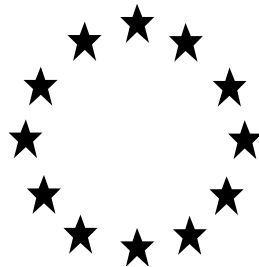


Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

**PRODUCT ASSESSMENT REPORT OF A
BIOCIDAL PRODUCT FOR NATIONAL
AUTHORISATION APPLICATIONS**

(submitted by the evaluating Competent Authority)



FREE LAND DUST

Product type PT 18

Cypermethrin as included in the Union
list of approved active substances

Case Number in R4BP: BC-HR058906-11

Evaluating Competent Authority: Greece

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Table of Contents

1	CONCLUSION	4
2	ASSESSMENT REPORT	5
2.1	SUMMARY OF THE PRODUCT ASSESSMENT	5
2.1.1	Administrative information	5
2.1.1.1	Identifier of the product	5
2.1.1.2	Authorisation holder	5
2.1.1.3	Manufacturer(s) of the product	5
2.1.1.4	Manufacturer(s) of the active substance	5
2.1.2	Product composition and formulation	6
2.1.2.1	Identity of the active substance	6
2.1.2.2	Candidate(s) for substitution	6
2.1.2.3	Qualitative and quantitative information on the composition of the biocidal product	7
2.1.2.4	Information on technical equivalence	7
2.1.2.5	Information on the substance of concern	7
2.1.2.6	Type of formulation	7
2.1.3	Hazard and precautionary statements	8
2.1.4	Authorised use(s)	9
2.1.4.1	Use description # 1	9
2.1.4.2	Use-specific instructions for use	9
2.1.4.3	Use-specific risk mitigation measures	10
2.1.4.4	Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment	10
2.1.4.5	Where specific to the use, the instructions for safe disposal of the product and its packaging	10
2.1.4.6	Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage	10
2.1.4.7	Use description # 2	10
2.1.4.8	Use-specific instructions for use	11
2.1.4.9	Use-specific risk mitigation measures	11
2.1.4.10	Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment	11
2.1.4.11	Where specific to the use, the instructions for safe disposal of the product and its packaging	11
2.1.4.12	Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage	12
2.1.4.13	Use description # 3	12
2.1.4.14	Use-specific instructions for use	13
2.1.4.15	Use-specific risk mitigation measures	13
2.1.4.16	Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment	13
2.1.4.17	Where specific to the use, the instructions for safe disposal of the product and its packaging	13
2.1.4.18	Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage	13
2.1.4.19	Use description # 4	13
2.1.4.20	Use-specific instructions for use	14
2.1.4.21	Use-specific risk mitigation measures	14
2.1.4.22	Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment	15
2.1.4.23	Where specific to the use, the instructions for safe disposal of the product and its packaging	15
2.1.4.24	Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage	15
2.1.4.25	Use description # 5	15
2.1.4.26	Use-specific instructions for use	15
2.1.4.27	Use-specific risk mitigation measures	16
2.1.4.28	Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment	16
2.1.4.29	Where specific to the use, the instructions for safe disposal of the product and its packaging	16
2.1.4.30	Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage	16
2.1.4.31	Use description # 6	16

2.1.4.32	Use-specific instructions for use.....	17
2.1.4.33	Use-specific risk mitigation measures	17
2.1.4.34	Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment	17
2.1.4.35	Where specific to the use, the instructions for safe disposal of the product and its packaging	17
2.1.4.36	Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage	18
2.1.5	General directions for use	18
2.1.5.1	Instructions for use	18
2.1.5.2	Risk mitigation measures	18
2.1.5.3	Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment.....	19
2.1.5.4	Instructions for safe disposal of the product and its packaging.....	19
2.1.5.5	Conditions of storage and shelf-life of the product under normal conditions of storage	19
2.1.6	Other information	19
2.1.7	Packaging of the biocidal product	20
2.1.8	Documentation	21
2.1.8.1	Data submitted in relation to product application	21
2.1.8.2	Access to documentation	21
2.2	ASSESSMENT OF THE BIOCIDAL PRODUCT	22
2.2.1	Intended uses as applied for by the applicant.....	22
2.2.2	Physical, chemical and technical properties.....	26
2.2.3	Physical hazards and respective characteristics.....	41
2.2.4	Methods for detection and identification	46
2.2.5	Efficacy against target organisms	51
2.2.5.1	Function and field of use	51
2.2.5.2	Organisms to be controlled and products, organisms or objects to be protected	51
2.2.5.3	Effects on target organisms, including unacceptable suffering	51
2.2.5.4	Mode of action, including time delay	51
2.2.5.5	Efficacy data.....	51
2.2.5.6	Occurrence of resistance and resistance management	56
2.2.5.7	Known limitations	57
2.2.5.8	Evaluation of the label claims	57
2.2.5.9	Relevant information if the product is intended to be authorised for use with other biocidal product(s)	62
2.2.6	Risk assessment for human health.....	63
2.2.6.1	Assessment of effects on Human Health	63
2.2.6.2	Exposure assessment.....	71
	List of scenarios	73
2.2.6.3	Risk characterisation for human health	89
2.2.7	Risk assessment for animal health	94
2.2.8	Risk assessment for the environment.....	95
2.2.8.1	Effects assessment on the environment.....	95
2.2.8.2	Exposure assessment.....	103
	PROFESSIONAL.....	105
	NON PROFESSIONAL.....	114
2.2.8.3	Risk characterisation.....	128
2.2.9	Measures to protect man, animals and the environment	139
2.2.10	Assessment of a combination of biocidal products	143
2.2.11	Comparative assessment	143
3	ANNEXES.....	144
3.1	LIST OF STUDIES FOR THE BIOCIDAL PRODUCT.....	144
3.2	OUTPUT TABLES FROM EXPOSURE ASSESSMENT TOOLS	147
3.3	NEW INFORMATION ON THE ACTIVE SUBSTANCE	168
3.4	RESIDUE BEHAVIOUR.....	168
3.5	SUMMARIES OF THE EFFICACY STUDIES (B.5.10.1-xx)	168
3.6	CONFIDENTIAL ANNEX	168
3.7	OTHER.....	168

1 CONCLUSION

Conclusion for Physico-chemistry:

Free Land Dust is a dustable powder insecticide (PT 18), containing nominal (pure) active ingredient of 0.25% w/w Cypermethrin.

Its physicochemical properties are considered acceptable for dustable powder product. The product is not expected to have explosive or oxidising properties, nor to be self-heating or flammable; thus has no classification according to CLP criteria.

Acceptable data from accelerated storage stability study and 2 years long term storage stability study at ambient temperature demonstrate that the product is stable for two years at ambient temperature when stored in its initial commercial packaging.

Acceptable analytical method was provided for the determination of the four isomers of the active substance in the formulation.

Conclusion for human health:

Regarding human health hazards the biocidal product FREE LAND DUST should not be classified.

Regarding risk assessment, the primary exposure of professional and non-professional users does not entail unacceptable risk for human health.

With respect to secondary exposure of the general public, a risk has been identified for infants entering into treated areas and touching with their hands the contaminated surfaces. A specific risk mitigation measure is proposed to be included in the product label, hence, no concern arises for this population group.

Conclusion for Environment

According to the environmental risk assessment, the risk for all relevant environmental compartments (STP, terrestrial, aquatic, primary and secondary poisoning) is acceptable when the product is used for all scenarios, according to label instruction.

Conclusion for Efficacy

Several efficacy studies (laboratory, simulated use and field studies) were submitted for FREE LAND DUST (Ready to Use product) containing cypermethrin 0.25%. Based on the results of the submitted efficacy studies, the product was effective when applied as:

- Crack and crevice application against crawling insects indoors at 8 gr/m², by professional and non-professionals. (Intended Uses 1 & 3)
- Direct application on wasp nests indoors at 10 gr/ nest, by professionals and non-professionals. (Intended Uses 2&4)
- Direct application on ant nests at 5 gr/ nest, by non-professionals. (Intended Use 5)
- Spot application outdoors around building in the vicinity of windows and doorsteps against *Blatta orientalis*, by non-professional users. (Intended Use 6)

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier	Country (if relevant)
FREE LAND DUST	Greece

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	Name	ACTIVA srl
	Address	Via Feltre, 32 – 20123, Milano, Italy
Authorisation number		
Date of the authorisation		
Expiry date of the authorisation		

2.1.1.3 Manufacturer(s) of the product

Name of manufacturer	ACTIVA srl
Address of manufacturer	Via Feltre, 32 -20132, Milano, Italy
Location of manufacturing sites	(1) c/o SINAPAK Viale Dell' Industria E Artigianato 7 - 27049 Stradella (PV) - Italy
	(2) c/o FERBI S.r.l Contrada Ripoli - 64023 Mosciano Sant'Angelo (TE) - Italy

2.1.1.4 Manufacturer(s) of the active substance

Active substance	Cypermethrin
Name of substance supplier according art. 95:	Limaru NV (acting for Tagros Chemicals India Private Limited)
Address of substance supplier according art. 95:	Paalsesteenweg 170 Bus 7, B-3583 BERINGEN, Belgium
Name of manufacturer	Tagros Chemicals India Private Ltd.
Address of manufacturer	Jhaver Centre, Rajah Annamalai Building, IV Floor, 72, Marshalls Road, 600 008 Egmore, Chennai, India
Location of manufacturing sites	A-4/1&2, Sipcot Industrial Complex, Pachayankuppam, Cuddalore, 607 005 Tamil Nadu India The address of the manufacturing plant for the active substance has been evaluated in the technical equivalence of Tagros Chemicals.

2.1.2 Product composition and formulation

NB: the full composition of the product according to Annex III Title 1 is provided in the confidential annex.

Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes

No

2.1.2.1 Identity of the active substance

Main constituent(s)	
Common name	Cypermethrin
Chemical name	cypermethrin cis:trans 40:60; (RS)- α -cyano-3 phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylate
C.A. name	Cyano(3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane carboxylate
IUPAC name	(RS)- α -cyano-3 phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylate(4 isomer pairs: cis-1, cis-2, trans-3, trans-4)
EC number	257-842-9
CAS number	52315-07-8
Index number in Annex VI of CLP	607-421-00-4
Minimum purity / content	Minimum purity according to Commission Implementing Regulation (EU) 2018/1130: 92% w/w Minimum purity from the technical of source used for the preparation of the product Free Land Dust: 95 % w/w (Tagros)
Structural formula	
Molecular weight	416.3 g/mol
Molecular formula	C ₂₂ H ₁₉ Cl ₂ NO ₃

2.1.2.2 Candidate(s) for substitution

Cypermethrin does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012.

Cypermethrin does not meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012, and is therefore not considered as a candidate for substitution. The exclusion and substitution criteria were assessed in line with the "Note on the principles for taking decisions on the approval of active substances under the BPR" and in line with "Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR" agreed at the 54th and 58th meeting respectively, of the representatives of Member States Competent Authorities for the implementation of Regulation 528/2012 concerning the making available on the market and use of biocidal products. This implies that the assessment of the exclusion

criteria is based on Article 5(1) and the assessment of substitution criteria is based on Article 10(1)(a, b, d, e and f).

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product

Common name	IUPAC name	Function	CAS number	EC number	Content
Cypermethrin (min. purity 95% w/w)	(RS)- α -cyano-3phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate	Active substance	52315-07-8	257-842-9	0.250 % w/w (pure) 0.263 % w/w (technical)
DPM – methoxymethylethoxy propanol	2-methoxymethylethoxy propanol	Solvent	34590-94-8	252-104-2	0.750 % w/w
Non-active substance	Confidential information. Please refer to the confidential information annex				Up to 100

The complete composition of the product is reported in the Confidential Annex.

2.1.2.4 Information on technical equivalence

The supplier of the active substance (i.e. cypermethrin) used in the formulation of the biocidal product FREE LAND DUST has been considered equivalent pursuant to Article 54 of Regulation (EU) no. 528/2012 to the reference source evaluated for approval

The active substance supplier LIMARU NV is the approved supplier of cypermethrin active substance in accordance with Article 95 of Regulation (EU) No. 528/2012. The respective Letter of Access/Supply has been submitted.

2.1.2.5 Information on the substance of concern

The biocidal product FREE LAND DUST contains (2-methoxymethylethoxy)propanol for which an Indicative Occupational Exposure Limit Value (IOELV) is available. Therefore, (2-methoxymethylethoxy) propanol should be considered as a Substance of Concern (SoC).

Please refer to the Confidential Annex for further details.

2.1.2.6 Type of formulation

DP Dustable powder

2.1.3 Hazard and precautionary statements

Classification and labelling of the product according to the Regulation (EC) 1272/2008

Classification	
Hazard category	Aquatic Acute 1 H400 Aquatic Chronic 1 H410
Hazard statement	H400 Very toxic to aquatic life H410 Very toxic to aquatic life with long lasting effects
Labelling	
GHS Pictogram	GHS09
Signal words	Warning
Hazard statements	H410 Very toxic to aquatic life with long lasting effects
Precautionary statements	P273 Avoid release to the environment. P391 Collect spillage. P501: Dispose of contents/container in accordance with local / regional / national / international regulations.
Note	This biocidal product contains Cypermethrin which is dangerous to bees.

2.1.4 Authorised use(s)

2.1.4.1 Use description # 1

Table 1. Use # 1 – **Crack and crevice application in voids and cavities, professional – Crawling insects**

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Dustable powder insecticide for use against crawling insects. For application in crack and crevices, voids and cavities.
Target organism (including development stage)	<p>Scientific name: <i>Blattella germanica</i> Common name: German cockroach Development stage: Adults</p> <p>Scientific name: <i>Blatta orientalis</i> Common name: Oriental cockroach Development stage: Adults</p> <p>Scientific name: <i>Lasius niger</i> Common name: Garden ant Development stage: Adults</p> <p>Scientific name: crawling insects Common name: Crawling insects Development stage: Adults</p>
Field of use	Indoor (domestic premises and large buildings) - in places where insects use to hide in.
Application method(s)	<p>Method: Manual application</p> <p>Detailed description: The product has to be applied only on restricted areas on surfaces not regularly cleaned, for example behind or under the fridge, under the kitchen sink, under the oven or the water heater, in all cracks and crevices that can be a harborage for cockroaches and ants.</p> <p>The application (dusting) has to be performed using the specific container equipped with the appropriate spreader (where available) or professional equipment for dusting application.</p>
Application rate(s) and frequency	<p>The application rate is 8 gr/m²</p> <p>Dilution (%): Ready to use</p> <p>Number and timing of application: Application can be performed up to 2 times per year</p>
Category(ies) of users	<p>Trained professional</p> <p>Professional</p>
Pack sizes and packaging material	1kg HDPE Bottle, 5 kg HDPE Bucket

2.1.4.2 Use-specific instructions for use

Application must be done at the recommended rate.
The persons responsible for cleaning the treated areas are to be informed by the

professional user about the risk mitigation measures to ensure that the product does not enter the sewer system.

2.1.4.3 Use-specific risk mitigation measures

The area where loading takes place must be covered with a disposable plastic sheet/foil in order to avoid contamination of adjacent surfaces and floor.

After treatment, dispose the plastic sheet/foil and the collected residues as hazardous waste.

The product has to be applied only on restricted areas on surfaces not regularly cleaned, for example behind or under the fridge, under the kitchen sink, under the oven or the water heater, in all cracks and crevices that can be a harborage for cockroaches and ants-

Do not apply to areas susceptible to routine wet cleaning.

No use of wet cleaning procedures. Use only dry-cleaning procedures (vacuum or broom) or use damp paper. After cleaning, dispose the collected in the dry cleaner materials or the damp papers used as solid wastes.

See also General directions for use.

2.1.4.4 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See General directions for use

2.1.4.5 Where specific to the use, the instructions for safe disposal of the product and its packaging

See General directions for use

2.1.4.6 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See General directions for use

2.1.4.7 Use description # 2

Table 2. Use # 2 – Wasp nest, professional

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Direct application on wasp nest for eradication
Target organism (including development stage)	Scientific name: <i>Vespula germanica</i> Common name: German wasp Development stage: Adults Common name: wasp nest Development stage: Adults

Field of use	Indoor Application on the nest
Application method(s)	Manual application. The application (dusting) has to be performed using an appropriate spreader (also long range spreader).
Application rate(s) and frequency	The application rate is 10 g/nest. One single nest per application. Dilution (%): Ready to use Number and timing of application: Treatment indoor can be performed up to 2 times per year.
Category(ies) of users	Trained professional Professional
Pack sizes and packaging material	1kg HDPE Bottle, 5 kg HDPE Bucket

2.1.4.8 Use-specific instructions for use

Application must be done at the recommended rate at the entrance of the nest. One single application can eradicate completely the colony. Spread gently the dust powder to direct the full quantity on the nest entrance. Apply preferably at dusk and dawn.
See also General directions for use.

2.1.4.9 Use-specific risk mitigation measures

The area where loading takes place must be covered with a disposable plastic sheet/foil in order to avoid contamination of adjacent surfaces and floor.
After treatment, dispose the plastic sheet/foil and the collected residues as hazardous waste.
Nest will be preferably removed and disposed (if feasible) by the professional as part of the service provided.
After the control of wasp nests, collect the nest in/on a disposable cover/bag and remove any product residue with a vacuum cleaner.
Treatment of one single nest per application.

2.1.4.10 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general directions for use.

2.1.4.11 Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use.

2.1.4.12 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use.

2.1.4.13 Use description # 3

Table 3. Use # 3 – **Crack and crevice application in voids and cavities, general public – Crawling insects**

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Dustable powder insecticide for use against crawling insects. For application in cracks and crevices, voids and cavities.
Target organism (including development stage)	<p>Scientific name: <i>Blattella germanica</i> Common name: German cockroach Development stage: Adults</p> <p>Scientific name: <i>Blatta orientalis</i> Common name: Oriental cockroach Development stage: Adults</p> <p>Scientific name: <i>Lasius niger</i> Common name: Garden ant Development stage: Adults</p> <p>Scientific name: crawling insects Common name: Crawling insects Development stage: Adults</p>
Field of use	Indoor (domestic premises) in places where insects use to hide in.
Application method(s)	<p>Method: Manual application</p> <p>Detailed description: The product has to be applied only on restricted areas on surfaces not regularly cleaned, for example behind or under the fridge, under the kitchen sink, under the oven or the water heater, in all cracks and crevices that can be a harborage for cockroaches and ants.</p> <p>The application (dusting) has to be performed using the specific container equipped with the appropriate spreader.</p>
Application rate(s) and frequency	<p>The application rate is 8 gr/m².</p> <p>Dilution (%): Ready to use</p> <p>Number and timing of application: Treatment can be performed up to 2 times per year</p>
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	<p>100g, 250g, 500g HDPE Dust spreader</p> <p>100g, 250g, 500g HDPE Dust spreader with stout cap</p>

2.1.4.14 Use-specific instructions for use

Application must be done at the recommended rate.

For bottle packaging with spreader cup: Shake gently the package, remove the cap and turn the bottle upside down. To treat a surface of a square meter, turn the bottle upside down 5 times, moving from the area to be treated, releasing a total dose of 8g per square meter.

For bottle packaging with stout cup: Shake gently the package, rotate the cup, and turn the bottle upside down. To treat a surface of a square meter, lightly squeeze the bottle for 3 seconds, moving across the area to be treated, releasing a total dose of 8g per square meter.

Knockdown of Oriental cockroaches is expected 4 hours after exposure to the treated surfaces.

See also General directions for use.

2.1.4.15 Use-specific risk mitigation measures

The product has to be applied only on restricted areas on surfaces not regularly cleaned, for example behind or under the fridge, under the kitchen sink, under the oven or the water heater, in all cracks and crevices that can be a harborage for cockroaches and ants.

Do not apply to areas susceptible to routine wet cleaning.

No use of wet cleaning procedures. Use only dry-cleaning procedures (vacuum or broom) or use damp paper. After cleaning, dispose the collected in the dry cleaner materials or the damp papers used as solid wastes.

2.1.4.16 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See General directions for use

2.1.4.17 Where specific to the use, the instructions for safe disposal of the product and its packaging

See General directions for use

2.1.4.18 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See General directions for use

2.1.4.19 Use description # 4

Table 4. Use # 4 – Wasp nest – general public

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
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Where relevant, an exact description of the authorised use	Direct application on wasp nest for eradication
Target organism (including development stage)	Scientific name: <i>Vespula germanica</i> Common name: German wasp Development stage: Adults Common name: wasp nest Development stage: Adults
Field of use	Indoors Application on the nest
Application method(s)	Method: Manual application. Detailed description: Manual application on the nest. The application (dusting) has to be performed using the specific container equipped with the appropriate spreader.
Application rate(s) and frequency	The application rate is 10 g/nest. Apply on the nest. One single nest per application. Dilution (%): Ready to use Number and timing of application: Treatment indoor can be performed up to 2 times per year.
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	100g, 250g, 500g HDPE Dust spreader 100g, 250g, 500g HDPE Dust spreader with stout cap

2.1.4.20 Use-specific instructions for use

Application must be done at the recommended rate at the entrance of the nest. One single application can eradicate completely the colony. Spread gently the dust powder to direct the full quantity on the entrance of the nest. Apply preferably at dusk and dawn.

For bottle packaging with spreader cup: Shake gently the package, remove the cap and turn the bottle upside down. To treat the entrance of the nest, turn the bottle upside down 6 times, moving from the area to be treated, releasing a total dose of 10g per nest.

For bottle packaging with stout cup: Shake gently the package, rotate the cap and turn the bottle upside down. To treat the entrance of the nest, lightly squeeze the bottle for 4 seconds, moving across the area to be treated, releasing a total dose of 10g per nest.

Remove treated nest (if feasible) after examination of nest making sure no single wasps are around (more or less 72 hours).

After the control of wasp nest, collect the nest in/on a disposable cover/bag and remove any product residue with a vacuum cleaner.

See also General directions for use.

2.1.4.21 Use-specific risk mitigation measures

Treatment of one single nest per application.

2.1.4.22 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general directions for use.

2.1.4.23 Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use.

2.1.4.24 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use.

2.1.4.25 Use description # 5

Table 5. Use # 5 – Ant nest treatment – general public

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Direct application on ant nest for eradication
Target organism (including development stage)	<i>Scientific name: Lasius niger</i> <i>Common name: Garden ant</i> <i>Development stage: Adults</i>
Field of use	Outdoor on the nest
Application method(s)	Method: Manual application Detailed description: Manual application around and at the entrance of the nest. The application (dusting) has to be performed using the specific container equipped with the appropriate spreader
Application rate(s) and frequency	The application rate is 5 g/nest. Dilution (%): Ready to use Number and timing of application: One application per nest per house.
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	100g, 250g, 500g HDPE Dust spreader 100g, 250g, 500g HDPE Dust spreader with stout cap

2.1.4.26 Use-specific instructions for use

Application must be done at the recommended rate.

For bottle packaging with spreader cup: Shake gently the package, remove the cup, and turn the bottle upside down. To treat a nest, turn the bottle upside down 3 times, moving from the area to be treated, releasing a total dose of 5g per nest.

For bottle packaging with stout cup: Shake gently the package, rotate the cup, and turn the bottle upside down. To treat a nest, lightly squeeze the bottle for 2 seconds, moving from the area to be treated, releasing a total dose of 5g per nest.

Single application per nest should be performed. One single nest application can eradicate completely the colony.

If ants appear from multiple entrance holes, the total amount of powder (5 g) must be divided for the number of entrance (for example if 5 entrances are present on the nest apply 1 g of product/entrance).

Application can be performed on both paved and unpaved surfaces.

To optimise the treatment efficacy, do not apply in case of rain or wind.

See also General directions for use

2.1.4.27 Use-specific risk mitigation measures

Treatment of one single nest per application.

2.1.4.28 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See General directions for use.

2.1.4.29 Where specific to the use, the instructions for safe disposal of the product and its packaging

See General directions for use.

2.1.4.30 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See General directions for use.

2.1.4.31 Use description # 6

Table 6. Use # 6 – **Spot application outdoor around building against *Blatta orientalis* - general public**

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Spot application around building in the vicinity of windows and doorsteps.

Target organism (including development stage)	<i>Scientific name: Blatta orientalis</i> <i>Common name: Oriental cockroach</i> <i>Development stage: Adults</i>
Field of use	Outdoor around building in the vicinity of windows and doorsteps
Application method(s)	Method: Manual application Manual application by dusting directly by the packaging. The application (dusting) has to be performed using the specific container equipped with the appropriate spreader.
Application rate(s) and frequency	The application rate is 8 gr/m ² Dilution (%): Ready to use.. Number and timing of application: Treatment can be performed up to 2 times per year.
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	100g, 250g, 500g HDPE Dust spreader 100g, 250g, 500g HDPE Dust spreader with stout cap

2.1.4.32 Use-specific instructions for use

Application must be done at the recommended rate in the vicinity of windows and doorsteps.
For bottle packaging with spreader cup: Shake gently the package, remove the cap and turn the bottle upside down. To treat a surface of a square meter, turn the bottle upside down 5 times, moving from the area to be treated, releasing a total dose of 8g per square meter.
For bottle packaging with stout cup: Shake gently the package, rotate the cup, and turn the bottle upside down. To treat a surface of a square meter, lightly squeeze the bottle for 3 seconds, moving across the area to be treated, releasing a total dose of 8g per square meter.
Application must be done only in roof covered (protected from rain) areas.
Knockdown of Oriental cockroaches is expected 4 hours after exposure to the treated surfaces.
See also General directions for use.

2.1.4.33 Use-specific risk mitigation measures

Apply only in the vicinity of windows and doorsteps.
Do not apply in case of rain and in windy days.

2.1.4.34 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See General directions for use

2.1.4.35 Where specific to the use, the instructions for safe disposal of the product and its packaging

See General directions for use.

2.1.4.36 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See General directions for use.

2.1.5 General directions for use

2.1.5.1 Instructions for use

See use specific directions for use.

Always read the label or leaflet before use and follow all the instructions provided.

For use only in areas that are inaccessible to infants, pets (in particular cats) and non-target animals.

Resistance management strategies

For professionals:

- Take into account the life cycle and characteristics of target insects to adapt treatments. In particular, target the most susceptible stage of the pest, timing of applications and areas to be treated.
- Where possible, application treatments should be recommended to be combined with non-chemical measures.
- Where an extended period of control is required, treatments should be alternated with products having active substances with different modes of action.
- Establish a baseline and monitor levels of effectiveness on populations in key areas in order to detect any significant changes in susceptibility to active substance. Information from resistance monitoring programs allows early detection of problems and gives information for correct decision making.
- The users should inform if the treatment is ineffective and report straightforward to the registration holder or the distributor.
- The authorization holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management.
- Do not use/apply the product in areas where resistance to the active substance contained in this product is suspected or established.
- Do not [use/apply] the product in areas where resistance to the active substance (s) contained in this product is suspected or established.

For non-professionals:

- If the infestation persists, contact a professional.

2.1.5.2 Risk mitigation measures

Contains cypermethrin, may be dangerous/toxic to pets (e.g. cats, bees, fish and other aquatic organisms).

Keep cats away from treated surfaces. Due to their particular sensitivity to cypermethrin, the product can cause severe adverse reactions in cats.

