents/general public to treated surfaces

Secondary exposure could occur in the residential environment following pest-control measures. These exposures include inhalation of volatilized residues and dermal contact of contaminated surfaces. Hand-to-mouth contact might apply to infants and toddlers playing on the floor. Adults may be subject to inhalation exposure only, whereas children may be exposed by inhalation and dermal contact (playing on the floor). Toddlers and infants may be additionally exposed via oral ingestion (hand-to-mouth contact).

Secondary exposure was considered as a mid-term event, as it could occur immediately after the treatment and/or later.

It is assumed that the entire floor in a residential room is sprayed and that exposure to the active can occur from subsequent inhalation and touching the tiled flooring (worst case) with bare hands. Given a default value of 25 m^3 for the volume of a residential room, it is assumed that the floor is approximately 10 m^2 and that this equates to 0.5 L of insecticide (based on 5L for covering 100 m^2 according to information provided by applicant's customers, at 0.1% a.s. concentration).

Calculation: 5 L of insecticide solution covers 100 -150 m^2.

Therefore, quantity of solution applied to floor (10 m^2) = 10/100 x 5 = 0.5 L solution

Quantity of active applied to floor (10 m^2) = 0.5 kg x 0.1% = 0.0005 kg = 0.5g (density = 1).

So, quantity of active per square metre of floor = 0.5/10 = **0.05 g/m^2**

Table 3.2.4.1.1.Indirect exposure to the biocide after professional spraying

Activity	Frequency	Duration	Potential exposure	Nos. exposed
Adults or children walking into residential room after it has been sprayed. Possible playing on the floor and crawling.	Assumed the room is sprayed once a year Exposure could occur immediately after the treatment and/or later	Assumed inhalation exposure duration 8 hours and 1 hour for dermal contact (hands) from playing/crawling on the floor	Inhalation for adults ; Inhalation and dermal for children ; Inhalation, dermal and incidental oral for infants and toddlers	All occupants in the house (Adults, Children, Toddlers and Infants)

3.2.4.2 Model calculations

a) Inhalation route (volatilized residues indoors) – Adults, children, toddlers and infants

In a conservative approach it is assumed that the indoor air is saturated with Cypermethrin vapour. The concentration in air is limited by vapour pressure and is be calculated from the following equation:

$W = (P*V*M) / (R*T)$

Where W is the amount of substance in 1 m^3 air (g)
P is the vapour pressure (6×10^{-7} Pa)
V is the volume of air (1 m^3)
M is the molecular weight (416 g/mol)
R is the gas constant (8.314 J/mol/K)
T is the temperature (298K)

The saturation concentration is calculated to be 1.010×10^{-7} g/m^3.

The body weights and inhalation rates for adults, children, toddlers and infants are 60 kg / 1.25 m^3/h (= 0.021 m^3/min), 23.9kg / 1.32 m^3/h, 10kg / 1.26 m^3/h and 8 kg / 0.84 m^3/h, respectively. The inhalation rates are the default values implemented from the Biocides Human Health Exposure Methodology (Oct 2015). The inhalation uptake fraction is equal to 1 (100% of inhalation absorption per default).

With the following equation,

Systemic dose (g of a.s./kg bw/8h exposure) = SVC × inhalation rate × exposure time × $(\text{body weight})^{-1}$ × inhalation uptake fraction

The following systemic doses are calculated for 8-h exposures:

Adult:	1.68×10^{-8} g a.s./kg / 8 h	1.68×10^{-5} **m**g a.s./kg / 8 h
Child:	4.46×10^{-8} g a.s./kg / 8 h	4.46×10^{-5} **m**g a.s./kg / 8 h
Toddler:	1.02×10^{-7} g a.s./kg / 8 h	1.02×10^{-4} **m**g a.s./kg / 8 h
Infant:	8.48×10^{-8} g a.s./kg / 8 h	8.48×10^{-5} **m**g a.s./kg / 8 h

b) Dermal and, when relevant, oral exposure to residues on the floor – Children, toddlers and infants

Dermal exposure may occur due to dermal contact with the treated floor. It is considered unlikely that adults will crawl or play on tiled flooring for a significant time period, but for children, toddlers and infants it could be significant.

Infants and toddlers exhibit a great deal of hand-to-mouth (HTM) contact. Therefore, a part of the cypermethrin residues present on the hands will be dislodged by saliva and eventually ingested. Oral exposure was calculated using the assumption of Bremmer et al. (2002) that 10 % of the amount ending up on the skin of the infant is taken up by hand-mouth contact.

The dermal and oral exposure assessments have been performed based on ConsExpo model considering the actual application rate. The Crack and crevice scenario and the General surface scenario were included. For **ConsExpo calculations and reports**, please refer to **annex 1** of this document. The following parameters were used for the calculation. The table 3.2.4.2.1 includes the used parameters and their justification.

Table 3.2.4.2.1. Parameters used to calculate the secondary exposure with ConsExpo.

Parameter	Calculation/Justification	Crack and crevice scenario	General surface scenario
exposure frequency , transfer coefficient, rubbed surface, contact time	Default value (RIVM – Pest Control Products Fact Sheet, 2006)	Exposure frequency: 126 x/year Transfer coefficient: 0.6 m^2/h Rubbed surface crack and crevice: 20,000 cm^2 Rubbed surface general surface: 220,000 cm^2 Contact time: 1 hour	
weight fraction compound	Weight fraction = 1 since the dislogeable amount (calculated below) is already in quantity of a.s.	1 (fraction)	
application rate	5 L of insecticide solution covers 100 -150 m^2. The product amount applied to floor (10 m^2) = 1/100 x 5 = 0.05 L solution (0.1% a.s.) = 0.05 kg (assuming a density 1) Quantity of active substance applied on floor per square meter = 0.05 kg x 0.1% = 0.00005 kg = 0.05 g/m^2.	0.05 g/m^2	
dislogeable amount	<u>For crack and crevice application</u>, Dislogeable amount (g a.s./m^2) = 0,05 g/m^2 (application rate) X **15%** (deposit on the floor of the treated area for a Crack and Crevice application – TNsG, Part 2, p.260 and RIVM report 320005002/2006) X 30% (dislogeable fraction - TNsG, Part 2, p.204 and RIVM report 320005002/2006) <u>For general surface application</u>, Dislogeable amount (g a.s./m^2) = 0,05 g/m^2 (application rate) X 30% (dislogeable fraction - TNsG, Part 2, p.204 and RIVM report 320005002/2006)	0.00225 g a.s. /m^2	0.015 g a.s. /m^2
Body weight, inhalation rate, exposed area (Surface of the hands)	Harmonized default values from BHHEM	Infant; 8 kg, 0.84 m^3/h, 196.8 cm^2 Toddler; 10 kg, 1.26 m^3/h, 230.4 cm^2 Child; 23.9 kg, 1.32 m^3/h, 427.8 cm^2	
Dermal and oral uptake fraction,	See doc IIB, point 4.1 Percutaneous absorption	Dermal uptake fraction : 0.13 Oral uptake fraction: 0.57	
ingested amount	Amount ingest were calculated as to be 10% of the available dermal external dose (calculated with ConsExpo).	Calculated	

The results can be found in the Table 3.2.4.2.2 Summary – Secondary Exposure. See below.

c) Secondary exposure: summary table.

For assessing total secondary exposure to Cypermethrin : adults may be subject to inhaling volatilised residues from treated floor, therefore only inhalation exposure has been considered. Children may be exposed by inhalation and dermal contact with treated floor (e.g. by playing on a treated floor). Toddlers and infants may be additionally exposed via oral ingestion, by mouthing hands following dermal contact (hand-to-mouth contact).

Taking into account the above mentioned considerations, the total secondary exposure to cypermethrin combining the secondary inhalation exposure determined previously and the dermal and oral secondary exposure.

These values are internal systemic dose since the absorption value has been taken into account in each respective route of exposure.

Table 3.2.4.2.2.Summary table - Secondary Exposure

Secondary exposure scenario / Exposed population	**Exposure to Cypermethrin (mg/kg bw/d)**			
	Inhalation exposure	Dermal exposure	Oral exposure	**Acute Total exposure**
Crack and crevice spray application				
Adult	1.68×10^{-5}	Not relevant for adult	Not relevant for adult	1.68×10^{-5}
Child	4.46×10^{-5}	0.00736	Not relevant for child	0.0074
Toddler	1.02×10^{-4}	0.0176	0.0077	0.0254
Infant	8.48×10^{-5}	0.022	0.00963	0.0317
General surface spray application				
Adult	1.68×10^{-5}	Not relevant for adult	Not relevant for adult	1.68×10^{-5}
Child	4.46×10^{-5}	0.049	Not relevant for child	0.049
Toddler	1.02×10^{-4}	0.117	0.0513	0.168
Infant	8.48×10^{-5}	0.146	0.0641	0.21

3.2.5 HUMAN EXPOSURE FROM INDIRECT EXPOSURE THROUGH FOOD AND FEED

During WG-IV-2016, it has been accepted that a dietary exposure assessment was not necessary due to the expected use of the substance.

Considering the use of the product, no direct contact with food should normally occur if precautionary measure are observed during the application of the product. The product will be applied only by professional user and they are supposed to do it in absence of any food.

The professional will normally use this product in accordance with HACCP principles.

The RMs advices nevertheless a mitigation measure: “do not use/apply directly on or near food, feed or drinks, nor on surfaces or utensils likely to be in direct contact with food, feed or drinks.

The RMs also recommend to assess, at product authorization level, residues in food if it’s seems likely to happen.

3.3 ENVIRONMENTAL EXPOSURE ASSESSMENT

3.3.1 FATE AND DISTRIBUTION IN THE ENVIRONMENT

The environmental exposure assessment has been produced using all available information. This has been taken from submitted studies and the Organisation for Economic Co-operation and Development (OECD) Task Force documents; Emission Scenario Document (ESD) for ‘Insecticides, acaricides and products to control arthropods (PT 18) for household and professional use’ (July 17, 2008). Information and guidance was also taken from part II of the Technical Guidance Document on Risk Assessment (TGD; EC, 2003).

This section relates to the environmental exposure assessment for the product formulation referred as:

- Cypermethrin 100g/l EW

The product is further diluted by the professional operator in a spray tank to achieve a final concentration of 0.1% cypermethrin. 5 liters is sufficient to cover 100-150m² according to label recommendations.

The product formulation will be used as insecticide (product-type 18) with a wide spectrum of activity against crawling insects (cockroaches, ants and other crawling insects) and flying insects (flies, including stable flies and other flying insects).

The proposed use of cypermethrin and its product formulations in the EU is a spray treatment both for indoor (within buildings) and outdoor (around buildings) applications as an insecticide for professional and non-professional uses. For the purpose of annex I entry the use of cypermethrin by Pest Control Operators is considered where the product is applied as a surface spray. Non-professional use is not considered for the purpose of Annex I entry and will be addressed at national level.

Cypermethrin 100g/l EW is designed for the control of flies, cockroaches, ants and other crawling and flying insects in residential and other buildings, in stables and animal transport utilities, in food processing industries as well as terraces and external (non-garden) perimeter of buildings (Table 3.3.2-01). **The concentration at which the active substance will be used is 0.1 % ($F_{AI, Final}$ = 0.001)**.

Professional pest control operators apply Cypermethrin 100g/l EW indoor and outdoor to crack and crevice, targeted spot, blanket and on band to cover insect access routes along floor/wall junctions, equipped of a standard knapsack sprayer (5L , 2-3 bars) for spraying.

3.3.2 APPROACH

The intended use of Cypermethrin 100g/L EW as biocidal agents for roach and fly control is presented in the following Table 3.3.2-01 on label claims.

Table 3.3.2-01: Intended uses of Cypermethrin 100g/L EW as biocidal agents for roach and fly control.

Application site	Use category	Application type	Dilution		Actual	
			Product in water	Applied	Applied spray	Applied
			[L_p /L_{water}]	[g a.s./L]	[L spray/m^2]	[g a.s./m^2]
Residential	Professional	Spray	0.01	1	5 / 100	0.05
Outdoor perimeter	Professional	Spray	0.01	1	5 / 100	0.05

This use of cypermethrin falls under the Product-type 18 as defined in Annex V of EU-Directive 98/8/EC:

Product-type 18: Insecticides, acaricides and products to control other arthropods

According to the "Overview of Emission Scenarios and Their Status" (see http://ecb.jrc.it/biocides/) an Emission Scenario Document (ESD) has been made available for the Product-type 18 in July 17, 2008. The scenario developed in this ESD on insecticides for household and professional uses covers the mixing/loading step, all kinds of possible releases during applications, releases from indoor treated surfaces by cleaning events and outdoor treated surfaces by weathering. Considering that Cypermethrin 100g/l EW can be applied indoor and outdoor, emissions to the environment for both scenarios will be considered. In order to assess the emission through STP, the following values has been considered: Koc= 575000, Foc= 0.3 Kp,susp = 172500 L/Kg, F water,stp= 0.0915

Emission following application in stable were not been evaluated in this document.

Releases into the environment can take place from processes at any stage of the life-cycle of a substance. However, the local scale environmental emissions associated with the Applicant's envisaged uses (indoor and outdoor) for cypermethrin 100g/l EW, are considered to represent the worst case scenario in terms of predicted environmental concentrations (PECs). In conclusion, considering the use pattern of cypermethrin 100g/l EW and due to low tonnage (approximately 10 tons of cypermethrin per year), it is not relevant to assess the regional risk. The environmental exposure assessment is performed only on a local basis.

Cypermethrin is also included in the list of authorised active substance under PT 8 for industrial, professional and amateur on site use. Simultaneous use of both PT8 and PT18 product in an industrial premises is very unlikely. Use of PT 18 cypermethrin based product inside a building were cypermethrin treated wooden piece stands should not be of concern since emission from treated wood inside building is very low and never considered relevant. However, use of PT 18 outside a building (on a terrace) in close connection to a cypermethrin treated wooden structure cannot be excluded. In this case emission to the environment may occurs after a rain event were both leaching from the wood in service and from the treated surface may occur simultaneously. It is not anticipated that such a combination may be very frequent. Since cypermethrin is not persistent, the effect observed in such a

case may be only transient and local and not deemed to be of concern. Therefore, no aggregated exposure is performed in this document.

The following environmental compartments might be exposed from the use of cypermethrin.

Sewage treatment plant (STP)

Sewage water treatment plants are regarded as the main receiving compartment of cypermethrin emissions after use as indoor insecticide. Possible entry pathways of wastewater during normal use of the product are via wet cleaning operations of treated surfaces, which will result in very low rates of active substance, which might be washed from treated surfaces. The consecutive cleaning of the spraying equipment can also be a possible source for cypermethrin to the sewer system.

For outdoor application of cypermethrin 100g/l EW in urban environments, it is considered that the ground surface receiving the emissions will likely consist of non-permeable substrates (paved, concrete, or asphalt ground) and that releases of insecticides will be washed with rain to the rain water/sewer system. The ESD for PT 18 therefore proposes to consider a theoretical urban environment where 100% of the releases are sent to sewers.

Surface water and sediment

Due to the intended indoor and outdoor uses, there are no direct emissions of cypermethrin to surface water and sediments. The exposure to surface water and sediment is indirect via STP effluents.

Soil, groundwater and air

Considering the intended indoor use-pattern of cypermethrin 100g/l EW as insecticide potential direct contamination of the environment via the pathways air, soil or groundwater is considered negligible. Contamination of soils via sludge application is expected to occur since the default partitioning constant value water - sewage sludge ($Fstp_{sludge}$) is set to 61% (TGD, Part II, Chapter 3, Appendix 2, based on the value of the Log Kow (mean=5.45) and Log H = -1.6), and therefore the concentration of cypermethrin in dry sewage sludge will also be important (Section 3.3.5.2).

For outdoor application of cypermethrin 100g/l EW in rural environments, it is considered that releases will end up on unpaved soil and that the relevant environmental compartments will here be the soil and groundwater. The ESD for PT 18 therefore proposes to consider a theoretical rural environment where 100% of the releases end up to soil. In the present scenario, as worst case, it is considered that when the product is applied outdoors, it is also prepared outside the building with releases occurring directly onto the ground. Considering the air compartment, liquid droplets sprayed outdoor are not expected to remain airborne but will eventually settle on the ground. Emission to air during mixing and loading is considered negligible by the ESD, for liquid product.

Biota

Risk from secondary poisoning for predators may arise during feeding on animals like earthworms or insects which contain residues via the food chain. Due to its Log P_{ow} value of (mean) 5.45, cypermethrin may bioaccumulate in the food chain. However, a BCF_{fish} of 374 has been derived which leads to less concern for the food chain. Nevertheless, secondary poisoning has been addressed in section 3.3.6

3.3.3 EMISSION RATES

The estimations of environmental emissions are based on the intended uses: professional indoor and outdoor as well as the application modes, spraying, as summarized in Table 3.3.3-01.