Do not apply in rooms where fish tanks and/or terrariums are present.

Keep out of reach of children and non-target animals/pets.

Keep uninvolved persons, children and pets away from treated surfaces/areas.

Do not dust onto people and pets.

N-122 [slightly modified] Cover all surfaces and facilities likely to be in contact with food, feed and drinking water.

N-127 Do not apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock/pets.

See use specific RMMs, as detailed in above sections.

2.1.5.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

If medical advice is needed, have product container or label at hand.

Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation).

If symptoms persist: Get medical advice.

IF EXPOSED: Call a POISON CENTRE or a doctor.

IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.

IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.

IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.

IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.

Do not release the product or its empty containers in the environment.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Dispose of contents/container in accordance with local waste management regulations.

Do not empty into drains. Do not contaminate ponds/lakes, water pipes or ditches with the product or with empty container.

Do not reuse packaging.

2.1.5.5 Conditions of storage and shelf-life of the product under normal conditions of storage

Keep out of reach of children and non-target animals/pets.

N-301 Do not store near food, drink and feed.

Shelf-life: 2 years, in original container at room temperatures. Avoid extreme temperatures and exposure to direct sunlight. Store in a dry place, protect from humidity.

2.1.6 Other information

The product contains a bittering agent.

2.1.7 Packaging of the biocidal product

All proposed packaging materials is not transparent, waterproof, and humidity proof (anticaking scope).

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
Bottle	1 kg	HDPE	PE, PP	Professional / Trained professional	Yes
Bucket	5 kg	HDPE	PE, PP	Professional / Trained professional	Yes
Bottle	100 g	HDPE	PE, PP / Dust spreader	General public	Yes
Bottle	250 g	HDPE	PE, PP / Dust spreader	General public	Yes
Bottle	500 g	HDPE	PE, PP / Dust spreader	General public	Yes
Bottle	100 g	HDPE	PE, PP Dust spreader with stout cap	General public	Yes
Bottle	250 g	HDPE	PE, PP Dust spreader with stout cap	General public	Yes
Bottle	500 g	HDPE	PE, PP Dust spreader with stout cap	General public	Yes

Conclusion on the packaging of the biocidal product

Accelerated storage stability test for 14 days at 54°C and two-year storage stability test at room temperature demonstrated compatibility with the packaging material: bottle from HDPE.

According to Guidance on the BPR (Volume I Parts A+B+C) for solid preparations extrapolation to all types of packaging is acceptable except to more flexible packs. Therefore, all the above-mentioned proposed packaging for the product Free Land dust is considered acceptable for commercial use.

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

- ✓ Physical state
- ✓ Colour
- ✓ Odour
- ✓ Acidity / alkalinity (pH)
- ✓ Relative density / bulk density
- ✓ Storage stability test – accelerated storage
- ✓ Two Years Storage Stability and Corrosion Characteristics
- ✓ Particle size distribution
- ✓ Dustiness
- ✓ Explosivity
- ✓ Flammable solids
- ✓ Oxidising solids
- ✓ Thermal Stability Testing
- ✓ Validation of the analytical method for the determination of Cypermethrin
- ✓ Determination of Efficacy of the product (laboratory and field tests)

2.1.8.2 Access to documentation

The applicant submits the Letter of Access granted by the manufacturer of the active substance; this cover the studies owned by the company and other information that have been used for including the active substance in the Union list of approved active substances under the Biocidal Products Regulation.

With such Letter of Access the applicant is authorized to use, refer to and rely on active substance data in order to apply for the authorization of the biocidal product.

2.2 Assessment of the biocidal product

2.2.1 Intended uses as applied for by the applicant

Table 7. Use # 1 – Spot application in crack and crevice, professional – Crawling insects

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Dustable powder insecticide for use against crawling insects by crack and crevice treatment indoors
Target organism (including development stage)	<i>Blattella germanica</i> <i>Periplaneta Americana</i> <i>Blatta orientalis</i> <i>Lasius niger</i>
Field of use	Indoor
Application method(s)	Manual application
Application rate(s) and frequency	The application rate is 0.02 g a.i./m ² Treatment can be performed up to 2 times per year
Category(ies) of users	Professional and trained professional
Pack sizes and packaging material	1kg HDPE Bottle, 5 kg HDPE Bucket

Table 8. Use # 2 – Spot application in voids and cavities, professional – Crawling insects

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Dustable powder insecticide for use against crawling insects by voids and cavities application indoors
Target organism (including development stage)	<i>Blattella germanica</i> <i>Periplaneta Americana</i> <i>Blatta orientalis</i> <i>Lasius niger</i>
Field of use	Indoor
Application method(s)	Manual application
Application rate(s) and frequency	The application rate is 0.02 g a.i./m ² Treatment can be performed up to 11 times per year
Category(ies) of users	Professional and trained professional
Pack sizes and packaging material	1kg HDPE Bottle, 5 kg HDPE Bucket

Table 9. Use # 3 – Wasp nest, professional

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Direct application on wasp nest for eradication
Target organism (including development stage)	<i>Vespula spp.</i> (German wasp) <i>Polistes spp.</i> (Paper wasp)

stage)	
Field of use	Indoor – Outdoor
Application method(s)	Manual application
Application rate(s) and frequency	The application rate is 10 g/nest. Apply on the nest. Treatment indoor can be performed up to 2 times per year.
Category(ies) of users	Professional and trained professional
Pack sizes and packaging material	1kg HDPE Bottle, 5 kg HDPE Bucket

Table 10. Use # 4 – Spot application in by crack and crevice application, non professional – Crawling insects

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Dustable powder insecticide for use against crawling insects by crack and crevice treatment indoors
Target organism (including development stage)	<i>Blattella germanica</i> <i>Periplaneta Americana</i> <i>Blatta orientalis</i> <i>Lasius niger</i>
Field of use	Indoor
Application method(s)	Manual application by dusting directly by the packaging
Application rate(s) and frequency	The application rate 0.02 g a.i./m ² Treatment can be performed up to 2 times per year
Category(ies) of users	Non professional (general public)
Pack sizes and packaging material	100g, 250g, 500g, 1 kg HDPE Dust spreader 100g, 250g, 500g, 1 kg HDPE Dust spreader with stout cap

Table 11. Use # 5 – Spot application in voids and cavities application, non professional – Crawling insects

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Dustable powder insecticide for use against crawling insects by voids and cavities treatment indoors
Target organism (including development stage)	<i>Blattella germanica</i> <i>Periplaneta Americana</i> <i>Blatta orientalis</i> <i>Lasius niger</i>
Field of use	Indoor
Application method(s)	Manual application
Application rate(s) and frequency	The application rate is 0.02 g a.i./m ² Treatment can be performed up to 11 times per year
Category(ies) of users	Non professional (general public)
Pack sizes and packaging material	100g, 250g, 500g, 1 kg HDPE Dust spreader 100g, 250g, 500g, 1 kg HDPE Dust spreader with stout cap

Table 12. Use # 6 – Wasp nest – non professional

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Direct application on wasp nest for eradication
Target organism (including development stage)	<i>Vespula spp.</i> (German wasp) <i>Polistes spp.</i> (Paper wasp)
Field of use	Indoor – Outdoor
Application method(s)	Manual application
Application rate(s) and frequency	The application rate is 10 g/nest. Apply on the nest Treatment indoor can be performed up to 2 times per year.
Category(ies) of users	Non professional (general public)
Pack sizes and packaging material	100g, 250g, 500g, 1 kg HDPE Dust spreader 100g, 250g, 500g, 1 kg HDPE Dust spreader with stout cap

Table 13. Use # 7 – Ant nest treatment – general public

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Direct application on ant nest for eradication
Target organism (including development stage)	<i>Lasius niger</i> (Black garden ant)
Field of use	Outdoor
Application method(s)	Manual application
Application rate(s) and frequency	The application rate is 5 g/nest to be applied at the entrance of the nest and around it.
Category(ies) of users	Non professional (general public)
Pack sizes and packaging material	100g, 250g, 500g, 1 kg HDPE Dust spreader 100g, 250g, 500g, 1 kg HDPE Dust spreader with stout cap

Table 14. Use # 8 – Around building barrier treatment against *Blatta orientalis*.
General public

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Targeted spot applications around building to prevent access of cockroaches
Target organism (including development stage)	<i>Blatta orientalis</i>
Field of use	Outdoor around building
Application method(s)	Manual application
Application rate(s) and frequency	The application rate is 0.02 g a.i./m ² Treatment can be performed up to 2 times per year

Category(ies) of users	Non professional (general public)
Pack sizes and packaging material	100g, 250g, 500g, 1 kg HDPE Dust spreader 100g, 250g, 500g, 1 kg HDPE Dust spreader with stout cap

2.2.2 Physical, chemical and technical properties

All the formulation test items ([REDACTED]) have the same composition with the one described in the Confidential Section.

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	Acceptability
Physical state at 20 °C and 101.3 kPa	OPPTS 830.6303 (1996)	Test item: Free Land Dust Cypermethrin: 0.26 % w/w (TGAI) Batch number: [REDACTED]	Powder	GLP Study No. CH – 0008/2020	Acceptable
Colour at 20 °C and 101.3 kPa	OPPTS 830.6302 (1996)	Test item: Free Land Dust Cypermethrin: 0.26 % w/w (TGAI) Batch number: [REDACTED]	White (shortcode NE12)	GLP Study No. CH – 0008/2020	Acceptable
Odour at 20 °C and 101.3 kPa	OPPTS 830.6304 (1996)	Test item: Free Land Dust Cypermethrin: 0.26 % w/w (TGAI) Batch number: [REDACTED]	Odourless	GLP Study No. CH – 0008/2020	Acceptable
Acidity / alkalinity	CIPAC method MT 75.3 and OECD Test No 122	Test item: Free Land Dust Cypermethrin: 0.26 % w/w (TGAI) Batch number: [REDACTED]	pH value of the 1 % w/v aqueous dispersion of the test item sample was 9.8 (rounded mean value of two measurements) at a temperature of 20°C. Acidity/alkalinity data is only required when this value is not between 4 and 10.	GLP Study No. CH – 0008/2020	Acceptable
Relative density / bulk density	CIPAC MT 186	Test item: Free Land Dust Cypermethrin: 0.26 % w/w (TGAI) Batch number: [REDACTED]	Pour density: 1.05 g/mL Bulk density: 1.29 g/mL	GLP Study No. CH – 0008/2020	Acceptable

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	Acceptability
Storage stability test – accelerated storage	<p>CIPAC MT 46 "Accelerated storage procedure"</p> <p>Cypermethrin active ingredient content with the Internal Analytical Method No. 0009/2020 adjusted and validated in GLP Study CH – 0009/2020.</p> <p>EPA Product Properties Test Guidelines: OPPTS 830.6302 (1996) "Color"; OPPTS 830.6303 (1996) "Physical State"; OPPTS 830.6304 (1996) "Odor".</p> <p>CIPAC Methods: MT 75.3 "Determination of pH values" MT 171.1 "Dustiness of</p>	<p>Test item: Free Land Dust Cypermethrin: 0.26 % w/w (TGAI) Batch number: [REDACTED]</p> <p>FREE LAND DUST formulation sample, packaged in a HDPE bottle.</p>	<p>Cypermethrin active ingredient content:</p> <p>Initial characterisation 0.24 ± 0.003 % w/w Cis: 0.11 ± 0.001 % w/w Trans: 0.13 ± 0.002 % w/w After 14 days of storage at 54°C 0.23 ± 0.002 % w/w Cis: 0.10 ± 0.001 % w/w Trans: 0.13 ± 0.002 % w/w</p> <p>Delta (%) from T0: -4.17</p> <p>Packaging Weight variation (%): After 14 days of storage at 54°C A: -0.11 % B: -0.12 %</p> <p>Appearance (Colour, odour and physical state): Initial characterisation White (shortcode NE 12) powder odourless After 14 days of storage at 54°C White (shortcode NE 12) powder odourless.</p> <p>pH value (1% w/v aqueous dilution): Initial characterisation 9.8 After 14 days of storage at 54°C 9.8</p> <p>Dustiness of granular products: Initial characterisation</p>	GLP Study No. CH – 0010/2020	<p>Acceptable</p> <p>No significant variation of physicochemical and technical properties appears during storage.</p> <p>The biocidal product Free Land Dust is considered stable when stored in its initial commercial packaging from HDPE under the tested accelerated storage conditions (54°C for 14 days).</p>

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	Acceptability
	<p>granular products - Gravimetric Method"</p> <p>MT 59 "Sieve analysis"</p> <p>MT 170 "Dry sieve analysis of water dispersible granules".</p> <p>MT 187 "Particle size analysis by laser diffraction"</p> <p>Note. Since the pH value ranged from 4 to 10, the acidity or alkalinity test (CIPAC MT 31 or 191) was not performed.</p>		<p>19.4 mg (essential non dusty)</p> <p>After 14 days of storage at 54°C</p> <p>22.1 mg (essential non dusty)</p> <p>Particle size distribution (sieve analysis)</p> <p>Initial characterisation</p> <p>More than 96.5 % of the test item presents a particle size higher than 0.180 mm and it is distributed between the 0.355 mm sieve (5.83%), the 0.250 mm sieve (62.53 %) and the 0.180 mm sieve (28.09 %).</p> <p>A 0.02 % of test item presents a particle size lower than 0.045 mm.</p> <p>After 14 days of storage at 54°C</p> <p>More than 97.5 % of the test item presents a particle size higher than 0.180 mm and it is distributed between the 0.355 mm sieve (5.95%), the 0.250 mm sieve (63.19 %) and the 0.180 mm sieve (28.33%).</p> <p>A 0.01 % of test item presents a particle size lower than 0.045 mm.</p> <p>Particle size distribution (laser diffraction)</p> <p>Initial characterisation</p> <p>Dv 10: 3.85 µm</p> <p>Dv 50: 30.1 µm</p> <p>Dv 90: 143 µm</p> <p>% < 45 µm: 60.00%</p> <p>% > 75 µm: 25.40%</p> <p>After 14 days of storage at 54°C</p> <p>Dv 10: 3.67 µm</p> <p>Dv 50: 27.3 µm</p> <p>Dv 90: 123 µm</p> <p>% < 45 µm: 62.39%</p>		

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	Acceptability
			<p>% > 75 µm: 23.11%</p> <p>eCA comment on Substance of concern: (2-methoxymethyl-ethoxy) propanol has been considered a substance of concern in the formulation Free Land Dust.</p> <p>No storage data and method of analysis of the substance of concern is required, since SoC cannot be formed during storage and its concentration remains unchanged as applicant stated.</p>		
Storage stability test – long term storage at ambient temperature	<p>- GIFAP Monograph No. 17, 2nd edition, June 2009</p> <p>Cypermethrin active ingredient content: Internal Analytical Method No. 0009/2020</p> <p>Appearance (Colour, odour and physical state): OPPTS 830.6302; OPPTS 830.6303; OPPTS 830.6304</p> <p>pH value (1%</p>	<p>Test item: Free Land Dust Cypermethrin: 0.26 % w/w (TGAI) Batch number: [REDACTED]</p> <p>FREE LAND DUST formulation sample, packaged in a HDPE bottle.</p>	<p>Cypermethrin active ingredient content</p> <p>Initial characterisation 0.24 ± 0.003 % w/w Cis: 0.11 ± 0.001 % w/w Trans: 0.13 ± 0.002 % w/w</p> <p>After 6 months storage 0.24 ± 0.001 (+ 0.46% from T0) Cis: 0.10 ± 0.004 Trans: 0.12 ± 0.004</p> <p>After 12 months storage 0.24 ± 0.001 (+ 0.89% from T0) Cis: 0.11 ± 0.001 Trans: 0.13 ± 0.0002</p> <p>After 24 months storage 0.24 ± 0.001 (+ 1.68% from T0) Cis: 0.11 ± 0.0002 Trans: 0.13 ± 0.001</p>	GLP Study No. CH – 0011/2020	<p>Acceptable</p> <p>No significant variation of physicochemical and technical properties appears during storage.</p> <p>The biocidal product Free Land Dust is considered stable for two years when stored in its initial commercial packaging from HDPE at ambient temperature.</p>

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	Acceptability
	<p>w/v aqueous dilution): CIPAC MT 75.3; OECD No. 122</p> <p>Dustiness of granular products: CIPAC MT 171.1</p> <p>Particle size distribution (sieve analysis): CIPAC MT 59 and MT 170 OECD No. 110</p> <p>Particle size distribution (laser diffraction): CIPAC MT 187 OECD No. 110</p>		<p>Appearance (Colour, odour and physical state)</p> <p>Initial characterisation White (shortcode NE 12) powder odourless</p> <p>After 6 months storage White (shortcode NE 12) powder odourless</p> <p>After 12 months storage White (shortcode NE 12) powder odourless</p> <p>After 24 months storage White (shortcode NE 12) powder odourless</p> <p>pH value (1% w/v aqueous dilution)</p> <p>Initial characterisation 9.8</p> <p>After 6 months storage 9.8</p> <p>After 12 months storage 9.8</p> <p>After 24 months storage 9.8</p> <p>Compatibility (resistance) of the packaging material (Visual examination of packaging both externally and internally)</p> <p>After 6 months storage The container didn't present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena</p> <p>After 12 months storage The container didn't present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena</p>		

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	Acceptability
			<p>After 24 months storage The container didn't present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena</p> <p>Dustiness of granular products</p> <p>Initial characterisation 19.4 mg (essential non dusty)</p> <p>After 6 months storage 22.3 mg (essential non dusty)</p> <p>After 12 months storage 29.7 mg (essential non dusty)</p> <p>After 24 months storage 29.3 mg (essential non dusty)</p> <p>Weight variation (%)</p> <p>After 6 months storage HDPE bottle, labelled as "C": 0.00%</p> <p>After 12 months storage HDPE bottle, labelled as "D": 0.00%</p> <p>After 24 months storage HDPE bottle, labelled as "E": -0.03% HDPE bottle, labelled as "F": -0.03%</p> <p>Particle size distribution (sieve analysis)</p> <p>Initial characterisation More than 96.5 % of the test item presents a particle size higher than 0.180 mm and it is distributed between the 0.355 mm sieve (5.83%), the 0.250 mm sieve (62.53 %) and the 0.180 mm</p>		

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	Acceptability
			<p>sieve (28.09 %). A 0.02 % of test item presents a particle size lower than 0.045 mm.</p> <p>After 6 months storage About 25.6 % of the test item presents a particle size higher than 0.180 mm. The particle size is distributed as follow: the 0.355 mm sieve (1.32%), the 0.250 mm sieve (1.77 %), the 0.180 mm sieve (22.47%), the 0.125 mm sieve (31.23%), the 0.075 mm sieve (26.63%) and the 0.045 mm sieve (14.84%). A 1.84 % of test item presents a particle size lower than 0.045 mm.</p> <p>After 12 months storage About 14.4 % of the test item presents a particle size higher than 0.180 mm. The particle size is distributed as follow: the 0.355 mm sieve (0.28%), the 0.250 mm sieve (0.41 %), the 0.180 mm sieve (13.70%), the 0.125 mm sieve (33.81%), the 0.075 mm sieve (29.46%) and the 0.045 mm sieve (19.13%). A 3.23 % of test item presents a particle size lower than 0.045 mm.</p> <p>After 24 months storage About 10.7 % of the test item presents a particle size higher than 0.180 mm. The particle size is distributed as follow: the 0.355 mm sieve (0.24%), the 0.250 mm sieve (0.26 %), the 0.180 mm sieve (10.24%), the 0.125 mm sieve (35.87%), the 0.075 mm sieve (30.83%) and the 0.045 mm sieve (18.23%). A 4.31 % of test item presents a particle size lower than 0.045 mm.</p> <p>Particle size distribution (laser diffraction)</p> <p>Initial characterisation Dv 10: 3.85 µm</p>		

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	Acceptability
			<p>Dv 50: 30.1 µm Dv 90: 143 µm % < 45 µm: 60.00% % > 75 µm: 25.40%</p> <p>After 6 months storage Dv 10: 3.77 µm Dv 50: 27.1 µm Dv 90: 110 µm % < 45 µm: 63.05% % > 75 µm: 21.55%</p> <p>After 12 months storage Dv 10: 3.43 µm Dv 50: 24.3 µm Dv 90: 105 µm % < 45 µm: 65.45% % > 75 µm: 19.74%</p> <p>After 24 months storage Dv 10: 3.48 µm Dv 50: 24.0 µm Dv 90: 106 µm % < 45 µm: 65.51% % > 75 µm: 19.68%</p> <p>The results from the long term storage study, shows that the Dustiness of the product increases along with an overall decrease in particle size, especially regarding the percentage of particles >180 µm (sieve analysis). During the long term stability, the samples were stock at ambient condition in a warehouse without stable Temperature and humidity. In the trials after 6 months the big aggregates (355µm; 250µm and 180 µm) were disaggregates during the phase of shaking on the sieves (5 minutes) more than fresh product because more dry. We can consider that this phenomena doesn't affect the</p>		

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	Acceptability
			<p>performance of the product after stability period: a major number of small aggregates can help to obtain a major availability of active ingredient and increase the efficacy.</p> <p><u>eCA comment on Substance of concern:</u> (2-methoxymethyl-ethoxy) propanol has been considered a substance of concern in the formulation Free Land Dust.</p> <p>No storage data and method of analysis of the substance of concern is required, since SoC cannot be formed during storage and its concentration remains unchanged as applicant stated.</p>		
Storage stability test – low temperature stability test for liquids	waived	-	The product is a solid		
Effects on content of the active substance and technical characteristics of the biocidal product - light	waived	-	Not applicable as the packaging is light-proof.		Acceptable
Effects on content of the active substance and technical characteristics of the biocidal product – temperature and humidity	CIPAC method MT 46 "Accelerated storage procedure"	Test item: Free Land Dust Cypermethrin: 0.26 % w/w (TGAI) Batch number: [REDACTED] Stored in HDPE bottle	<p>No significant change was found in the active ingredient content for the test item stored right doses, compared with the results obtained in the validation study, and the analyses after 2 weeks comply with the tolerance and therefore are in accordance with the declared value.</p> <p>No change in the appearance, colour, odour and weight variation was found and no variation was found in colour or in either the internal or external configuration, or loss of sample or evident corrosion</p>	GLP Study No. CH – 0010/2020	Acceptable

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	Acceptability
			<p>phenomena of packaging. Moreover, no significant changes in physical properties. After 14 days of storage at 54°C and long term storage at ambient temperature, no weight variation for the test item sample stored in the HDPE bottles occurred and its physical properties have not changed. Test item in sound condition, sealed and without leakages. It can be excluded that the product has hygroscopic properties. From the above reported data, it can be concluded that the FREE LAND DUST sample is stable in its commercial packaging under the tested accelerated storage conditions.</p>		
Effects on content of the active substance and technical characteristics of the biocidal product - reactivity towards container material	Visual examination	<p>Test item: Free Land Dust Cypermethrin: 0.26 % w/w (TGAI) Batch number: ██████████</p> <p>Stored in HDPE bottle</p>	<p>Compatibility (resistance) of the packaging material (Visual examination of packaging both externally and internally)</p> <p>After 6 months storage The container didn't present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena</p> <p>After 12 months storage The container didn't present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena</p>	<p>GLP Study No. CH – 0011/2020</p>	Acceptable
Wettability	-	-	Data waiving since the data are required only for solid preparations which are to be dispersed in water.	-	
Suspensibility, spontaneity and dispersion	Justification for the non-submission of	-	Data waiving since the product is a dusting powder	-	

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	Acceptability
stability	data				
Wet sieve analysis and dry sieve test	Particle size distribution (sieve analysis) (CIPAC MT 59 and MT 170; OECD No. 110)	Test item: Free Land Dust Cypermethrin: 0.26 % w/w (TGAI) Batch number: ██████████	More than 96.5 % of the test item presents a particle size higher than 0.180 mm and it is distributed between the 0.355 mm sieve (5.83%), the 0.250 mm sieve (62.53 %) and the 0.180 mm sieve (28.09 %). A 0.02 % of test item presents a particle size lower than 0.045 mm.	GLP Study No. CH – 0008/2020	Acceptable
Emulsifiability, re-emulsifiability and emulsion stability	Justification for the non-submission of data	-	Data waiving since the product is a dusting powder	-	
Disintegration time	Justification for the non-submission of data	-	Data waiving since disintegration time is applicable only to products that are tablets (depend on disintegration of the tablet in a solvent).	-	

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	Acceptability
Particle size distribution, content of dust/fines, attrition, friability	Particle size distribution by laser diffraction (CIPAC MT 187 and OECD No. 110)	Test item: Free Land Dust Cypermethrin: 0.26 % w/w (TGAI) Batch number: [REDACTED]	<p>The test item formulation sample presents the following particle size distribution:</p> <p>The interpolated results are expressed as percent of the total results under that size. This value is known as percentile.</p> <p>The results show the percentile sizes for 10%, 50%, 90%, the percentile volume under 45 µm and the percentile volume above 75 µm.</p> <p>Dv: Standard Percentile Volume. Dv 10 µm: size in microns at which 10% of the test item is smaller and the 90% is larger. Dv 50 µm: size in microns at which 50% of the test item is smaller and the 50% is larger.</p> <p>T0 Dv 10: 3.85 µm Dv 50: 30.1 µm = MMAD Dv 90: 143 µm % < 45 µm: 60.00% % > 75 µm: 25.40%</p> <p>T2 Dv 10: 3.67 µm Dv 50: 27.3 µm = MMAD Dv 90: 123 µm % < 45 µm: 62.39% % > 75 µm: 23.11%</p>	GLP Study No. CH – 0008/2020	Acceptable

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	Acceptability
	Dustiness (CIPAC MT 171)	Test item: Free Land Dust Cypermethrin: 0.26 % w/w (TGAI) Batch number: [REDACTED]	Determination: A -W _s (g) 30.01 Collected dust (mg) 18.89 B -W _s (g) 30.04 Collected dust (mg) 21.04 C -W _s (g) 30.14 Collected dust (mg) 18.00 Collected dust Mean value (mg) 19.4 Following the criteria reported in the CIPAC method MT 171, it can be concluded that the test item formulation sample is categorised as "essential non dusty".	GLP Study No. CH – 0008/2020	Acceptable
Persistent foaming	Justification for the non-submission of data	-	Data waiving since the preparation is not applied as a foam.	-	
Flowability/ Pourability/ Dustability	Justification for the non-submission of data	-	The product is sold in an easy-to-grip plastic bottle with a spray cap. The packaging provides good control for the user to apply the desired amount of product, along cracks or crevices. The plastic bottle can be crushed or shaken to control the quantity dispensed. The product was designed so that consumers can easily spray dust on problem areas where target parasites persist.	-	Acceptable
Burning rate — smoke generators	Justification for the non-submission of data	-	Data waiving since the preparation is not applied as a smoke.	-	

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	Acceptability
Burning completeness — smoke generators	Justification for the non-submission of data	-	Data waiving since the preparation is not applied as a smoke.	-	
Composition of smoke — smoke generators	Justification for the non-submission of data	-	Data waiving since the preparation is not applied as a smoke.	-	
Spraying pattern — aerosols	Justification for the non-submission of data	-	Data waiving since the preparation is not applied as a spray.	-	
Physical compatibility	-	-	Not required. The product is not intended to be used with other products (including other biocidal products).	-	
Chemical compatibility	-	-	Data waiving. Data to address the physical and chemical compatibility must not be provided since the biocidal product can not co-apply with other substances, mixtures or biocidal or non-biocidal products.	-	
Degree of dissolution and dilution stability	Justification for the non-submission of data	-	Data waiving. The product is not used in a water soluble bag or tablets. The dilution stability is not determined since the product is not a water-soluble preparations.	-	
Surface tension	Justification for the non-submission of data	-	Not applicable to powder formulations.	-	
Viscosity	Justification for the non-submission of data	-	The study does not need be conducted because the substance is a solid.	-	

Conclusion on the physical, chemical and technical properties of the productPhysical-chemical properties:

The preparation is an odourless white powder, containing 0.25 % w/w (pure) cypermethrin. The pH value (of 1% w/v aqueous dilution) is 9.8 at temperature of 20°C. Dustiness of product is 19.4 mg (essential non dusty). The bulk density is 1.29 g/mL (pour density 1.05 g/mL).

Storage stability studies:

After storage at 54°C for 14 days and 2 years at ambient temperature (in HDPE bottle), the test item did not show any significant difference in terms of active ingredient content, pH, dustiness and particle size, compared to the initial conditions.

The product FREE LAND DUST is considered stable for two years when stored in its initial commercial packaging.

The physico-chemical properties of the biocidal product have been evaluated and are deemed acceptable for the appropriate use, storage and transportation of the biocidal product.

2.2.3 Physical hazards and respective characteristics

All the formulation test items ([REDACTED]) have the same composition with the one described in the Confidential Section.

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	Acceptability
Explosives	A.14 – Explosivity exemption by DSC	Test item: Free Land Dust Cypermethrin: 0.25 % w/w (TGAI) Batch number: [REDACTED]	The total heat of decomposition has been determined to be 38.52 J g ⁻¹ . The sample is not a candidate for classification as a UN Class 1 explosive substance as the total heat of decomposition is < 500 J/g.	Report number: S3016007067BR1/2020 DEKRA GLP compliance	Acceptable
Flammable gases	Justification for the non-submission of data	-	Data waiving since the product is not a gas.	-	
Flammable aerosols	Justification for the non-submission of data	-	Data waiving since the product is not used as aerosol.	-	
Oxidising gases	Justification for the non-submission of data	-	Data waiving since the product is not a gas.	-	
Gases under pressure	Justification for the non-submission of data	-	Data waiving since the product is not a gas under pressure.	-	
Flammable liquids	Justification for the non-submission of data	-	Data waiving since the product is not a liquid.	-	
Flammable solids	UN Test N.1 - Flammability of	Test item: Free Land Dust	Preliminary Test: The sample discoloured to grey and glowed red when the test flame was	Report number: S3016007067BR1/2020	Acceptable

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	Acceptability
	Solids	Cypermethrin: 0.25 % w/w (TGAI) Batch number: [REDACTED]	in contact with it. No flame, smoke or propagation was observed. From the preliminary screening test the sample was seen not to ignite and therefore no further testing is required. Classification of substance: Not classified as a Flammable Solid of Division 4.1	DEKRA GLP compliance	
Self-reactive substances and mixtures	Justification for the non-submission of data	-	According to CLP, substances and mixtures with no chemical groups present in the molecule associated with explosive or self-reactive properties (Tables A6.1 and A6.3 in Appendix 6 of the UN RTDG) and the total heat of decomposition it is less than 300 J/g (38.52 J/g for the product Free Land Dust, report number 3016007067BR1/2020) must not be considered for classification as a self-reactive substance or mixture.	-	Acceptable
Pyrophoric liquids	Justification for the non-submission of data	-	Data waiving since the product is not a liquid.	-	
Pyrophoric solids	Justification for the non-submission of data	-	Data waiving since the experience in manufacture and handling shows that the product does not ignite spontaneously on coming into contact with air at normal temperatures, i.e. the product is known to be stable at room temperature for prolonged periods of time (days).	-	Acceptable
Self-heating substances and mixtures	UN Test N.4: Self-heating Substances	Test item: Free Land Dust Cypermethrin: 0.25 % w/w (TGAI)	-Basket Size (mm cube): 100 -Test Temperature (°C): 140 -Test System: 10 -Sample Weight (g): 1344.7 -Ignition: No	Report number: S3016007747R1/2020 DEKRA GLP compliance	Acceptable

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	Acceptability
		Batch number: [REDACTED]	<p>Not Division 4.2 : Assigned to any substance which:</p> <p>a) gives a negative test result in a 100 mm basket at 140°C.</p> <p>b) gives a positive test result in a 100 mm basket at 140°C and a negative test result in a 100 mm basket at 120°C and is contained in packages of less than 3 m³ volume</p> <p>c) gives a positive test result in a 100 mm basket at 140°C and a negative test result in a 100 mm basket at 100°C and is contained in packages of less than 450 l volume.</p> <p>Results: Free Land Dust does not show signs of exothermic activity during the first trial, and therefore is not subject to transportation restrictions of UN Class 4 Division 4.2.</p>		
Substances and mixtures which in contact with water emit flammable gases	Justification for the non-submission of data	-	Data waiving since the chemical structure of the substance or mixture does not contain metals or metalloids.	-	Acceptable
Oxidising liquids	Justification for the non-submission of data		Data waiving since the product is not a liquid.	-	
Oxidising solids	UN Test O.1 Oxidising Solids	Test item: Free Land Dust Cypermethrin: 0.25 % w/w	In all test runs the test coil broke before the reaction had reached completion. However, as the coil broke after a duration greater than the slowest burn time of the reference mixture in	Report number: S3016007067BR1/2020 DEKRA	Acceptable

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	Acceptability
		(TGAI) Batch number: ██████████	<p>all the 1:1 test item mixtures and reaction was limited with little or no propagation for the 4:1 test mixtures it is beyond doubt that the material does not possess oxidising properties.</p> <p>It has been determined that Free Land Dust should not be classified as a material of Class 5.1</p>	GLP compliance	
Organic peroxides	Justification for the non-submission of data	-	Data waiving since FREE LAND DUST does not contain organic peroxides.	-	Acceptable
Corrosive to metals	Justification for the non-submission of data	-	<p>Data waiving since application of classification criteria in the UN-MTC, Section 37.4 excludes solids, while 'liquids and solids that may become liquids (during transport)', have to be considered for such a classification. Solids may become liquids by melting (due to increase in temperature). Solids having a melting point lower than 55 °C.</p> <p>Melting point of Free Land Dust is expected to be > 55°C, since the product is composed of about 97% of calcium carbonate and the melting point of calcium carbonate is over than 850 °C. Therefore, the test can be avoided and the product is not considered corrosive.</p>	-	Acceptable
Auto-ignition temperatures of products (liquids and gases)	Justification for the non-submission of data	-	Data waiving since the product is not a liquid.	-	

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	Acceptability
Relative self-ignition temperature for solids	-	-	Results: Free Land Dust does not show signs of exothermic activity	Report number: S3016007747R1/2020 DEKRA GLP compliance	Acceptable
Dust explosion hazard	-	-	Not relevant. BPR Guidance Guidance on the BPR: Volume I Parts A+B+C Version 2.0 May 2018 states that materials that cannot be oxidised are exempt from testing. According to Guidance on the Biocidal Products Regulation Volume I, a combustible dust is defined as finely divided solid particles that are liable to catch fire or explode on ignition when dispersed in air or other oxidising media. Based on the composition of Free Land Dust (please refer to confidential annex for more information) and considering tests conducted for explosive, self-heating and flammable properties of the product, it is foreseeable that the product Free Land Dust is not a combustible dust.	-	Acceptable

Conclusion on the physical hazards and respective characteristics of the product

The product Free Land Dust is not expected to have explosive or oxidising properties, nor to be self-heating, self-reactive or flammable. None of the components is known to evolve any flammable gases in contact with water/humid air or to be pyrophoric. The product is not expected to be corrosive to metals. Thus, has no classification according to CLP criteria.

2.2.4 Methods for detection and identification

Scope

This method is applicable to the quantitative determination of Cypermethrin active ingredient in FREE LAND DUST formulation samples. The method has been validated by the analysis of reference material and test item solutions.

Principle of the method

The determination of the active ingredient was performed by HPLC using an external standard and a UV detector. The quantification of active ingredient, as Cypermethrin, is performed by comparing the sum of the four peak areas of Cypermethrin (Cypermethrin Cis I, Cypermethrin Cis II, Cypermethrin Trans I, Cypermethrin Trans II) of reference material versus the sum of the four peaks areas in FREE LAND DUST test item solutions.

Chromatographic conditions

HPLC column	Agilent Technologies or equivalent Zorbax RX-SIL, 150 x 4.60 mm i.d., 5.0 µm
Detector	UV/Vis operating at 278 nm
Column temperature	35°C
Eluent C	iso octane/ethyl acetate = 99.5 / 0.5 % v/v
Eluent (isocratic)	100% eluent C
Eluent flow	2.0 mL/min
Volume of injection	10 µL
Cypermethrin Cis I ret. time	about 12 minutes
Cypermethrin Cis II ret. time	about 13 minutes
Cypermethrin Trans I ret. time	about 17 minutes
Cypermethrin Trans II ret. time	about 19 minutes
Total analysis time	30 minutes

In order to define the elution order of the four isomers of Cypermethrin, the method was developed starting from CIPAC method 332/TC/M/- (volume 1C, pages 2047-2056) and preliminary non GLP tests on the test item were performed to find the best conditions to avoid any interference and analysis procedure.

CIPAC method 332/TC/M/- stated that using a RX-SIL column and 0.5 % v/v ethyl acetate in iso-octane as eluent the order of elution is isomer αR, 1R-cis + αS, 1S-cis (Cypermethrin Cis I isomer), isomer αS, 1R-cis + αR, 1S-cis (Cypermethrin Cis II isomer), isomer αR, 1R-trans + αS, 1S-trans (Cypermethrin Trans I isomer) and isomer αS, 1R-trans + αR, 1S-trans (Cypermethrin Trans II isomer).

Moreover the detector wavelength to use for Cypermethrin is 278 nm since the four isomers of Cypermethrin have the same molar absorption and consequently the same response.

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of quantification (LOQ) or other limits	Reference
					Range	Mean	RSD		
<i>Cypermethrin</i> (active substance)	The determination of the active ingredient was performed by HPLC using an external standard and a UV detector operating at 278 nm.	<p>Spike A Cypermethrin added (g/kg) 2.47</p> <p>Cypermethrin found (g/kg) 2.34</p> <p>Cypermethrin Recovery (%) 94.71</p> <p>Spike B Cypermethrin added (g/kg) 2.49</p> <p>Cypermethrin found (g/kg) 2.38</p> <p>Cypermethrin Recovery (%) 95.71</p> <p>Total mean recovery (%): 95.2</p>	<p>Cypermethrin Injected range (µg/mL) 51.88 – 207.50 Linearity Range 0.13 - 0.52 % w/w y=16083 x-28960 r=0.9989</p> <p>Cypermethrin Cis isomer Injected range (µg/mL) 23.06 – 92.22 y= 16195 x-16994 r= 0.99993</p> <p>Cypermethrin Trans isomer Injected range (µg/mL) 28.82 –</p>	A comparison of the chromatograms obtained for the different solutions shows that, following the operating conditions recommended in the analytical method, the Cypermethrin active ingredient peaks were well separated and interferences with the Placebo peak were not evidenced. Cypermethrin Cis I RT = 11.629 min Cypermethrin Cis II RT =	Placebo spiked in duplicate at single fortification level. The test was performed by spiking two aliquots of the Placebo with Cypermethrin technical test substance, corresponding to additions of 100 % of the nominal concentration of the active ingredient. Spike A Cypermethrin added (g/kg) 2.47 Cypermethrin found (g/kg) 2.34 Cypermethrin	Total mean recovery (%): 95.2	Cypermethrin 1.27 Cypermethrin Cis isomer 1.01 Cypermethrin Trans isomer 1.55	Not required.	GLP Study No. CH – 0009/2020

	<p>Five test item replicates.</p> <p>Cypermethrin: 0.24±0.003 % w/w Horrat value: 0.38</p> <p>Cypermethrin Cis isomer: 0.11±0.001 % w/w Horrat value: 0.27</p> <p>Cypermethrin Trans isomer: 0.13±0.002 % w/w Horrat value: 0.43</p> <p>cis:trans ratio 46:54</p>	<p>115.28 y= 15993 x-11966 r= 0.99984</p>	<p>13.231 min Cypermethrin Trans I RT = 16.823 min Cypermethrin Trans II RT = 19.220 min</p> <p>Specific: interference from other substances <3% of total peak area.</p>	<p>Recovery (%) 94.71</p> <p>Spike B Cypermethrin added (g/kg) 2.49</p> <p>Cypermethrin found (g/kg) 2.38</p> <p>Cypermethrin Recovery (%) 95.71</p>				
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Specificity

The SANCO/3030/99 rev. 5 guideline requires any interference from other substances present in the preparation should not contribute more than 3 % to the total peak area measured for the active substance.

The specificity test was conducted injecting, in the adjusted chromatographic conditions, the following samples, comparing the chromatograms in order to check possible cross contaminations.

Injected solutions	Nominal injected concentration (µg/mL)
Blank (eluent)	0
Cypermethrin reference material	100
Cypermethrin technical test substance	100
Test item	100

Placebo	0
Fortified Placebo	100

Using the conditions stated in the method, interferences can be avoided and the active ingredient can be reliably determined in test item formulation samples.

Linearity

Linear regression analysis was performed using the least squares method. The correlation coefficient was calculated using regression analysis.

To check linearity, five working standard solutions were prepared and each solution was analysed by HPLC/UV.

No significant memory signal was detected in the washing injected after the highest working standard solution and the range tested for the active ingredient was found to be linear (correlation coefficient $r > 0.99$).

Repeatability (Precision)

Five solutions of the test item (labelled from A to E) were prepared and analysed as detailed in Internal Analytical Method No. 0009/2020.

The stock reference material solution and relevant working standard solutions are the same already prepared for Linearity.

The test item solutions were analysed by HPLC/UV, with those of the working standard solutions.

The precision test was performed by five determinations of the test item (labelled A to E).

From data obtained, the Horrat value resulted to be lower than 1 for the active ingredient and therefore the precision of the analytical method is considered acceptable.

Conclusion on the methods for detection and identification of the product

The HPLC-UV analytical method was found to be valid in terms of linearity, precision, accuracy in accordance with ECHA guidance, for the determination of Cypermethrin (including its isomers), in Free Land Dust formulation.

Analytical methods for monitoring of active substances and residues in food and feeding stuff

Acceptable analytical methods for cypermethrin residues in soil, air and water (as summarized below) are available in the CAR of cypermethrin.

Soil (principle of method and LOQ) (Annex IIA, point 4.2)	GC with MS detection, LOQ = 0.05 mg/kg (LOQ = 0.5 µg/kg for sediment)
Air (principle of method and LOQ) (Annex IIA, point 4.2)	GC with MS detection, LOQ = 0.375 µg/m ³
Water (principle of method and LOQ) (Annex IIA, point 4.2)	GC with electron capture detection, LOQ = 0.01 µg/L
Body fluids and tissues (principle of method and LOQ) (Annex IIA, point 4.2)	Not evaluated
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)	GC with electron capture detection, LOD = 0.05 mg/kg (oilseed rape) and 0.025 mg/kg (wheat)
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)	GC with MS detection, LOQ = 0.05 mg/kg (bovine tissue), 0.005 mg/kg (bovine milk), 0.01 mg/kg (hen eggs).

No analytical methods for residues are necessary for any other co-formulants in the product since none of them is classified as Acute toxicity (cat. 1 - 3), CMR (cat. 1) or STOT (cat. 1). As for co-formulants classified hazardous for the environment, none is present at concentrations which lead to the classification of the product. In conclusion, no co-formulant needs to be monitored.

Conclusion on analytical methods for monitoring of the active substance and residues

Acceptable validated analytical methods for monitoring are available for the detection of cypermethrin in soil, air, water and residues in food and feeding stuff, reported in the CAR for cypermethrin (Belgium, 2017).

A letter of access covering the complete dossier of Agriphar Sprl (now Arysta LifeScience Benelux Sprl) for the active substance Cypermethrin, product type 18, is available from Limaru representing Tagros Chemicals India Ltd on the Article 95 list.

Analytical methods for the detection of Cypermethrin in animal and human body fluids and tissues or further data are not required.

Analytical methods for substances of concern

Please see the confidential annex for further details on evaluation substances of concern.

Conclusion on the methods for Substances of Concern in the product.

An analytical method for the determination of the identified Substance of Concern in the formulation Free Land Dust is not required since SoC cannot be formed during storage and its concentration remains unchanged during storage as applicant stated. However, a GC-FID analytical method has been proposed by the applicant capable to determine the SoC. For further information please refer to confidential section.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

FREE LAND DUST is an insecticide used indoors and outdoors by non-professional and professional users.

All uses can be summarized as follow:

- Crack and crevice application against crawling insects, for non-professional and professional use.
- Direct application against wasp nests, for non-professional and professional use.
- Direct application against ant nests, for non-professional use.
- Spot application around building in the vicinity of windows and doorsteps against *Blatta orientalis*, for non-professional use.

2.2.5.2 Organisms to be controlled and products, organisms or objects to be protected

Efficacy of the product has been demonstrated against the following target organisms:

- ✓ *Lasius niger* (black garden ant)
- ✓ *Blattella germanica* (German cockroaches)
- ✓ *Blatta orientalis* (Oriental cockroaches)
- ✓ *Vespula spp.* (German wasp)

2.2.5.3 Effects on target organisms, including unacceptable suffering

FREE LAND DUST is an insecticide with the following effects on target organisms:


- Knockdown effect
- killing effect
- population reduction
- eradication of both ants and wasps nests.

2.2.5.4 Mode of action, including time delay

Cypermethrin is a synthetic pyrethroid effective by contact and ingestio. 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.

2.2.5.5 Efficacy data

Experimental data on the efficacy of the biocidal product against target organism(s)					
Test substance	Test organism	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
Cypermethrin 0.25 % "Free Land Dust"	<i>Blattella germanica</i> , <i>Periplaneta americana</i> Development stage: adults Laboratory strains <i>Lasius niger</i> Development	Laboratory test	Laboratory conditions. T: 25 °C+/-1%, RH: 60%+/-5%. No-choice test. The product is applied in non-porous surfaces (ceramic tiles side up) at a dose of 8g per 1m ² . For cockroaches 3 batches (replicates) of 20 adults and for ants 4 batches (replicates) of 25 workers were forced to stay in contact with the treated surfaces	<i>Blattella germanica</i> Knock down was 100% in 7 minutes and mortality was 100% after 24 hours, for fresh and 4 weeks deposits. Mortality in untreated control: 0%. <i>Periplaneta americana</i> Knock down was 100% in 30-	██████, 2019a Trial 1

	stage: adult workers Laboratory strains		for 1 hour. The insects were transferred to untreated inert surfaces with a nutritious substratum and water available. Assessments of knockdown and/or killing effect were performed up to 1 hour after exposure. Mortality was recorded 24 hours later. The tests were conducted after treatment and repeated with the treated non-porous tiles stored for 4 weeks to measure the residual effect (1, 2, 3, 4 weeks after the first treatment). Untreated control was included.	50 minutes and mortality was 100% after 24 hours, for fresh and 4 weeks deposits. Mortality in untreated control: 0%. <i>Lasius niger</i> Knock down was 100% in 10 minutes and mortality was 100% after 24 hours, for fresh and 4 weeks deposits. Mortality in untreated control: 0%.	
Cypermethrin 0.25 % "Free Land Dust"	<i>Blatta orientalis</i> Development stage: adults & nymphs Laboratory strains	Simulated use test Choice test C&C	Laboratory conditions. T: 25 °C+/-1%, RH: 60%+/-5%. Choice test. The trial was carried out in a test chamber of 12m ³ (6m ² floor – 3 m long x 2 m wide x 2 m high) in porous and non-porous surfaces. Inside the test chamber, a device simulating "cracks and crevices" is set and contains the treated tiles (porous and non-porous in two separate trials). The "cracks and crevices device" is a pile of 5 non-porous lacquer wood boards of 1 m x 1 m (usual dimensions of kitchen furniture), assembled together but letting a 3 cm space between each other in order to create the cracks/crevices. On the first 15 cm of these cracks/crevice (entry of the "furniture"), some tiles 15 cm x 15 cm are set and they are the materials that are treated. Water & food source were set on the corners of the test chamber. The pests were able to reach water and food sources without being in contact with the treated surfaces. The panels present in the treated area are useful to keep the insecticide intact, to be used for assessments in the following weeks. The product was applied using its bottle directly onto the harborages on the treated side at 8 gr per 1 m ² . The cracks and crevices treatment was done on a max area of 2m ² to adhere as closely as possible to practical conditions. Then 5 batches of 25 cockroaches (adults and nymphs) were placed in the test arenas after the treatment. Assessments of knockdown and/or killing effect were performed 4 hour after exposure. Mortality was recorded 24 hours later.	In all types of surfaces knockdown was 100% in 4 hours in fresh and 4 weeks deposits. In all types of surfaces mortality was 100% 24 hours after the treatment in fresh and 4 weeks deposits. Mortality in untreated control: 0%.	 2020a Trial 2

			<p>The tests were conducted after treatment and repeated with the treated tiles stored for 4 weeks to measure the residual effect (1, 2, 3, 4 weeks after the first treatment). 5 replications were carried out. Untreated control was used.</p>		
<p>Cypermethrin 0.25 % "Free Land Dust"</p>	<p><i>Blatta orientalis</i> Development stage: adults & nymphs Laboratory strains</p>	<p>Simulated use test Choice test Spot application</p>	<p>Laboratory conditions. T: 25 °C+/-1%, RH: 60%+/-5%. Choice test. The trial was carried out in a test chamber of 12m³ (6m² floor – 3 m long x 2 m wide x 2 m high) in porous and non-porous surfaces. A few cardboards (to give harborages to the pests) and a water & food source were set on the floor of the test chamber, both sides, treated and untreated. Food and water sources were placed along all the floor, also on the treated surfaces. The pests were able to reach water and food sources without being in contact with the treated surfaces. The pests have many places to hide: harborages, also in the treated part. Harborages, food and water are evenly distributed throughout the floor but only the harborages in the treated half area, are treated with insecticide. The panels present in the treated half area are useful to move and keep the insecticide intact, to be used for assessments in the following weeks. 5 batches of 25 cockroaches (adults and nymphs) were placed in the test arenas after the treatment. The product was applied at 8 gr per 1 m² by scattering the dust in some spots among the total treated area. Assessments of knockdown and/or killing effect were performed 4 hour after exposure. Mortality was recorded 24 hours later. The tests were conducted after treatment and repeated with the treated tiles stored in outdoor conditions (roof-covered) for 4 weeks to measure the residual effect (1, 2, 3, 4 weeks after the first treatment). 5 replications were carried out. Untreated control was used.</p>	<p>In all types of surfaces knockdown was 100% in 4 hours in fresh and 4 weeks deposits. In all types of surfaces mortality was 100% 24 hours after the treatment in fresh and 4 weeks deposits. Mortality in untreated control: 0%.</p>	<p>██████████, 2020b Trial 3</p>
<p>Cypermethrin 0.25 % "Free Land Dust"</p>	<p><i>Blattella germanica</i></p>	<p>Field test Indoors C&C</p>	<p>Field conditions in occupied public housing for the elderly with infestation of German cockroaches. The presence of cockroaches was evaluated using sticky traps for three nights</p>	<p>Mean percentage reduction in <i>B. germanica</i> population were 93.7% 4 days after treatment. 100% population reduction was recorded against German</p>	<p>██████████, 2020a Trial 4</p>

			<p>before the treatment. Then the product was applied at 8 gr of product per 1m² in cracks and crevices. Maximum area of the application was 2 m²/replication (25m²).</p> <p>The presence of cockroaches was evaluated 4 days, 1, 2 and 4 weeks after the treatment using sticky traps for three nights for each assessment.</p> <p>3 sites of 25 m² (replicates) with infestation were treated. Untreated control was used.</p>	<p>cockroaches after 1 and 2 weeks.</p> <p>98.8% population reduction was recorded against German cockroaches after 3 and 4 weeks.</p> <p>Untreated control: before the treatment the mean number of cockroaches per replicate was 12.7.</p> <p>Mean number of cockroaches per replicate was 10.3, 9.5, 11, 11.2 and 12.3 24 hours, 1, 2, 3 and 4 weeks later, respectively.</p>	
<p>Cypermethrin 0.25 %</p> <p>"Free Land Dust"</p>	<i>Blatta orientalis</i>	Field test Indoors C&C	<p>Field conditions in occupied public housing for the elderly with infestation of Oriental cockroaches. The presence of cockroaches was evaluated using sticky traps for three nights before the treatment.</p> <p>Then the product was applied at 8 gr of product per 1m² in cracks and crevices. Maximum area of the application was 2 m²/replication (25m²).</p> <p>The presence of cockroaches was evaluated 4 days, 1, 2 and 4 weeks after the treatment using sticky traps for three nights for each assessment.</p> <p>3 sites of 25 m² (replicates) with infestation were treated. Untreated control was used.</p>	<p>Mean percentage reduction in <i>B. orientalis</i> population were 100% 4 days and 1 week after treatment.</p> <p>89.6%, 95.5% and 98% population reduction was recorded against Oriental cockroaches after 2, 3 and 4 weeks, respectively.</p> <p>Untreated control: before the treatment the mean number of cockroaches per replicate was 14.7.</p> <p>Mean number of cockroaches per replicate was 9.3, 11, 9.8, 10.7 and 13.8 24 hours, 1, 2, 3 and 4 weeks later, respectively.</p>	<p>██████████, 2020b Trial 5</p>
<p>Cypermethrin 0.25 %</p> <p>"Free Land Dust"</p>	<i>Lasius niger</i>	Field test Indoors C&C	<p>Field conditions in occupied public housing for the elderly with infestation of ants. The presence of ants was evaluated using sticky traps.</p> <p>Then the product was applied at 8 gr of product per 1m² in cracks and crevices. Maximum 16 gr per room.</p> <p>The presence of cockroaches was evaluated 24 hours, 1, 2 and 4 weeks after the treatment using sticky traps for three nights for each assessment.</p> <p>3 sites of 15-32 m² (replicates) with infestation were treated. Untreated control was used.</p>	<p>Mean percentage reduction in <i>L. niger</i> population were 91.8% 24 hours after treatment.</p> <p>97.4% population reduction was recorded against ants after 1 week.</p> <p>100% population reduction was recorded against ants after 3 and 4 weeks.</p> <p>Untreated control: Mean population increase of ants per replicate was 0.6%, 4.1%, 7.4%, 6.9% and 13.5% 24 hours, 1, 2, 3 and 4 weeks later, respectively.</p>	<p>██████████, 2021 Trial 6</p>
<p>Cypermethrin 0.25 %</p> <p>"Free Land Dust"</p>	<i>Lasius niger</i>	Field test Outdoors Ant nests	<p>Ant nests outdoors (house gardens/terrace) were treated with the product at 5gr per nest. Treatment is performed at the entrances of the nests and in a zone of 1 m² around the nests. The frequency of ant's passage was counted for 5 minutes on 1 m² surfaces around nest entrance 1 day before and 1, 3, 7, 14, 21 and 28 days after the treatment. 4 weeks (28 days) post treatment the nests were opened to check for any living</p>	<p>Mean population reduction was 68.2%, 94.5%, 97.1% 99.5% 24 hours, 3 days, 1 week and 2 weeks after treatment.</p> <p>100% population reduction was recorded against ants after 3 and 4 week with total nest kill (adults/larvae/nymphs/queens).</p> <p>In the untreated control nests 11.7% population increase was recorded after 4 weeks.</p>	<p>██████████, 2020c Trial 7</p>

			insects/brood/queen. Untreated nests were used for control. 5 treated and 5 untreated nests were used as replicates.		
Cypermethrin 0.25 % "Free Land Dust"	<i>Vespula germanica</i> Field collected	Laboratory test	Laboratory conditions. T: 25 oC+/-1%, RH: 60%+/-5%. No-choice test. The product is applied in non-porous surfaces (ceramic tiles side up) at 8g per 1m ² . 3 batches (replicates) of 10 wasps were forced to stay in contact with the treated surfaces for 10 minutes. Then the insects were transferred to a healthy environment to observe mortality after 1 hour. Untreated control was included.	Knock down was 100% in 7 minutes and mortality was 100% after 1 hour. Mortality in untreated control: 0%.	, 2019b Trial 8
Cypermethrin 0.25 % "Free Land Dust"	<i>Vespula germanica</i>	Field test	Five wild wasps nests of <i>Vespula germanica</i> were found in the field in cavities (ground cavity, concrete cavity). 3 of them were found outdoors and 2 indoors. The product was applied at the entrance (opening) of the nest at a dose of 10gr/nest. The activity of the nest was determined 1 day before the treatment and the day of the treatment counting the number of the wasps entering or leaving the nest for five minutes at two different times of day. The same counting was done 24 hours, one week and two weeks after the treatment. The assessments were done at the same hour for the whole test. 5 replications were carried out (nests). Untreated control was used (5 nests). Climatic parameters during the tests: T: 13-28.5°C, 20mm rain/day.	Mean percentage reduction in <i>V. germanica</i> population was 100%, 24 hours, 1 week and 2 weeks after treatment. Untreated control nests: before the treatment the number of wasps per nest was 43-72. Mean number of wasps per nest was 62.6, 58.6 and 61.6 24 hours, 1 week and 2 weeks later, respectively.	, 2020d Trial 9

Conclusion on the efficacy of the product

Several efficacy studies (laboratory, simulated use and field studies) were submitted for FREE LAND DUST (Ready to Use product) containing cypermethrin 0.25%. Based on the results of the submitted efficacy studies, the product was effective when applied as:

- Crack and crevice application against crawling insects indoors at 8 gr/m², by professional and non-professionals. (Intended Uses 1 & 3)
- Direct application on wasp nests indoors at 10 gr/ nest, by professionals and non-professionals. (Intended Uses 2&4)
- Direct application on ant nests at 5 gr/ nest, by non-professionals. (Intended Use 5)
- Spot application outdoors around building in the vicinity of windows and doorsteps against *Blatta orientalis*, by non-professional users. (Intended Use 6)

2.2.5.6 Occurrence of resistance and resistance management

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

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

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

Resistance management strategies

Because resistance is well known to be a potential problem, strategies to avoid resistance are normal practice. For example, the use of alternating sequences, mixtures and avoidance of frequent repeated use are standard. General advice is provided by IRAC (Anon. 1987).