Table 3.3.3-01: summary of the emission scenarios of Cypermethrin 100g/l EW.

Scenario	Cypermethrin 100g/l EW			
1a	Professional	indoor	Residential spraying	0.1% a.s.
1b		outdoor	Around building and beyond spraying	0.1% a.s.

Scenario 1a: Professional indoor residential spraying of cypermethrin 100g/l EW containing 0.1% active substance after dilution (corresponding to 0.05 g a.s./ m²).

i: Application to the total surface

According to the use instruction, the maximum prescribed application rate is defined as 0.05 L/m² of cypermethrin 100g/l EW diluted in 5L of water directly in the spray tank to reach a final concentration in active substance of 0.1%, applied by low pressure (3 bars) to infested areas. The concentration of cypermethrin is 100 g a.s./L in the biocidal product Cypermethrin 100g/l EW resulting in a total amount 5 g a.s. on a treated surface of 100 m^2. Considering that 5L are needed to treat 100-150 m^2, the applied active substance per m^2 amounts to max 0.05 g a.s./m² (Table 3.3.2-01). BE CA considered these values to calculate the quantity of commercial product applied or Q_{prod} = 0.0005 kg/m² (Table 3.3.3-02). BE CA also assumed that a professional user applying a total quantity of 15L/day will prepare up to 3 times x 5L in a knapsack sprayer.

The mean surface of a private house was considered to be 130 m² (according to the scenario of wood preservatives, OECD 2003). The surface cleaned by water was estimated to be 38.5 m² (the size of the kitchen and the bathroom) according to the Workshop on PT 18 ESDs (December 2007). This former value was used for the exposure assessment considering that only product applied in "wet rooms" (kitchen, bathroom) was directed to sewage treatment plant after cleaning.

Considering that larger building can also be treated (buildings and places for collective, professional, industrial and commercial uses) BE CA has used the default size of large building. The surface of the typical large building is then 609 m² according to TM I 2010. The surface considered to be cleaned by water in larger building was estimated to be 181 m² (TM I 2010). These values for larger buildings were used for exposure assessment. The calculations of the exposure assessment were made on a total of 4000 houses (N_{houses}) and 300 larger buildings ($N_{larger\ buildings}$) connected to one STP (TM I 2010).

Emission to the environment result of the cleaning of treated areas and floor where the dilution step occurs and cleaning of applicator coveralls

The ESD assumes treatment and cleaning occur on the same day. Emissions due to both steps are added to estimate the final releases into the environment. The following formulas (ESD for PT 18 products, July 17, 2008) were used to calculate daily local emission to STP (as STP are regarded as the major pathway of direct Cypermethrin emissions after indoor use of cypermethrin 100g/L EW)

$$(1)\ E_{prep,applicator} = Q_{prod,prep} \times F_{AI} \times N_{prep,building} \times F_{prep,applicator} \times 10^{-3}$$

$$(2)\ E_{prep,floor} = Q_{prod,prep} \times F_{AI} \times N_{prep,building} \times F_{prep,floorr} \times 10^{-3}$$

(3) $E_{application,air} = N_{appl,building} \times F_{application,air} \times Q_{prod} \times F_{AI} \times AREA_{treated}$

(4) $E_{application,applicator} = N_{appl,building} \times F_{application,applicator} \times Q_{prod} \times F_{AI} \times AREA_{treated}$

(5) $E_{application,floor} = N_{appl,building} \times F_{application,floor} \times Q_{prod} \times F_{AI} \times AREA_{treated}$

(6) $E_{application,treated} = N_{appl,building} \times F_{application,treated} \times Q_{prod} \times F_{AI} \times AREA_{treated}$

(7) $E_{applicator,ww} = (E_{prep,applicator} + E_{application,applicator}) \times F_{applicator,ww}$

(8) $E_{treated,ww} = (E_{prep,floor} + E_{application,floor} + E_{application,treated}) \times F_{ww} \times F_{CE}$

(9) $Elocal_{waste\ water} = E_{applicator,ww} + E_{treated,ww}$

The values used to calculate daily local emission to STP after total surface treatment are summarised in Table 3.3.3-02 below.

Table 3.3.3-02: Calculation of the local emissions to waste water – total surface spraying- Dose rate 0.05 g a.i./m².

Parameter	Symbol	Unit	S/D/O*	Houses	Larger buildings
Area treated	$AREA_{treated}$	m²	D	130	609
Area wet rooms	$AREA_{wet\ rooms}$	m²	D	38,5	181
Fraction emitted to waste water during the cleaning step	F_{ww}	-	O	0,296	0,297
Fraction of active substance in the commercial product	F_{AI}	-	S	0,1	0,1
PREPARATION					
Container volume		L	S	10	10
Fraction emitted to applicator during preparation step	$F_{prep,applicator}$	-	D	0,0012	0,0012
Fraction emitted to floor during preparation step	$F_{prep,floor}$	-	D	0,0005	0,0005
Quantity of a.i. in the dilluted product per preparation	Q_{prod}~~a.i.~~$_{,prep}$	g	S	100	100
Number of preparations per day	$N_{prep,building}$	d^{-1}	S	1	3
Emission to the applicator during preparation step (1)	$\mathbf{E_{prep,applicator}}$	kg a.s. /d	O	**1,20E-05**	**3,60E-05**
Emission to floor during preparation step (2)	$\mathbf{E_{prep,floor}}$	kg a.s./d	O	**5,00E-06**	**1,50E-05**
APPLICATION					
Final fraction of active substance in the diluted product	$F_{AI,diluted}$	-	O	0,1	0,1

Fraction emitted to air during application	$F_{application,air}$	-	D	0,02	0,02
Fraction emitted to applicator during application	$F_{application,applicator}$	-	D	0,0023	0,0023
Fraction emitted to floor during application	$F_{application,floor}$	-	D	0,128	0,128
Fraction emitted to treated surfaces during application	$F_{application,treated}$	-	D	0,85	0,85
Number of application per day per building	$N_{application,building}$	d^{-1}	S	1	1
Quantity of commercial product applied	~~Qai~~ Qprod	kg/m²	S	5,00E-04	5,00E-04
Emission to the air during application step (3)	**$E_{application,air}$**	kg/d	O	**1,30E-04**	**6,09E-04**
Emission to the applicator during application step (4)	**$E_{application,applicator}$**	kg/d	O	**1,50E-05**	**7,00E-05**
Emission to wet cleaned floor during application step (5)	**$E_{application,floor}$**	kg/d	O	**2,46E-04**	**1,16E-03**
Emission to wet cleaned treated surfaces during application (6)	**$E_{application,treated}$**	kg/d	O	**1,64E-03**	**7,69E-03**
PREPARATION AND APPLICATION					
Fraction emitted to waste water by the applicator during the cleaning step	$F_{applicator,ww}$	-	D	**1**	**1**
Emission to waste water from applicator (7)	**$E_{applicator,ww}$**	kg/d	O	**2,70E-05**	**1,06E-04**
Cleaning efficiency for floor and treated surfaces	F_{CE}	-	D	0,5	0,5
Emission to waste water from floor and treated surfaces (8)	**$E_{treated,ww}$**	kg/d	O	**9,44E-04**	**4,43E-03**
Local emission to STP/building (9)	**$E_{localww}$**	kg/d	O	**9,71E-04**	**4,54E-03**
Simultaneity factor	$F_{simultaneity}$	-	O	0,00204	0,00204

S/D/O*: Set/Default/Output value.

According to the ESD, household insecticides have diffuse character as emissions are released to the environment from a large numbers of small point sources.[1] To take this into account the ESD defines a

[1] According to MOTA Version 4, 2011, the number of houses (N_{house}) receiving an indoor treatment connected to one STP is 4,000. The corresponding value for commercial buildings ($N_{building}$) is 300.

simultaneity factor ($F_{Simultaneity}$) which represents the number of buildings in which an insecticide can be simultaneously applied. The PT 18 ESD states that the default values for simultaneity are 0.055 for indoor use. However, at the PT 18 workshop held on 10th December 2007, it was proposed that the simultaneity factor could be modified if there is '*detailed information on the application frequency of the biocidal product'*. The CA notes the simultaneity factor has been modified for several actives that are progressing through the Review Programme. The maximum number of permitted indoor applications of cypermethrin is twice per year per premises). This results in an indoor simultaneity factor for permethrin of 0.2 %, based on the following calculation:

Indoor simultaneity factor = (37.82 x 0.54)/100 = 0.2 %

Daily local emission to STP in the case of a total surface application at a dose rate of 0.05 g a.i./m² are calculated with the following formula:

$E_{local\ waste\ water,total} = ((E_{local\ waste\ water,\ houses} \times N_{houses}) + (E_{local\ waste\ water,\ larger\ buildings} \times N_{larger\ buildings})) \times F_{simultaneity}$

Total surface treatment (0.05 g a.s./m²): $\mathbf{E_{local\ waste\ water,total}}$ = 1.7E-^{02}**kg/d**

In case of application in area which are only dry cleaned, emissions to the stp is limited to the emission to applicator during dilution step and emission to the applicator during application

In this case $E_{local\ waste\ water} = E_{local,applicator}$ = ((2.7^{-05} x 4000)+ (1.06^{-04}x 300) x 0.00204) = 2.85^{-04} kg/d

ii: Application to limited surface (chemical barrier, cracks and crevices)

A more realistic case is limited application where the biocidal product is used to create a chemical barrier (*e.g.* along walls) against crawling insects or to treat the locations preferentially infected with flies and crawling insects (Cracks and crevices). According to the Manual of Technical Agreements (MOTA) Biocides Technical Meeting, Version 4; 2011 the total surface of a chemical barrier is considered to be 20 m² for a private house and 93 m² for larger building. The default value for spot treatment for a domestic house is 2 m^2 as stated in the ESD. The default value for commercial buildings is 9.3 m^2 for a spot treatment.

Emission to the environment result of the cleaning of treated areas and floor where the dilution step occurs and cleaning of applicator coveralls

The ESD assumes treatment and cleaning occur on the same day. Emissions due to both steps are added to estimate the final releases into the environment.

Daily local emission to STP in the case of a chemical barrier application at a dose rate of 0.05 g a.s./m² are calculated with the following formula:

Elocalwaste water,total = ((Elocalwaste water, houses × Nhouses) + (Elocalwaste water, larger buildings × Nlarger buildings)) × Fsimultaneity

Chemical barrier treatment (0.05 g a.s./m²): **Elocal waste water,total = 8.630E^{-04} kg/d**

In case of application in area which are only dry cleaned, emissions to the stp is limited to the emission to applicator during dilution step and emission to the applicator during application

In this case, $E_{local\ waste\ water} = E_{local,applicator} = ((6.68^{-06} \times 4000) + (2.11^{-05} \times 300) \times 0.00204) = 6.741^{-05}$kg/d

The values to calculated daily local emission to STP after a chemical barrier treatment are summarised in Table 3.3.3-03 below.

Table 3.3.3-03a: Calculation of the local emissions to waste water –Chemical barrier application- Dose rate 0.05 g a.i./m².

Parameter	Symbol	Unit	S/D/O*	Houses	Larger buildings
Area treated	$AREA_{treated}$	m²	D	20	93
Area wet rooms	$AREA_{wet\ rooms}$	m²	D	5,9	27
Fraction emitted to waste water during the cleaning step	F_{ww}	-	O	0,296	0,297
Fraction of active substance in the commercial product	F_{AI}	-	S	0,1	0,1
PREPARATION					
Container volume		L	S	10	10
Fraction emitted to applicator during preparation step (solid granules)	$F_{prep,applicator}$	-	D	0,0012	0,0012
Fraction emitted to floor during preparation step	$F_{prep,floor}$	-	D	0,0004	0,0004
Quantity of commercial product used for the preparation per day	$Q_{prod,prep}$	g	S	50	50
Number of preparations per day	$N_{prep,building}$	d^{-1}	S	1	3
Emission to the applicator during preparation step (1)	**$E_{prep,applicator}$**	**kg/d**	**O**	**6,00E-06**	**1,80E-05**
Emission to floor during preparation step (2)	**$E_{prep,floor}$**	**kg/d**	**O**	**2,00E-06**	**6,00E-06**
APPLICATION					
Dillution factor	Dil	-	**S**	100	100
Final fraction of active substance in the applied product	$F_{AI,\ Final}$	-	O	0,1	0,1
Fraction emitted to air during application	$F_{application,air}$	-	D	0,02	0,02
Fraction emitted to applicator during application	$F_{application,applicator}$	-	D	0,0023	0,0023
Fraction emitted to floor during application, which are wet cleaned	$F_{application,floor}$	-	D	0,128	0,128

Fraction emitted to treated surfaces during application, which are wet cleaned	$F_{application,treated}$	-	D	0,85	0,85
Number of application per day per building	$N_{application,building}$	d^{-1}	D	1	1
Quantity of commercial product	Q_{prod}	kg/m²	S	5,00E-04	5,00E-04
Emission to the air during application step (3)	**$E_{application,air}$**	**kg/d**	**O**	**5,90E-06**	**2,70E-05**
Emission to the applicator during application step (4)	**$E_{application,applicator}$**	**kg/d**	**O**	**6,79E-07**	**3,11E-06**
Emission to floor during application step (5)	**$E_{application,floor}$**	**kg/d**	**O**	**3,78E-05**	**1,73E-04**
Emission to treated surfaces during application (6)	**$E_{application,treated}$**	**kg/d**	**O**	**2,51E-04**	**1,15E-03**
PREPARATION AND APPLICATION					
Fraction emitted to waste water by the applicator during the cleaning step	$F_{applicator,ww}$	-	D	**1**	**1**
Emission to waste water from applicator (7)	**$E_{applicator,ww}$**	kg/d	**O**	**6,68E-06**	**2,11E-05**
Cleaning efficiency for floor and treated surfaces	Fce	-	**D**	**0,25**	**0,25**
Emission to waste water from floor and treated surfaces (8)	**$E_{treated,ww}$**	kg/d	**O**	**7,26E-05**	**3,32E-04**
Local emission to STP/building (9)	**$E_{localww}$**	kg/d	**O**	**7,93E-05**	**3,53E-04**
Simultaneity factor	$F_{simultaneity}$	-	**O**	0,00204	0,00204

S/D/O*: Set/Default/Output value.

Daily local emission to STP in the case of a cracks and crevices application at a dose rate of 0.05 g a.s./m² are calculated with the following formula:

Elocalwaste water,total = ((Elocalwaste water, houses × Nhouses) + (Elocalwaste water, larger buildings × Nlarger buildings)) × Fsimultaneity

Cracks and crevices treatment (0.05 g a.s./m²): **Elocal waste water,total = 2.82E^{-04} kg/d**

In case of application in area which are only dry cleaned, emissions to the stp is limited to the emission to applicator during dilution step and emission to the applicator during application

In this case, $E_{local\ waste\ water} = E_{local,applicator} = ((1.43^{-06} \times 4000) + (2.27^{-06} \times 300) \times 0.00204) = 1.31^{-05}$kg/d

Table 3.3.3-03b: Calculation of the local emissions to waste water –Cracks and crevices application- Dose rate 0.05 g a.i./m².

Parameter	Symbol	Unit	S/D/O*	Houses	Larger buildings
Area treated	$AREA_{treated}$	m²	D	2	9,3
Area wet rooms	$AREA_{wet\ rooms}$	m²	D	2	9,3
Fraction emitted to waste water during the cleaning step	F_{ww}	-	O	1	1
Fraction of active substance in the commercial product	F_{AI}	-	S	0,1	0,1
PREPARATION					
Container volume		L	S	1	1
Fraction emitted to applicator during preparation step (solid granules)	$F_{prep,applicator}$	-	D	0,0012	0,0012
Fraction emitted to floor during preparation step	$F_{prep,floor}$	-	D	0,0001	0,0001
Quantity of commercial product used for the preparation per day	$Q_{prod,prep}$	g	S	10	10
Number of preparations per day	$N_{prep,building}$	d^{-1}	S	1	1
Emission to the applicator during preparation step (1)	**$E_{prep,applicator}$**	**kg/d**	**O**	**1,20E-06**	**1,20E-06**
Emission to floor during preparation step (2)	**$E_{prep,floor}$**	**kg/d**	**O**	**1,00E-07**	**1,00E-07**
APPLICATION					
Dillution factor	Dil	-	**S**		
Final fraction of active substance in the applied product	$F_{AI,\ Final}$	-	O	0,1	0,1
Fraction emitted to air during application	$F_{application,air}$	-	D	0,02	0,02
Fraction emitted to applicator during application	$F_{application,applicator}$	-	D	0,0023	0,0023
Fraction emitted to floor during application, which are wet cleaned	$F_{application,floor}$	-	D	0,128	0,128
Fraction emitted to treated surfaces during application, which are wet cleaned	$F_{application,treated}$	-	D	0,85	0,85
Number of application per day per building	$N_{application,building}$	d^{-1}	D	1	1
Quantity of commercial product	Q_{prod}	kg/m²	S	5,00E-04	5,00E-04
Emission to the air during application step (3)	**$E_{application,air}$**	**kg/d**	**O**	**2,00E-06**	**9,30E-06**
Emission to the applicator during application step (4)	**$E_{application,applicator}$**	**kg/d**	**O**	**2,30E-07**	**1,07E-06**
Emission to floor during application step (5)	**$E_{application,floor}$**	**kg/d**	**O**	**1,28E-05**	**5,95E-05**

Emission to treated surfaces during application (6)	**$E_{application,treated}$**	**kg/d**	**O**	**8,50E-05**	**3,95E-04**
PREPARATION AND APPLICATION					
Fraction emitted to waste water by the applicator during the cleaning step	$F_{applicator,ww}$	-	D	**1**	**1**
Emission to waste water from applicator (7)	**$E_{applicator,ww}$**	kg/d	**O**	**1,43E-06**	**2,27E-06**
Cleaning efficiency for floor and treated surfaces	Fce	**-**	**D**	**0,25**	**0,25**
Emission to waste water from floor and treated surfaces (8)	**$E_{treated,ww}$**	kg/d	**O**	**2,45E-05**	**1,14E-04**
Local emission to STP/building (9)	**$E_{localww}$**	kg/d	**O**	**2,59E-05**	**1,16E-04**
Simultaneity factor	$F_{simultaneity}$	**-**	**O**	0,00204	0,00204

S/D/O*: Set/Default/Output value.

Scenario 1b: Professional outdoor spraying of residential building walls, and foundations with cypermethrin 100g/l EW containing 0.1% active substance (corresponding to 0.05 g a.s./ m²).

Professional pest control operators apply cypermethrin 100g/l EW outdoor to walls and foundations of buildings to cover flying-insect access routes, equipped of a standard knapsack sprayer (5-10 l, 3 bars) for spraying. This typical biocidal treatment is designed to control heavy infestation by house or other flying insects around building perimeters. According to the applicant the application rate and quantity used per day are similar to that described in the first scenario for professional indoor residential spraying, thus being:

- a total quantity of 10L per day is used to treat a total surface of 200-300 m²;
- 1 preparation steps per day per house and 3 for large buildings.

BE CA considered these values to calculate the quantity of commercial product applied or Q_{prod} = 0.0005 kg/ m² (Table 3.3.3-02). BE CA also assumed that a professional user applying a total quantity of 10L/day will prepare 2 x 5L in a knapsack sprayer which contains a maximum of 10L.

Following ESD PT 18, two theoretical environments will be considered for the risk assessment:

- urban environment: 100% of the releases are sent to sewers;
- rural environment: 100% of the releases end up to soils.

Removal processes (like degradation or volatilisation) from the receiving compartments are not taken into account in this assessment. Spray application to entire walls and adjacent soil surfaces for Flying insects has been considered as recommended in ESD PT 18.

The following formulas have been used to derive the local emissions to the relevant compartments:

(1) $E_{prep,applicator} = Q_{prod,prep} \times F_{AI} \times N_{prep} \times F_{prep,applicator} \times 10^{-3}$

(2) $E_{prep,floor/soil} = Q_{prod,prep} \times F_{AI} \times N_{prep} \times F_{prep,soil} \times 10^{-3}$

(3) $C_{prep,soil} = E_{prep,soil} / (V_{prep,\ soil} \times RHO_{soil})$

(4) $E_{spray,\ wall,appl,soil} = Q_{prod} \times F_{AI} \times AREA_{foundation} \times F_{spray,\ wall}$

(5) $E_{spray,wall\text{-}wasoff,\ soil} = Q_{prod} \times F_{AI} \times AREA_{soil} \times F_{spray,washoff,soil}$

(6) $E_{spray,\ flying} = E_{spray,\ wall,soil} + E_{spray,wall,\ washoff\ soil}$

(7) $E_{applicator,ww} = E_{prep,applicator} + E_{prep,floor} + E_{spray,\ wall,appl,soil} + E_{spray,wall\text{-}wasoff,\ soil}$

(8) $C_{spray,\ wall,\ soil} = (E_{spray,\ wall,soil} + E_{spray,wall,\ washoff\ soil}) / (V_{spray,\ soil} \times RHO_{soil})$

(9) $C_{spray,\ wall,\ washoff,\ soil} = (E_{spray,\ wall,washoff,\ soil}) / (V_{spray,\ soil} \times RHO_{soil})$

(10) $C_{spray,flying\ total} = C_{spray,\ wall,\ soil} + C_{spray,\ wall,\ washoff,\ soil}$

- Urban area

In urban environment, the local emissions to STP have been calculated taking into account that Cypermethrin 100g/l EW could be applied to control flying insects. Emissions from the preparation step have also been considered as those are assumed to be sent to a sewage treatment plant as well.

Table 3.3.3-05: Calculation of the local emissions to waste water –Outdoor flying insects- Urban- Dose rate 0.05 g a.i./m²

Parameter	Symbol	Unit	S/D/O*	House	Larger buildings
$Area_{treated,foudation}$	$AREA_{treated}$ foundation	m²/d	D	25	125
$Area_{treated,\ wall}$	$AREA_{treated}$ wall	m²/d	D	125	625
Area Untreated	$AREA_{untreated}$	m²/d	D	28	128
Fraction of active substance in the commercial product	F_{AI}	-	S	0,1	0,1
PREPARATION					
Container volume		L	S	10	10
Fraction emitted to air during preparation step	$F_{prep,air}$	-	D	0	0
Fraction emitted to applicator during preparation step	$F_{prep,applicator}$	-	D	0,0012	0,0012
Fraction emitted to floor during preparation step	$F_{prep,soil}$	-	D	0,0005	0,0005
Quantity of commercial product used for the preparation	$Q_{prod,prep}$	g	S	100	100

Number of preparations per day	$N_{prep,building}$*	d^{-1}	S	1	3
Emission to the applicator during preparation step (1)	**$E_{prep,applicator}$**	**kg/d**	**O**	**1,20E-05**	**3,60E-05**
Emission to soil during preparation step (2)	**$E_{prep,floor}$**	**kg/d**	**O**	**5,00E-06**	**1,50E-05**
APPLICATION					
Dillution factor	Dil	-	**S**	100	100
Final fraction of active substance in the applied product	$F_{AI, Final}$	-	O	0,1	0,1
Fraction emitted to air during application	$F_{spray,wall}$	-	D	0,3	0,3
Fraction emmited to soil due to wash-off during rainfall	$F_{spray, wash-off}$			0,5	0,5
Number of application per day per building	$N_{application,building}$	d^{-1}	D	1	1
Quantity of commercial product	Q_{prod}	kg/m²	S	5,00E-04	5,00E-04
Local Emission from outdoor spray application on wall due to deposition on Floor (4)	**$E_{spray,wall,appl,soil}$**	**kg/d**	**O**	**1,88E-03**	**9,38E-03**
Local Emission to floor from outdoor spray applicationon wall due to was-off by rainfall (5)	**$E_{spray,wall,wash-off,soil}$**	**kg/d**	**O**	**3,13E-03**	**1,56E-02**
PREPARATION AND APPLICATION					
Fraction emitted to waste water by the applicator during the cleaning step	$F_{applicator,ww}$	-	D	**1**	**1**

Local emision to stp from outdoor spray application on wall due to application and wash-off by rainfall	**$E_{spray, flying}$**	kg/d	**O**	**5,00E-03**	**2,50E-02**
Simultaneity factor	$F_{simultaneity}$	-	**O**	0,0275	0,0275

S/D/O*: Set/Default/Output value

According to the ESD PT 18, up to 120 houses in a city of 10000 inhabitants could be treated per day. However, the number of large buildings which could also be treated simultaneously is not mentioned. Therefore, the BE CA has considered a worst-case approach and taken into account that 120 houses and 1 larger buildings (Workshop PT 18) could be simultaneously treated within a city of 10000 inhabitants and has applied the following formula:

$$E_{local\ waste\ water,\ (houses)} = E_{prep,\ floor} + E_{prep,applicator} + E_{spray,\ flying}$$

and

$$E_{local\ waste\ water,\ (larger\ buildings)} = E_{prep,\ soil} + E_{prep,applicator} + E_{spray,\ flying}$$

Thus,

$$E_{local\ waste\ water\ ,total} = ((E_{local\ waste\ water,\ (houses)} \times N_{houses}) + (E_{local\ waste\ water,\ (larger\ buildings)} \times N_{larger\ buildings})) \times F_{simultaneity}$$

In urban environment, the total daily emission to local waste water treatment plant has thus been calculated to be:

$E_{local\ waste\ water\ total}$: 1.102 kg/d

- Rural area

Table 3.3.3-06: Calculation of the local emissions to soil and waste water –Outdoor flying insects- Rural - Dose rate 0.05 g a.i./m²

Parameter	Symbol	Unit	House	Large building	S/D/O*
Area of exterior wall treated per day	$Area_{treated,\ wall}$	m²/d	125	625	D
Area Untreated	$AREA_{untreated}$	m²/d	28	128	D
Fraction of active substance in the commercial product	F_{AI}	-	0,1	0,1	S
PREPARATION					
Container volume		L	10	10	S
Fraction emitted to applicator during preparation step ()	$F_{prep,applicator}$	-	0,0012	0,0012	D
Fraction emitted to floor during preparation step	$F_{prep,\ floor}$	-	0,0005	0,0005	D
Quantity of commercial product used for the preparation per day	$Q_{prod,prep}$	g	100	100	S

Soil volume for the mixing/loading step	$V_{prep,soil}$	m^3	4,00E-01	4,00E-01	D
Number of preparations per day	$N_{prep,building}$*	d^{-1}	1	3	S
Emission to the applicator during preparation step (2)	**$E_{prep,applicator}$**	**kg/d**	**1,20E-05**	**3,60E-05**	**O**
Emission to soil during preparation step (3)	**$E_{prep,floor}$**	**kg/d**	**5,00E-06**	**1,50E-05**	**O**
Local concentration of active substance in soil during mixing/loading	**$C_{prep,soil}$**	**$kg.kgww^{-1}/d$**	**7,35E-09**	**2,21E-08**	**O**
APPLICATION					
Dillution factor	Dil	-			**S**
Final fraction of active substance in the applied product	$F_{AI, Final}$	-	0,1	0,1	O
Fraction emitted to air during application	$F_{spray,wall}$	-	0,3	0,3	D
Fraction emmited to soil due to wash-off during rainfall	$F_{spray, wash-off}$		0,5	0,5	
Number of application per day per building	$N_{application,building}$	d^{-1}	1	1	D
Quantity of commercial product	Q_{prod}	kg/m^2	5,00E-04	5,00E-04	S
Soil volume around building	$V_{spray,soil}$	m^3	13	63	P
Local Emission from outdoor spray application on wall due to deposition on soil (5)	**$E_{spray,wall,appl,soil}$**	**kg/d**	**1,88E-03**	**9,38E-03**	**O**
Local Emission to soil from outdoor spray applicationon wall due to was-off by rainfall (6)	**$E_{spray,wall,wash-off,soil}$**	**kg/d**	**3,13E-02**	**1,56E-01**	**O**
Local concentration of active substance in soil adjacent to the house due to wall application against flying insects	**$C_{spray,wall,appl,soil}$**	**$kg/kgww^{-1}$**	**8,48E-08**	**8,75E-08**	**O**
Local concentration of active substance in soil adjacent to the house due to wash-off and application	**$C_{spray, was-off, soil}$**	**$kg/kgww^{-1}$**	**1,41E-06**	**1,46E-06**	**O**
PREPARATION AND APPLICATION					
Fraction emitted to waste water by the applicator during the cleaning step	$F_{applicator,ww}$	-	**1**	**1**	D

Emission to waste water from applicator	**$E_{applicator,ww}$**	kg/d	**1,20E-05**	**3,60E-05**	**O**
Total concentration in soil due to application and washing -off by rain water	**$C_{spray, flying total}$**	**Kg/Kgww^{-1}**	**1,50E-06**	**1,55E-06**	**D**
Local emission to STP/building (10)	**$E_{localww}$**	kg/d	**1,20E-05**	**3,60E-05**	**O**
Simultaneity factor	$F_{simultaneity}$	-	0,0275	0,0275	**O**

S/D/O*: Set/Default/Output value

In the rural environment emissions will be mainly directed to the surrounding soil surface. To calculate the local concentration in soil, the BE CA has taken into account that cypermethrin 100g/l EW could be applied to wall to control flying insects. Emissions from the preparation step have also been considered. However, as the ESD PT18 stipulates that the preparation step does not occur in the treated area, these local emissions to soil due to preparation have been considered separately:

Local concentration in soil due to preparation (n=1): **$C_{prep, soil house}$ = 7.35E^{-09} kg/kg ww^{-1}**

:

$C_{prep,soil,buildings}$ = 2.21E^{-08} kg/kg ww^{-1}

In rural areas, it is considered that the preparation step is performed outside. Therefore, emission to stp can only occurs through emission to the applicator during preparation step. Daily emission to STP due to mixing/loading : $E_{local,STP, prep}$ = 1.20E^{-05}kg/d

According to the ESD PT 18, local concentrations in soils have been calculated considering:

Local concentration in treated soil around Houses: **$C_{spray,flying, total,house}$= 1.50E^{-06}/kg wwt**

Local concentration in treated soil around large buildings: **$C_{spray,flying, total,building}$= 1.55E^{-06}kg/kg wwt**

Scenario 1d: Professional outdoor spraying of residential building perimeters and terraces with cypermethrin 100g/l EW containing 0.1% active substance (corresponding to 0.05 g a.s./ m²).

Professional pest control operators apply cypermethrin 100g/l EW outdoor to terraces and external (non-garden) perimeter of buildings to cover insect access routes along floor/wall junctions, equipped of a standard knapsack sprayer (5-10 l, 3 bars) for spraying. This typical biocidal treatment is designed to control crawling insects around building perimeters. According to the applicant the application rate and quantity used per day are similar to that described in the first scenario for professional indoor residential spraying, thus being:

- a total quantity of 10 L per day is used to treat a total surface of 200-300 m²;
- 1 preparation step per day per house and 3 for large buildings

BE CA considered these values to calculate the quantity of commercial product applied or Q_{prod} = 0.0005 kg/ m² (Table 3.3.3-02). BE CA also assumed that a professional user applying a total quantity of 10L/day will prepare 2 x 5 L in a knapsack sprayer which contains a maximum of 10 L.

Following ESD PT 18, two theoretical environments will be considered for the risk assessment:

- urban environment: 100% of the releases are sent to sewers;

- rural environment: 100% of the releases end up to soils.

Removal processes (like degradation or volatilisation) from the receiving compartments are not taken into account in this assessment. Spray application to the lower parts of the walls and adjacent soil for crawling insects has been considered as recommended in ESD PT 18.