The eCA proposes the following principles of strategies for managing the development of resistance:

For professionals:

- Take into account the life cycle and characteristics of target insects to adapt treatments. In particular, target the most susceptible stage of the pest, timing of applications and areas to be treated.
- Where possible, application treatments should be recommended to be combined with non-chemical measures.
- Where an extended period of control is required, treatments should be alternated with products having active substances with different modes of action.
- Establish a baseline and monitor levels of effectiveness on populations in key areas in order to detect any significant changes in susceptibility to active substance. Information from resistance monitoring programs allows early detection of problems and gives information for correct decision making.
- The users should inform if the treatment is ineffective and report straightforward to the registration holder or the distributor.
- The authorization holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management.
- Do not use/apply the product in areas where resistance to the active substance contained in this product is suspected or established.
- Do not [use/apply] the product in areas where resistance to the active substance (s) contained in this product is suspected or established.

For non-professionals:

- If the infestation persists, contact a professional.

2.2.5.7 Known limitations

Unintended effects

According to the efficacy trials on FREE LAND DUST and to cypermethrin properties, no limitations of FREE LAND DUST are known.

Known limitations on efficacy of the biocidal product

According to the efficacy trials on FREE LAND DUST and to cypermethrin properties, no limitations of FREE LAND DUST are known.

2.2.5.8 Evaluation of the label claims

According to the submitted PAR and SPC, the intended uses (label claims) as applied for by the applicant including target organisms, dose rates and application methods are as follows:

The product is intended to be used as spot treatment in cracks and crevices indoors against crawling insects, for non-professional and professional use (Intended uses 1&3), as direct application against wasp nests indoors and outdoors, for non-professional and professional use (Intended uses 2&4), as direct application against ant nests outdoors, for non-professional use (Intended use 5) and as spot application around building outdoors against *Blatta orientalis*, for non-professional use (Intended use 6).

Trials submitted by the applicant to substantiate label claims:

Intended Uses 1&3 (professional & non-professional use)

Cracks and crevice application in voids and cavities indoors against crawling insects

Trial 1

The results of the laboratory study (non-choice test) by [REDACTED] (2019a) show that Free Land Dust was effective when applied at 8 gr product/ m² in non-porous surfaces, against *B. germanica*, *P. americana* and *L. niger* for up to 4 weeks post treatment, providing 100% knockdown in 7-50 minutes and 100% mortality 24 hours after exposure of all the target species to fresh and 4-week aged non-porous treated surfaces.

In the study report it is stated that the product was tested against cockroaches and ants on non-porous surfaces, whereas according to the guidance treated surfaces should include at least one porous and one non-porous substrate, representing surfaces that might, typically, be treated for cockroach and ant control.

The applicant to support testing only on non-porous surfaces provided the following justification (available in R4BP3):

"A general definition of porous material, is that a porous material has accessible voids which are permeable to liquids or gases. But it is not complete definition and scientifically acceptable. Another definition results from the book "Novel Materials for Carbon Dioxide Mitigation Technology, 2015": A porous material can be defined simply as any solid containing void space(s), i.e., space not occupied by the main framework of atoms that make up the structure of the solid. Following this last definition, there are a lot of porous material with different kinds of properties. Therefore, one of the basic requisites of comprehensive characterization of porous material is the characterization and classification of pores. In the case of use of Freeland DUST and to evaluate its bioavailability on the treated surfaces, it's important understand if it's possible that the porous surface adsorb

the product avoids the contact with the target's organisms. In order to understand if the particles of product can penetrate the surface it's necessary to define the pores sizes. There are various categorizations of pores described in the literature, but it's difficult to give a consistent global classification of porous substances. The study "Pore classification in the characterization of porous materials" (Borislav D. Zdravkov*, Jiřr'ı J. ĀCerm'ak, Martin ĀSefara, Josef Jank'ou Department of Environmental Chemistry, The Institute of Chemical Technology Prague, 2006; accepted 16 January 2007) it's possible to find a generic definition based on pores sizes:

Table 2 Unified pore size classification.

Pore types	Macro-	Meso-	Supermicro -	Micro-	Submicro-	Ultramicro-	Subultramicro-
Pore size, nm	$d > 50$	$50 > d$ $d > 3 \div 3.2$	$3 \div 3.2 > d$ $d > 1.4$	$d = 1.2 \div 1.4$	$1.2 > d$ $d > 0.7$	$0.7 > d$ $d > 0.35$	$d < 0.35$

In the Guidance on the Biocidal Products Regulation Volume II: Efficacy Part A: Information Requirements Version 2.1, March 2022, there isn't a definition on porous surface, anyway there are a lot of example in Guidance Efficacy Evaluation of Insecticides PT 18 and 19: At point 3.2.2.2 about cockroaches: "Treated surfaces should include at least two porous and one non-porous substrate representing surfaces that might, typically, be treated for bedbug control (e.g. plywood, painted plywood, textile fabric, wallpaper, according to the label claim)", now considering that this type of product is not recommended for use on wallpaper, as more porous surfaces than painted plywood; we can take in consideration plywood as representative porous surface for this kind of product.

The study "Porosity and pore size distribution of different wood types as determined by mercury intrusion porosimetry" (Michael Plötze · Peter Niemz Published online: 27 November 2010" give a complete description of pores sizes of different kinds of woods. In this study the wood with largest pores is Kiefer/Scots pine: Most frequent pore radius of 12454,8nm and Characteristic pore radius of 4044,4nm. We can consider this kind of wood very porous in relation to the table 2. The Study number CH-0008/2020 by methods CIPAC MT59 and MT170 of Chemservice on Freeland dust show that more than 96.5 % of the test item presents a particle size higher than 180µm (180000nm) and 0.02 % of test item presents a particle size lower than 45µm (45000nm).

If we consider a general definition of porous surface, it is possible to conclude that Freeland DUST doesn't be adsorbed from porous surface, because it is a solid and not liquid or gas. Anyway, according to the scientific literature, is acceptable consider the wood of pine very porously material (medium size of 4000nm and most frequent radius of 12454,8nm).

It can also be considered that the porous surfaces, used during a normal use of the product, cannot decrease the bioavailability of the product (adsorb the product) because it's physically impossible that the particles of Freeland DUST creeps in a pore of surface. More than 96.5 % of Freeland dust have a particle size higher than 180µm: minimum 14 times a lot bigger than the pores of porous surface.

In conclusion, the Bioavailability of the product and of the active ingredients is the same in porous and nonporous surfaces, therefore the efficacy is expected to be the same if the product is used on porous or on nonporous

surfaces”

Following the aforementioned justification by the applicant, the eCA suggests that the study by [REDACTED] (2019a) using only non-porous surfaces supports the claim against *B. germanica* and *L. niger*.

Trial 2

In the simulated use test (choice test) by [REDACTED] (2020a) Free Land Dust was applied as crack and crevice at 8 gr product/m² against Oriental cockroach in fresh and 4 weeks deposits, providing 100% knockdown in 4 hours and 100% mortality 24 hours after exposure of the Oriental cockroach to fresh and 4-week aged porous and non-porous treated surfaces.

It is noted that according to the results, 100% knock down against cockroaches was achieved in 4 hours, after contact with fresh and 4 weeks aged surfaces. However, according to the efficacy guidance, for non-professional use >90% knock down within a few minutes after contact with the product, direct after spray and at the end of the residual period, is required.

Trial 4

The results of the field study by [REDACTED] (2020a) show that Free Land Dust when applied as crack and crevice treatment at 8gr of product/ m² was effective against German cockroaches providing 93.7-100% cockroach population reduction for up to 4 weeks after treatment. According to the study report the first assessment of population reduction was done 4 days after the treatment.

Trial 5

The results of the field study by [REDACTED] (2020b) show that Free Land Dust when applied as crack and crevice treatment at 8gr of product/ m² was effective against Oriental cockroaches providing 89.6-100% cockroach population reduction for up to 4 weeks after treatment. According to the study report the first post assessment of population reduction was done 4 days after the treatment.

Trial 6

The results of the field study by [REDACTED] (2021) show that Free Land Dust when applied as crack and crevice treatment at 8gr of product/ m² was effective against *L. niger* providing 89.6-100% ant population reduction for up to 4 weeks after treatment. According to the study report the first assessment of population reduction was done 24 hours after the treatment.

Based on the results of the aforementioned efficacy studies, the intended uses 1 (professional use) & 3 (non-professional use), from an efficacy point of view, are acceptable as applied for by the applicant, noting however the following:

- In the simulated use test (choice test) by [REDACTED] (2020a) the product provided 100% knockdown in 4 hours after exposure of the Oriental cockroach to fresh and 4-week aged porous and non-porous treated surfaces. However, according to the efficacy guidance, for non-professional use >90% knock down within a few minutes after contact with the product, direct after spray and at the end of the residual period, is required. Hence, the following limitation is proposed to be added in Intended use 3 for non-professionals: “Knockdown of Oriental cockroaches is expected 4 hours after exposure to the treated surfaces”.

- For consistency reasons, the application method against crawling insects indoors is proposed to be "Crack and crevice application in voids and cavities against crawling insects", because it should align with the application method tested in the simulated use and field efficacy studies, noting that according to the guidance, the spot treatment and the crack & crevice treatment are two different application methods.

Intended Uses 2&4 (professional & non-professional use) **Direct application against wasp nests indoors and outdoors**

Trial 8

The results of the laboratory study (non-coice test) by █████ (2019b) show that Free Land Dust was effective when applied at 8 gr product/ m² in non-porous surfaces, against *V. germanica*, providing 100% knockdown in 7 minutes and 100% mortality 24 hours after exposure of wasps to non-porous treated surfaces.

Trial 9

The results of the field study by █████ (2020d) show that Free Land Dust, was effective as direct application against wasp nests at 10gr/nest, providing no visible signs of nest activity (100% mortality) against wasps 2 weeks after treatment in all treated wasp nests. Mean percentage reduction in *V. germanica* population was 100%, 24 hours, 1 week and 2 weeks after treatment.

As clarified by the applicant, the nest treated were found indoors and outdoors (3 outdoors and 2 indoors).

According to the guidance for products intended for the control of wasp nests, field trial with at least 5 treated nests is required, which means that 5 treated nests outdoors should have been treated in order to support the outdoor use.

Hence, it seems that this study does not fulfil the requirements of the guidance, in terms of test design, to support the label claim against wasp nests outdoors.

The sum of 5 replicates of the study (3 outdoors+2 indoors) support efficacy against wasp nests indoors considering wasp nests outdoors as worse case scenario covering the indoor use.

Based on the results of the aforementioned efficacy studies, the intended uses 2 (professional use) & 4 (non-professional use), from an efficacy point of view, are acceptable as applied for by the applicant, noting however the following:

- The wasp nest treatment outdoors is not supported by the efficacy field study by █████ (2020d) considering that only 3 replicates (wasp nests) outdoors were used, not 5 as required in the guidance.
- The instructions for the product to be applied "Application must be done at recommended rate on the nest or possibly at the entrance of the nest" is proposed to be changed to "Application must be done at recommended rate at the entrance of the nest", following the application method of the product in the field study by █████ 2020d.

Intended Use 5

Direct application against ant nests outdoors, for non-professional use

Lab study (non-choice test) by [REDACTED], 2019a (Described in intended uses 1&3).

Trial 7

The results of the field study by [REDACTED] (2020c) show that Free Land Dust, was effective as direct application against ant nests at 5 gr/nest, providing a total nest kill 4 weeks after treatment in all treated ant nests.

Mean percentage reduction in *L. niger* population was 68.2%, 94.5%, 97.1% and 99.5%, 24 hours, 3 days, 1 week and 2 weeks after treatment, respectively.

Mean percentage reduction in *L. niger* population was 100%, 3 and 4 weeks after treatment, respectively.

Based on the results of the aforementioned efficacy studies, the intended use 5, from an efficacy point of view, is acceptable as applied for by the applicant, noting however the following:

- The instructions for the product to be applied "Manual application at the entrance of the nest" is proposed to be changed to "Manual application around and at the entrance of the nest", following the application method of the product in the field study by [REDACTED] (2020c).

Intended Use 6

Spot application around building against *Blatta orientalis* outdoors, for non-professional use

Trial 3

In the simulated use test (choice test) by [REDACTED] (2020b) Free Land Dust was applied as spot application at 8 gr product/m² against Oriental cockroach in fresh and 4 weeks deposits, providing 100% knockdown in 4 hours and 100% mortality 24 hours after exposure of the Oriental cockroach to fresh and 4-week aged porous and non-porous treated surfaces. It was clarified by the applicant that the product was applied by scattering the dust in some spots among the total treated area, thus simulating a spot treatment. In the study report it is mentioned that the treated porous and non-porous surfaces were stored in outdoor conditions in order to support the outdoor use.

Based on the results of the aforementioned efficacy study, the intended use 6, from an efficacy point of view, is acceptable as applied for by the applicant, noting however the following:

- In the simulated use test (choice test) by [REDACTED] (2020b) the product provided 100% knockdown in 4 hours after exposure of the Oriental cockroach to fresh and 4-week aged porous and non-porous treated surfaces. However, according to the efficacy guidance, for non-professional use >90% knock down within a few minutes after contact with the product, direct after spray and at the end of the residual period, is required. Hence, the following limitation is proposed to be added in Intended use 6: "Knockdown of Oriental cockroaches is expected 4 hours after exposure to the treated surfaces".

2.2.5.9 Relevant information if the product is intended to be authorised for use with other biocidal product(s)

FREE LAND DUST is not intended to be authorised for use with other biocidal products.

2.2.6 Risk assessment for human health

General information

Human health risk assessment has been performed according to indication provided in ECHA Guidance on the Biocidal Products Regulation, Volume III, Human Health - Assessment & Evaluation (Parts B+C), Version 4.0, December 2017. Exposure assessment has been performed according to the ECHA Biocides Human Health Exposure Methodology (2015), the TNSG on Human Exposure (2002) and, where applicable, the User Guidance (2002) as well as the TNSG on Human Exposure (2007).

The assessment of effects on human health for FREE LAND DUST has been developed having as starting point the rules outlined in CLP Regulation. More specifically, article 11 of CLP Regulation states *"where a mixture contains a substance classified as hazardous, whether as a component or in the form of an identified impurity or additive, this information shall be taken into account for the purposes of classification, if the concentration of that substance is equal to or greater than its cut-off value. The cut-off value referred shall be determined as set out in CLP Regulation, section 1.1.2.2 of Annex I"*. This approach was deemed as appropriate also in the light of the criteria outlined in article 3.1(f) of Biocidal Products Regulation to identify the substances of concern in a biocidal product.

The biocidal product FREE LAND DUST contains:

- several substances that are not classified (i.e. not hazardous)
- one substance that is classified; this substance is present in the biocidal product in a concentration below the cut-off values determined according to art. 11 of CLP Regulation.

The toxicological hazard assessment of the biocidal product FREE LAND DUST relied on the toxicological information available for the active substance (i.e. cypermethrin) and all the co-formulants (please refer to the Confidential Annex).

Regarding the active substance cypermethrin, the classification adopted in the RAC Opinion in December 2019 was taken into account for the toxicological risk assessment. According to the RAC opinion, cypermethrin is classified H302; H332; H335; H373.

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not irritant to skin.
Justification for the value/conclusion	<p>No data for FREE LAND DUST is provided. The classification of the product was conducted by the calculation method, based on the RAC opinion of cypermethrin (December 2019) and the MSDS of the other components of the product in respect to classification criteria of the Regulation (EC) No. 1272/2008 (CLP).</p> <p>Neither the active substance nor the co-formulants of the biocidal product FREE LAND DUST are classified for skin corrosion and irritation, hence no classification is triggered for the biocidal product,</p>

	<p>according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP).</p> <p>For more information please refer to Confidential Annex.</p>
Classification of the product according to CLP	Not classified.

Data waiving

Information requirement	<p>Skin corrosion and irritation.</p> <p>Testing on the product does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP).</p>
Justification	<p>Since the available data on each of the components allow to estimate the classification of the product, data waiving is acceptable and the classification of the product can be estimated by calculation method considering all the components relevant for this endpoint.</p>

Eye irritation

Conclusion used in Risk Assessment – Eye irritation

Value/conclusion	Not irritant to eyes.
Justification for the value/conclusion	<p>No data for FREE LAND DUST is provided. The classification of the product was conducted by the calculation method, based on the RAC opinion of cypermethrin (December 2019) and the MSDS of the other components of the product in respect to classification criteria of the Regulation (EC) No. 1272/2008 (CLP).</p> <p>The biocidal product FREE LAND DUST contains one co-formulant classified for Eye Damage Cat. 1 (H318). However, as its concentration is well below the generic concentration limit set out in Regulation (EC) No. 1272/2008 (CLP), no classification for eye damage/irritation is triggered for the biocidal product FREE LAND DUST.</p> <p>For more information please refer to Confidential Annex.</p>
Classification of the product according to CLP	Not classified.

Data waiving

Information requirement	<p>Eye irritation.</p> <p>Testing on the product does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP).</p>
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Justification	Since the available data on each of the components allow to estimate the classification of the product, data waiving is acceptable and the classification of the product can be estimated by calculation method considering all the components relevant for this endpoint.
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Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	Not irritating to the respiratory tract.
Justification for the conclusion	<p>There are currently no designated tests for the determination of respiratory tract irritation.</p> <p>No data for FREE LAND DUST is available on respiratory tract irritation.</p> <p>The classification of the product was conducted by the calculation method, based on the RAC opinion of cypermethrin (December 2019) and the MSDS of the other components of the product in respect to classification criteria of the Regulation (EC) No. 1272/2008 (CLP).</p> <p>The active substance cypermethrin is the only ingredient of the biocidal product FREE LAND DUST classified as STOT SE Cat. 3, H335. However, as its concentration in the product is well below the generic concentration limit set out in Annex I of Regulation (EC) No. 1272/2008, the product is not expected to exert respiratory tract irritation.</p> <p>Therefore, the biocidal product FREE LAND DUST is not classified as a respiratory tract irritant, according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP).</p> <p>For more information please refer to Confidential Annex.</p>
Classification of the product according to CLP	Not classified.

Data waiving	
Information requirement	<p>Respiratory tract irritation.</p> <p>Testing on the product/mixture does not need to be conducted, if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP). Please refer to the Confidential Annex of this PAR.</p>
Justification	Since the available data on each of the components allow to estimate the classification of the product, data waiving is acceptable and the classification of the product can be estimated by calculation method considering all the components relevant for this endpoint.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not sensitizing to skin.
Justification for the value/conclusion	<p>No data for FREE LAND DUST is provided. The classification of the product was conducted by the calculation method, based on the RAC opinion of cypermethrin (December 2019) and the MSDS of the other components of the product in respect to classification criteria of the Regulation (EC) No. 1272/2008 (CLP).</p> <p>Neither the active substance nor the co-formulants of the biocidal product FREE LAND DUST are classified for skin sensitisation, hence no classification is triggered for the product, according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP).</p> <p>For more information please refer to Confidential Annex.</p>
Classification of the product according to CLP	Not classified.

Data waiving	
Information requirement	<p>Skin sensitisation.</p> <p>Testing on the product/mixture does not need to be conducted, if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP).</p>
Justification	<p>Since the available data on each of the components allow to estimate the classification of the product, data waiving is acceptable and the classification of the product can be estimated by calculation method considering all the components relevant for this endpoint.</p>

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not a respiratory sensitizer.
Justification for the value/conclusion	<p>There are currently no standard tests and no OECD test guidelines available for respiratory sensitisation and there is no testing requirement for this endpoint under the BPR.</p> <p>No specific respiratory sensitisation study is available for FREE LAND DUST.</p> <p>The classification of the product was conducted by the calculation method, based on the RAC opinion of cypermethrin (December 2019) and the MSDS of the other components of the product in respect to classification criteria of the Regulation (EC) No. 1272/2008 (CLP).</p> <p>Neither the active substance nor the co-formulants of FREE LAND DUST are classified as respiratory sensitizers. Therefore, the biocidal product does not meet the criteria for classification for respiratory sensitisation according to the rules laid down in Regulation (EC) No.</p>

	1272/2008 (CLP). For more information please refer to Confidential Annex.
Classification of the product according to CLP	Not classified.

Data waiving

Information requirement	Respiratory sensitization (ADS). Testing on the product does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP).
Justification	Since the available data on each of the components allow to estimate the classification of the product, data waiving is acceptable and the classification of the product can be estimated by calculation method considering all the components relevant for this endpoint.

Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity

Value	Non-toxic <i>via</i> the oral route.
Justification for the selected value	Acute oral toxicity data are not available for FREE LAND DUST. For this endpoint the classification has been estimated by the application of the rules of CLP Regulation, Annex I, point 3.1.3.6. Classification of mixtures based on ingredients of the mixture (Additivity formula). Cypermethrin and one co-formulant of the biocidal product FREE LAND DUST are classified for Acute Oral Toxicity Cat. 4 (H302). However, as their concentration in the product is below 1%, no classification for acute oral toxicity is triggered for the biocidal product, according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP). For more information please refer to Confidential Annex.
Classification of the product according to CLP	Not classified.

Data waiving

Information requirement	Acute oral toxicity. Testing on the product/mixture does not need to be conducted, if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP).
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Justification	Since the available data on each of the components allow to estimate the classification of the product, data waiving is acceptable and the classification of the product can be estimated by calculation method considering all the components relevant for this endpoint.
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Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Non-toxic <i>via</i> the inhalation route.
Justification for the selected value	<p>Acute inhalation toxicity data are not available for FREE LAND DUST. For this endpoint the classification has been estimated by the application of the criteria of CLP Regulation, Annex I, point 3.1.3.6. Classification of mixtures based on ingredients of the mixture (Additivity formula).</p> <p>Cypermethrin and one co-formulant of the biocidal product FREE LAND DUST are classified for Acute Inhalation Toxicity Cat. 4 (H332). However, as their concentration in the product is below 1%, no classification for acute inhalation toxicity is triggered for the biocidal product, according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP).</p> <p>For more information please refer to Confidential Annex.</p>
Classification of the product according to CLP	Not classified.

Data waiving	
Information requirement	<p>Acute inhalation toxicity.</p> <p>Testing on the product/mixture does not need to be conducted, if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP).</p>
Justification	Since the available data on each of the components allow to estimate the classification of the product, data waiving is acceptable and the classification of the product can be estimated by calculation method considering all the components relevant for this endpoint.

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Non-toxic <i>via</i> the dermal route.
Justification for the selected value	<p>Acute dermal toxicity data are not available for FREE LAND DUST. For this endpoint the classification has been estimated by the application of the criteria of CLP Regulation, Annex I, point 3.1.3.6. Classification of mixtures based on ingredients of the mixture (Additivity formula).</p> <p>Neither the active substance nor the co-formulants of FREE LAND</p>

	DUST are classified for acute dermal toxicity. Therefore, the biocidal product does not meet the criteria for classification for acute dermal toxicity according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP).
Classification of the product according to CLP	Not classified.

Data waiving

Information requirement	Acute dermal toxicity. Testing on the product/mixture does not need to be conducted, if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP).
Justification	Since the available data on each of the components allow to estimate the classification of the product, data waiving is acceptable and the classification of the product can be estimated by calculation method considering all the components relevant for this endpoint.

Other effects

Conclusion used in Risk Assessment – Other effects

Value/conclusion	STOT RE Cat. 2
Justification for the value/conclusion	According to the RAC opinion (December 2019), cypermethrin is classified as STOT RE Cat. 2, H373. However, as its concentration in the biocidal product FREE LAND DUST (0.263%) is below 10%, which is the generic concentration limit triggering classification of a product for STOT RE Cat. 2, no classification is triggered for the biocidal product FREE LAND DUST, according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP). For more information please refer to Confidential Annex.
Classification of the product according to CLP	Not classified.