The following formulas have been used to derive the local emissions to the relevant compartments:

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

$$C_{prep,soil} = E_{prep,soil} / (V_{prep,\ soil} \times RHO_{soil})$$

$$E_{spray,\ foundation} = Q_{prod} \times F_{AI} \times AREA_{\ foundation} \times F_{spray,\ foundation}$$

$$E_{spray,\ soil} = AREA_{\ soil} \times Q_{prod} \times F_{AI\ x}\, F_{spray,\ soil}$$

$$E_{spray,\ untreated\ soil} = Q_{prod} \times F_{AI} \times F_{spray,\ untreated\ soil} \times AREA_{\ untreated}$$

$$E_{spray,\ foundation,\ wash\text{-}off} = AREA_{\ foundation} \times Q_{prod} \times F_{AI\ x}\, F_{spray,\ wash\text{-}off}$$

$$E_{spray,\ crawling\ insects,ww} = E_{spray,\ foundation} + E_{spray,\ soil} + E_{spray,\ foundation,\ wash\text{-}off}$$

$$E_{local,\ ww} = E_{spray,\ crawling\ insects} + E_{\ prep,applicator}$$

$$C_{spray,\ treated\ soil} = (E_{spray,\ foundation} + E_{spray,\ soil} + E_{spray,\ foundation,\ wash\text{-}off}) / (V_{spray,\ treated\ soil\ x}\, RHO_{soil})$$

$$C_{spray,\ untreated\ soil} = (E_{spray,\ untreated\ soil}) / (V_{spray,\ untreated\ soil\ x}\, RHO_{soil})$$

- Urban area

Table 3.3.3-07: Calculation of the local emissions to waste water –Outdoor crawling insects- Urban- Dose rate 0.05 g a.i./m²

Parameter	Symbol	Unit	House	Large building	S/D/O*
$Area_{treated,foudation}$	$AREA_{treated}$	m²/d	25	125	D
$Area_{treated,\ wall}$		m²/d	125	625	D
$Area_{treated,soil}$		m²/d	26	126	D
Area Untreated	$AREA_{untreated}$	m²/d	28	128	D
Fraction of active substance in the commercial product	F_{AI}	-	0,1	0,1	S
PREPARATION					
Container volume		L	10	10	S
Fraction emitted to applicator during preparation step ()	$F_{prep,applicator}$	-	0,0012	0,0012	D
Fraction emitted to floor during preparation step	$F_{prep,soil}$	-	0,0005	0,0005	D
Quantity of commercial product used for the preparation per day	$Q_{prod,prep}$	g	100	100	S
Soil volume for the mixing/loading step	$V_{prep,soil}$	m³	4,00E-01	4,00E-01	D
Number of preparations per day	$N_{prep,building}$*	d^{-1}	1	3	S
Emission to the applicator during preparation step (2)	**$E_{prep,applicator}$**	**kg/d**	**1,20E-05**	**3,60E-05**	**O**

Emission to soil during preparation step (3)	**$E_{prep,floor}$**	**kg/d**	**5,00E-06**	**1,50E-05**	**O**
APPLICATION					
Dillution factor	Dil	-			**S**
Final fraction of active substance in the applied product	$F_{AI, Final}$	-	0,1	0,1	O
Fraction emitted to soil during outdoor foundation spray application against crawling insects during application	$F_{spray,foundation}$	-	0,3	0,3	D
Fraction emmited to soil during outdoor ground spray application	$F_{spray,soil}$	-	0,99	0,99	D
Fraction emmited to soil during outdoor ground spray application	$F_{spray,untreated,soil}$	-	0,0042	0,0042	D
Fraction emmited to soil due to washing by rain water	$F_{spray, wash-off}$	-	0,5	0,5	D
Number of application per day per building	$N_{application,building}$	d^{-1}	1	1	D
Quantity of commercial product	Q_{prod}	kg/m²	5,00E-04	5,00E-04	S
Soil volume around building	$V_{spray,soil}$	m³	13	63	P
Soil volume for deposition and application	$V_{spray, untreated,soil}$	m³	14	64	P
Emission from outdoor spray application on foundations against crawling insects (5)	**$E_{spray,foundation}$**	**kg/d**	**3,75E-04**	**1,88E-03**	**O**
Emission to soil from outdoor spray application on soil (6)	**$E_{spray,soil}$**	**kg/d**	**1,29E-03**	**6,24E-03**	**O**
Emission to untreated soil from outdoor spray application (6)	**$E_{spray, untreated, soil}$**	**kg/d**	**5,88E-06**	**2,69E-05**	**O**
Emission from outdoor spray application on foundation due to wash-off	**$E_{spray,foundation, wash-off}$**	**kg/d**	**6,25E-04**	**3,13E-03**	**O**
PREPARATION AND APPLICATION					
Fraction emitted to waste water by the applicator during the cleaning step	$F_{applicator,ww}$	-	**1**	**1**	D
Emission to waste water from application	**$E_{applicator,ww}$**	kg/d	**6,31E-04**	**3,15E-03**	**O**
Local emission to STP/building (10)	**$E_{localww}$**	kg/d	**6,48E-04**	**3,20E-03**	**O**
Simultaneity factor	$F_{simultaneity}$	-	0,0275	0,0275	**O**

S/D/O*: Set/Default/Output value

In urban environment, the local emissions to STP have been calculated taking into account that cypermethrin 100g/l EW could be applied to control crawling insects. Emissions from the preparation step have also been considered as those are assumed to be sent to a sewage treatment plant as well. According to TM2010, up to 2500 houses and 300large buildings in a city of 10000 inhabitants could be treated per day. Therefore:

$$E_{\text{local waste water, (houses)}} = E_{\text{prep, soil}} + E_{\text{spray crawling}}$$

and

$$E_{\text{local waste water, (larger buildings)}} = E_{\text{prep, soil}} + E_{\text{spray crawling}}$$

Thus,

$$E_{\text{local waste water ,total}} = ((E_{\text{local waste water, (houses)}} \times N_{\text{houses}}) + (E_{\text{local waste water, (larger buildings)}} \times N_{\text{larger buildings}})) \times F_{\text{simultaneity}}$$

In urban environment, the total daily emission to local waste water treatment plant has thus been calculated with a simultaneity factor of 0.0275 to be:

$E_{\text{local waste water total}}$: 7.097^{-02}kg/d

- Rural area

Table 3.3.3-08: Calculation of the local emissions to waste water –Outdoor crawling insects- Rural- Dose rate 0.05 g a.i./m²

Parameter	Symbol	Unit	House	Large building	S/D/O*
$Area_{treated,foundation}$	$AREA_{treated}$	m²/d	25	125	D
$Area_{treated, wall}$		m²/d	125	625	D
$Area_{treated,soil}$		m²/d	26	126	D
Area Untreated	$AREA_{untreated}$	m²/d	28	128	D
Fraction of active substance in the commercial product	F_{AI}	-	0,1	0,1	S
PREPARATION					
Container volume		L	10	10	S
Fraction emitted to air during preparation step (solid granules)	$F_{prep,air}$	-	0	0	D
Fraction emitted to applicator during preparation step ()	$F_{prep,applicator}$	-	0,0012	0,0012	D
Fraction emitted to floor during preparation step	$F_{prep,soil}$	-	0,0005	0,0005	D
Quantity of commercial product used for the preparation per day	$Q_{prod,prep}$	g	100	100	S
Soil volume for the mixing/loading step	$V_{prep,soil}$	m³	4,00E-01	4,00E-01	D
Number of preparations per day	$N_{prep,building}$*	d^{-1}	1	3	S
Emission to the air during preparation step (1)	**$E_{prep,air}$**	**kg/d**	**0**	**0**	**O**

Emission to the applicator during preparation step (2)	**$E_{prep,applicator}$**	**kg/d**	**1,20E-05**	**3,60E-05**	**O**
Emission to soil during preparation step (3)	**$E_{prep,floor}$**	**kg/d**	**5,00E-06**	**1,50E-05**	**O**
Local concentration of active substance in soil during mixing/loading	**$C_{prep,soil}$**	**kg.kgww/d**	**7,35E-09**	**2,21E-08**	**O**
APPLICATION					
Dillution factor	Dil	-			**S**
Final fraction of active substance in the applied product	$F_{AI, Final}$	-	0,1	0,1	O
Fraction emitted to soil during outdoor foundation spray application against crawling insects during application	$F_{spray,foundation}$	-	0,3	0,3	D
Fraction directly emmited to soil during outdoor ground spray application	$F_{spray,soil}$	-	0,99	0,99	D
Fraction emmited to soil during outdoor ground spray application (untreated)	$F_{spray,untreated,soil}$	-	0,0042	0,0042	D
Fraction emmited to soil due to washing by rain water	$F_{spray, wash-off}$	-	0,5	0,5	D
Number of application per day per building	$N_{application,building}$	d^{-1}	1	1	D
Quantity of commercial product	Q_{prod}	kg/m²	5,00E-04	5,00E-04	S
Soil volume around building	$V_{spray,soil}$	m³	13	63	P
Soil volume for deposition and application	$V_{spray, untreated,soil}$	m³	14	64	P
Emission from outdoor spray application on foundations against crawling insects (5)	**$E_{spray,foundation}$**	**kg/d**	**3,75E-04**	**1,88E-03**	**O**
Emission to soil from outdoor spray application on soil (6)	**$E_{spray,soil}$**	**kg/d**	**1,29E-03**	**6,24E-03**	**O**
Emission to untreated soil from outdoor spray application (6)	**$E_{spray, untreated, soil}$**	**kg/d**	**5,88E-06**	**2,69E-05**	**O**
Emission from outdoor spray application on foundation due to wash-off	**$E_{spray,foundation, wash-off}$**	**kg/d**	**6,25E-05**	**3,13E-04**	**O**

Concentration of active substance in treated soil up to 0,5 m from the house due to application	**$C_{spraytreatedl,soil}$**	**kg/kgwww**	**1,66E-03**	**8,11E-03**	**O**
Concentration of active substance in untreated soil due to application	**$C_{spray,\ untreated,\ soil}$**	**kg/kgwww**	**2,47E-10**	**2,47E-10**	**O**
PREPARATION AND APPLICATION					
Fraction emitted to waste water by the applicator during the cleaning step	$F_{applicator,ww}$	-	**1**	**1**	D
Emission to waste water from applicator (8)	**$E_{applicator,ww}$**	kg/d	**1,70E-05**	**5,10E-05**	**O**
Total concentration in soil due to mixing/loadin, application and washing - off by rain water	**$C_{spray,\ flying\ total}$**	**Kg/Kgwww**	**1,66E-03**	**8,11E-03**	**D**
Local emission to STP/building (10)	**$E_{localww}$**	kg/d	**1,70E-05**	**5,10E-05**	**O**
Simultaneity factor	$F_{simultaneity}$	-	0,0275	0,0275	**O**

S/D/O*: Set/Default/Output value

In the rural environment emissions will be mainly directed to the surrounding soil surface. To calculate the local concentration in soil, the BE CA has taken into account that cypermethrin 100g/l EW could be applied to wall/floor junctions to control crawling insects. Emissions from the preparation step have also been considered. However, as the ESD PT18 stipulates that the preparation step does not occur in the treated area, these local emissions to soil due to preparation have been considered separately:

Local concentration in soil due to preparation (n=1): $\mathbf{C_{local\ prep,soilhouse} = 7.35E^{-09}\ kg/kg\ ww^{-1}}$

Local concentration in soil due to preparation (n=3): $\mathbf{C_{local\ prep,soil,}}$ building = 2.21E-08

According to the ESD PT 18, local concentrations in soils have been calculated considering:

- the soil in the treated area;
- the soil in the non treated/adjacent area.

Local concentration in treated soil around treated house: $\mathbf{C_{local\ soil\ treated} = 1.66\ E^{-03}\ kg/kg_{\ ww-1}}$

Local concentration in untreated soil around treated house: $\mathbf{C_{local\ soil\ untreated} = 2.47\ E^{-10}\ kg/kg_{\ ww-1}}$

Local concentration in treated soil around large buildings: $\mathbf{C_{local\ soil\ treated} = 8.11\ E^{-03} kg/kg_{\ ww-1}}$

Local concentration in untreated soil around large buildings: $\mathbf{C_{local\ soil\ untreated} = 2.47\ E\text{-}^{10}\ kg/kg_{\ ww-1}}$

Emission to waste water due to mixing loading step applicator is equivalent as in previous scenario.

3.3.4 PEC IN SURFACE WATER AND SEDIMENT

For each above scenario's, Pec surface water has been calculated according to the STP scenario describe in the TDG (2004). F_{stp} has been set to 9.15% , K_{oc} to 5750000 and F_{oc} to 0.3. The results are summarised in the table 3.3.4-01 below.

Table 3.3.4-01 Predictive Environmental Concentration in surface water after STP (simple treat).

Scenario	Elocal water	Pec surf water
	kg/d	mg/l
Indoor	1,07E-02	2,63E-05
Indoor , dry	2,85E-04	7,00E-07
Chemical barrier	1,66E-03	4,07E-06
Chemical barrier, dry	1,82E-03	4,48E-06
Craks and Crevices	7,641E-03	1,88E-05
Cracks and Crevices, dry	3,533E-04	8,68E-07
Stable and animal housing	N.C.	N.C.
Outdoor flying urban	1,10E+00	1,79E-11
Outdoor flying rural	1,20E-05	1,95E-16
Outdoor crawling urban	7,10E-02	1,15E-12
Outdoor crawling rural	5,75E-05	9,33E-16

N.C. not calculated since scenario removed after WG IV 2016.

From these values, PNEC sed can be derived by EPM. See doc II C

3.3.5 PEC SOIL.

Direct emission of cypermethrin to soil has been predicted for flying and crawling insects scenario's which correspond to local concentration of cypermethrin in the surrounding of the application area.

Table 3.3.5-01 Pec soil due to direct emission to soil

Scenario	Pec soil house	Pec soil large building
	kg/kg ww^{-1}	kg/kg ww^{-1}
Indoor	n.a	n.a
Indoor , dry	n.a	n.a
Chemical barrier	n.a	n.a
Chemical barrier, dry	n.a	n.a
Craks and Crevices	n.a	n.a
Cracks and Crevices, dry	n.a	n.a
Stable and animal housing*	N.C.	N.C.
Outdoor flying urban		

Outdoor flying rural	1.50E-^{06}	1.55E-^{06}
Outdoor crawling urban		
Outdoor crawling rural	1.66E^{-03}	8.11E^{-03}

N.C. not calculated since scenario removed after WG IV 2016

In addition to the direct emission of active substance in local soil due to leaching or to drifting during application, agricultural soil and arable land may be exposed to active substance. A large proportion of the cypermethrin load entering an STP will partition to sludge, contamination of agricultural and grassland soil following sludge, slurry and/or manure application should be considered. Sludge application is foreseeable for the "flying", "crawling" and "crack" and crevice"" scenario. Slurry/manure application is foreseeable for the stable and animal housing. Emission to soil following sludge application has been calculated according to TGD and application of slurry/manure has been calculated according to esd for PT 18.

The concentration in dry sewage sludge is calculated from the emission rate to water, the fraction of the emission sorbed to sludge and the rate of sewage sludge production:

$Csludge = F_{stpsludge} \times Elocal_{water} \times 10^6 / SLUDGERATE$

where:
$Elocal_{water}$ = (see table 3.3.4-01 above) kg/d
$Fstp_{sludge}$ = fraction of emission directed to sludge by STP = 0.61
SLUDGERATE = (2/3 x 0.45 x 2000) + (0.011 x 10000) = 710 kg/d (calculated as presented below according to TGD)
$SLUDGERATE = 2/3 \times SUSPCON_{inf} \times EFFLUENT_{stp} \times SURPLUSsludge \times CAPACITY_{stp}$

Where:

Variable/parameter (unit)	**Symbol**	**Unit**	**Value**	**Source***
Concentration of suspended matter in STP influent	*SUSPCONCinf*	[kg.m-3]	0.45	Default
Effluent discharge rate of STP	$EFFLUENT_{stp}$	[$m_3.d_{-1}$]	2000	Calculated**
Surplus sludge per inhabitant equivalent	*SURPLUSsludge*	[$kg.d_{-1}.eq_{-1}$]	0.011	Default
Capacity of the STP	$CAPACITY_{stp}$	[eq]	10000	Default
Rate of sewage sludge production	*SLUDGERATE*	[kg.d-1]	710	Output

* All default values were taken from the Technical Guidance Document (EC, 2003)
** Adjusted to change Units from $l.d^{-1}$ to $m^3.d^{-1}$

The concentration in soil can be calculated for a single application of for repeated application during 10 years. A DT_{50} (12°C) of 17.5 day has been used to calculate the Kbiosoil. K leach and K volat has been calculated according to TGD and to the agreed endpoints such as listed in the LOEP for PT 8. Dair is considered negligible since Elocal,air and Estp,air are considered negligible (Low vap pressure). The contribution of the regional scale has been considered negligible as well since the molecule strongly bind to soil and has a low vapour pressure, only local contribution has been deemed relevant. The resulting concentration in soil is presented in the table 3.3.5_02 below.

Table 3.3.5_02 Concentration in sludge and soil due to sludge application on soil after 1 application and after 10 applications.

Scenario	Csludge	$Csludge_{soil1}$	$Csludge_{soil\ 10}$	Clocal

				soil
	mg/kg	mg/kg	mg/kg	
Indoor	1,36E+02	1,99E-01	1,99E-01	1,37E-03
indoor ,dry	3,61E+00	5,31E-03	5,31E-03	3,66E-05
Chemical barrier	2,10E+01	3,09E-02	3,09E-02	1,11E-04
Chemical barrier dry	2,31E+01	3,40E-02	3,40E-02	8,66E-06
Cracks and crevices	9,69E+01	1,42E-01	1,42E-01	9,81E-04
Cracks and crevices, dry	4,48E+00	6,59E-03	6,59E-03	4,54E-05
Stable and animal housing	N.C.	N.C.	N.C.	N.C.
Outdoor flying urban	1,40E+04	2,05E+01	2,05E+01	1,41E-01
Outdoor flying rural	1,52E-01	2,24E-04	2,24E-04	1,54E-06
Outdoor crawling urban	9,00E+02	1,32E+00	1,32E+00	9,11E-03
Outdoor crawling rural	7,29E-01	1,07E-03	1,07E-03	7,38E-06

N.C. not calculated since scenario removed after WG 2016.

3.3.6 NON COMPARTMENT SPECIFIC EXPOSURE RELEVANT TO THE FOOD CHAIN (SECONDARY POISONING)

BE eCA did evaluated the secondary exposure following cypermethrin application outdoor or in stable. Following the risk assessment, the only scenario acceptable is application indoor in area which are only dry cleaned. As a consequence the use of cypermethrin containing product will be very limited and the product will be applied in area with very limited access to wild life. Therefore, a secondary poisoning evaluation in no more needed.

4 HUMAN HEALTH EFFECTS ASSESSMENT OF THE PRODUCT

The data highlighted by the use of a grey background in the tables are from studies where a full (robust) **STUDY SUMMARY** made in accordance with the Technical Notes for Guidance on Dossier Preparation was available, i.e. the **KEY STUDIES.** Summaries of the rest of the studies are available as

IUCLID entries only. Unless otherwise stated, all studies were made according to international accepted guidelines and principles for Good Laboratory Practice (GLP).

4.1 PERCUTANEOUS ABSORPTION

Table 4.1.1 Percutaneous absorption of Cypermethrin 100 g/L EW

Route	Species	Test substance	Dose	Method	Results	Reference
Dermal	Rat males 4/group	**Cypermethrin 500 g/L EC** **^{14}C-Cypermethrin *cis:trans*/40:60**	500 g/L 25 mg/L	OECD 427	Dermal absorption: Radioactivity absorption (%) at 216h 500 g/L / 25mg/L Absorbed: 3.44 / 11.03 + residual skin: 4.77 / 11.2 +18 tape strips: 6.7 / 12.7	[redacted] DocIIIA6.2 (05)
Dermal	In vitro Human skin 4 donors	**Cypermethrin 100 g/L EC** **^{14}C-Cypermethrin *cis:trans*/40:60**	25 mg/L (0.00025 mg/cm²) 100 g/L (1.0 mg/cm²) 8h exposure	OECD 428 Static cell system The membranes were not occluded and exposed for 8 hours, then the skin was washed. Receptor fluid collected up to 24h post dose. At 24h post dose the skin was tape stripped.	Dermal absorption: Absorption was rapid with detectable levels in the receptor fluid at 1 h. Radioactivity absorption (%) 100 g/L / 25mg/L Receptor fluid: 1.5 / 13 + residual skin: 27 / 68.6 +5 tape strips: 37.5 / 78.6 Conclusion on dermal absorption: concentrate (100 g/L): 37.5% dermal absorption spray dilution (25 mg/L): 78.6% dermal absorption	Hardwick, 2006 DocIIIA6.2 (02)
Dermal	Human volunteer males, n=6	**Cypermethrin *cis:trans*/56:44**	Single dose 26 mg/ml in soya bean oil on 800 cm² = 31 mg	Metabolism Collection of urine samples over the periods 0-4, 4-8, 8-12h post treatment, then over 12h intervals up to 120 hrs after dosing Urinary metabolites DCVA, 3PBA,	41% of the dermal dose (range 36-48%) was recovered in the detergent skin wash after the completion of the 8 hour exposure period. Extracts from the T-shirt cover used overnight post exposure produced a further 24% of applied dose. On average in this study at least 65% of the applied dose was not absorbed. Cypermethrin metabolites were detectable in the majority of urine samples over the first four hours of exposure but peak excretion rates occurred between 12 and 36 hours post dosing. No metabolites were detected beyond the 96 h sampling point (except for trace amounts of 4OH3PBA in two individuals). The elimination half life for total metabolites was 13 h (range 8-22h, standard deviation ±5.1 h). Four individual volunteers took part in both	[redacted] DocIIIA6.2 (04)

				4OH4PBA, 2OH3PBA were analysed	the oral and dermal phases of the assay, these individuals had similar elimination half lives for both exposure routes. The average *trans:cis* DCVA ratio was 1:1.2. The amounts of cyclopropane acid metabolites in urine samples following dermal application were circa four times lower than the metabolites derived from the phenoxybenzyl moiety. The estimate of Cypermethrin dermal absorption, based on *cis* or *trans* DCVA metabolite presence, was 0.3%, this was much lower than the same estimate based on 3PBA and 4OH3PBA – mean of 1.2% dermal absorption estimated.	

Conclusion: (from Doc. III-A6.2 and Doc. III-B6.4)

No dermal absorption study was performed using the biocidal product "Cypermethrin 100 g/L EW".

However, studies *in vivo* and *in vitro* were performed using typical formulations (Cypermethrin 100 g/L EC, Cypermethrin 500 g/L EC), concentrated or as spray dilution, and an 8 hour exposure.

In vitro

The percutaneous absorption of [^{14}C]-Cypermethrin *cis:trans*/40:60 through viable human epidermal membranes was studied using a static test system according to OECD guideline 428 by Hardwick (2006). Skin absorption was investigated at two application rates. The high dose rate, nominally 1.0 mg/cm^2, represented the undiluted EC formulation; the low dose, nominally 0.00025 mg/cm^2, represented the diluted spray solution used in normal agricultural spraying operations. The membranes were not occluded and the skin was exposed to the test substance for 8 h, after which time the skin was washed. Due to the low solubility of Cypermethrin, the receptor fluid selected was ethanol/water (1:1, v/v). Receptor fluid was collected up to 24 h post dose. At 24 h post dose the skin was tape stripped 5 times to remove the stratum corneum. Radioactivity was determined in the receptor fluid, residual skin, skin washings, tape strips and diffusion cell washings to determine the overall mass balance of radioactivity. Recovery of radioactivity was essentially quantitative for both dose levels.

Following a 1 mg/cm² application of [^{14}C]-Cypermethrin cis:trans 40:60 (concentrate, 100 g/L), there was a mean lag phase of ca 2.1 hours. The mean maximum rate of absorption was 1553 ng/cm²/h. The mean concentration/time curve showed that absorption slowed down 10 hours following dose application with a mean permeability coefficient (Kp) of 1.6^{-5} cm/h. Absorbed radioactivity, in the receptor fluid, accounted for 1.5% of the applied dose by the terminal timepoint, corresponding to a mean of 21990 ng equivalents/cm^2. The majority of the radioactivity was removed from the skin during the washing procedure at 8 hours following dose application (43.2%). The remainder of the radioactivity was recovered the tape strips (10.5%) or following solubilisation of the residual skin (25.5%). Residual radioactivity extracted from the diffusion chamber accounted for 17.4% of the applied radioactivity.

Following a 0.00025 mg/cm^2 application of [^{14}C]-Cypermethrin cis:trans 40:60 (spray dilution, 25mg/L), there was a mean lag phase of ca 0.16 hours. The mean maximum rate of absorption was 3.328 ng/cm^2/h. The mean concentration/time curve showed that absorption was steady throughout the

study and did not plateau. The mean Kp for [^{14}C]-Cypermethrin cis:trans 40:60 at this concentration was 1.3^{-4} cm/h.

Absorbed radioactivity, in the receptor fluid, accounted for 13.1% of the applied dose by the terminal timepoint, corresponding to a mean of 42.7 ng equivalents/cm^2. The majority of the radioactivity was recovered following solubilisation of residual skin (55.6%). The remainder of the radioactivity was removed from the skin during the washing procedure at 8 hours following dose application (16.6%) or recovered from the tape strips (9.9%). Residual radioactivity extracted from the diffusion chamber accounted for 6.8% of the applied radioactivity.

Absorption of radioactivity was rapid, with detectable levels in the receptor fluid at 1 h. At study termination, 1.5 and 13% of the applied dose were recovered in the receptor fluid for the concentrate (100 g/L) and spray dilution (25 mg/L), respectively. The amount absorbed (found in the receptor fluid) increased only ca 500 fold for a 4,000 fold increase in exposure, i.e. absorption was not proportional to increasing exposure thus indicating saturation of absorption at the higher dose level. The washing procedure removed variable amounts of radioactivity. For the concentrate, the majority of applied radioactivity was removed but, for the spray dilution, the majority remained associated with the skin. The washing procedure had no noticeable effect on the rate of absorption of radioactivity. Approximately 10% of the applied radioactivity was associated with the stratum corneum that was removed during the tape stripping process.

In conclusion, the residual amounts within the skin have to be included. It cannot be excluded that the amount present in the skin could not be potentially absorbed. Dermal absorption values including residual skin are:

Concentrate **27%**, Spray dilution **68.6%.** According to the general consensus at TM (2008) and Mota, the material found in the stratum corneum should also be included in the absorbed dose unless tape stripping data is available that allows to discount the top 25% of the stratum corneum. As there is no information for the tape strips individually, dermal absorption values including residual skin and all 5 tape strips are: Concentrate **37.5%,** Spray dilution: **78.6%.**

Note: this study has not been reevaluated according to EFSA Guidance on Dermal Absorption (2012). At the WG meeting, it was agreed that re-evaluation of this is not essential, as the results from the in vivo study were used for risk assessment.

In vivo

The applicant submitted a new *in vivo* rat absorption study in September 2010 to the RMS, together with a robust summary. The Applicant considers the study as valid and therefore is of the opinion that any human exposure assessment must be revised taking into account the dermal penetration rate obtained in this study. This new data was accepted, evaluated and taken into account by the RMS.

The dermal absorption after single dermal administration of an 500 g/L EC formulation of [^{14}C]-Cypermethrin *cis:trans*/40:60 was studied in the rat according to the OECD guideline 427 by [redacted]. Cypermethrin was tested at two target concentrations: the emulsifiable concentrate (500 g a.i./L) and a representative field dilution (25 mg a.i./L). The study objectives were to determine the extent of percutaneous absorption of the compound related radioactivity, its permeation through the skin into the body, and its elimination *via* excreta following a contact time of 8 hours. The bioavailability of the residues remaining in/on skin after washing of the application site and the kinetics of percutaneous absorption were estimated at 3 time points, 24, 72 and 216 hours after the beginning of

the 8 hour exposure time. Furthermore, the distribution of radioactivity between the upper skin layer (*stratum corneum*) and the rest of the skin was estimated. At sacrifice the following samples were collected: 'O'-ring + protective device; skin wash; surface tape strips (stratum corneum), 20 in total, individually sampled; application site (tape stripped); skin (non treated area); whole blood; plasma; gastrointestinal tract; residual carcass. The cage washings at the end of the collection period were also retained.

Total absorption was assessed from recoveries of radioactivity in urine and faecal samples, cage wash, tissues, GI tract and residual carcass as 0.98% of the high dose absorbed within 24 h. The total absorption increased to 1.09% at 72 h and to 3.44% at 216 h after dosing. For the low dose 5.62% of the dose was absorbed within 24 h. The total absorption increased to 8.63% at 72 h and to 11.03% at 216 h after dosing. The systemic dose per day showed a low systemic dose (ca 1%) in the time groups of the high dose and a steady decrease from 5.6% after 24 h to ca 1% after 216 h in the low dose. The highest amount of radioactivity, 0.59% of the administered dose, was the residual amount found in the low dose carcasses, at the 24 h sacrifice. Levels in blood and plasma were close to or below the limit of detection. The low dose values were considerably less than 1 ng/g tissue.

Skin strips: In the high dose mean radioactivity in skin strips was 7.11% after 24 h, 6.73% after 72 hours and 5.03% at 216 h after dosing.

For the low dose, residual radioactivity in skin strips was 7.41% after 24 h, 6.54% after 72 hours and 4.34% after 216 h.

These values include all 20 tape strip amounts. Due to the persistence of absorption over the extended observation period and in accordance with current guidance on use of tape strip data (eg EFSA or MOTA 3), the total amount of absorbed material or biologically available material for absorption was adjusted to exclude the amounts recovered at each time point in the first two tape strips – see discussion below.

At both dose levels skin stripping revealed that most radioactivity in the stratum corneum was concentrated in the upper layer and/or hair at 216 h after the start of application and therefore the potential for further absorption was limited.

Stripped skin: Radioactivity in the dermis (stripped skin) increased from 0.82% at 24 h to 1.23% at 216 h after application in the high dose group. For the low dose the radioactivity decreased from 1.12% at 24 h to 0.20% at 216 h after application.

In the high dose group sacrificed 16 hours after the 8 hour exposure, 0.82% of administered dose was found in the skin (after washing the dislodgeable amount and removing the stratum corneum by tape stripping). This residual amount in the skin increased slightly to 1.23% of administered dose when assessed at 216 hours.

For the low dose groups, radioactivity in stripped skin was 1.12% of administered dose after 24 h and decreased to just 0.20% by 216 hours.

Elimination: The majority of the radioactivity associated with administered Cypermethrin was removed by washing. The dislodgeable, non –absorbed radioactivity in the skin wash was 84-91% of the applied radioactivity for the low dose and in the high dose circa 91% of the applied radioactivity was removed in the skin wash.

Additionally significant amounts of radioactivity were associated with the 'O'-ring and cover - 6-8% in the high dose group and slightly lower, 2.0-2.5%, in the low dose.

Urinary excretion accounted for 2.26% and 8.18% of the high and low dose, respectively, measured over the 216 h assessment period.

Urinary excretion at 24 and 72 hours equated to 0.28% and 0.71% of the administered dose in the high dose group and 2.74% and 6.43% in the low dose.

Faecal excretion accounted for small amounts of radioactivity - 0.38% and 2.08% of the administered high and low doses respectively, within 216 h. High dose faecal excretion at 24 or 72h was 0.07% and 0.15%. The values for the low dose group were 0.38% and 1.12% respectively.

Based on the results of this study and taking account of the Manual of Technical Agreements (MOTA3) Biocides Technical Meeting, 24 Feb, 2010, the RMS considered *in vivo* percutaneous absorption study of an EC formulation in rats (concentrate 500g ai/L; spray dilution 25 mg a.i./L = agriculture field dilution, 8 h exposure, post exposure times 24h, 72h, 216h), revealed dermal absorption values, including residual skin (stripped skin) at 24h, 72h or 216 h after dosing:

Concentrate: 1.8, 2.1, and 4.7%

Spray dilution: 6.5, 9.2, and 11.2%.

The dermal absorption values including residual skin and **all 20** tapestrips at 24h, 72h or 216 h after dosing:

Concentrate: 8.9, 8.9, and 9.7%

Spray dilution: 13.94, 15.8, and 15.6%.

The draft 'Guidance on Dermal Absorption' recently circulated by EFSA Panel on Plant Protection Products and their Residues (PPR) seeks to clarify the use of data obtained by skin stripping. In the current study, a total of 20 strips were used and the total dermal absorption values calculated above reflect either the inclusion of results from all strips or from none. Neither position is thought to accurately reflect the role of the stratum corneum as a partial barrier to dermal absorption and a means of removal of non-absorbable material. The EFSA Guidance reflects the conclusions of MOTA3 in the Biocides Technical Meeting. Where there is no evidence for continuing absorption at the end of the observation period, it is justified to exclude the tape strip data entirely. In cases where more than 75% of absorption occurs within half of the observation period, then tape strip data may also be excluded unless only pooled data are available. In this study the absorption after 72 hours was less than 75% of the total after 216 h and so inclusion of some tape strip data is considered appropriate. There is general agreement, reflected in both MOTA3 (4.1.1 Q2) and the most recent EFSA Guidance on Dermal Absorption (point 5.1.1) that the amount of dose removed by the initial two tape strips represents material that will not become biologically available and that practically and pragmatically these data can be excluded for the total absorption calculation.

Based on these assumptions the dermal absorption values for cypermethrin including total absorbed, residual skin absorption and 18 tape strips (first two excluded) at 24 h, 72 h or 216 h after dosing are:

Concentrate (500 g a.s./L): 6.7, 7.0, 7.6%

Spray dilution (25 mg a.s./L): **12.5,** **13.6,** **12.7%**

Human data from the open literature

Cypermethrin was administered dermally on the dorsum to 6 male volunteers at a dose of 31 mg/800 cm² (*cis:trans*/56:44, purity 91.4%) as a soya oil-based formulation, 26 mg a;s./ml ([redacted]). The area remained unoccluded for 8 hours and was then washed with 1ml of 3% aq. Teepol. The volunteers then wore a T-shirt until taking a shower 24 hours after dosing. Urine was recovered over the periods 0-4, 4-8, 8-12 h post treatment and then over 12h intervals up to 120 hours after dosing. Total volume, creatinine concentration and pH were analysed in the samples together with linear regression analysis of half-life – assessed on excretion rate versus mid-point time from 18 h post treatment t the point at which metabolites fell below the limit of detection. Urinary metabolites of Cypermethrin (DCVA, 3PBA, 4OH4PBA and 2OH3PBA) were analysed together with internal standards 4PBA and 4OH4PBA. The rat metabolite, 2OH3PBA, was not detected in human samples. The limit of detection was typically 0.5µg/L for all four metabolites and the precision is cited in the publication to be typically 5% relative standard deviation.

41% of the dermal dose (range 36-48%) was recovered in the detergent skin wash after the 8h exposure period. A further 24% was recovered from the T-shirt cover worn overnight. On average, in this study at least 65% of the applied dose was not absorbed.