Information on dermal absorption

Dermal absorption data for FREE LAND DUST is not available; therefore, default value of dermal absorption has to be used in the risk assessment, as proposed in the current EFSA Guidance on dermal absorption [EFSA Journal, 2017; 15(6): 4873].

Value(s) used in the Risk Assessment – Dermal absorption

Substance	Cypermethrin
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Value(s)	50%
Justification for the selected value	<p>A dermal study has not been performed with the biocidal product FREE LAND DUST, therefore a default value of dermal absorption has to be used.</p> <p>According to EFSA Guidance on dermal absorption [EFSA Journal, 2017; 15(6): 4873], in order to choose the suitable default value, the formulation category of the product and the concentration of the active substance in the product must be taken into consideration.</p> <p>FREE LAND DUST is a solid formulation and the concentration of cypermethrin in the biocidal product is 0.263%. As the percentage of the active substance in the product is below 5%, that is the threshold used to identify dilutions according to the previous EFSA Guidance on Dermal Absorption (2012, section 6.1), a default dermal absorption value of 50% will be considered in the risk assessment, as proposed in the current EFSA Guidance for dilutions of solid formulations.</p>

Data waiving	
Information requirement	Dermal absorption
Justification	In the absence of relevant dermal absorption data with FREE LAND DUST, the default value of 50% will be considered in the risk assessment for the active substance, as proposed in the current EFSA Guidance on dermal absorption for dilutions of solid formulations [EFSA Journal, 2017; 15(6): 4873].

Available toxicological data relating to non active substance(s) (i.e. substance(s) of concern)

The biocidal product FREE LAND DUST contains the co-formulant (2-methoxymethylethoxy)propanol (CAS No. 34590-94-8). Based on the submitted MSDS of the supplier and the REACH registration dossier, (2-methoxymethylethoxy)propanol is not classified as hazardous according to CLP Regulation, therefore there is no impact on the classification of the biocidal product FREE LAND DUST.

However, according to the Guidance on the Biocidal Product Regulation (Volume III Human Health – Part B and C Risk Assessment– Version 4.0 – December 2017), (2-methoxymethylethoxy)propanol should be considered as a Substance of Concern (SoC), as there is available European Union-agreed Occupational Exposure Limit (OEL). The long-term (8 hours) occupational exposure limit of (2-methoxymethylethoxy)propanol is 308 mg/m³ (<https://echa.europa.eu/el/substance-information/-/substanceinfo/100.047.353>) with a skin note (a skin notation assigned to the OEL identifies the possibility of significant uptake through the skin).

According to the BPR Guidance (p. 424), *for SoCs for which Community workplace exposure limits (IOELVs – Indicative Occupational Exposure Limit Values) have been set, a quantitative inhalation risk assessment for the professional operator against the IOELV should always be conducted.* If the IOELV is associated with a “skin notation” and is driven by systemic rather than local effects, then a dermal quantitative risk assessment for the professional operator should be performed.

However, in case of (2-methoxymethylethoxy)propanol, a dermal quantitative risk assessment has not been performed, as a dermal NOAEC value for this co-formulant has not been peer reviewed and agreed under the BPR. Furthermore, according to the available MSDS (2-methoxymethylethoxy)propanol is not classified for any human health hazards, while in the ECHA C&L inventory the notified classification from a number of registrants relates only to local effects. Therefore, only an inhalation quantitative risk assessment has been undertaken for this co-formulant.

Available toxicological data relating to a mixture

The biocidal product FREE LAND DUST contains only one mixture: Denatonium benzoate (CAS No. 3734-33-6). Available toxicological data relating to the mixture contained in the biocidal product FREE LAND DUST is provided in the MSDS attached to current submission.

Endocrine-disrupting properties for human health: screening for co-formulants

The assessment of the endocrine-disrupting properties of the co-formulants in the biocidal product FREE LAND DUST has been performed according to the instructions described in the document agreed in the Coordination Group (CG-39-2020-11 AP 16.4 e-c ED co-formulant assessment by MS).

To assess the endocrine-disrupting (ED) potential of each co-formulant in the biocidal product, a step-wise approach was performed, which included screening of relevant databases and searching for freely available information in reliable literature sources. The information provided in the MSDSs by the suppliers of the co-formulants was also used.

The sources of information, the databases consulted as well as the results of the screening for endocrine-disrupting properties of the co-formulants in the biocidal product FREE LAND DUST are presented in detail in the Confidential Annex of this PAR.

Overall, based on available information it is concluded that the product FREE LAND DUST does not contain co-formulants with endocrine-disrupting properties for human.

Other

No other data are available.

2.2.6.2 Exposure assessment

The biocidal product FREE LAND DUST is a ready-to-use dustable powder insecticide (PT18), containing as active substance cypermethrin and (2-methoxymethylethoxy)propanol as Substance of Concern.

The nominal (pure) concentration of cypermethrin is 0.25% and the minimum purity is 95% as stated in the technical equivalence for cypermethrin and ECHA decision on chemical equivalence (██████████). Therefore, TGAI is 0.263% w/w (i.e. $0.25\% \times 100/95$), which is used for the risk assessment calculations.

Exposure assessment has been performed according to the ECHA Biocides Human Health Exposure Methodology (2015), the TNsG on Human Exposure (2002) and, where applicable, the User Guidance (2002) as well as the TNsG on Human Exposure (2007).

The relevant uses of the biocidal product FREE LAND DUST are reported in the table below.

Professional users			
Use		a.s concentration	Dose
Use 1	Crack and crevice application in voids and cavities - Crawling insects	0.263%	8 g/m ²
Use 2	Wasp nest	0.263%	10 g/nest
Non-professional users			
Use		a.s. concentration	Dose
Use 3	Crack and crevice application in voids and cavities - crawling insects	0.263%	8 g/m ²
Use 4	Wasp nest	0.263%	10 g/nest
Use 5	Ant nest	0.263%	5 g/nest
Use 6	Spot application outdoor around buildings - Blatta orientalis	0.263%	8 g/m ²

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

Summary table: relevant paths of human exposure							
Exposure path	Primary (direct) exposure			Secondary (indirect) exposure			
	Industrial use	Professional use	Non-professiona use	Industrial use	Professional use	General public	Via food
Inhalation	n.a.	yes	yes	n.a.	n.a	yes	n.a.
Dermal	n.a.	yes	yes	n.a.	yes	yes	n.a.
Oral	n.a.	no	no	n.a.	n.a	yes	n.a.

n.a. = not applicable

List of scenarios

Summary table: scenarios			
Scenario number	Scenario (e.g. mixing/loading)	Primary or secondary exposure Description of scenario	Exposed group (e.g. professionals, non-professionals, bystanders)
1.	Mixing and loading	Primary exposure: direct Loading product into the application device.	Professional users
2.	Application	Primary exposure: direct Indoor application by dusting in cracks and crevices, voids and cavities.	Professional users
3.	Application	Primary exposure: direct Indoor application by dusting in cracks and crevices, voids and cavities.	Non-professional users
4.	Application	Primary exposure: direct Outdoor application by dusting on ant's nest.	Non-professional users
5.	Post-application	Secondary exposure Secondary exposure is relevant to the general public entering to treated areas after the product application and is derived <i>via</i> inhalation, dermal and oral route.	General public: infants toddlers children
6.	Post-application	Secondary exposure Adult professional users laundering contaminated work clothes at home.	Professional users

Industrial exposure

BPR is not applied to the formulation phase; therefore, risk assessment has not been performed.

Professional exposure

FREE LAND DUST is a ready-to-use dustable powder insecticide for use against crawling insects.

The biocidal product may be used by professionals indoors in domestic premises and large buildings. The product should be applied manually by dusting only on restricted areas on surfaces not regularly cleaned, for example behind or under the fridge, under the kitchen sink, under the oven or the water heater, in all cracks and crevices that can be a harborage for cockroaches and ants. The recommended application rate of the product is 8 g product/m².

The product may also be used by professionals indoors *via* direct application on wasp nest for eradication. The recommended application rate of the product is 10g/nest.

The model taken into consideration in Scenario 2 (application in cracks and crevices, voids and cavities/indoor) for the assessment of primary human exposure does not take into account the actual application rate of the product, nor the surface treated, but only has the concentration of the active substance in the product as input value; therefore, although the uses have different usage doses, the model used is not affected by this difference. Model used in Scenario 2 (cracks and crevices, voids and cavities) is based on a quantity of applied biocidal product that is higher than the quantity of biocidal product used for wasp nest eradication; therefore, exposure assessment performed for Scenario 2 is conservative and is considered as worst case.

Primary exposure of professional users will be *via* inhalation and dermal route. The exposure is anticipated to be chronic in nature.

The model and the parameters used for the professional exposure to FREE LAND DUST are summarised below, while the calculations are presented in the Annex 3.2 of this document.

Scenario 1

Description of Scenario 1: Loading of the product into the application device by professional users.		
Model: Mixing and loading model 5 "Professional pouring formulation from a container into a fixed receiving vessel" (TNsG part 2, p 137).		
Parameters	Value	Comments
Exposed group	Professionals	-
Scenario	Loading	-
Application rate	8 g/m ²	Product label claim.
Body weight	60 kg	Default value for body weight for an adult, according to Recommendation no. 14 "Default human factor values for use in exposure assessments for biocidal products".
Weight fraction of cypermethrin	0.263%	Concentration of cypermethrin (TGAI) in the biocidal product.
Area treated/day	100 m ²	It is assumed that the professional user treats approximately 1000 m of 10 cm crack/crevice per day, therefore the surface of the treated area is 100 m ² . The selection of this value is considered precautionary given that the product is applied in cracks and crevices, voids and cavities.
Amount of a.s. handled/day	0.0021 kg a.s./day	The amount of a.s. handled per day is calculated as follows: 8 g product/m ² x 100 m ² x 0.263% a.s./product = 2.104 g a.s. per day = 0.0021 kg a.s./day.

Description of Scenario 1: Loading of the product into the application device by professional users.		
Tier 1: no PPE	Penetration to skin: 100%	As a worst-case scenario, it is assumed that no protective equipment is worn.
Dermal exposure		
Indicative dermal exposure	Hands: 10.2 mg a.s./kg a.s.	Default value for dermal exposure according to Mixing and loading model 5" (TNsG part 2, p 137).
Dermal absorption	50%	Default dermal absorption value for cypermethrin, as proposed by EFSA Guidance on dermal absorption [EFSA Journal, 2017; 15(6): 4873] for solid-formulated products.
Inhalation exposure		
Indicative inhalation exposure	0.66 mg a.s./kg a.s.	Default value for inhalation exposure according to Mixing and loading model 5" (TNsG part 2, p 137).
Inhalation absorption	100%	Assessment report of cypermethrin.

Scenario 2

Description of Scenario 2: Indoor application by dusting of FREE LAND DUST by professional users		
Model: Biocides Human Health Exposure Methodology, ECHA, October 2015, p.126: "Scattering powder against ants from a hand-held flexible duster/hand-held canister by consumers and professionals"; <u>Approach 2</u> : Hand-held flexible Duster (TNsG 2007, p. 63).		
Parameters	Value	Comments
Exposed group	Professionals	-
Scenario	Application	-
Application rate	8 g/m ²	Product label claim.
Body weight	60 kg	Default value for body weight for an adult, according to Recommendation no. 14 "Default human factor values for use in exposure assessments for biocidal products".
Weight fraction of cypermethrin	0.263%	Concentration of cypermethrin (TGAI) in the biocidal product.
Application duration	120 minutes	The application duration default value for dusting is 120 min, according to Recommendation no. 6 of the BPC Ad hoc Working Group on Human

Description of Scenario 2: Indoor application by dusting of FREE LAND DUST by professional users		
		Exposure.
Exposure duration	240 minutes	The exposure duration is a sum of the time required for application and the time of the user remaining in the room after application. According to RIVM report 320005002/2006 (p.70) a total time of 4 hours is set as the default value for the exposure duration assuming that the user stays in the treated room for 4 hours after the application.
Dermal exposure		
Indicative dermal exposure: hand/forearm: 2.73 mg/min legs/feet/face: 2.74 mg/min	2.73 + 2.74 = 5.47 mg/min	Worst-case dermal exposure, according to Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure.
Dermal absorption	50%	Default dermal absorption value for cypermethrin, as proposed by EFSA Guidance on dermal absorption [EFSA Journal, 2017; 15(6): 4873] for solid-formulated products.
Penetration to skin (Tier 1)	100%	As a worst-case scenario, it is assumed that no protective equipment is worn. Tier 1 human exposure assessments 'must not take account of exposure reduction measures such as personal protective equipment', according to TNsG, January 2008, p. 27.
Inhalation exposure		
Indicative inhalation exposure	2.47 mg/m ³	Default value according to Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure.
Inhalation absorption	100%	Assessment report of cypermethrin.
Inhalation rate	1.25 m ³ /hour	Default short-term inhalation rate for an adult, according to Recommendation no. 14 "Default human factor values for use in exposure assessments for biocidal

Description of Scenario 2: Indoor application by dusting of FREE LAND DUST by professional users

		products”.
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Calculations for Scenarios 1&2 for cypermethrin

Summary table: estimated exposure from professional uses					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
		mg/kg bw/day			
Scenario 1	1/no PPE	2.31×10^{-5}	1.8×10^{-4}	-	2.0×10^{-4}
Scenario 2	1/no PPE	2.7×10^{-4}	1.44×10^{-2}	-	1.47×10^{-2}

Further information and considerations on Scenario 2

The biocidal product FREE LAND DUST contains the co-formulant (2-methoxymethylethoxy)propanol (CAS No. 34590-94-8) at a concentration of 0.75%.

As (2-methoxymethylethoxy)propanol has a European Union-agreed IOELV (308 mg/m^3), a quantitative inhalation risk assessment for the professional operator against the IOELV has been conducted. Therefore, for scenario 2, the inhalation exposure of professional users to (2-methoxymethylethoxy)propanol has been calculated.

The parameters used for the inhalation exposure of professional users to (2-methoxymethylethoxy)propanol during the application (Scenario 2) of FREE LAND DUST are summarised below, while the calculations are presented in the Annex 3.2 of this document.

Scenario 2

Scenario 2: Inhalation exposure of professional users to (2-methoxymethylethoxy)propanol during the application of FREE LAND DUST		
Parameters	Value	Comments
Concentration of (2-methoxymethylethoxy)propanol	0.75%	Concentration of (2-methoxymethylethoxy)propanol in the biocidal product.
Body weight of adult	60 kg	Default value for body weight for an adult, according to Recommendation no. 14 “Default human factor values for use in exposure assessments for biocidal products”.

Inhalation rate of adult	1.25 m ³ /h	Default short-term inhalation rate for an adult, according to Recommendation no. 14 "Default human factor values for use in exposure assessments for biocidal products".
Penetration through RPE	100%	As a worst-case scenario, it is assumed that no respiratory protective equipment is worn. Tier 1 human exposure assessments 'must not take account of exposure reduction measures such as personal protective equipment', according to TNsG, January 2008, p. 27.
Indicative inhalation exposure	2.47 mg/m ³	Default value according to Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure.
Inhalation absorption	100%	Worst-case assumption.
Application duration	120 min	The application duration default value for dusting is 120 min, according to Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure.

Calculations for Scenario 2 for (2-methoxymethylethoxy)propanol

Summary table: estimated exposure from professional uses					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
		mg/kg bw/day			
Scenario 2	1/no PPE	7.7 x 10 ⁻⁴	4.1 x 10 ⁻²	-	4.18 x 10⁻²

In addition to the above exposure assessment and in order to address the concerns raised during the bilateral discussions as regards exposure *via* inhalation to the SoC after evaporation, a worst-case approach calculation has been considered assuming that the whole amount of the SoC applied in a room evaporates at the same time while the professional user is still in the room.

The parameters used for the inhalation exposure of professional users to (2-methoxymethylethoxy)propanol and the estimated inhalation exposure are summarized below:

- Room volume = 20 m³
- Room height = 2.5 m
- Room surface = 8 m²

- Application rate of the product = 8 g/m²
- Application rate of SoC = 0.75% x 8 = 0.06 g/m²
- Total amount of SoC applied in the room = 8 m² x 0.06 g/m² = 0.48 g SoC
- SoC concentration in the room = 0.48 g/20 m³ = 0.024 g/m³ = 24 mg/m³, i.e. **7.8%** of the respective IOELV.

Non-professional exposure

FREE LAND DUST is a ready-to-use dustable powder insecticide for use against crawling insects.

The biocidal product may be used by non-professionals indoors in domestic premises. The product should be applied manually by dusting only on restricted areas on surfaces not regularly cleaned, for example behind or under the fridge, under the kitchen sink, under the oven or the water heater, in all cracks and crevices that can be a harborage for cockroaches and ants. The product may also be used outdoors around building on windows and doorsteps. For both uses, the recommended application rate of the product is 8 g product/m².

In addition, the product may also be used by non-professionals indoors and outdoors *via* direct application on wasp nest for eradication or outdoors *via* direct application on ant nest. The recommended application rate of the product is 10 g/nest and 5 g/nest, respectively.

It is considered that the direct exposure estimates for indoor treatments encompass those for outdoor treatments (i.e., it is considered to be within the 'risk envelope' as defined by the indoor use). However, for completeness reasons the exposure assessment has been also performed for the outdoor application by dusting at the entrance of ant's nest by non-professional users.

The model taken into consideration in Scenario 3 (application in cracks and crevices, voids and cavities/indoor) for the assessment of primary human exposure does not take into account the actual application rate of the product, nor the surface treated, but only has the concentration of the active substance in the product as input value; therefore, although the uses have different usage doses, the model used is not affected by this difference. Model used in Scenario 3 (cracks and crevices, voids and cavities) is based on a quantity of applied biocidal product that is higher than the quantity of biocidal product used for wasp/ant nest eradication; therefore, exposure assessment performed for Scenario 3 is conservative and is considered worst-case.

Primary exposure of non-professional users will be *via* inhalation and dermal route.

The model and the parameters used for the non-professional exposure to FREE LAND DUST are summarised below, while the calculations are presented in the Annex 3.2 of this document.

Scenario 3

Description of Scenario 3: Indoor application by dusting of FREE LAND DUST by non-professional users

Model: Biocides Human Health Exposure Methodology, ECHA, October 2015, p.126: "Scattering powder against ants from a hand-held flexible duster/hand-held canister by consumers and professionals"; Approach 2: Hand-held flexible Duster (TNSG 2007, p. 63).

Description of Scenario 3: Indoor application by dusting of FREE LAND DUST by non-professional users		
Parameters	Value	Comments
Exposed group	Non-professionals	-
Scenario	Application	-
Application rate	8 g/m ²	Product label claim.
Body weight	60 kg	Default value for body weight for an adult, according to Recommendation no. 14 "Default human factor values for use in exposure assessments for biocidal products".
Weight fraction of cypermethrin	0.263 %	Concentration of cypermethrin (TGAI) in the biocidal product.
Application duration	10 minutes	<p>According to RIVM report 320005002/2006; Pest Control Products Fact Sheet (p. 72), it is estimated that it takes 5 minutes for dusting 1 m².</p> <p>Default value for spot and cracks/crevices treatment for a domestic house is 2 m² (Technical Agreements for Biocides (TAB) - ENV v.2.1, ENV 142).</p> <p>Therefore, the application duration is calculated as follows: 5 min x 2 m² = 10 min</p>
Exposure duration	240 minutes	<p>The exposure duration is a sum of the time required for application and the time of the user remaining in the room after application.</p> <p>According to RIVM report 320005002/2006 (p.70) a total time of 4 hours is set as the default value for the exposure duration assuming that the user stays in the treated room for 4 hours after the application.</p>
Dermal exposure		
Indicative dermal exposure: hand/forearm: 2.73 mg/min legs/feet/face: 2.74 mg/min	2.73 + 2.74 = 5.47 mg/min	Worst-case dermal exposure, according to Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure.
Dermal absorption	50%	Default dermal absorption value for cypermethrin, as proposed by EFSA Guidance on dermal absorption [EFSA Journal, 2017; 15(6): 4873] for solid-

Description of Scenario 3: Indoor application by dusting of FREE LAND DUST by non-professional users

		formulated products.
Inhalation exposure		
Indicative inhalation exposure	2.47 mg/m ³	Default value according to Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure.
Inhalation absorption	100%	Assessment report of cypermethrin.
Inhalation rate	1.25 m ³ /hour	Default short-term inhalation rate for an adult, according to Recommendation no. 14 "Default human factor values for use in exposure assessments for biocidal products".

Calculations for Scenario 3

Summary table: systemic exposure from non-professional uses

Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
		mg/kg bw/day			
Scenario 3	Tier 1/no PPE	2.3 x 10 ⁻⁵	1.2 x 10 ⁻³	-	1.22 x 10⁻³

Scenario 4

Description of Scenario 4: Outdoor application by dusting at the entrance of ant's nest of FREE LAND DUST by non-professional users

Model: Biocides Human Health Exposure Methodology, ECHA, October 2015, p.126: "Scattering powder against ants from a hand-held flexible duster/hand-held canister by consumers and professionals"; Approach 2: Hand-held flexible Duster (TNsG 2007, p. 63).

Parameters	Value	Comments
Exposed group	Non-professionals	-
Scenario	Outdoor application	-
Application rate	5 g/nest	Product label claim.

Description of Scenario 4: Outdoor application by dusting at the entrance of ant's nest of FREE LAND DUST by non-professional users		
Body weight	60 kg	Default value for body weight for an adult, according to Recommendation no. 14 "Default human factor values for use in exposure assessments for biocidal products".
Weight fraction of cypermethrin	0.263 %	Concentration of cypermethrin (TGAI) in the biocidal product.
Application duration	10 minutes	According to RIVM report 320005002/2006; Pest Control Products Fact Sheet (p. 72), it is estimated that it takes 5 minutes for dusting 1 m ² . Default value for spot and cracks/crevices treatment for a domestic house is 2 m ² (Technical Agreements for Biocides (TAB) - ENV v.2.1, ENV 142). Therefore, the application duration is calculated as follows: 5 min x 2 m ² = 10 min
Exposure duration	240 minutes	According to RIVM report 320005002/2006 (p.70) a total time of 4 hours is set as the default value for the exposure duration assuming that the user stays in the treated room for 4 hours after the application.
Dermal exposure		
Indicative dermal exposure: hand/forearm: 2.73 mg/min legs/feet/face: 2.74 mg/min	2.73 + 2.74 = 5.47 mg/min	Worst-case dermal exposure, according to Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure.
Dermal absorption	50%	Default dermal absorption value for cypermethrin, as proposed by EFSA Guidance on dermal absorption [EFSA Journal, 2017; 15(6): 4873] for solid-formulated products.
Inhalation exposure		
Indicative inhalation exposure	2.47 mg/m ³	Default value according to Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure.
Inhalation absorption	100%	Assessment report of cypermethrin.

Description of Scenario 4: Outdoor application by dusting at the entrance of ant's nest of FREE LAND DUST by non-professional users

Inhalation rate	1.25 m ³ /hour	Default short-term inhalation rate for an adult, according to Recommendation no. 14 "Default human factor values for use in exposure assessments for biocidal products".
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Calculations for Scenario 4

Summary table: systemic exposure from non-professional uses					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
		mg/kg bw/day			
Scenario 4	Tier 1/no PPE	2.3 x 10 ⁻⁵	1.2 x 10 ⁻³	-	1.22 x 10⁻³

Exposure of the general public

Subsequent to the use of the biocidal product, indirect secondary exposure of general public could occur in the residential environment. Secondary exposure is derived *via* inhalation, dermal and oral route.

Inhalation exposure to volatilised residues of cypermethrin is expected to occur for infants, toddlers, children and adults entering to treated areas.

Dermal exposure is expected to occur for the general public *via* direct contact to deposits of the biocide on the surface of contact after product application. Dermal exposure may occur to infants, toddlers and children crawling on floor or playing around treated surfaces for a significant time period.

It is noted that the biocidal product FREE LAND DUST contains denatonium benzoate which is a substance inserted in the formulation specifically to give it a bitter taste and prevent it from being ingested by the children. Therefore, the oral exposure of infants and toddlers from hand-to-mouth contact would be negligible.

It is assumed that infants, toddlers and children would not be permitted to be present during the application operation and therefore, there would be no acute exposure.

Secondary exposure for the general public is considered as a medium-term event, because it is estimated that the duration of exposure is more important than a single event, among others considering inhalation exposure. The exposure time would be high, 8 hours for inhalation of the residues and a dermal contact of one hour for children, toddlers and infants playing on the treated floor.

The models used for the secondary exposure assessment for the general public are summarized in the following table.

Overview of models used for secondary human health exposure assessment.		
Inhalation route	Models	Population
Vapours (volatilised residues)	HEEG opinion 13 - Assessment of inhalation exposure of volatilised biocidal active	Infant Toddler

	substances.	Child Adult
Dermal route	Model	Population
Dermal contact with treated surfaces	ConsExpo Web, version 1.0.6 - RIVM Pest Control Products Fact Sheet, 2006 - Secondary exposure - Rubbing off.	Infant Toddler Child
Dermal contact during laundering of contaminated work clothes		Professional users

Assessment of Inhalation Exposure of Volatilised Biocidal Active Substance

Inhalation exposure to volatilised residues of cypermethrin is expected to occur for infants, toddlers, children and adults entering to treated areas.

Volatization of cypermethrin is expected to be minimal due to low vapour pressure, low Henry's Law constant and high adsorption potential. Therefore, inhalation exposure due to evaporation is considered to be negligible. However, the assessment of inhalation exposure of volatilised residues of active substances was performed for completeness.

Tier-1 screening tool

As a Tier-1 screening tool whether inhalation exposure can be neglected or should be included into the risk assessment, the following screening test which is based on the toddler representing the worst case is proposed in HEEG Opinion 13 (Assessment of Inhalation Exposure of Volatilised Biocide Active Substance).

Let m_w and v_p denote the molecular weight (in g/mol) and the vapour pressure (in Pa). For toddler (based on an inhalation rate of $8 \text{ m}^3/24 \text{ hr}$ and body weight of 10 kg) and using an AEL in mg a.s./kg bw/d, if $0.328 \times [(m_w \times v_p) / \text{AEL}_{\text{long-term}}] \leq 1$

then risk from inhalation exposure for the toddler is negligible, otherwise inhalation exposure should be included in the risk assessment. If the inhalation risk for the toddler is negligible, then the inhalation risk for the infant, child and for the adult can also be considered to be negligible.

Tier-1 screening tool has been applied for cypermethrin as detailed in the following table.

Screening tool of inhalation exposure of volatilised biocidal active substance					
Active substance	MW (g/mol)	v_p (Pa)	$\text{AEL}_{\text{long-term}}$ (mg/kg bw/d)	$0.328 \times m_w \times v_p / \text{AEL}_{\text{long-term}}$	Result
cypermethrin	416.3	6×10^{-7}	0.022	0.0037	<1 risk from inhalation exposure for the toddler is negligible

As a result of the application of Tier-1 screening tool, the risk from the inhalation exposure for toddlers is negligible in long-term exposure. Therefore, the inhalation risk for infants, children and adults is also considered negligible.