Cypermethrin metabolites were detectable in the majority of urine samples over the first four hours of exposure but peak excretion rates occurred between 12 and 36 hours post dosing. No metabolites were detected beyond the 96 h sampling point (except for trace amounts of 4OH3PBA in two individuals). The elimination half life for total metabolites was 13 h (range 8-22h, standard deviation ±5.1 h). The average *trans:cis* DCVA ratio was 1:1.2. The amounts of cyclopropane acid metabolites in urine samples following dermal application were circa four times lower than the metabolites derived from the phenoxybenzyl moiety. This indicated that the cyclopropane acid part of the molecule may either not be effectively absorbed, or more probably is converted to other metabolites which are not measured using the assay procedure. The estimate of cypermethrin dermal absorption, based on *cis* or *trans* DCVA metabolite presence, was 0.3%, this was much lower than the same estimate based on 3PBA and 4OH3PBA – mean of 1.2% dermal absorption estimated. A recovery of only 66.6%was calculated.

It has to be noted that there is no mass balance reported. The purpose of this study was to provide a basis for interpretation of urinary metabolite data in studies of worker exposure, not a complete accounting of administered dose.

Conclusion on dermal absorption

Dermal absorption was studied in the rat, using human tissue, and in human volunteers.

Studies *in vivo* and *in vitro* were performed using typical formulations (Cypermethrin 100 g/l EC, Cypermethrin 500 g/l EC), concentrated or as spray dilution, and an 8 hour exposure.

Based on the results of the *in vitro* dermal absorption in human skin study performed with an EC formulation, the dermal absorption values for cypermethrin including total absorbed, residual skin absorption and 5 tape strips (all tape strips) at 24 h after dosing are for the concentrate (100 mg a.s./L) 37.5%, and for the spray dilution (25 mg a.s./L) 78.6%.

Based on the results of the *in vivo* rat dermal absorption study performed with an EC formulation, the dermal absorption values for cypermethrin including total absorbed, residual skin absorption and 18 tape strips (first two excluded) at 24 h, 72 h or 216 h after dosing are for the concentrate (500 mg a.s./L):6.7%, 7.0%, 7.6%; and for the spray dilution (25 mg a.s./L): 12.5%, 13.6%, 12.7%. The total absorption increased over time. This was expected as pyrethroids are stored in the skin following dermal exposure and are slowly released in to the systemic circulation.

The outcome of the rat study is supported by the human volunteer study by [redacted]. The estimated dermal absorption based on the phenoxybenzoic acid metabolites 120 h after dosing is 1.2% (range 0.85 to 1.8%) for a 26g/L formulation (applied dose 31mg/800cm²), and only a recovery of 66.6% (skin wash, T-shirt, urine metabolites).

It is well known that the rat skin is more permeable than human skin and it is also well known that the *in vitro* findings generally overpredict the *in vivo* situation (Nohynek et al., 2010, Toxicol. Appl. Pharmacol. 243, 239-259). Moreover, the *in vitro* system used was a static test system, whereas today the more reliable flow-through systems are generally used. In the human volunteer study a recovery of only 66.6%was calculated. However, the purpose of this study was to provide a basis for interpretation of urinary metabolite data in studies of worker exposure, not a complete accounting of administered dose. No mass balance was reported.

Therefore, the *in vivo* dermal absorption study in rats performed with the Cypermethrin 500 g/L EC formulation ([redacted]) provides the most reliable dermal absorption data. The dermal absorption of cypermethrin determined in rats *in vi*vo resulted in an absorption of 7.6% and 12.7% of the applied dose for the concentrate (500 g/L) and spray dilution (25 mg/L). The solvents used in the latter formulation are considered to be more likely to carry the active substance through the skin due to the more lipophilic nature. Therefore, this can be used as a worst case. For the assessment of the human internal dermal exposure to the biocidal product Cypermethrin 100 g/L EW, a value of **13%** is used, as humans are exposed to a water-based biocidal formulation containing cypermethrin 100 g/L (10% a.s. concentration) or less when applied as a solution (0.1% a.s. concentration in final applied product).

4.2 ACUTE TOXICITY

4.2.1 ANIMAL DATA

Table 4.2.1.: Acute toxicity of Cypermethrin 100 g/L EW

Route	Method Guideline	Test substance	Species Strain Sex no/group	Dose levels duration of exposure	Value LD50/LC50	Reference
Oral	OECD 423	Cypermethrin 100 g/L EW lot 157004F22 E5+6 *cis:trans*/40:60	Rat: Wistar female 3/group	2000 mg/kg bw, 300 mg/kg bw; 14 days post exposure period	cut-off = 500 mg/kg bw	[redacted]
Dermal	OECD 402	Cypermethrin 250 g/L EC	Rat: Sprague-	Limit test: 4000 mg/kg bw;	>4000 mg/kg bw	[redacted]

		(Cyperkill 25 EC) lot 5541161 *cis:trans*/40:60	Dawley male/female 5/sex/group	10% of body surface, semi-occlusive, 24 h 14 days post exposure period		
Inhalation	OECD 403	Cypermethrin 250 g/L EC lot 81290 *cis:trans*/40:60	Rat: Sprague-Dawley male/female 5/sex/group	5 mg/L; aerosol, nose only, 4 hours; 14 days post exposure period	> 5 mg/L (4hrs)	[redacted]

Summary and conclusions of acute toxicity: (from Doc.III-B6.1)

Oral:

Cypermethrin 100 g/L EW: Oral toxicity was tested in the rat (LD_{50} cut-off = 500 mg/kg bw; [redacted]). A total of 3 animals were used in the first set of tests at 2000 mg/kg: two females were found dead and one was sacrificed for ethical reasons (clonic and saltatory spasms, flat posture, laboured respiration, rales) on day 1 (exposure day). A second set of 3 females was administered 300 mg/kg, and one animal was found dead at day 1. In a third set (300 mg/kg, n=3), no mortality was observed. No macroscopic abnormalities were found at necropsy. No effects on body weight were observed. Clinical symptoms recorded for the animals dosed at 300 mg/kg were hunched posture, and/or piloerection, uncoordinated movements on day 1.

Dermal:

Cypermethrin 250 g/L EC: Dermal toxicity was tested in the rat, but with no systemic effects/mortalities, nor skin irritation, nor abnormalities noted at necropsy at the limit dose of 4000 mg/kg bw (LD50 > 4000 mg/kg bw; [redacted]). This higher concentration of the EC formulation is considered as worst case.

Inhalation:

Cypermethrin 250 g/L EC: Inhalative toxicity was tested in the rat. An LC_{50} > 5000 mg/m^3 (aerosol) was determined by nose-only exposure for 4 hours ([redacted]). Clinical observations during exposure included increased respiration rate, hunched posture, pilo-erection and wet fur. There were isolated instances of ataxia, laboured or noisy respiration, heightened sensitivity to external stimuli, and tip-toe gait. Two male animals were euthanized immediately post-exposure for humane reasons. Surviving animals recovered quickly and appeared normal from d3-4 onwards. Apart from one animal with abnormal dark lungs, no macroscopic abnormalities were detected at necropsy amongst survivors. Pale lungs with dark patches and gaseous distensions of the stomach were noted in the 2 killed animals during the study. Body weight was not affected. This higher concentration of the EC formulation is considered as worst case.

For classification and labelling, we base our conclusions only on the acute oral, dermal, and inhalation toxicity data obtained from these studies. Extrapolations are made from the results with formulations with higher concentrations of a.s. for dermal and inhalation toxicity. In conclusion, Cypermethrin 100 g/L EW is considered acutely harmful/acute tox. 4 by oral exposure, but is not considered acutely toxic by dermal and inhalation exposure.

Classification/labelling of biocidal product 'Cypermethrin 100 g/L EW' for acute toxicity according to the criteria in Directive 67/548/EEC and Directive 1999/45/EEC, and according to the criteria in CLP-Regulation (EC) No 1272/2008:

Xn, R22: Harmful if swallowed

Acute Tox. 4, H302: Harmful if swallowed

4.3 IRRITATION AND CORROSIVITY

4.3.1 ANIMAL DATA

Table 4.3.1.1. Skin irritation by Cypermethrin 100 g/L EW

Species	Method	TS	Individual score 24, 48, 72 h Erythema (R), Edema (ED)				Reversi-bility yes/no	Result	Reference
			24 h	48 h	72 h	Mean 24-72 h			
Rabbit	OECD 404	Cypermethrin 100 g/L EW lot 157004F22 E5+6 *cis:trans*/40:60	R: 2/2/2 ED:2/1/1	R: 2/2/2 ED:1/0/1	R: 2/2/2 ED:1/0/0	R: 2/2/2 ED: 1.3/0.3/0.7	Yes	Skin irritant (67/548/EEC) Non-irrita-ting (EC No 1272/2008)	[redacted]

Table 4.3.1.2. Eye irritation by Cypermethrin 100 g/L EW

Species	Method	TS	Individual Score (mean after 72 h)				Reversibility yes/no	Result	Reference
			Cornea	Iris	Conjunctiva Redness	Conjunctiva Chemosis			
Rabbit	OECD 405	Cypermethrin 100 g/L EW lot 157004F22 E5+6 *cis:trans*/40:60	0/0/0	0/0/0	0.3/0.7/0.3	0/0/0	Yes	Not irritating	[redacted]

Summary and conclusions of skin and eye irritation: (from Doc.III-B6.2)

Cypermethrin 100 g/L EW is an irritant to rabbit skin ([redacted]) according to the provisions of Council Directive 67/548/EEC and Council Directive 99/45/EEC. However, according to the criteria of CLP Regulation EC No 1272/2008, Cypermethrin 100 g/L EW is not considered a skin irritant. Exposure resulted in well-defined erythema and very slight or slight oedema in all three animals. Scaliness was noted in all animals at 72 hours after exposure. Skin irritation had resolved within 7 days. No symptoms of systemic toxicity or mortalities occurred during the study.

Cypermethrin 100 g/L EW is not an irritant to the eyes in the rabbit ([redacted]). Irritation of the conjunctivae consisted of redness, chemosis and discharge. The irritation had completely resolved within 48 hours in two animals, and within 72 hours in the other animal. There was no evidence of ocular corrosion. No symptoms of systemic toxicity and no mortalities occurred during the study.

Classification/labelling of the biocidal product 'Cypermethrin 100 g/L EW' for irritation/corrosivity according to the criteria in Directive 67/548/EEC, Directive 1999/45/EEC: **Xi, R38: Irritating to skin**

Classification/labelling of the biocidal product 'Cypermethrin 100 g/L EW' for irritation/corrosivity according to the criteria in Regulation EC No 1272/2008: **None**

4.4 SENSITISATION

4.4.1 ANIMAL DATA

Table 4.4.1: Sensitisation by Cypermethrin 100 g/L EW

Substance	Species	Method	Number of animals sensitized/total number of animals	Result	Reference
Cypermethrin 100 g/L EW lot 157004F22 E5+6 *cis:trans*/40:60 vehicle: methyl ethyl ketone	Mouse: CBA female 5/group	OECD 429 (LLNA)	induction: 0, 2.5, 10, 25 % cypermethrin 100 g/l EW in methyl ethyl ketone (preliminary irritation study performed) Mean DPM / SI value solvent: 118 / 1.0 2.5% 315 / 2.7 10% 1361 / 11.5 25% 3478 / 29.4 cypermethrin 100 g/l EW in methyl ethyl ketone: SI > 3, EC3 = 2.8% Historical positive control data: Mean DPM / SI value HCA 5% in AOO 235 / 1.0	Sensitising	[redacted]

			HCA 10% in AOO	766	3.2		
			HCA 25% in AOO	1708	7.1		
			AOO (4:1)	241	1.0		
			An EC3 value of 9.5% was calculated (in the acceptable range of 2 and 20%).				
			Results of the 6 monthly HCA reliability checks of the recent years: 8.8, 5.5, 7.3, and 10.3%.				

Summary and conclusions of skin sensitisation: (from Doc. III-B6.3)

Cypermethrin 100 g/L EW is considered a skin sensitizer in the mouse LLNA, using methyl ethyl ketone as vehicle ([redacted]). No irritation was observed after the third epidermal exposure apart from one animal of the 25% group with slight erythema (1 ear). The largest lymph nodes were found in the higher dose groups. Bodyweight and bodyweight gain remained in the same range as the control animals. No symptoms of systemic toxicity and no mortalities occurred during the study. The results indicate that Cypermethrin 100 mg/L EW could elicit a stimulation index (SI) ≥ 3. An EC3 value of 2.8% was calculated.

Classification/labelling of the biocidal product 'Cypermethrin 100 g/L EW' for sensitisation according to criteria in Directive 67/548/EEC and Directive 1999/45/EEC, and according to the criteria in CLP-Regulation (EC) No 1272/2008:

R43: May cause sensitisation by skin contact

Skin Sens. 1, H317: May cause an allergic skin reaction

4.5 OTHER: REPEATED DOSE TOXICITY

Further inherent properties of the active substance the classification of which has to be adopted to the biocidal product Cypermethrin 100g/L EW according to CLP Regulation EC No 1272/2008:

For a comprehensive discussion: see DocIIA section 3.5.

Table 4.5.1.: Short-term repeated dose toxicity of cypermethrin

Route	Method Guideline	TS	Duration of study	Species Strain Sex No/group	Dose levels frequency of application	Results	LO(A)EL	NO(A)EL	Reference

Oral feed	Method B7 with deviations: limited inquiries, absence of raw data	Cypermethrin 50:50 (WL43467)	5 weeks	Rat Charles River m/f 6/ sex/ group	25, 100, 250, 750, 1500 ppm. 1.25, 5, 12.5, 37.5, 75 mg/kg bw/d. Daily	No test substance-related mortalities. **25, 100, 250 and 750 ppm**: No test substance-related changes **1500 ppm**: Clinical signs: piloerection, nervousness, uncoordinated movements from 2 weeks onwards in 4/6 ♂ and 1/6 ♀ Bw gain, food intake, terminal bw: reduced for m&f Organ weight: ↑ abs. and rel; liver weight in ♀ Clinical chemistry: ↑ hemoglobin and blood urea conc. in ♂; ↑ plasma alkaline phosphatase in ♀ **Neurotoxicity**	1500 ppm 75 mg/kg bw/d	750 ppm 37.5 mg/kg bw/d	[redacted]
Oral feed	Method B7 with deviations: limited inquiries, absence of raw data	Cypermethrin 50:50 (WL43467)	5 weeks	Dog Beagle m/f 3/sex/group	0, 15, 150, 1500 ppm. 0, 0.375, 3.75, 37.5 mg/kg bw/d. Daily	No test substance-related mortalities. **0, 15, 150 ppm**: No test substance-related changes **1500 ppm**: Clinical signs: apprehension, diarrhoea, vomiting, licking and chewing of the paws, whole body tremors and stiff exaggerated hind leg gait, ataxia. 2 animals convulsed during week 1 and 5. Bw gain, food intake, terminal bw: ↓ bw gain Organ weight: ↑ rel. thyroid weight in ♂&♀ Clinical chemistry: ↑ WBC and KCCT at week 5 in ♂; ↑ blood urea levels, ↓ blood glucose levels at week 5 in ♀ **Neurotoxicity**	1500 ppm 37.5 mg/kg bw/d	150 ppm 3.75 mg/kg bw/d	[redacted]

i.p.	No guideline	Cypermethrin 50 :50, purity 91%	7 days	Rat Wistar Males, n=7	0, 300 mg/kg bw/d vehicle: Pluronic F-68 daily	No test substance-related mortalities. Clinical signs: scratching, salivation, somnolence, ataxia, convulsion and hind limb paralysis noted at every time point. Bw: reduced at d7. Organ weight: ↑ rel liver weight (20%) Clinical chemistry: ↓serum albumin Histology liver at 72 h post-exposure: hepatocytes with ovoid nucleus; intra-cytoplasmatic droplets; mitochondria: normal to dilated, small mitochondria with electron dense inclusions. Proliferation and swelling of smooth endoplasmic reticulum more evident on d5 and subsequently. **Neurotoxicity and liver toxicity**	Not determined	Not determined	[redacted]
Oral	No guideline	Cypermethrin, unknown purity	3 weeks	Rat albino males	31.5 mg/kg bw/d vehicle: corn oil	Liver: cytoplasmatic hypertrophy with intracytoplasmatic droplets. Mitochondrial ATPase activity: inhibitory effect (70.8%) **Liver toxicity**	Not determined	Not determined	[redacted]
Oral	No guideline	Cypermethrin, 91%	5 days	Rat, Wistar males	75 mg/kg bw/d vehicle: corn oil	No mortalities and clinical signs. Hepatic and cerebral tissues: enhanced peroxidation, as indicated by increased TBARS levels	Not determined	Not determined	[redacted]
Dermal	Method B.9 with deviations: Performed on abraded skin, under occluded patch, Limited clinical description, bilirubine and creatinine not measured, coagulation parameters not examined	Cypermethrin 53:47, 91.5%	3 weeks (15 days)	Rabbit, New Zealand White m/f 10/sex/group	0, 2, 20, 200 mg/kg bw/d vehicle: PEG300 (6 hours/day)	**2 and 20 mg/kg bw/d:** Local effects: slight to mild erythema, dose dependent, slight to moderate oedema, dose dependent **200 mg/kg bw/d:** ↓ food intake, bw gain, weight of gonads Local effects: erythema and oedema Slight to severe erythema, Slight to severe oedema Focal liver necrosis	200 mg/kg bw/d	20 mg/kg bw/d	[redacted] in 91/414 DAR for cypermethrin made by the BE CA