Dermal exposure to residues on the floor – infants, toddlers and children

Secondary dermal exposure due to the entering into areas treated with the product is not expected for the general public, as the product is applied in cracks and crevices, voids and cavities. However, as a worst case, a scenario for the secondary dermal exposure of infants, toddlers and children has been included in the risk assessment.

The models and the parameters used to calculate the secondary exposure assessment for the general public are described in detail in the following table, while the calculations are presented in the Annex 3.2 of this document.

Scenario 5

Description of Scenario 5: Secondary dermal exposure of the general public.		
The assessment for the dermal exposure of the general public has been performed using ConsExpo Web, version 1.0.6, considering the application rate of the product (8 g/m ²). The parameters used were from the RIVM report 320005002/2006, Chapter 7, Dusting powders, Exposure after application (p. 71-73).		
Parameter	Value	Comments
Exposed group	General public: infant, toddler, child	-
Product database	Pest control products	-
Product category	Dusting powders	-
Product	Dusting powders	-
Scenario	Post-application (child)	-
Application rate	8 g/m ²	Product label claim.
Body weight	Infant: 8 kg Toddler: 10 kg Child: 23.9 kg	Recommendation no. 14 "Default human factor values for use in exposure assessments for biocidal products".
Weight fraction substance	0.263%	Concentration of cypermethrin (TGAI) in the biocidal product.
Dermal exposure		
Model	Direct product contact	-
Loading	Rubbing off	-
Exposed area (palms and backs of both hands)	Infant: 196.8 cm ² Toddler: 230.4 cm ² Child: 427.8 cm ²	Recommendation no. 14 "Default human factor values for use in exposure assessments for biocidal products".
Transfer coefficient	Infant/toddler/child: 0.2 m ² /hr	Recommendation no. 12 of the BPC Ad hoc Working Group on Human Exposure: "New default values for indoor Transfer Coefficient" (agreed at the Human Health Working Group V on 22 November 2016).

Dislodgeable amount (product)	2.04 g/m ²	Dislodgeable amount has been calculated as reported in RIVM report 320005002/2006: "Pest Control Products Fact Sheet" (p. 71), using the application rate of FREE LAND DUST (8 g/m ²). According to RIVM report 320005002 (p.71), "the default value for the dislodgeable fraction is set at 30%. The airborne fraction is taken to be 15%, so 85% of the powder is sprinkled onto 1 m ² ". Therefore, the dislodgeable amount for FREE LAND DUST is calculated as follows: $8 \text{ g/m}^2 \times 0.85 \times 0.3 = 2.04 \text{ g/m}^2$
Contact time	60 min/day	Default value, as reported in RIVM report 320005002/2006: "Pest Control Products Fact Sheet" (p. 73).
Rubbed surface	2 m ²	Default value for spot and cracks/crevices treatment for a domestic house is 2 m ² (Technical Agreements for Biocides (TAB) - ENV v.2.1, ENV 142).
Dermal absorption	50%	Default dermal absorption value for cypermethrin, as proposed by EFSA Guidance on dermal absorption [EFSA Journal, 2017; 15(6): 4873] for solid-formulated products.

Calculations for Scenario 5

Summary table: systemic exposure for general public					
Exposure scenario	Exposed group	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
		mg/kg bw/day			
Scenario 5	Infant	-	6.7×10^{-2}	-	6.7×10^{-2}
Scenario 5	Toddler	-	5.4×10^{-2}	-	5.4×10^{-2}
Scenario 5	Child	-	2.2×10^{-2}	-	2.2×10^{-2}

Scenario 6

Description of Scenario 6: Adult professional users laundering contaminated work clothes at home.

Exposure of adult professional users to the product FREE LAND DUST can potentially occur *via* contact with the contaminated coveralls, during laundering at home. The worst-case exposure is *via* the dermal route – mainly to the hands – from handling the contaminated clothing prior to introduction into the washing machine.

The amount of product contaminating the coverall is considered to be equivalent to the potential dermal exposure estimated by the scenario "Scattering powder against ants from a hand held flexible duster/hand-held canister by consumers and professionals (TNsG 2007,

p. 63). The indicative exposure value for the total body of the adult user is 5.47 mg/min. With an estimated duration of the application of 120 minutes for professional users and a.s. concentration in the product of 0.263%, the potential contamination is 0.863 mg a.s./day. It is assumed that the coverall is washed weekly, after 5 days wear. Please refer to Annex 3.2 for the detailed calculations.

Parameters	Value	Comments
Exposed group	Professionals users	
Scenario	Laundering work clothes	
Body weight	60 kg	Default value for body weight for an adult, according to Recommendation no. 14 "Default human factor values for use in exposure assessments for biocidal products".
Weight fraction of cypermethrin	0.263%	Concentration of cypermethrin (TGAI) in the biocidal product.
Application duration	120 minutes	The application duration default value for dusting is 120 min, according to Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure.
Indicative dermal exposure: hand/forearm: 2.73 mg/min legs/feet/face: 2.74 mg/min	2.73 + 2.74 = 5.47 mg/min	Worst-case dermal exposure, according to Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure.
Dermal absorption	50%	Default dermal absorption value for cypermethrin, as proposed by EFSA Guidance on dermal absorption [EFSA Journal, 2017; 15(6): 4873] for solid-formulated products.
Total outer surface area of a medium sized coverall	22700 cm ²	Surface area of a medium sized coverall.
Total area of both hands of an adult	820 cm ²	Recommendation no. 14 "Default human factor values for use in exposure assessments for biocidal products".
Dislodgable fraction	30%	The default value for the dislodgeable fraction is set at 30%, according to RIVM report 320005002 (p.71).

Calculations for Scenario 6 for cypermethrin

Summary table: estimated exposure from professional uses

Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
		mg/kg bw/day			
Scenario 6	1/no PPE	-	1.56×10^{-4}	-	1.56×10^{-4}

Additional considerations on scenarios

Combined exposure (combined scenarios 1+2+6) has been assessed for the professional user who is exposed to the active substance cypermethrin during the loading of the product into the dusting equipment (primary direct exposure – Scenario 1), the application of the product by dusting (primary direct exposure – Scenario 2) and during the laundering of the contaminated work clothes at home (secondary exposure – Scenario 6).

Combined exposure (combined scenarios 3+4) has been also assessed for the non-professional user who is exposed to the active substance cypermethrin during indoor application of the product by dusting (primary direct exposure – Scenario 3) and during outdoor application at the entrance of ant's nest (primary direct exposure – Scenario 4).

Combined scenarios

Summary table: combined systemic exposure from professional uses				
Scenarios combined	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
	mg/kg bw/day			
Scenarios 1&2&6 Cypermethrin Professional users	2.31×10^{-5} + 2.7×10^{-4}	1.8×10^{-4} + 1.44×10^{-2} + 1.56×10^{-4}	-	1.5×10^{-2}
Scenarios 3&4 Cypermethrin Non-professional users	2.3×10^{-5} + 2.3×10^{-5}	1.2×10^{-3} + 1.2×10^{-3}	-	2.44×10^{-3}

Dietary exposure

Information regarding residues in food/feedstuff or drinking water was not submitted by the applicant nor are required since no dietary exposure assessment is deemed necessary

The biocidal product FREE LAND DUST is not intended to be applied directly on food/feed, drinking water facilities or livestock premises and therefore it is not expected that consumer or livestock animals may be exposed to the product. In addition different mitigation measures are proposed in the label in order to avoid any accidental

contamination on food/feedstuff from animal or vegetal origin such as described in "2.1.5.2 Risk mitigation measures" above.

Summary of exposure assessment

Scenarios and values to be used in risk assessment				
Scenario number	Exposed group	Tier/PPE	Substance	Estimated total uptake (mg/kg bw/day)
1.	Professional users	1/no PPE	Cypermethrin	2.0×10^{-4}
2.	Professional users	1/no PPE	Cypermethrin	1.47×10^{-2}
			(2-methoxymethylethoxy) propanol	4.18×10^{-2}
3.	Non-professional users	1/no PPE	Cypermethrin	1.22×10^{-3}
4.	Non-professional users	1/no PPE	Cypermethrin	1.22×10^{-3}
5.	Infant	1/no PPE	Cypermethrin	6.7×10^{-2}
5.	Toddler	1/no PPE	Cypermethrin	5.4×10^{-2}
5.	Child	1/no PPE	Cypermethrin	2.2×10^{-2}
6.	Professional users	1/no PPE	Cypermethrin	1.56×10^{-4}
1+2+6	Professional users	1/no PPE	Cypermethrin	1.5×10^{-2}
3+4	Non-professional users	1/no PPE	Cypermethrin	2.44×10^{-3}

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation for cypermethrin

For Risk Characterisation AELs determined for cypermethrin have been used, as reported in the CAR of cypermethrin and as detailed in the table below.

Reference	Study	NOAEL (LOAEL)	AF ¹	Correction for oral absorption	Value
AEL _{short-term}	Rat, acute delayed neurotoxicity	20 mg/kg bw/day	100	44%	0.088 mg/kg bw/day
AEL _{medium-term}	Dog, 90-days	12.5 mg/kg	100	44%	0.055 mg/kg

		bw/day			bw/day
AEL _{long-term}	Rat, 2-year	5 mg/kg bw/day	100	44%	0.022 mg/kg bw/day

As indicated in the Technical Agreements for Biocidal Products for Human Health (TOX 22) version 2.0, the internal dose on the day of exposure is compared with the AEL long-term of the active substance for the primary exposure of professional users and compared with the AEL medium-term for the primary exposure of non-professional users and secondary exposure of the general public.

At WG-IV-2016, the following values for ADI and ARfD were agreed (based on derivation made for the Plant Protection Products regulation; DAR Cypermethrin, EFSA Feb 2005) as detailed in the following table.

ADI and ARfD values for cypermethrin

Type of reference value	Value	Unit
ADI	0.05	mg/kg bw/day
ARfD	0.2	mg/kg bw/day

Maximum residue limits or equivalent

As to support the uses of Cypermethrin as a plant protection product, MRLs have been set for "Cypermethrin (cypermethrin including other mixtures of constituent isomers (sum of isomers))" in plant and animal commodities with (Reg. (EU) 2017/626).

Reference values to be used in Risk Characterisation for 2-methoxymethyl-ethoxy propanol (CAS No. 34590-94-8)

European IOELV according to Commission Directive (EU) 2017/164		Skin notation
8 hours		
mg/m ³	ppm	yes
308	50	

The European IOELV (308 mg/m³) of 2-methoxymethyl-ethoxy propanol (CAS No. 34590-94-8) has been converted in the systemic inhalation uptake of 12.83 mg/kg bw/day, considering an inhalation rate of 1.25 m³/h, body weight of 60 kg, 100% inhalation absorption and 2 h duration of exposure for the professional user:

$$308 \text{ mg/m}^3 \times 1.25 \text{ m}^3/\text{h} \times 2 \text{ h} \times 100\% / 60\text{kg} = 12.83 \text{ mg/kg bw/day}$$

Risk for industrial users

BPR is not applied to the formulation phase; therefore, risk assessment has not been performed.

Risk for professional users

Treatment of cracks and crevices, voids and cavities is considered the worst case for professional use, therefore risk characterization has only been evaluated for this use.

Systemic effects for cypermethrin

Task/Scenario	Tier	AEL _{long-term} (mg/kg bw/day)	Estimated uptake (mg/kg bw/day)	HQ: uptake/AEL	Acceptable (yes/no)
Loading Professionals Scenario 1	1	0.022	2.0×10^{-4}	0.0091	yes
Application Professionals Scenario 2	1	0.022	1.47×10^{-2}	0.668	yes
Laundrying Professionals Scenario 6	1	0.022	1.56×10^{-4}	0.0071	yes

Systemic effects for 2-methoxymethyl-ethoxy propanol

Task/Scenario	IOELV (mg/m ³)	Converted reference value (mg/kg bw/day)	Estimated uptake (mg/kg bw/day)	HQ: uptake/ reference value	Acceptable (yes/no)
Application Professionals Scenario 2	308	12.83	4.18×10^{-2}	3.26×10^{-3}	yes

Combined scenarios for cypermethrin

Scenarios combined	Tier	AEL _{long-term} (mg/kg bw/day)	Estimated uptake (mg/kg bw/day)	HQ: uptake/AEL	Acceptable (yes/no)
Loading, application & laundrying Professionals Scenarios 1 & 2 & 6	1	0.022	1.5×10^{-2}	0.682	yes

Local effects

Pyrethroids are known to cause paresthesia (burning and prickling of the skin without irritation). This local effect is normally not severe and disappears when direct exposure is terminated. Therefore, this instruction for use is proposed:

- The biocidal product contains cypermethrin (synthetic pyrethroid). DO NOT USE if under medical advice NOT to work with such compounds; and/or

- Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice.

Residues of cypermethrin on treated surfaces are predicted to be low due to the presence of adequately ventilated areas. Hence, the final concentration of cypermethrin is assumed to be lower than 2630 ppm.

Therefore, no local effects are foreseen from the application of the biocidal product FREE LAND DUST product under label instructions.

Conclusion

The primary exposure of professional users is considered acceptable for both the active substance and the substance of concern, as the total internal dose is below the long-term AEL. Also combined exposure of scenarios 1, 2 and 6 is considered acceptable for the active substance.

Therefore, there is no risk for the professionals using the biocidal product FREE LAND DUST, provided that the product is used according to the instructions of use.

Risk for non-professional users

Systemic effects

Task/Scenario	Tier	AEL_{medium-term} (mg/kg bw/day)	Estimated uptake (mg/kg bw/day)	HQ: uptake/AEL	Acceptable (yes/no)
Indoor application Non-professionals Scenario 3	1	0.055	1.22×10^{-3}	0.022	yes
Outdoor application Non-professionals Scenario 4	1	0.055	1.22×10^{-3}	0.022	yes

Combined scenarios for cypermethrin

Scenarios combined	Tier	AEL_{medium-term} (mg/kg bw/day)	Estimated uptake (mg/kg bw/day)	HQ: uptake/AEL	Acceptable (yes/no)
Indoor & outdoor application Non-professionals Scenarios 3 & 4	1	0.055	2.44×10^{-3}	0.044	yes

Local effects

Pyrethroids are known to cause paresthesia (burning and prickling of the skin without irritation). This local effect is normally not severe and disappears when direct exposure is terminated. Therefore, this instruction for use is proposed:

- The biocidal product contains cypermethrin (synthetic pyrethroid). DO NOT USE if under medical advice NOT to work with such compounds; and/or
- Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice.

Residues of cypermethrin on treated surfaces are predicted to be low due to the presence of adequately ventilated areas. Hence, the final concentration of cypermethrin is assumed to be lower than 2630 ppm.

Therefore, no local effects are foreseen from the application of the biocidal product FREE LAND DUST product under label instructions.

Conclusion

As a result of risk assessment performed for Scenarios 3 and 4, the primary exposure of non-professional users is considered acceptable as the total internal dose is well below the medium-term AEL. Also combined exposure of scenarios 3 and 4 is considered acceptable. Therefore, there is no risk for the non-professionals using the biocidal product FREE LAND DUST provided that the product is used according to the instructions of use.

Risk for the general public

Systemic effects

Task/ Scenario	Tier	AEL _{medium-term} (mg/kg bw/day)	Estimated uptake (mg/kg bw/day)	HQ: uptake/AEL	Acceptable (yes/no)
Infant Scenario 5	1	0.055	6.7×10^{-2}	1.22	no
Toddler Scenario 5	1		5.4×10^{-2}	0.98	yes
Child Scenario 5	1		2.2×10^{-2}	0.4	yes

Combined scenarios

Combined scenarios are not relevant for the general public.

Local effects

Pyrethroids are known to cause paresthesia (burning and prickling of the skin without irritation). This local effect is normally not severe and disappears when direct exposure is terminated. Therefore, this instruction for use is proposed:

- The biocidal product contains cypermethrin (synthetic pyrethroid). DO NOT USE if under medical advice NOT to work with such compounds; and/or
- Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice.

Residues of cypermethrin on treated surfaces are predicted to be low due to the presence of adequately ventilated areas. Hence, the final concentration of cypermethrin is assumed to be lower than 2630 ppm.

Therefore, no local effects are foreseen from the application of the biocidal product FREE LAND DUST product under label instructions.

Conclusion

Secondary inhalation exposure due to evaporation of the active substance is considered to be negligible for the general public.

Secondary dermal exposure due to the entering in areas treated with the product is not expected for the general public, as the product is applied in cracks and crevices, voids and cavities. However, as a worst case, a scenario for the secondary dermal exposure of infants, toddlers and children has been performed.

For toddlers, children and adults there is no concern for indirect secondary exposure from the use of the biocidal product FREE LAND DUST. In contrast, a risk has been identified for infants as the total internal dose is above the medium-term AEL for this population group.

Therefore, the following risk mitigation measure is proposed to be included in the product label: "For use only in areas that are inaccessible to infants, pets (in particular cats) and non-target animals".

Risk for consumers via residues in food

Risk for consumers *via* residues in food has not been assessed since the product is proposed for a non-crop use.

Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product

No combined exposure is foreseen.

2.2.7 Risk assessment for animal health

Risk assessment for animal health is not necessary, since exposure of animals is not expected (i.e. FREE LAND DUST is not intended to be applied to animals).

The following risk mitigation measures should be added in order to ensure the safety of pets and cats in particular:

- For use only in areas that are inaccessible to infants, pets (in particular cats) and non-target animals.
- Contains cypermethrin, may be dangerous/toxic to pets (e.g. cats, bees, fish and other aquatic organisms).
- Keep cats away from treated surfaces. Due to their particular sensitivity to cypermethrin, the product can cause severe adverse reactions in cats.
- Do not apply in rooms where fish tanks and/or terrariums are present.
- Keep out of reach of children and non-target animals/pets.
- Keep uninvolved persons, children and pets away from treated surfaces/areas.

- Do not dust onto people and pets.

2.2.8 Risk assessment for the environment

General information

Risk assessment for the environment has been performed according requirements and approaches of Biocidal Products Regulation (BPR) EU No 528/2012. The assessment of effects on environment for FREE LAND DUST has been performed following ECHA Guidance on the BPR: Volume IV Environment, Assessment & Evaluation (Parts B+C), Version 2.0, October 2017.

The biocidal product "FREE LAND DUST" contains:

- several substances that are not classified (i.e. not hazardous)
- one substance that is classified, that is present in the biocidal product in a concentrations below the cut-off values determined according to art. 11 of CLP Regulation.

Moreover, available toxicological information for:

- the active substance (i.e. cypermethrin), and
- all co-formulants

are deemed sufficient for the hazard assessment of FREE LAND DUST.

For these reasons, in the sections below the human health hazard assessment shortly summarizes the information discussed in detail in the CAR of cypermethrin (for PT18). The use of data on active substance and model formulation is covered by the Letter of Access.

2.2.8.1 Effects assessment on the environment

PNECs values

PNECs values used for the risk assessment of the product are the same PNECs values used for the active substance cypermethrin, and are detailed in the table below.

Cypermethrin	
Surface water	0.004 µg/l (0.000004 mg/l)
Freshwater sediment (*)	0.0050 mg/Kg wwt
Microorganisms in STP	1.63 mg/l
Soil	0.0708 mg/Kg wwt (0.08 mg/Kg soil dw)

(*) CAR cypermethrin Document II-A Effects Assessment for the Active Substance CYPERMETHRIN. According to Guidance on the Biocidal Products Regulation Volume IV Environment - Assessment and Evaluation (Parts B + C), Version 2.0, October 2017, due to the limitations of the equilibrium partitioning approach, to account for additional exposure via sediment ingestion, for substances with a log Kow ≥ 5 an additional safety factor of 10 is applied to the PNECs_{sediment}. The additional factor takes into account the possible additional uptake via sediment ingestion.

Oral bird	33.3 mg a.s/kg feed
Oral small mammal	3.3 mg a.s/kg food

Metabolites

The relevant metabolites are 3-PBA and DCVC.

For 3-PBA, the following PNEC values are available (same values used in CAR of permethrin, April 2014).

PBA	
Surface water	> 0.010 mg/L
Soil (wet weight)	1.44 mg/kg wwt
Sediment	0.042 mg/kg dwt (0.009 mg/kg wwt)

For Trans-DCVC and Cis-DCVC PNECs values are not available, in Competent Authority Report of Cypermethrin (Document I, January 2017) it is reported:
 "According to the DAR of cypermethrin, TDCVC and CDCVC metabolites have toxicity values which are 10000x higher than those of cypermethrin."

In Competent Authority Report of Cypermethrin (Document II-A, January 2017) it is reported:
 "With such high concentrations of metabolites rapidly found in the various metabolism/ degradation studies, one can consider that its toxicity is covered by the studies on cypermethrin (Evaluation report on the equivalence; Agriphar Confidential 2007)".

Since TDCVC and CDCVC metabolites have toxicity values which are 10000x higher than those of cypermethrin but PNECs are not available for these metabolites, as a conservative approach, for DCVC PNECs of cypermehrin have been used.

Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required

Ecotoxicity data for the product are not available. Ecotoxicity data are available for each components of the product, and as a result of the application of the classification rules of Annex I of CLP Regulation, the product is classified as Aquatic Acute 1 and Aquatic Chronic 1.

Further Ecotoxicological studies

Further ecotoxicological studies are not needed.

Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)

Not applicable.

Supervised trials to assess risks to non-target organisms under field conditions

Not applicable.

Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk

Not applicable.

Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)

Not applicable.

Foreseeable routes of entry into the environment on the basis of the use envisaged

Please, refer to section Fate and distribution in exposed environmental compartments.

Further studies on fate and behaviour in the environment (ADS)

Not applicable.

Leaching behaviour (ADS)

Not applicable.

Testing for distribution and dissipation in soil (ADS)

Not applicable.

Testing for distribution and dissipation in water and sediment (ADS)

Not applicable.

Testing for distribution and dissipation in air (ADS)

Not applicable.

If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)

Not applicable.

Acute aquatic toxicity

Product environmental classification – Acute aquatic toxicity	
Value/conclusion	Aquatic Acute 1 H400: Very toxic to aquatic life.
Justification for the value/conclusion	<p>The classification system for mixtures covers all classification categories which are used for substances, i.e. categories Acute 1 and Chronic 1 to 4. In order to make use of all available data for purposes of classifying the aquatic environmental hazards of the mixture, the following is applied where appropriate:</p> <p>The 'relevant components' of a mixture are those which are classified 'Acute 1' or 'Chronic 1' and present in a concentration of 0.1 % (w/w) or greater, and those which are classified 'Chronic 2', 'Chronic 3' or 'Chronic 4' and present in a concentration of 1 % (w/w) or greater, unless there is a presumption (such as in the case of highly toxic components (see section 4.1.3.5.5.5 of CLP Regulation)) that a component present in a lower concentration can still be relevant for classifying the mixture for aquatic environmental hazards. Generally, for substances classified as 'Acute 1' or 'Chronic 1' the concentration to be taken into account is (0.1/M) %.</p> <p>The approach for classification of aquatic environmental hazards is tiered, and is dependent upon the type of information available for the mixture itself and for its components. Elements of the tiered approach include:</p> <ul style="list-style-type: none"> - classification based on tested mixtures, - classification based on bridging principles, - the use of 'summation of classified components' and/or an 'additivity formula'. <p>The classification of the product has been determined using ecotoxicological data on active substance and co-formulants.</p> <p>More specifically, in the product only cypermethrin is classified as hazardous for the environment and is a relevant substance, due to its concentration, for the classification of the product.</p>

Data waiving	
Information requirement	Acute aquatic toxicity
Justification	According to the specific adaptation rules described in Annex III of BPR, testing on the product was not conducted because there were valid data available on each of the components in the mixture sufficient to allow the classification according to the rules of CLP Regulation (EC) n. 1272/2008 and no synergistic effects between the components of the mixture were expected.

Chronic aquatic toxicity

Product environmental classification - Chronic Aquatic toxicity	
Value/conclusion	Aquatic Chronic 1 H410: Very toxic to aquatic life with long lasting effects.
Justification for the value/conclusion	<p>The classification system for mixtures covers all classification categories which are used for substances, i.e. categories Acute 1 and Chronic 1 to 4. In order to make use of all available data for purposes of classifying the aquatic environmental hazards of the mixture, the following is applied where appropriate:</p> <p>The 'relevant components' of a mixture are those which are classified 'Acute 1' or 'Chronic 1' and present in a concentration of 0.1 % (w/w) or greater, and those which are classified 'Chronic 2', 'Chronic 3' or 'Chronic 4' and present in a concentration of 1 % (w/w) or greater, unless there is a presumption (such as in the case of highly toxic components (see section 4.1.3.5.5.5 of CLP Regulation)) that a component present in a lower concentration can still be relevant for classifying the mixture for aquatic environmental hazards. Generally, for substances classified as 'Acute 1' or 'Chronic 1' the concentration to be taken into account is (0,1/M) %. (For explanation M-factor see section 4.1.3.5.5.5.)</p> <p>The approach for classification of aquatic environmental hazards is tiered, and is dependent upon the type of information available for the mixture itself and for its components. Elements of the tiered approach include:</p> <ul style="list-style-type: none"> - classification based on tested mixtures, - classification based on bridging principles, - the use of 'summation of classified components' and/or an 'additivity formula'. <p>The classification of the product has been determined using ecotoxicological data on active substance and co-formulants.</p> <p>More specifically, in the product only cypermethrin is classified as hazardous for the environment and is a relevant substance, due to its concentration, for the classification of the product.</p>

Data waiving	
Information requirement	Chronic aquatic toxicity
Justification	According to the specific adaptation rules described in Annex III of BPR, testing on the product was not conducted because there were valid data available on each of the components in the mixture sufficient to allow the classification according to the rules of CLP Regulation (EC) n. 1272/2008 and no synergistic effects between the components of the mixture were expected.

Measured aquatic bioconcentration

Conclusion used in Risk Assessment –Aquatic bioconcentration	
Value/conclusion	Cypermethrin does not meet the B or vB screening criteria.
Justification for the value/conclusion	<p>Data on bioconcentration are available in the CAR of cypermethrin, as reported below.</p> <p><i>Data on cypermethrin from CAR</i> Cypermethrin cis:trans/40:60 is not bioconcentrated according to a flow through OECD 305 E test, with a measured BCF of $373 \pm 45 < 2000$ L/Kg wwt. The result is further confirmed by BCFwin (EPISUIT) which provide a BCF of 417L/Kgwwt Cypermethrin cis:trans/40:60 is not bioaccumulable (B).</p> <p>TDCVC and CDCVC metabolite have a Log Pow of 2.672 (calculation based on their smiles code) according to the eq.74 of the TGD, the corresponding BCF is 37.25; therefore, TDCVC and CDCVC metabolites does not fulfil the B criteria.</p>

Data waiving	
Information requirement	Aquatic bioconcentration
Justification	Data suggest that cypermethrin does not meet the B or vB screening criteria.

If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions (ADS)

Not applicable.

Endocrine-disrupting properties for environment: screening for co-formulants

Screening of endocrine-disruption properties of co-formulants has been performed according to CG document "Assessment of endocrine disruption (ED) properties of co-formulants in biocidal products – instructions for applicants".

Overall, based on available information it is concluded that the product does not contain co-formulants with endocrine disruptor properties for environment. Please, refer to the Confidential Annex for further details.

2.2.8.2 Exposure assessment

As already described in the exposure assessment for humans, according to the following request of e-CA Greece : "The minimum purity 93% of Tagros source reported in the PAR is not the one stated in the Technical equivalence for cypermethrin and ECHA decision on chemical equivalence (No TAP-D-1477453-13-00/F), where is it clearly indicating a min purity of 95%..... the risk assessment of the product should be corrected (where needed) using the correct min. at 95%".

The risk assessment calculations proposed are at 95% of purity. Therefore, TGAI is 0.263% w/w (i.e. $0.250 \times 100/95$).

Environmental exposure assessment for each relevant use of the product has been performed following the indication provided in the Emission Scenario Document for PT18 and following ECHA Guidance on the BPR: Volume IV Environment, Assessment & Evaluation (Parts B+C), Version 2.0, October 2017. Moreover, recent modifications agreed upon by Member States at the Biocides Technical Meetings and published in the most recent version of the Manual of Technical Agreements were also included to derive the PECs values.

Environmental exposure has been determined for each relevant primary and secondary compartment exposed as a result of indoor and outdoor uses of the product.

Emissions to environmental compartments have been calculated using the European Union System for the Evaluation of Substances (EUSES version 2.2.0).

Environmental toxicity of relevant metabolites of cypermethrin have been discussed in the CAR of cypermethrin, although no metabolite exposure assessment was performed in the CAR for cypermethrin, as overall it was considered that this was covered by the assessment performed for cypermethrin, the applicant did assess the exposure of the main metabolites of cypermethrin.

Groundwater concentrations of cypermethrin have been assumed the same of porewater concentration.

General information

Assessed PT	PT 18
Assessed scenarios	<p>Scenario 1: Crack and crevice application in voids and cavities-Crawling insects-professional use</p> <p>Scenario 2: Wasp nest, indoor - professional</p> <p>Scenario 3: Wasp nest, outdoor - professional</p> <p>Scenario 4: Crack and crevice application in voids and cavities-Crawling insects- non professional use</p> <p>Scenario 5: Wasp nest, indoor – non professional</p> <p>Scenario 6: Wasp nest, outdoor – non professional</p> <p>Scenario 7: Ant nest, outdoor – non professional</p> <p>Scenario 8a: Spot application outdoor around building against <i>Blatta orientalis</i> (Urban) – non professional</p> <p>Scenario 8b: Spot application outdoor around building against <i>Blatta orientalis</i> (Rural) – non professional</p>
ESD(s) used	Emission Scenario Document for Product Type 18: EMISSION SCENARIO DOCUMENT FOR INSECTICIDES, ACARICIDES AND PRODUCTS TO CONTROL OTHER ARTHROPODS FOR HOUSEHOLD AND PROFESSIONAL USES. 17-Jul-2008.
Approach	The approach followed is average consumption based for all scenarios.
Distribution in the environment	Calculated based on Guidance on the Biocidal Products Regulation Volume IV Environment - Assessment and Evaluation (Parts B + C) Version 2.0 October 2017.
Groundwater simulation	The concentration in porewater of agricultural soil has been calculated to provide an indication for potential groundwater contamination risk.
Confidential Annexes	YES: EUSES calculations for all scenarios are reported in confidential Annex.
Life cycle steps assessed	Uses of the biocidal product. Production of the biocidal product (that is a formulation) has not been assessed since it out of scope of BPR. Service life is not relevant for this product.
Remarks	No remarks.

Emission estimation

Formulation of the product

Production of FREE LAND DUST is an industrial formulation process. Exposure estimation for the formulation of FREE LAND DUST was not performed since:

- releases into the environment cannot take place from formulation process since in the formulation plants typically automated equipment is used to add the formulation ingredients and to fill the formulated product into the respective vessels (closed systems). Since a close system is used no emission is expected; in any case eventual (i.e. accidental or due to maintenance) releases of the product are collected and managed as waste
- emissions from product formulation are considered less relevant (since potentially covered by other legislations) compared to emissions from the application - and in service phase of the product, as reported in "Guidance on the Biocidal Products Regulation, Volume IV Environment - Part B Risk Assessment, Version 1.0".

PROFESSIONAL

2.2.8.2.1 Scenario 1 - Crack and crevice application in voids and cavities

Main input parameters used in EUSES 2.2.0 for calculating the local emission arising from use of the biocidal product are reported in the table below.

TIER 1 - Wet cleaning of treated surfaces			
In TIER 1 exposure assessment has been performed assuming wet cleaning of treated surfaces and a maximum number of permitted applications of 2 times per year.			
Input	Value	Unit	Remarks
General			
Select formulation/use	Dust/powders		
Fraction of active substance in the commercial product	0.00263	-	FREE LAND DUST is a biocidal product with 0.263% of cypermethrin. Technical grade active ingredient (TGAI).
Cover mixing/loading?	No	-	The product is a ready to use (RTU). Applicable RMMs: The area where loading takes place must be covered with a disposable plastic sheet/foil in order to avoid contamination of adjacent surfaces and floor. After treatment, dispose the plastic sheet/foil and the collected residues as hazardous waste.
Total area treated in a standard house	20	m ²	Default value for barrier treatment, crack and crevices treatment for a domestic house is 20 m ² (Technical Agreements for Biocides (TAB) - ENV

			v.2.1, ENV 142).
Total area treated in a large building	93	m ²	Default value for barrier treatment, crack and crevice treatment for large building (Technical Agreements for Biocides (TAB) - ENV v.2.1, ENV 142).
Wet cleaning zone in a standard house (leading to releases to the STP)	5.9	m ²	Default value, ENV TAB 2.1 (2019).
Wet cleaning zone in a large building (leading to releases to the STP)	27	m ²	Default value, ENV TAB 2.1 (2019).
Number of standard houses connected to the same STP	4000		Default value agreed for indoor use (Technical Agreements for Biocides (TAB) - ENV v.2.1, ENV 140)
Number of large buildings connected to the same STP	300		Default value agreed for indoor use (Technical Agreements for Biocides (TAB) - ENV v.2.1, ENV 140)
Application			
Quantity of commercial product applied per m ²	8.0	g/m ²	8 g/m ²
Number of applications per day in a standard house	1	d ⁻¹	-
Number of applications per day in a large building	1	d ⁻¹	-
Simultaneity factor for indoor uses of insecticide in standard houses	2.042×10^{-3}	-	The maximum number of permitted applications is 2 times per year.
Simultaneity factor for indoor uses of insecticide in large buildings	2.042×10^{-3}	-	The maximum number of permitted applications is 2 times per year.
Fraction emitted to air during application	0.02	-	Default value (OECD ESD PT18).
Fraction emitted to the applicator during application	0	-	Default value (OECD ESD PT18).
Fraction emitted to the floor during application	0.18	-	Default value (OECD ESD PT18).
Fraction emitted to treated surfaces	0.8	-	Default value (OECD ESD PT18).
Cleaning			
Cleaning efficiency (of treated surfaces and floor from application)	0.25	-	Default cleaning efficiency for Dust/powders – crack and crevice, as reported in (Technical Agreements for Biocides (TAB) - ENV v.2.1, ENV 149)
Washable coveralls or disposable coveralls	washable coveralls	-	-
Dry or wet cleaning of	Wet cleaning of	-	-

treated surfaces	treated surfaces		
TIER 2 - Dry cleaning of treated surfaces			
In TIER 2 exposure assessment has been performed assuming dry cleaning of treated surfaces and a maximum number of permitted applications of 2 times per year.			
Input	Value	Unit	Remarks
General			
Select formulation/use	Dust/powders		
Fraction of active substance in the commercial product	0.00263	-	FREE LAND DUST is a biocidal product with 0.263% of cypermethrin. Technical grade active ingredient (TGAI).
Cover mixing/loading?	No	-	The product is a ready to use (RTU). Applicable RMMs: The area where loading takes place must be covered with a disposable plastic sheet/foil in order to avoid contamination of adjacent surfaces and floor. After treatment, dispose the plastic sheet/foil and the collected residues as hazardous waste.
Total area treated in a standard house	20	m ²	Default value for barrier treatment, crack and crevices treatment for a domestic house is 20 m ² (Technical Agreements for Biocides (TAB) - ENV v.2.1, ENV 142).
Total area treated in a large building	93	m ²	Default value for barrier treatment, crack and crevice treatment for large building (Technical Agreements for Biocides (TAB) - ENV v.2.1, ENV 142).
Wet cleaning zone in a standard house (leading to releases to the STP)	5.9	m ²	Default value, ENV TAB 2.1 (2019).
Wet cleaning zone in a large building (leading to releases to the STP)	27	m ²	Default value, ENV TAB 2.1 (2019).
Number of standard houses connected to the same STP	4000		Default value agreed for indoor use (Technical Agreements for Biocides (TAB) - ENV v.2.1, ENV 140)
Number of large buildings connected to the same STP	300		Default value agreed for indoor use (Technical Agreements for Biocides (TAB) - ENV v.2.1, ENV 140)
Application			
Quantity of commercial product applied per m ²	8.0	g/m ²	8 g/m ²
Number of applications	1	d ⁻¹	-

per day in a standard house			
Number of applications per day in a large building	1	d ⁻¹	-
Simultaneity factor for indoor uses of insecticide in standard houses	2.042×10^{-3}	-	The maximum number of permitted applications is 2 times per year.
Simultaneity factor for indoor uses of insecticide in large buildings	2.042×10^{-3}	-	The maximum number of permitted applications is 2 times per year.
Fraction emitted to air during application	0.02	-	Default value (OECD ESD PT18).
Fraction emitted to the applicator during application	0	-	Default value (OECD ESD PT18).
Fraction emitted to the floor during application	0.18	-	Default value (OECD ESD PT18).
Fraction emitted to treated surfaces	0.8	-	Default value (OECD ESD PT18).
Cleaning			
Cleaning efficiency (of treated surfaces and floor from application)	0.25	-	Default cleaning efficiency for Dust/powders – crack and crevice, as reported in (Technical Agreements for Biocides (TAB) - ENV v.2.1, ENV 149)
Washable coveralls or disposable coveralls	washable coveralls	-	-
Dry or wet cleaning of treated surfaces	Dry cleaning of treated surfaces	-	As specified in the use description, the application of the FREE LAND DUST product must be carried out on areas not regularly wet cleaned (dry cleaning).

Calculations for Scenario 1

TIER 1			
Resulting local emission to relevant environmental compartments			
Compartment		Local emission (E_{local,compartment}) [kg/d]	Remarks
Private Use (Houses)	Air	6.87×10^{-5}	-
	Wastewater	2.48×10^{-4}	-
Industrial use (Houses & Large buildings)	Air	9.27×10^{-5}	-
	Wastewater	3.34×10^{-4}	-

TIER 2			
Resulting local emission to relevant environmental compartments			
Compartment		Local emission ($E_{\text{local,compartment}}$) [kg/d]	Remarks
Private Use (Houses)	Air	6.87×10^{-5}	-
	Wastewater	4.56×10^{-5}	-
Industrial use (Houses & Large buildings)	Air	9.27×10^{-5}	-
	Wastewater	6.13×10^{-5}	-

2.2.8.2.2 Scenario 2 - Wasps nest - indoor

The use named "Wasps nest eradication indoor" consists in the direct application of the product to wasp nest in an indoor environment. For this use, dose is 10.0 g of commercial product (0.263% TGAI) product per nest that correspond to 26.3 mg a.s./nest.

According to 'Generic Treatment Areas assigned to each specific pest' (WGII2018_ENV_7.3e 1 (11), ENV-A21 TAB-ENV v.2.1, December, 2019) for wasps/nest, indoor, the spot scenario has been adapted.

The product is intended for one single nest per application, indoors, for a standard home or larger building. Therefore the total amount calculated for the emission estimate will be 10 g for the single nest application, regardless of the area of the building and the treatment surface.

The input parameters for calculating the local emission of cypermethrin arising from domestic use of FREE LAND DUST are reported in the table below.

Input parameters for calculating the local emission			
Input	Value	Unit	Remarks
General			
Select formulation/use	-	-	It is not really a surface treatment since the product is applied on a single wasp nest; however, could be regarded as a spot application.
Fraction of active ingredient	0.00263	-	Technical grade active ingredient (TGAI).
Cover mixing and loading	No	-	The product is a ready to use. (RTU)
Select treatment	Spot, surface		It is not really a surface treatment since the product is applied on a single wasp nest; however, could be regarded as a spot application.
Number of houses per STP	4000	-	Default value agreed for indoor use (Technical Agreements for Biocides (TAB) - ENV v.2.1, ENV 140)
Number of large building per STP	300		Default value agreed for indoor use (Technical Agreements for Biocides (TAB) - ENV v.2.1, ENV 140)
Application			
Quantity of product used per application, house	10.0	g/nest	Quantity of product used per single nest is 10.0 g. Exposure assessment has been performed using model for spot application, where

			treated area is by default 2 m ² . Therefore, the quantity of product used per nest entered in EUSES was 5.0 g, so the total amount used per nest calculated in EUSES is 5.0 g/m ² x 2 m ² = 10.0 g
Number of applications per day in a standard house	1	day	Default value for a standard house.
Area for treated floor, house	2	m ²	Relevant area for wet cleaning for wasps indoor scenario (Generic Treatment Areas)
Simultaneity factor in indoor uses of insecticide in standard house	2.042×10^{-3}	-	Frequency of use: 1 to 2 time per year.
Fraction emitted to air during application	0.002	-	Default value (OECD ESD PT18).
Fraction emitted to the applicator during application	0	-	Default value (OECD ESD PT18).
Fraction emitted to the floor during application	0.18	-	Default value (OECD ESD PT18).
Fraction emitted to treated surfaces during application	0.8	-	Default value (OECD ESD PT18).
Cleaning			
Cleaning efficiency (of treated surfaces and floor from application)	0.25	-	-
Washable or disposable applicators	Washable	-	-
Dry or wet cleaning of treated surface?	Wet cleaning	-	-

Calculations for Scenario 2

Resulting local emission to relevant environmental compartments		
Compartment	Local emission ($E_{\text{local, compartment}}$) [kg/d]	Remarks
Air	4.3×10^{-6}	-
Wastewater	5.26×10^{-5}	-

2.2.8.2.3 Scenario 3 - Wasps nest- Outdoor

Note that in the PT18 emission scenario document there is no specific model recommended for this use (i.e. wasp nest eradication with powder – only model for spray is available); therefore, the model for outdoor application of spray products on wasp nests has been used as detailed in the following tables.

According to ESD PT18 the surface treated with the product is the nest attached to a tree in countryside which corresponds to a worst-case. For such applications, only local releases to soil are taken into account. Releases to rainwater in urban situation are not considered to be significant.

Releases due to washing by rainwater are not relevant for this treatment because all wasps should be normally dead from 24 to 48 hours following the application, and subsequently the nest is removed. Furthermore, it is expected that outdoor treatments are not performed on rainy days.

Input parameters for calculating the local emission			
Input	Value	Unit	Remarks
Fraction of active ingredient	0.263	%	FREE LAND DUST is a biocidal product with 0.263% of cypermethrin. Technical grade active ingredient (TGAI).
Quantity of product used per application, house	10.0	g	10.0 g/nest of a commercial product. TGAI
Number of nests treated per day	1	d	Default value for spray product against wasp nest in outdoor applications. This value can also be considered relevant for the outdoor use of a powder product.
Fraction emitted to soil during nest application due to deposition ($F_{\text{spray, nest, deposition}}$)	0.3	-	Default value for spray product against wasp nest in outdoor applications. This value can also be considered relevant for the outdoor use of a powder product.
Area exposed to insecticide (50cm diameter circular surface)	0.19635	m ²	Default value
Depth of exposed soil	0.5	m	
Volume of exposed soil	0.098	m ³	
Bulk density of soil	1700	Kgwwt/m ³	
Density of solid phase	2500	Kg/m ³	
Volume fraction of solids in soil	0.6	m ³ /m ³	

Calculations for Scenario 3

Calculation of PECsoil for Cypermethrin

Cypermethrin

Local emission related to the treatment of wasps nest for one application is derived from the following model calculation:

$$E_{\text{spray, nest, soil}} = Q_{\text{prod}} \times F_{\text{AI}} \times F_{\text{spray, nest, deposition}} \quad (\text{eq. 56, ESD PT18})$$

$$E_{\text{spray, nest, soil}} = 10.0 \times 0.00263 \times 0.3 = 7.89 \times 10^{-6} \text{ kg/day}$$

The local concentration of the active substance in soil resulting of the nest spray application step in the countryside can be calculated from the following model calculation:

$$C_{\text{spray, nest, soil}} = E_{\text{spray, nest, soil}} / (V_{\text{spray, nest, soil}} \times \text{RHO}_{\text{soil}}) = 4.7 \times 10^{-2} \text{ mg/kg}_{\text{ww}} = \text{PEC}_{\text{local soil}}$$

Calculation of PECgroundwater

$$\text{PEC}_{\text{local soil}} \times \text{RHO}_{\text{soil}} / K_{\text{soil-water}} \times 1000$$

Ksoil-water = Fairsoil × Kair-water + Fwatersoil + Fsolidsoil × Kpsoil / 1000 × RHOsolid		
Calculation of air-water partitioning coefficient (Kair-water)		
Parameter	Symbol	Value
Henry's law constant at env temperature [Pa × m ³ /mol]	HENRY	0.0151
Gas constant [Pa × m ³ /mol × k]	R	8.314
Temperature at the air water interface [K]	TEMP	285
Air-water partitioning coefficient	Kair-water = HENRY / (R × TEMP) (Eq. 22, TGD)	6.39×10 ⁻⁶
Calculation of partition coefficient solid-water in soil (Ksoil-water)		
Parameter	Symbol	Value
Weight fraction organic carbon in soil [kg/kg]	Focsoil	0.02
Partition coefficient organic carbon-water [L/kg]	Koc	575000
Calculation of partition coefficient solid-water in soil [L/kg]		
Kpsoil = Focsoil × Koc / 1000 (Eq. 23, TGD)		
Fraction air in soil [m ³ /m ³]	Fairsoil	0.2
Air-water partitioning coefficient [m ³ /m ³]	Kair-water	6.39×10⁻⁶
Fraction solids in soil [m ³ /m ³]	Fsolidsoil	0.6
Density of the solid phase [kg/m ³]	RHOsolid	2500
Soil-water partitioning coefficient [m ³ /m ³]	Ksoil-water	17300
Calculation of the concentration in soil porewater		

Parameter	Symbol	Value
Predicted Environmental Concentration in soil [mg/kg]	PEC_{localsoil}	4.7 × 10⁻²
Soil-water partitioning coefficient [m ³ /m ³]	K_{soil-water}	17300
Bulk density of soil [kg/m ³]	RHO _{soil}	1700
Predicted Environmental Concentration in porewater [mg/L]	PEC_{soil,porewater} local	4.66 × 10⁻⁶

NON PROFESSIONAL

2.2.8.2.4 Scenario 4 – Crack and crevice application in voids and cavities

This Scenario is the same of the Scenario #1 but performed by non-professional users. Usually non-professional users don't use the product in large buildings, but only in house. Therefore, this Scenario is covered by Scenario #1.

2.2.8.2.5 Scenario 6 - Application in voids and cavities application, non professional – Crawling insects

This use is the same of scenario #2 but performed by non professional users. See Scenario #2.

2.2.8.2.6 Scenario 5 - Wasps nest - indoor – non professional

This use is the same of the Scenario #2 but performed by non-professional users. Therefore, this use is covered by use #2.

2.2.8.2.7 Scenario 6 - Wasps nest - outdoor – non professional

This use is the same of the Scenario #3 but performed by non-professional users. Therefore, this use is covered by use #3.

2.2.8.2.8 Scenario 7 - Ant nest treatment - outdoor

As reported in ESD PT18 the term of "spot application" is meant to cover the variety of situations in which local applications of insecticide are used on insect pathway or nest to control undesirable organisms.

Powders are often used outside to control ants around buildings. It is usually recommended to apply the powder directly on nest entrances. It is expected that direct powdering on nest would lead to more limited releases than spray application and should be considered as spot application on soil. In this case, the possible receiving compartments are the soil and to a lesser extent, the air. Release to the air is considered negligible.

Therefore, it is considered that the fraction released during powder application to the environment is 90%, either directly or through ultimate releases after target insect death.

In Emission Scenario Document (OECD, 2008) it is reported that direct powdering on ant nests should be considered as spot application on soil. In this case, the possible receiving compartments are soil and to a lesser extent, the air.

Releases to air from outdoor powder application are considered negligible in Emission Scenario Document (OECD, 2008) due to instant dilution and turbulence in air. Exposure of the air compartment is considered limited in time and restricted to a local scale.

Input parameters for calculating the local emission

Input parameters for calculating the local emission			
Input	Value	Unit	Remarks
Fraction of active ingredient	0.263	%	FREE LAND DUST is a biocidal product with 0.263% of cypermethrin. Technical grade active ingredient (TGAI).
Quantity of product used per application, house	5.0	g	5.0 g/nest of a commercial product.
Type of spot application	Powder	-	-
Fraction emitted to soil during outdoor powder application on ant nest Foutdoor, nest powder, soil	0.9	-	Default value ESD PT18 (p. 147)
Number of application sites Nsites	1	-	The product is intended to treated just one nest per application
Number of applications during a campaign Nappl	1	-	Default value ESD PT18 - (p. 147)
Area treated - Single point of release	0.250	m ²	Default value ESD PT18 - (p. 148)
Depth of exposed soil DEPTHsoil	0.5	m	Default value ESD PT18 (p. 148)
Volume of soil exposed VOLUMEsoil	0.125	m ³	Default value ESD PT18 (p. 148)
Bulk density of soil RHOSoil	1700	kg _{ww} /m ³	Default value ESD PT18 (p. 148)
Density of solid phase	2500	kg/m ³	[p.53]
Volume fraction of solids in soil	0.6	m ³ / m ³	[8 p.53]
Soil-water partition coefficient	17300	m ³ / m ³	Calculated with EUSES.

Calculations for Scenario 7

Calculation of PECsoil for Cypermethrin

Cypermethrin

The local emission related to the treatment of ants nest for one house application (number of points 1), per day is derived from the following model calculation:

$$E_{\text{spot, soil}} = Q_{\text{prod}} \times \text{FAI} \times N_{\text{sites}} \times N_{\text{appl}} \times F_{\text{spot, soil}} \quad (\text{eq. 58, ESD PT18})$$

$$E_{\text{spot, soil}} = 5.0 \text{ g} \times 0.00263 \times 1 \times 1 \times 0.9 = 1.18 \times 10^{-5} \text{ kg}$$

The local concentration of the active substance in soil from one house, resulting on the nest application in the countryside can be calculated from the following model calculation:

$$\text{PEC}_{\text{localsoil}} = E_{\text{spot, soil}} / \text{AREA}_{\text{exposed}} \times \text{DEPTH}_{\text{soil}} \text{ RHO}_{\text{soil}} \quad (\text{eq. 60, ESD PT18})$$

$$\text{PEC}_{\text{localsoil}} = \mathbf{0.056 \text{ mg/kgwwt}} = \mathbf{PEC_{\text{localsoil}}}$$

Calculation of PECgroundwater

$$\mathbf{PEC_{\text{localsoil}} \times RHO_{\text{soil}} / K_{\text{soil-water}} \times 1000}$$

Ksoil-water = Fairsoil × Kair-water + Fwatersoil + Fsolidsoil × Kpsoil / 1000 × RHOsolid		
cypermethrin		
Calculation of air-water partitioning coefficient (Kair-water)		
Parameter	Symbol	Value
Henry's law constant at env temperature [Pa × m ³ /mol]	HENRY	0.0151
Gas constant [Pa × m ³ /mol × k]	R	8.314
Temperature at the air water interface [K]	TEMP	285
Air-water partitioning coefficient	Kair-water = HENRY / (R × TEMP) (Eq. 22, TGD)	6.39 × 10⁻⁶
Calculation of partition coefficient solid-water in soil (Ksoil-water)		
Parameter	Symbol	Value
Weight fraction organic carbon in soil [kg/kg]	Focsoil	0.02
Partition coefficient organic carbon-water [L/kg]	Koc	575000
Calculation of partition coefficient solid-water in soil [L/kg]		
Kpsoil = Focsoil × Koc / 1000		
Fraction air in soil [m ³ /m ³]	Fairsoil	0.2
Air-water partitioning coefficient [-]	Kair-water	6.39 × 10⁻⁶
Fraction solids in soil [m ³ /m ³]	Fsolidsoil	0.6
Density of the solid phase [kg/m ³]	RHOsolid	2500
Soil-water partitioning coefficient [m ³ /m ³]	Ksoil-water	17300
Calculation of the concentration in soil porewater		

Parameter	Symbol	Value
Predicted Environmental Concentration in soil [mg/kg]	PEC_{localsoil}	0.05
Soil-water partitioning coefficient [m ³ /m ³]	K_{soil-water}	17300
Bulk density of soil [kg/m ³]	RHO _{soil}	1700
Predicted Environmental Concentration [mg/L]	PEC_{local soil,porewater}	5.49×10⁻⁶

2.2.8.2.9 Scenario 8a - Spot application outdoor around building against *Blatta orientalis* – non professional (Urban)

The product may be applied outdoors and this may include application to doorsteps, window frames etc. to control crawling insect. No specific scenario is presented in the ESD to cover this type of use.

If such applications take place on hard surfaces (patios, paths etc.), then there may be some potential for the product to be transported by rainfall into drain system or on adjacent soil.

Model of ESD PT18 for crawling insect in outdoor application has been used with some adaptations.

The model includes urban and rural areas; ECHA - Generic treatment areas assigned to each specific parasite (continuation of the WG-I-2018) May 2018. The document on page 2 indicates a length of 10 meters, for a treatment of doors and windows. As indicated in the document, *"refinement for window/door step TAB 1.3, also width of band refinement possible"*.

If we take into consideration a width of band of 0.1 m, a conservative value of width for a powder product we obtain as a total surface:

$$10 \text{ m} \times 0.10 \text{ m} = 1 \text{ m}^2$$

To assess the worst case it was decided, to use as a fraction emitted a value of 1 both in urban and in rural scenario.