Table 4.5.2.: Subchronic toxicity of cypermethrin

Route	Method Guideline	TS	Dura-tion of study	Species Strain Sex No/group	Dose levels frequency of application	Results	LO(A)EL	NO(A)EL	Reference
Oral feed	Deviating OECD 408: Histopathology not performed on all organs. Target organs were not examined at all doses.	Cypermethrin, WL43467, 98.5%	90 days	Rat, CD m/f 12/sex/group	0, 25, 100, 400, 1600 ppm. 0, 1.25, 5, 20, 80 mg/kg bw/d. Daily	No mortality occurred in the study at any dose level **25, 100, 400 ppm:** General health and behaviour unaffected. **400 ppm:** ↑ kidney weight in ♂ (5%) **1600 ppm:** Clinical signs: Ataxia, hypersensitivity and abnormal gait during the first 5 weeks. Mortality: 1 ♂ died, 3 were killed. 2 of these rats showed axon breaks and vacuolation of myelin in the sciatic nerve. **Neurotoxicity** Males and females: ↓ BW (♂ 17%, ♀ 10%), ↓ food intake (♂, ♀), ↓ Hb (♂ 4%, ♀ 6%), ↑ urea (♂ 20%, ♀ 39%), ↑ kidney weight (♂ 7%, ♀ 14%), Males: ↓KCCT (11%), ↑ K^+ (13%) Females: ↓ RBC (6%), ↑ AP (40%), ↑ liver weight (10%), ↑ spleen weight (17%)	80 mg/kg bw/d	20 mg/kg bw/d	[redacted]
Oral feed	Deviating OECD 408: Means: standard deviation not calculated.	Cypermethrin, WL43467, 98.5%	90 days	Dog, Beagle m/f 4/sex/group	0, 5, 50, 500, 1500 ppm. 0, 0.125, 1.25, 12.5, 37.5 mg/kg bw/d vehicle: acetone Daily	**0, 5, 50, 500 ppm** No overt signs of intoxication and no other test compound related effects were found. **1500 ppm** Clinical signs: diarrhea, licking and chewing of the paws, whole body tremors, a stiff exaggerated hind leg gait, ataxia, incoordination and hyperaesthesia. These signs were observed along with ↓ food intake and ↓bw in both males and females (17-18%). Mortality: 2 ♂ and 2 ♀ were sacrificed during week 6 and 10, 10 and 12, respectively, for humane reasons. Haematology: ♀ ↓ RBC (6%), ↓ KCCT (kaolin-cephalin clotting time) (21%). Pathology: focal bronchopneumonia in several animals. **Neurotoxicity**	37.5 mg/kg bw/d	12.5 mg/kg bw/d	[redacted]

Route	Method Guideline	TS	Dura-tion of study	Species Strain Sex No/group	Dose levels frequency of application	Results	LO(A)EL	NO(A)EL	Reference
Oral	No guideline	Cypermethrin, technical grade	90 days	Rat, albino male	0, 5, 10, 20, 40 mg/kg bw/d. vehicle: ground nut oil daily	Dose-dependent decrease in delayed type hypersensitivity reaction on d61 post-treatment; **20 mg/kg bw/d** ↓spleen weight, ↑ adrenal weight **40 mg/kg bw/d** ↓spleen weight, ↑ adrenal weight, leucopenia on d90 **Immunotoxicity**	20 mg/kg bw/d	10 mg/kg bw/d	[redacted]
Oral	No guideline	Cypermethrin 25% EC	12 weeks	Rabbit New Zealand White Male, n=6	0, 24 mg/kg bw every other day	↓ bw gain ↑ rel. liver, spleen, kidney weight ↑ plasma glucose, urea, creatinine, total bilirubine. ↓ plasma total protein, albumin. ↑ plasma total lipid, cholesterol, TG, LDL, VLDL. ↓ HDL. ↓ Hb, RBC, PCV,↑ total leucocyte count.	24 mg/kg bw every other day	< 24 mg/kg bw every other day	[redacted]

Table 4.5.3.: Chronic toxicity of cypermethrin

Route	Method Guideline	TS	Dura-tion of study	Species Strain Sex no/group	Dose levels frequency of application	Results	LO(A)EL	NO(A)EL	Reference
Oral feed	Deviating OECD 453 Deviations: low number of rats; blood albumin, glucose, glucose, GGT, ornithine decarboxylase not measured; urinalysis not performed.	Cypeermethrin 50:50, WL43467, 98%	24 months	Rat: Wistar m/f 24/sex/group	0, 1, 10, 100, 1000 ppm. 0, 0.05, 0.5, 5, 50 mg/kg bw/d Daily	No test substance related mortalities or signs of clinical toxicity in any of the treatment groups Histopathology sciatic nerves: at 1 year and later sciatic nerves showed very small numbers of nerve fibers exhibiting the changes of Wallerian degeneration. Lesions consisted of swelling and fragmentation of axons and myelin. There was no difference in severity between dose groups. **1000 ppm:** Food consumption: ↓ (♂ 7%, ♀ 10%) Body weight: ↓ (♂ 7%, ♀ 7%) Hematology: platelets ↑ (♀ 4%) Clinical chemistry:liver PNOD ↑ (♂,♀), urea ↑ (♂ 58%), AP ↓ (♂ 33%) Other (minor) changes in hematological and clinical chemical parameterswere not considered of toxicological significance as not supported by histopathological or other evidence of tissue damage. Organ weights: Testes, rel.: ↓ (♂, 6 months) Liver, abs, rel: ↑ (♂, 18 mth) Heart, rel: ↑ (♂, 6 mth) Heart, abs: ↓ (♂, 12 mth) Kidney, rel: ↑ (♂, 12 mth; ♀, 6 mth) Kidney, abs:↑ (♂, 18 mth)	1000 ppm 50 mg/kg bw/d	100 ppm 5 mg/kg bw/d	[redacted]

Conclusion on repeated dose toxicity: (from Doc. III-A 6.3, 6.4 and 6.5)

The **short-term dermal toxicity** of cypermethrin was studied in a 21-day dermal toxicity study in rabbits. This resulted in irritation of the skin and was associated to systemic effects such as focal liver necrosis. NOAEL = 20 mg/kg bw/d.

The **short/medium-term oral toxicity** of cypermethrin was studied in rats and dogs. The central nervous system and the liver were detected as the target tissue/organ. Neurotoxicity was characterised by clinical signs including piloerection, nervousness and uncoordinated movements, ataxia, splayed gait and hyperesthesia. In the dog, clinical signs of neurotoxicity were observed at 37.5 mg/kg bw/d in a 90-day study (NOAEL = 12.5 mg/kg bw/d). In the rat, clinical signs of neurotoxicity were observed at 80 mg/kg bw/d in a 90-day study (NOAEL = 20 mg/kg bw/d). In rats, neurotoxicity was confirmed by histopathology by peripheral nerve damage (not in dogs). In addition, body weight was reduced, liver weight increased, and rats presented signs of anemia. In the open literature liver toxicity was characterised by inhibition of the rat liver ATPase activity. The oxidative stress induced by cypermethrin in the cerebral and hepatic tissues was evidenced by enhanced lipid peroxidation. Additionally, a decrease in delayed type hypersensitivity, leucopenia and immunotoxicity were observed when rats were dosed cypermethrin orally for 90 days at doses of 40 mg/kg bw/d (NOAEL = 10 mg/kg bw/d.

The **long-term oral toxicity** of cypermethrin was studied in rats. The effects were in line with those observed in the medium-term studies. The central nervous system, liver, and kidneys were detected as the target tissues/organs. Hepatotoxicity was characterised by increased liver weight associated with microsomal enzyme activity induction, but not associated with histological lesions. Increased kidney weight was associated with an increase in blood urea.

Classification/labelling of the active substance 'cypermethrin' for repeated-dose toxicity according to the criteria in Directive 67/548/EEC and agreed at the 29th ATP: **None**

Classification/labelling of the active substance 'cypermethrin' for repeated-dose toxicity as listed in Annex VI, Table 3.1 to CLP-Regulation (EC) No 1272/2008: **None.**

No new scientific information/data is available that may affect the classification of the active substance. Nevertheless, in CLP-Regulation (EC) No 1272/2008 the guidance values are modified for 'specific target organ toxicity following repeated exposure'. Because of the change in guidance values, the clinical effects of neurotoxicity observed in both animals and humans, and the liver toxicity observed in animals, **Classification/labelling of the active substance 'cypermethrin'** for repeated-dose toxicity according to the criteria (modified guidance values) in CLP-Regulation (EC) No 1272/2008: **STOT RE2; H373. May cause damage to organs through prolonged or repeated exposure.**

As the biocidal product Cypermethrin 100 g/L EW contains ≥ 10% cypermethrin cis:trans/40:60, the biocidal product should be classified according to the criteria in CLP-Regulation (EC) No 1272/2008: **STOT RE2; H373. May cause damage to organs through prolonged or repeated exposure.**

4.6 OTHER: RELEVANT NON-ACTIVE SUBSTANCES

As far as known, there are no further inherent properties of non-active substances the classification of which has to be adopted to the biocidal product according to Directive 1999/45/EEC and CLP Regulation EC No 1272/2008.

Cypermethrin 100 g/L EW does not contain any components defined as substances of concern according to the classification in accordance with Directive 67/548/EEC at or above the concentration limits specified in Directive 1999/45/EEC and CLP Regulation EC No 1272/2008.

5 ENVIRONMENTAL EFFECTS ASSESSMENT OF THE PRODUCT

Currently the formulation is classified as R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. This is taken from the supplier's safety data sheet. From studies carried out so far, this looks acceptable.

5.1 AQUATIC COMPARTMENT

No studies for acute toxicity of Cypermethrin 100g/L EW in fish, Daphnia magna or algae have been carried out. However, using the results from the studies on the active, the product would be classified as very toxic to both fish and Daphnia magna and toxic to algae. This is based on calculation using the concentration of the active in the product and the concentration of this product required to give the LC(E)50 'active concentration' figures seen in the studies. It also assumes –reasonably- that the other components in the formulation are relatively harmless to aquatic organisms at an identical concentration.

Example of calculation: Concentration of cypermethrin in formulation = 10%

LC50 fish = 2.83µg/L =2.83E-03mg/L

Amount of formulation to give this amount is 10 x 2.83E-03 = 0.0283mg.

According to the classification and labeling legislation, ≤ 1mg/L is assigned as very toxic.

5.2 ATMOSPHERE

No information for this endpoint is available for cypermethrin 100g/L EW, but is not expected to differ from the active.

5.3 TERRESTRIAL COMPARTMENT

No information for this endpoint is available for Cypermethrin 100g/L EW. However an earthworm study on the 10% EC formulation showed an LC50 of 575mg/kg substrate but given this is a different formulation it is not considered for this endpoint, given the presence of data for the active itself.

5.4 NON COMPARTMENT SPECIFIC EFFECTS RELEVANT TO THE FOOD CHAIN (SECONDARY POISONING).

No information for this endpoint is available for Cypermethrin 100g/L EW, but is not expected to differ from the active.

6 HAZARD IDENTIFICATION FOR PHYSICO-CHEMICAL PROPERTIES

	Physical and Chemical Properties of Biocidal Product						
	Method	**Purity/ Specification**	**Results**	**Remarks/ Justification**	**GLP (Y/N)**	**Reliability**	**Reference**
3.1 Appearance (IIB3.1/Pt. I-B3.1)	Visual method	99.29 ± 0.57 g/l as EW		Acceptable	Yes	1	B. de Ryckel, 2005
3.1.1 Physical state and nature			Homogenous liquid				
3.1.2 Colour			Opaque white				
3.1.3 Odour			Faint, chemical odour				
3.2 Explosive properties (IIB3.2/Pt. I-B3.2)	EEC A14	99.29 ± 0,57 g/l as EW	Not explosive	Acceptable	Yes	1	B. de Ryckel, 2005
3.3 Oxidising properties (IIB3.3/Pt. I-B3.3)			Not oxidising based on data on the a.s. and co-formulants: Cypermethrin (a.s.)	Not oxidising according to EPA OPPTS 830-6314. No adverse reaction			DocIV_A3.11 (Bates, 2002b)

	Physical and Chemical Properties of Biocidal Product						
	Method	**Purity/ Specification**	**Results**	**Remarks/ Justification**	**GLP (Y/N)**	**Reliability**	**Reference**
				observed.			
			Confidential	Not classified as oxidising			MSDS (section 15),
			Confidential	Not classified as oxidising			MSDS (section 15),
			Confidential	Not classified as oxidising			MSDS (section 15),
			Confidential	Not classified as oxidising			MSDS (section 15),
			Confidential	Not classified as oxidising			MSDS (section 15),
			Confidential	Not classified as oxidising			MSDS (section 15),
			Confidential	Not classified as oxidising			MSDS (section 15),
3.4 Flash-point and other indications of flammability or spontaneous ignition (IIB3.4/Pt. I-B3.4)							

	Physical and Chemical Properties of Biocidal Product						
	Method	**Purity/ Specification**	**Results**	**Remarks/ Justification**	**GLP (Y/N)**	**Reliability**	**Reference**
Flash point	CIPAC MT12.2 (equivalent to EEC A96)	99.29 ± 0,57 g/l as EW	> 79°C	Acceptable	Yes	1	B. de Ryckel, 2005
Autoflammability	EEC Method A.15	99.29 ± 0,57 g/l as EW	Auto-ignition temperature: 385°C	Acceptable	Yes	1	B. de Ryckel, 2005
Other indications of flammability			Not highly flammable based on data on the a.s. and co-formulants	Not applicable. The active ingredient cypermethrin is not considered flammable and product does not contain any flammable co-formulants (see suppliers MSDS)			
3.5 Acidity/Alkalinity (IIB3.5/Pt. I-B3.5)	CIPAC MT 31.2.3	99.29 ± 0,57 g/l as EW	0.034% w/w as H_2SO4, pH pure formulation: 4.26	Acceptable	Yes	1	B. de Ryckel, 2005
	CIPAC MT 75.3	99.29 ± 0,57 g/l as EW	4.84 (1%)	Acceptable	Yes	1	

	Physical and Chemical Properties of Biocidal Product						
	Method	**Purity/ Specification**	**Results**	**Remarks/ Justification**	**GLP (Y/N)**	**Reliability**	**Reference**
	(1% aq solution)						
3.6 Relative density/bulk density (IIB3.6/Pt. I-B3.6)	CIPAC MT 3.3.2 calculation (equivalent EC method A3 under Directive 92/69/EC) Methods MT33, MT159 and MT169 are tap and bulk density for solids only and therefore not applicable	99.29 ± 0,57 g/l as EW	0.9785 g/ml	Acceptable	Yes	1	B. de Ryckel, 2005
3.7 Storage stability – stability and shelf life (IIB3.7/Pt. I-B3.7)							
	CIPAC MT 46.3 (after 14 days at 54 °C)	99.29 ± 0,57 g/l as EW	Stable (no change of content). No modification of appearance. Acidity: 0.062 % w/w. pH: 4.11 (pure), 4.77 (1%) Emulsion stability: 97-104%	Acceptable	Yes	1	B. de Ryckel, 2005

	Physical and Chemical Properties of Biocidal Product						
	Method	**Purity/ Specification**	**Results**	**Remarks/ Justification**	**GLP (Y/N)**	**Reliability**	**Reference**
	CIPAC MT39.3 Low temperature stability (7 days at 0°C)	99.29 ± 0,57 g/l as EW	No modification of appearance. Acidity: 0.033 % w/w. pH: 4.22 (pure), 4.78 (1%) Emulsion stability: 93-102%	Acceptable	Yes	1	B. de Ryckel, 2005
Effect of Light			Not sensitive to light	Not applicable, product is not sensitive to light and does not contain any co-formulants known to be photosensitive (see suppliers MSDS)			
Reactivity towards container material			Stable in commercial packaging (HDPE)	2 year storage stability showed no change in appearance and stability in the finished pack.			

	Physical and Chemical Properties of Biocidal Product						
	Method	**Purity/ Specification**	**Results**	**Remarks/ Justification**	**GLP (Y/N)**	**Reliability**	**Reference**
3.8 Technical characteristics (IIB3.8/Pt. I-B3.8)							
Emulsifiability	CIPAC MT173 (a.s. content determination). Method MT173 is considered acceptable in the past for dilute emulsions (0.1-2.0%). As the lower level is below 0.1% the cypermethrin level was determined in emulsions. The easiest way to do this is by MT173.	99.29 ± 0,57 g/l as EW	0.015% or 1.0% v/v at 30°C in CIPAC water A and D : 98 to 101% after 30 minutes up to 4 hours	Acceptable.	Yes	1	B. de Ryckel, 2005
Persistence of foaming	CIPAC MT47.2	99.29 ± 0,57 g/l as EW	Ring (<0.5 ml) after 10 seconds.	Acceptable	Y	1	B. de Ryckel, 2005
3.9 Compatibility with other products (IIB3.9/Pt. I-B3.9)				Not applicable, Cypermethrin 100 g/L EW is not designed to be used with			

	Physical and Chemical Properties of Biocidal Product						
	Method	**Purity/ Specification**	**Results**	**Remarks/ Justification**	**GLP (Y/N)**	**Reliability**	**Reference**
				other products			
3.10 Surface tension (Pt. I-B3.10)	Mettens (EEC A5)	99.29 ± 0,57 g/l as EW	At 25°C ± 1°C : 25.6 mN/m At 40°C ± 1°C : 24.2 mN/m	The test item is surface active	Yes	1	B. de Ryckel, 2005
3.11 Viscosity (Pt. I-B3.10)	METVISCO (Based on OECD n°114)	99.29 ± 0,57 g/l as EW	At 20°C ± 0.5°C : 64 to 15 mPa.s At 40°C ± 0.5°C : 64 to 10 mPa.s	No Newtonian flow behaviour	Yes	1	B. de Ryckel, 2005
3.12 Particle size distribution (Pt. I-B3.11)	*Only for powders and granules*			Not applicable			

7 REFERENCES

[redacted]. Assessment of acute oral toxicity with cypermethrin 100 g/L EW in the rat (acute toxic class method). [redacted]. Chimac-Agriphar SA, document no. KIII A, 7.1.1/01. GLP, unpublished.

[redacted] Primary skin irritation/corrosion study with Cypermethrin 100 g/L EW in the rabbit (4-hour semi-occlusive application). [redacted]. Chimac-Agriphar SA, document no. KIII A, 7.1.4/01. GLP, unpublished.

[redacted]. Acute eye irritation/corrosion study with Cypermethrin 100 g/L EW in the rabbit. [redacted]. Chimac-Agriphar SA, document no. KIII A, 7.1.5/01. GLP, unpublished.

[redacted] Assessment of contact hypersensitivity to Cypermethrin 100 g/L EW in the mouse (Local lymph node assay). [redacted]. Chimac-Agriphar SA, document no. KIII A, 7.1.6/01. GLP, unpublished.

De Ryckel, B., 2005a. Physical and chemical properties and storage stability tests for Cypermethrin 100 EW. Agricultural Research Centre (CRA-W), Gembloux, Belgium, report ref. Chimac-Agriphar/FO20896/Ch.3174/2004/178. Chimac-Agriphar company ref. KIII A, 2.1/01. GLP, unpublished

De Ryckel, B., 2005b Validation of an analytical HPLC method for the determination of active substance content in a formulation emulsion, oil in water (EW) containing cypermethrin. Agricultural Research Centre (CRA-W), Gembloux, Belgium, report ref. Chimac-Agriphar/FO20891/Ch.3174 /2004/177. Chimac-Agriphar SA document no. KIIIA, 5.1.1/01. GLP, unpublished

Griffiths, 2005. Cypermethrin 250 g/L EC: acute inhalation toxicity (nose only) study in the rat. Safepharm Laboratories Ltd, report no. 722/031, 16/03/2005. Chimac-Agriphar SA, document no. KIII A, 7.1.3/01.GLP, unpublished.

Hardwick, 2006. [^{14}C]-Cypermethrin *cis:trans* 40:60 – Rates of penetration through human skin using a static cell *in vitro* system. Covance Laboratories Lt., Study no. 1669/028. GLP, unpublished.

[redacted]. Cyperkill 25 EC: Acute dermal toxicity (limit test) in the rat. [redacted]. Chimac-Agriphar SA, document no. KIII A, 7.1.2/01. GLP, unpublished.

ANNEX I: Human Exposure Calculation

Professional Spray Application: Tier 1 – No PPE	
Active substance	Cypermethrin
Exposure Descriptor	
Concentration a.s. in applied product (% w/w)	0.1%
Number of exposure events per year (days)	240
Hand Exposure	
Indicative value [mg of in-use product/minute]	181.00
Task duration [minutes]	120
Amount of in-use product on hands [mg]	21720.0000
Rest Of Body Exposure	
Indicative value [mg in-use product/minute]	92.00
Task duration [minutes]	120
Potential dermal deposit on body [mg in-use product]	11040.0000
Clothing penetration [%]	100.00
Actual dermal deposit on body [mg in-use product]	11040.0000
Total product on feet, hands and rest of body [mg]	32760.0000
Total amount of active substance on feet, hands and rest of body [mg a.s.]	32.7600
Skin penetration [%]	13.00
Total systemic dermal exposure [mg a.s.]	**4.2588**
Acute systemic dermal route dose [mg a.s./kg/d]	**0.07098**
Chronic (annual TWA) dermal route dose [mg a.s./kg/d]	**0.04667**
Inhalation Exposure	
Indicative value [mg of in-use product/m^3]	130.00
Task duration [minutes]	120
Volume of air inhaled over task duration [m^3]	2.5000
Inhalation rate of person [m^3/h]	1.25
Potential inhalation exposure over task duration [mg in-use product]	325.00
Systemic inhalation exposure (100 % absorption- no RPE) [mg a.s.]	**0.3250**
Acute systemic inhalation route dose [mg a.s./kg/d]	**0.0054**
Chronic (annual TWA) inhalation route dose [mg a.s./kg/d]	**0.0036**
Systemic exposure, skin and inhalation (no RPE) [mg a.s./d]	4.5838
Body weight of operator [kg]	60.00
Acute total systemic dose [mg a.s./kg/d]	**0.0764**
Chronic (annual TWA) systemic dose, [mg a.s./kg/d]	**0.0502**

Professional Spray Application: Tier 2a – Gloves (only) PPE.	
Active substance	Cypermethrin
Exposure Descriptor	
Concentration a.s. in applied product (% w/w)	0.1%
Number of exposure events per year (days)	240
Hand Exposure (in glove)	
Indicative value [mg of in-use product/minute]	10.7
Task duration [minutes]	120
Amount of in-use product on hands [mg]	1284.00
Rest Of Body Exposure	
Indicative value [mg in-use product/minute]	92.00
Task duration [minutes]	120
Potential dermal deposit on body [mg in-use product]	11040.0000
Clothing penetration [%]	100.00
Actual dermal deposit on body [mg in-use product]	11040.0000
Total product on feet, hands and rest of body [mg]	12324.0000
Total amount of active substance on feet, hands and rest of body [mg a.s.]	12.3240
Skin penetration [%]	13.00
Total systemic dermal exposure [mg a.s.]	**1.6021**
Acute systemic dermal route dose [mg a.s./kg/d]	**0.02670**
Chronic (annual TWA) dermal route dose [mg a.s./kg/d]	**0.0176**
Inhalation Exposure	
Indicative value [mg of in-use product/m^3]	130.00
Task duration [minutes]	120
Volume of air inhaled over task duration [m^3]	2.5000
Inhalation rate of person [m^3/h]	1.25
Potential inhalation exposure over task duration [mg in-use product]	325.00
Systemic inhalation exposure (100 % absorption- no RPE) [mg a.s.]	**0.3250**
Acute systemic inhalation route dose [mg a.s./kg/d]	**0.0054**
Chronic (annual TWA) inhalation route dose [mg a.s./kg/d]	**0.0036**
Systemic exposure, skin and inhalation (no RPE) [mg a.s./d]	1.9271
Body weight of operator [kg]	60.00
Acute total systemic dose [mg a.s./kg/d]	**0.0321**
Chronic (annual TWA) total systemic dose [mg a.s./kg/d]	**0.0211**

1. Secondary exposure – ConsExpo 4.1 report.

ConsExpo 4.1 report - C&C - Infant

Post application exposure following to a **Crack and crevice** spray application of pest control products
Exposed population : Infant

Product

Cypermethrin 100g/L EW

Compound

Compound name :	Cypermethrin	
CAS number :	52315-07-8	
molecular weight	416	g/mol
vapour pressure	6E-7	Pascal
KOW	5,45	linear

General Exposure Data

exposure frequency	126	1/year
body weight	8	kilogram

Dermal model: Direct dermal contact with product : rubbing off

weight fraction compound	1	fraction
exposed area	197	cm2
transfer coefficient	0,6	m2/hr
rubbed surface	2E4	cm2
contact time	3,6E3	second
dislodgeable amount	0,00225	g/m2

Uptake model: fraction

uptake fraction	0,13	fraction

Oral model: Oral exposure to product : direct intake

weight fraction compound	1	fraction
amount ingested	0,135	milligram

Uptake model: Fraction

uptake fraction	0,57	fraction

Output

Dermal : point estimates

dermal load :	0,00687	mg/cm2
dermal external dose :	0,169	mg/kg
dermal acute (internal) dose :	0,022	mg/kg
dermal chronic (internal) dose :	0,00758	mg/kg/day

Oral : point estimates

oral external dose :	0,0169	mg/kg
oral acute (internal) dose :	0,00963	mg/kg
oral chronic (internal) dose :	0,00332	mg/kg/day

Integrated (point estimates)

total external dose:	0,186	mg/kg
total acute dose (internal):	0,0316	mg/kg
total chronic dose (internal):	0,0109	mg/kg/day

ConsExpo 4.1 report - C&C - Toddler

Post application exposure following to a **Crack and crevice** spray application of pest control products
Exposed population : toddler

Product

Cypermethrin 100g/L EW

Compound

Compound name :	Cypermethrin	
CAS number :	52315-07-8	
molecular weight	416	g/mol
vapour pressure	6E-7	Pascal
KOW	5,45	linear

General Exposure Data

exposure frequency	126	1/year
body weight	10	kilogram

Dermal model: Direct dermal contact with product : rubbing off

weight fraction compound	1	fraction
exposed area	230	cm2
transfer coefficient	0,6	m2/hr
rubbed surface	2E4	cm2
contact time	3,6E3	second
dislodgeable amount	0,00225	g/m2

Uptake model: fraction

uptake fraction	0,13	fraction

Oral model: Oral exposure to product : direct intake

weight fraction compound	1	fraction
amount ingested	0,135	milligram

Uptake model: Fraction

uptake fraction	0,57	fraction

Output

Dermal : point estimates

dermal load :	0,00588	mg/cm2
dermal external dose :	0,135	mg/kg
dermal acute (internal) dose :	0,0176	mg/kg
dermal chronic (internal) dose :	0,00607	mg/kg/day

Oral : point estimates

oral external dose :	0,0135	mg/kg
oral acute (internal) dose :	0,0077	mg/kg
oral chronic (internal) dose :	0,00265	mg/kg/day

Integrated (point estimates)

total external dose:	0,149	mg/kg
total acute dose (internal):	0,0253	mg/kg
total chronic dose (internal):	0,00872	mg/kg/day

ConsExpo 4.1 report - C&C - Child

Post application exposure following to a **Crack and crevice** spray application of pest control products
Exposed population : child

Product

Cypermethrin 100g/L EW

Compound

Compound name :	Cypermethrin	
CAS number :	52315-07-8	
molecular weight	416	g/mol
vapour pressure	6E-7	Pascal
KOW	5,45	linear

General Exposure Data

exposure frequency	126	1/year
body weight	23.9	kilogram

Dermal model: Direct dermal contact with product : rubbing off

weight fraction compound	1	fraction
exposed area	428	cm2
transfer coefficient	0,6	m2/hr
rubbed surface	2E4	cm2
contact time	3,6E3	second
dislodgeable amount	0,00225	g/m2

Uptake model: fraction

uptake fraction	0,13	fraction

Output

Dermal : point estimates

dermal load :	0,00316	mg/cm2
dermal external dose :	0,0566	mg/kg
dermal acute (internal) dose :	0,00736	mg/kg
dermal chronic (internal) dose :	0,00254	mg/kg/day

Integrated (point estimates)

total external dose:	0,0566	mg/kg
total acute dose (internal):	0,0736	mg/kg
total chronic dose (internal):	0,00254	mg/kg/day

ConsExpo 4.1 report - GS - Infant

Post application exposure following to a **general surface** spray application of pest control products
Exposed population : Infant

Product

Cypermethrin 100g/L EW

Compound

Compound name :	Cypermethrin	
CAS number :	52315-07-8	
molecular weight	416	g/mol
vapour pressure	6E-7	Pascal
KOW	5,45	linear

General Exposure Data

exposure frequency	126	1/year
body weight	8	kilogram

Dermal model: Direct dermal contact with product : rubbing off

weight fraction compound	1	fraction
exposed area	197	cm2
transfer coefficient	0,6	m2/hr
rubbed surface	2,2E5	cm2
contact time	3,6E3	second
dislodgeable amount	15	mg/m2

Uptake model: fraction

uptake fraction	0,13	fraction

Oral model: Oral exposure to product : direct intake

weight fraction compound	1	fraction
amount ingested	0,9	milligram

Uptake model: Fraction

uptake fraction	0,57	fraction

Output

Dermal : point estimates

dermal load :	0,0457	mg/cm2
dermal external dose :	1,13	mg/kg
dermal acute (internal) dose :	0,146	mg/kg
dermal chronic (internal) dose :	0,0505	mg/kg/day

Oral : point estimates

oral external dose :	0,112	mg/kg
oral acute (internal) dose :	0,0641	mg/kg
oral chronic (internal) dose :	0,0221	mg/kg/day

Integrated (point estimates)

total external dose:	1,24	mg/kg
total acute dose (internal):	0,21	mg/kg
total chronic dose (internal):	0,0726	mg/kg/day

ConsExpo 4.1 report - GS - Toddler

Post application exposure following to a **general surface** spray application of pest control products
Exposed population : toddler

Product

Cypermethrin 100g/L EW

Compound

Compound name :	Cypermethrin	
CAS number :	52315-07-8	
molecular weight	416	g/mol
vapour pressure	6E-7	Pascal
KOW	5,45	linear

General Exposure Data

exposure frequency	126	1/year
body weight	10	kilogram

Dermal model: Direct dermal contact with product : rubbing off

weight fraction compound	1	fraction
exposed area	230	cm2
transfer coefficient	0,6	m2/hr
rubbed surface	2,2E5	cm2
contact time	3,6E3	second
dislodgeable amount	15	mg/m2

Uptake model: fraction

uptake fraction	0,13	fraction

Oral model: Oral exposure to product : direct intake

weight fraction compound	1	fraction
amount ingested	0,9	milligram

Uptake model: Fraction

uptake fraction	0,57	fraction

Output

Dermal : point estimates

dermal load :	0,0391	mg/cm2
dermal external dose :	0,9	mg/kg
dermal acute (internal) dose :	0,117	mg/kg
dermal chronic (internal) dose :	0,0404	mg/kg/day

Oral : point estimates

oral external dose :	0,09	mg/kg
oral acute (internal) dose :	0,0513	mg/kg
oral chronic (internal) dose :	0,0177	mg/kg/day

Integrated (point estimates)

total external dose:	0,99	mg/kg
total acute dose (internal):	0,168	mg/kg
total chronic dose (internal):	0,0581	mg/kg/day

ConsExpo 4.1 report - GS - Child

Post application exposure following to a **general surface** spray application of pest control products
Exposed population : child

Product

Cypermethrin 100g/L EW

Compound

Compound name :	Cypermethrin	
CAS number :	52315-07-8	
molecular weight	416	g/mol
vapour pressure	6E-7	Pascal
KOW	5,45	linear

General Exposure Data

exposure frequency	126	1/year
body weight	23.9	kilogram

Dermal model: Direct dermal contact with product : rubbing off

weight fraction compound	1	fraction
exposed area	428	cm2
transfer coefficient	0,6	m2/hr
rubbed surface	2,2E5	cm2
contact time	3,6E3	second
dislodgeable amount	15	mg/m2

Uptake model: fraction

uptake fraction	0,13	fraction

Output

Dermal : point estimates

dermal load :	0,021	mg/cm2
dermal external dose :	0,377	mg/kg
dermal acute (internal) dose :	0,049	mg/kg
dermal chronic (internal) dose :	0,0169	mg/kg/day

Integrated (point estimates)

total external dose:	0,377	mg/kg
total acute dose (internal):	0,049	mg/kg
total chronic dose (internal):	0,0169	mg/kg/day