Input parameters for calculating the local emission			
Input	Value	Unit	Remarks
<i>General input</i>			
Fraction of active ingredient	0.00263	-	FREE LAND DUST is a biocidal product with 0.263% of cypermethrin. Technical grade active ingredient (TGAI).
Location of the treated surface	urban area	-	-
Cover mixing/loading	no	-	The product is a ready to use. (RTU)
Number of standard houses connected to the same STP	2500	-	Default value agreed for outdoor use (Technical Agreements for Biocides (TAB) - ENV v.2.0, ENV 140)
<i>Application</i>			
Area treated	Crawling space	-	-
Quantity of commercial product applied per m ²	8	g/ m ²	8.0 g/m ² of a commercial product (0.263% TGAI)
Simultaneity factor for outdoor use of insecticide in standard houses	0.002042	-	Frequency of use: 1-2 times per year Default value 0.2042%

Area of walls and ceiling (crawling space) treated per day	0	m ²	Set to 0 since it is not relevant. The product is not intended to be applied on the walls of the house, but only on the floor.
Area of soil (crawling space) treated per day	1	m ²	As previously detailed, in the absence of a specific predefined treatment area, it is proposed to adopt the value indicated in the document " <i>ECHA - Generic treatment areas assigned to each specific pest (follow up of WG-I-2018) May, 2018</i> ", band length of 10 m and band width of 0.1 m. To assume the worst-case scenario, a value of 1 m ² has been used
Fraction emitted to soil during application on walls and ceiling	0	-	Not being a spray treatment on the walls around the house, but a direct treatment of small parts of the floor this value is not relevant.
Fraction emitted to soil during application on soil	1	-	There is not a specific scenario for this type of use and; therefore, no default values are available. In order to assess the worst case it has been decided to set fraction emitted to soil = 1

Calculations for Scenario 8a

Resulting local emission to relevant environmental compartments		
Compartment	Local emission (E_{local,compartment}) [kg/d]	Remarks
Wastewater	1.07 × 10 ⁻⁴	-

2.2.8.2.10 Scenario 8b – Spot application outdoor around building against *Blatta orientalis* – (Rural area)

Input parameters

Input parameters for calculating the local emission			
Input	Value	Unit	Remarks
<i>General input</i>			
Fraction of active ingredient	0.00263	-	Technical grade active ingredient (TGAI).
Location of the treated surface	rural area	-	-
Cover mixing/loading	no	-	The product is a ready to use. (RTU)
Number of standard houses connected to the same STP	2500	-	Default value agreed for outdoor use (Technical Agreements for Biocides (TAB) - ENV v.2.0, ENV 140)
Bulk density of soil	1700	kg _{ww} /m ³	Default value
Density of solid phase	2500	kg/m ³	Default value
Volume fraction of solids in soil	0.6	m ³ /m ³	Default value
Soil-water partition coefficient	17300	m ³ /m ³	Calculated.
<i>Application</i>			
Area treated	Crawling space	-	-
Quantity of commercial product applied per m ²	8	g/ m ²	8.0 g/m ² of a commercial product (0.263% TGAI).
Area of walls and ceiling (crawling space) treated per day	2	m ²	This scenario is not a treatment on the walls around the house, but a direct treatment of small parts of the floor; therefore, this value is not relevant.
Soil volume for application and deposition, treated	2.5	m ³	* There is no specific scenario for this type of use and therefore no default value. The soil volume was obtained as detailed below.
Fraction emitted to soil during application on walls and ceiling	0	-	The product is not intended for treatment of the walls of the house; therefore, this value is not relevant.
Fraction emitted to soil during application on soil	1	-	There is no specific scenario for this type of use and; therefore, no default values are available. To assess the worst case it has been decided to consider 1 the fraction emitted on soil.

* If the soil volume distant from the wall is kept as 0.5 m, and the soil depth of 0.5 m is also retained, a receiving compartment of $10 \times 0.5 \times 0.5 = 2.5 \text{ m}^3$ is generated.

Calculations for Scenario 8b

Calculation of PECsoil for Cypermethrin

Cypermethrin

Local emission related to the treatment of spot application around building is derived from the following model calculation:

$$E_{\text{powder, soil}} = Q_{\text{prod}} \times \text{AREA}_{\text{soil}} \times F_{\text{AI}} \times F_{\text{powder, soil}} \text{ (based on ESD PT18 eq. 48)}$$

Where:

$$Q_{\text{prod}} = 8.0 \text{ g/m}^2$$

$$\text{AREA applied} = 2 \text{ m}^2$$

$$F_{\text{AI}} = 0.00263$$

No value for $F_{\text{powder, soil}}$ is provided in the ESD. As an extreme worst case 1st tier assessment in the absence of any measured data, it is assumed that 100 % of the powder applied can be washed into the surrounding soil, therefore $F_{\text{powder, soil}}$ is set to 1.

$$E_{\text{powder, soil}} = 8.0 \times 2 \times 0.00263 \times 1 = 4.21 \times 10^{-5} \text{ kg d}^{-1}$$

This amount of active substance is released into the surrounding soil.

If the soil volume distant from the wall is kept as 0.5 m, and the soil depth of 0.5 m is also retained, a receiving compartment of $10 \times 0.5 \times 0.5 = 2.5 \text{ m}^3$ is generated.

$$\text{PEC}_{\text{local soil}} = C_{\text{powder, treated soil}}$$

$$C_{\text{powder, treated soil}} = E_{\text{local soil}} / (V_{\text{powder, soil}} \times \text{RHO}_{\text{soil}}) \text{ (adapted from ESD PT 18 eq. 52)}$$

Where:

$$E_{\text{local soil}} = 4.21 \times 10^{-5} \text{ kg d}^{-1}$$

$$\text{RHO}_{\text{soil}} = 1700 \text{ kg}_{\text{ww}} \text{ m}^{-3}$$

$$V_{\text{powder, soil}} = 2.5 \text{ m}^3$$

$$C_{\text{powder, treated soil}} = 4.21 \times 10^{-5} \text{ kg d}^{-1} / (2.5 \times 1700) = 9.9 \times 10^{-3} \text{ mg kg}_{\text{wwt}}$$

$$\text{PEC}_{\text{local soil}} = \mathbf{9.9 \times 10^{-3} \text{ mg kg}_{\text{wwt}}}$$

Calculation of PECgroundwater

$$\text{PEC}_{\text{local soil}} \times \text{RHO}_{\text{soil}} / K_{\text{soil-water}} \times 1000$$

$$0.0099 \text{ mg kg}^{-1} \times 1700 \text{ kg}_{\text{ww}} \text{ m}^{-3} / K_{\text{soil-water}} \text{ (calculated)} \times 1000 = \mathbf{9.76 \times 10^{-7} \text{ mg/l}}$$

Fate and distribution in exposed environmental compartments

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	Value	Unit	Remarks
Molecular weight	416	g/mol	-
Melting point	47	°C	-
Boiling point	Not determined	°C	Boiling did not occur: decomposition was observed
Vapour pressure (at 25°C)	0.0000006	Pa	-
Water solubility (at 20°C)	0.004	mg/l	-
Log Octanol/water partition coefficient	5.45	Log 10	-
Organic carbon/water partition coefficient (Koc)	575000	l/kg	-
Henry's Law Constant (at 20 °C)	0.024	Pa/m ³ /mol	-
Biodegradability	Not biodegradable	-	-
Rate constant for STP [<i>if measured data available</i>]	Not available	h ⁻¹	Experimental data not available
DT ₅₀ for degradation in soil	17.2	d (at 12°C)	based on the geom.mean
DT ₅₀ for degradation in air	0.749	d	-

Calculated fate and distribution in the STP		
Compartment	Percentage [%]	Remarks
Air	5.44 × 10 ⁻⁴	For all scenario where STP is a relevant compartment.
Water	8.356	
Primary settler	66.15	
Surplus sludge	25.5	
Degraded in STP	0	

Metabolites

As reported in the Competent Authority Report of Cypermethrin (Document II-A, January 2017) the major degradation pathway of cypermethrin in water, soil, plants, insects, birds and fish consists in the cleavage of cypermethrin into a cyclopropane carbonic acid and dibenzyl (3-phenoxybenzoic acid) moiety (= 3pba). In these degradation studies, DCVC acid accounted for up to 40% of the applied dose in water, 17.4% in soil and 33.4% in plants (as conjugate in this latter case).

Maximum percentage of cypermethrin degradation product identified in degradation studies are reported in Table below.

	3-PBA	DCVC	3 PBAD
Photolyse in water *	15%	18%	3%
Photolyse in soil *	6%	3%	/
Water	21%	38%	/
Sediment	29%	20%	/
Aerobic soil degradation	10.2%	17.5% ⁽¹⁾	
Anaerobic degradation soil	35.1%	31.2%	0.7

*irradiated samples

⁽¹⁾ Trans-DCVC + Cis-DCVC

Calculated PEC values

PEC Scenario 1 - TIER 1	Unit	Industrial Use	Private Use
PEC _{air}	mg/m ³	2.12 x 10 ⁻⁸	1.91 x 10 ⁻⁸
PEC _{water}	mg/l	7.49 x 10 ⁻⁷	5.57 x 10 ⁻⁷
PEC _{sed}	mg/kgwwt	9.36 x 10 ⁻³	6.97 x 10 ⁻³
PEC _{agric. soil (averaged over 30 days)}	mg/kgwwt	3.2 x 10 ⁻⁴	2.38 x 10 ⁻⁴
PEC _{agric. soil (averaged over 180 days)}	mg/kgwwt	7.61 x 10 ⁻⁵	5.66 x 10 ⁻⁵
PEC _{grassland (averaged over 180 days)}	mg/kgwwt	3.05 x 10 ⁻⁵	2.27 x 10 ⁻⁵
PEC _{pore water (agric. soil)}	mg/l	7.5 x 10 ⁻⁹	5.58 x 10 ⁻⁹
PEC _{pore water (grassland)}	mg/l	3.01 x 10 ⁻⁹	2.24 x 10 ⁻⁹
PEC _{groundwater}	mg/l	7.5 x 10 ⁻⁹	5.58 x 10 ⁻⁹
PEC _{STP}	mg/l	1.39 x 10 ⁻⁵	1.04 x 10 ⁻⁵
PEC Scenario 1 - TIER 2	Unit	Industrial Use	Private Use
PEC _{air}	mg/m ³	2.12 x 10 ⁻⁸	1.91 x 10 ⁻⁸
PEC _{water}	mg/l	1.37 x 10 ⁻⁷	1.02 x 10 ⁻⁷
PEC _{sed}	mg/kgwwt	1.72 x 10 ⁻³	1.28 x 10 ⁻³
PEC _{agric. soil (averaged over 30 days)}	mg/kgwwt	5.89 x 10 ⁻⁵	4.38 x 10 ⁻⁵
PEC _{agric. soil (averaged over 180 days)}	mg/kgwwt	1.4 x 10 ⁻⁵	1.04 x 10 ⁻⁵
PEC _{grassland (averaged over 180 days)}	mg/kgwwt	5.7 x 10 ⁻⁶	4.26 x 10 ⁻⁶
PEC _{pore water (agric. soil)}	mg/l	1.38 x 10 ⁻⁹	1.03 x 10 ⁻⁹
PEC _{pore water (grassland)}	mg/l	5.61 x 10 ⁻¹⁰	4.2 x 10 ⁻¹⁰
PEC _{groundwater}	mg/l	1.38 x 10 ⁻⁹	1.03 x 10 ⁻⁹
PEC _{STP}	mg/l	2.56 x 10 ⁻⁶	1.91 x 10 ⁻⁶

PEC Scenario 2	Unit	Single wasp nest in Standard house and Large buildings
PEC _{air}	mg/m ³	1.19 x 10 ⁻⁹
PEC _{water}	mg/l	1.18 x 10 ⁻⁷
PEC _{sed}	mg/kgwwt	1.48 x 10 ⁻³
PEC _{agric. soil (averaged over 30 days)}	mg/kgwwt	5.05 x 10 ⁻⁵
PEC _{agric. soil (averaged over 180 days)}	mg/kgwwt	1.20 x 10 ⁻⁵
PEC _{grassland (averaged over 180 days)}	mg/kgwwt	4.8 x 10 ⁻⁶
PEC _{pore water (agric. soil)}	mg/l	1.18 x 10 ⁻⁹
PEC _{pore water (grassland)}	mg/l	4.73 x 10 ⁻¹⁰

PECgroundwater	mg/l	1.18×10^{-9}
PECSTP	mg/l	2.2×10^{-6}

PEC Scenario 3	Unit	Value
PEC Soil	mg/Kg wwt	4.7×10^{-2}
PECgroundwater	mg/l	4.66×10^{-6}

PEC Scenario 7	Unit	Value
PEC Soil	mg/Kg wwt	0.056
PECgroundwater	mg/l	5.49×10^{-6}

PEC Scenario 8a URBAN	Unit	Standard house
PEC _{air}	mg/m ³	1.62×10^{-13}
PECwater	mg/l	2.41×10^{-7}
PECsed	mg/kgwwt	3.01×10^{-3}
PECagric. soil (averaged over 30 days)	mg/kgwwt	1.03×10^{-4}
PECagric. soil (averaged over 180 days)	mg/kgwwt	2.45×10^{-5}
PECgrassland (averaged over 180 days)	mg/kgwwt	9.79×10^{-6}
PECpore water (agric. soil)	mg/l	2.41×10^{-9}
PECpore water (grassland)	mg/l	9.65×10^{-10}
PECgroundwater	mg/l	2.41×10^{-9}
PECSTP	mg/l	4.49×10^{-6}

PEC Scenario 8b RURAL	Unit	Value
PEC Soil	mg/kgwwt	9.9×10^{-3}
PECgroundwater	mg/l	9.76×10^{-7}

Calculated PECs for the metabolites

Local PEC values for the metabolites of a.i have been calculated and presented below for the relative compartments. Metabolite exposures in water, sediment, soil compartments were calculated based on the estimated emissions for the parent, taking into account the molecular weight difference between parent and metabolites along with the formation fraction (f_{ij}), according to the equation:

$$PEC_{metabolite} = PEC_{parent} \times f_{ij} \times \frac{Mass_{molar-metabolite}}{Mass_{molar-parent}}$$

Local concentrations of metabolites in groundwater were calculated based on TAB ENV10, according to the equation:

$$PEC_{local,agr.soil.porew.metabolite} = \frac{PEC_{local,agr.soil.metabolite} \times RHO_{soil}}{K_{soil-water} \times 1000}$$

Local concentration of metabolites were calculated using the highest PECs of the parent compound. Based on the calculated PEC values presented above, the highest PEC for soil was found at scenario 7 (use #5) and the highest PECs for water and sediment were found at scenario 8a (Use #6) (scenario 1-Tier 1 was not considered since it leads to unacceptable risk). Since the examined PEC values are considered as worst-case, the exposure assessment of metabolites covers all the other uses.

Metabolites of Cypermethrin in the relevant environmental compartments

Surface water			
Metabolite / parent	f_{ij}^*	Molar mass	PEC _{sw} [mg/L]
Cypermethrin	-	416.3	2.41×10^{-7}
3-PBA	1	214.2	1.24×10^{-7}
DCVC	1	209.1	1.21×10^{-7}

*Based on Harmonised list of endpoints for pyrethroid metabolites, the formation fraction for RA is 1.

Sediment of surface water			
Metabolite / parent	f_{ij}^*	Molar mass	PEC _{sed} [mg/kg ww]
Cypermethrin	-	416.3	3.01×10^{-3}
3-PBA	1	214.2	1.55×10^{-3}
DCVC	1	209.1	1.51×10^{-3}

*Based on Harmonised list of endpoints for pyrethroid metabolites, the formation fraction for RA is 1.

Soil			
Metabolite / parent	f_{ij}^*	Molar mass	PEC _{soil} [mg/kg]
Cypermethrin	-	416.3	5.60×10^{-2}
3-PBA	1	214.2	2.88×10^{-2}
DCVC	1	209.1	2.81×10^{-2}

*Based on Harmonised list of endpoints for pyrethroid metabolites, the formation fraction for RA is 1.

For the groundwater exposure of metabolites, the following parameters were used as inputs:

Parameter	Values
Henry's law constant (Pa m ³ mole ⁻¹) *	3-PBA: 2.4×10^{-4} at 25°C
	DCVC : 5.16×10^{-2} at 25°C
K _{oc} *	3-PBA: 217.8
	DCVC: 59.47
K _{air-water}	3-PBA: 4.85×10^{-8}
	DCVC : 1.04×10^{-5}
K _{soil-water}	3-PBA: 6.7
	DCVC: 2.0
RHO _{soil} (kg/m ³)	1700

*Input parameters have been estimated with EPIWEB4.1 tool, considering the smiles coding for the relevant compounds related to the CAS number.

Groundwater		
Metabolite	PECsoil [mg/kg]	PECgroundwater [mg/l]
3-PBA	2.88E-02	7.27E-03
DCVC	2.81E-02	2.41E-02

Primary and secondary poisoning

Primary poisoning

According to OECD Emission Scenario Document for PT18 primary poisoning for birds or mammals, i.e. the direct consumption of insecticide by birds or mammals may mainly occur in the following cases:

- insecticides are applied together with food attractant, or
- insecticides are applied as granular formulation.

Furthermore in ESD PT 18 it is reported that "it is not believed that powder, gels or any other sort of insecticides are in a form that could be sufficiently appetent to bird or mammals so they would be at risk".

Therefore, for FREE LAND DUST primary poisoning assessment for birds or mammals is not relevant.

Secondary poisoning

According to the TGD (EC, 2003) a calculation for $PEC_{oral,predator}$ should be conducted if the a.s. shows a potential for bioaccumulation, indicated by a log Kow value >3. Since Cypermethrin has a slight potential for bioaccumulation (log Kow of 5.45) the calculation of a possible risk to man via the food chain was conducted according to the TGD (EC, 2003).

2.2.8.3 Risk characterisation

Atmosphere

The very low vapour pressure and Henry law constant suggests that atmospheric concentrations will be negligible.

Sewage treatment plant (STP)

Scenario	Tier	PEC (mg/l)	PNEC (mg/l)	PEC / PNEC
Scenario 1 - Private use	1	1.04×10^{-5}	1.63	6.38×10^{-6}
Scenario 1 - Industrial use	1	1.39×10^{-5}	1.63	8.53×10^{-6}
Scenario 1 - Private use	2	1.91×10^{-6}	1.63	1.17×10^{-6}
Scenario 1 - Industrial use	2	2.56×10^{-6}	1.63	1.57×10^{-6}
Scenario 2 - Single wasp nest in Standard house or Large buildings	1	2.2×10^{-6}	1.63	1.35×10^{-6}
Scenario 3	1	not relevant	-	-
Scenario 4	Refer to scenario # 1	-	-	-
Scenario 5	Refer to scenario # 2	-	-	-
Scenario 6	Refer to scenario # 3	-	-	-
Scenario 7	1	not relevant	-	-
Scenario 8a URBAN	1	4.49×10^{-6}	1.63	2.75×10^{-6}
Scenario 8b RURAL	1	not relevant	-	-

Conclusion:

Regarding Scenario 1, only the TIER 2 (dry cleaning of treated surfaces) is relevant and is taken into consideration for the risk characterization.

Risk characterization ratios for STP calculated for Cypermethrin are for all scenarios below 1, indicating the absence of unacceptable risks for the microorganisms of the wastewater treatment plant. A safe use of the product FREE LAND DUST is demonstrated.

Aquatic compartment

Surface water

Due to the intended indoor use, there are no direct emissions to surface water. The exposure of surface water is indirect via STP effluents.

Scenario	Tier	PEC (mg/l)	PNEC (mg/l)	PEC / PNEC
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Scenario 1 - Private use	1	5.57×10^{-7}	4.00×10^{-6}	1.39×10^{-1}
Scenario 1 - Industrial use	1	7.49×10^{-7}	4.00×10^{-6}	1.87×10^{-1}
Scenario 1 - Private use	2	1.02×10^{-7}	4.00×10^{-6}	2.55×10^{-2}
Scenario 1 - Industrial use	2	1.37×10^{-7}	4.00×10^{-6}	3.43×10^{-2}
Scenario 2 - Single wasp nest in Standard house or Large buildings	1	1.18×10^{-7}	4.00×10^{-6}	2.95×10^{-2}
Scenario 3	1	not relevant	-	-
Scenario 4	Refer to scenario # 1	-	-	-
Scenario 5	Refer to scenario # 2	-	-	-
Scenario 6	Refer to scenario # 3	-	-	-
Scenario 7	1	not relevant	-	-
Scenario 8a URBAN	1	2.41×10^{-7}	4.00×10^{-6}	6.03×10^{-2}
Scenario 8b RURAL	1	not relevant	-	-

Conclusion:

Regarding Scenario 1, only the TIER 2 (dry cleaning of treated surfaces) is relevant and is taken into consideration for the risk characterization.

Risk characterization ratio for surface water calculated for Cypermethrin is below 1 for all relevant scenarios, indicating no unacceptable risk to aquatic organisms, when following the label instructions of FREE LAND DUST.

Sediment

Due to the intended use, there are no direct emissions to sediments. The exposure to sediment is indirect via STP effluents.

Scenario	TIER	PEC (mg/Kg) wwt	PNEC (mg/Kg) wwt*	PEC / PNEC
Scenario 1 - Private use	1	6.97×10^{-3}	0.005	1.39×10^0
Scenario 1 - Industrial use	1	9.36×10^{-3}	0.005	1.87×10^0
Scenario 1 - Private use	2	1.28×10^{-3}	0.005	2.56×10^{-1}
Scenario 1 - Industrial use	2	1.72×10^{-3}	0.005	3.44×10^{-1}
Scenario 2 - Single wasp nest in Standard house or Large buildings		1.48×10^{-3}	0.005	2.96×10^{-1}
Scenario 3		not relevant	-	-
Scenario 4	Refer to scenario # 1	-	-	-

Scenario 5	Refer to scenario # 2	-	-	-
Scenario 6	Refer to scenario # 3	-	-	-
Scenario 7		not relevant	-	-
Scenario 8a URBAN		3.01×10^{-3}	0.005	6.02×10^{-1}
Scenario 8b RURAL		not relevant	-	-

**As reported in the CAR of active substance Cypermethrin an extra factor AF of 10 should be applied since PNEC_{sediment} can be provisionally calculated using the equilibrium partitioning method.*

Conclusion:

Regarding Scenario 1, only the TIER 2 (dry cleaning of treated surfaces) is relevant and is taken into consideration for the risk characterization.

Risk characterization ratios calculated for sediment are below 1 for all scenarios, indicating no unacceptable risk to sediment dwelling organisms, when following the label instructions of FREE LAND DUST.

Terrestrial compartment

Soil

Indirect exposure to the soil compartment can occur through application of sewage sludge from a sewage treatment plant. Exposure estimation has been performed using EUSES. Three different PECs soil were generated:

- PEC in local soil for comparison against terrestrial ecosystem endpoints (for the terrestrial ecosystem the concentration is averaged over 30 days),
- PEC in agricultural soil for comparison against crop endpoints for human consumption (for human indirect exposure a period of 180 days is used)
- PEC in grassland soil for comparison against endpoints in grass for cattle.

For outdoor scenarios where there is direct external application, the main compartment exposed is the soil.

Scenario	TIER	PEC (mg/Kg) wwt	PNEC (mg/Kg) wwt	PEC / PNEC
Scenario 1 - Private use	1	local soil 2.38×10^{-4} (worst case)	0.0708	3.36×10^{-3}
Scenario 1 - Industrial use	1	local soil 3.2×10^{-4} (worst case)	0.0708	4.52×10^{-3}
Scenario 1 - Private use	2	local soil 4.38×10^{-5} (worst case)	0.0708	6.19×10^{-4}
Scenario 1 - Industrial use	2	local soil 5.89×10^{-5} (worst case)	0.0708	8.32×10^{-4}
Scenario 2 - Single wasp	1	local soil 5.05×10^{-5}	0.0708	7.13×10^{-4}

nest in Standard house or Large buildings		(worst case)		
Scenario 3	1	4.70×10^{-2}	0.0708	6.64×10^{-1}
Scenario 4	-	Refer to scenario # 1	-	-
Scenario 5	-	Refer to scenario # 2	-	-
Scenario 6	-	Refer to scenario # 3	-	-
Scenario 7		5.60×10^{-2}	0.0708	7.91×10^{-1}
Scenario 8a URBAN		local soil 1.03×10^{-4} (worst case)	0.0708	1.45×10^{-3}
Scenario 8b RURAL		9.9×10^{-3}	0.0708	1.40×10^{-1}

Conclusion:

Regarding Scenario 1, only the TIER 2 (dry cleaning of treated surfaces) is relevant and is taken into consideration for the risk characterization.

Risk characterization ratios for local soil (which was considered as worst-case) are below one, indicating no unacceptable risk to terrestrial organisms, when the product FREE LAND DUST is used as detailed on the label.

Groundwater

Use	TIER	PEC ($\mu\text{g/l}$)	EU trigger value ($\mu\text{g/l}$)	Acceptable (yes-no)
Scenario 1 - Private use	1	5.58×10^{-6}	0.1	yes
Scenario 1 - Industrial use	1	7.5×10^{-6}	0.1	yes
Scenario 1 - Private use	2	1.03×10^{-6}	0.1	yes
Scenario 1 -Industrial use	2	1.38×10^{-6}	0.1	yes
Scenario 2 - Single wasp nest in Standard house or Large buildings	1	1.18×10^{-6}	0.1	yes
Scenario 3	1	4.66×10^{-3}	0.1	yes
Scenario 4	-	Refer to scenario # 1	-	-
Scenario 5	-	Refer to scenario # 2	-	-
Scenario 6	-	Refer to scenario # 3	-	-
Scenario 7	1	5.49×10^{-3}	0.1	yes
Scenario 10a URBAN	1	2.41×10^{-6}	0.1	yes
Scenario 10b RURAL	1	9.76×10^{-4}	0.1	yes

All groundwater concentrations of Cypermethrin are below the EU trigger value of 0.1 $\mu\text{g/L}$.

Risk characterisation Metabolites

Metabolites of Cypermethrin in surfacewater

	PEC aquatic (mg/l)	PNEC aquatic (mg/l)	PEC/PNEC
3-PBA	2.75×10^{-8}	> 0.010	1.24×10^{-5}
DCVC	4.86×10^{-8}	0.000004 (*)	3.03×10^{-2}

(*) Since TDCVC and CDCVC metabolites have toxicity values which are 10000x higher than those of cypermethrin but PNECs are not available for these metabolites, as a conservative approach, for DCVC PNECs of cypermethrin have been used.

Metabolites of Cypermethrin in sediment

	PEC (mg/kg ww)	PNEC (mg/kg ww)	PEC/PNEC
3-PBA	4.75×10^{-4}	0.009	1.72×10^{-1}
DCVC	3.20×10^{-4}	0.005 (*)	3.02×10^{-1}

(*) Since TDCVC and CDCVC metabolites have toxicity values which are 10000x higher than those of cypermethrin but PNECs are not available for these metabolites, as a conservative approach, for DCVC PNECs of cypermethrin have been used.

Metabolites of Cypermethrin in soil

	PEC soil (mg/kg ww soil)	PNEC soil (mg/kg ww soil)	PEC/PNEC
3-PBA	2.93×10^{-3}	1.44	2.00×10^{-2}
DCVC	4.92×10^{-3}	0.0708 (*)	3.97×10^{-1}

(*) Since TDCVC and CDCVC metabolites have toxicity values which are 10000x higher than those of cypermethrin but PNECs are not available for these metabolites, as a conservative approach, for DCVC PNECs of cypermethrin have been used.

Metabolites of Cypermethrin in groundwater

Groundwater concentrations of Cypermethrin metabolites are above the EU trigger value of 0.1 µg/L. A refinement of $PEC_{local,grw,metabolite}$ was performed using FOCUS PEARL as indicated in ENV 10.

As presented in the table below, groundwater concentrations of Cypermethrin metabolites are above 0.1 µg/L at Scenarios 3, 7 and 8b where direct application to soil is considered. Further calculations with FOCUS PEARL were performed considering Scenario 7 which is a worst-case and covers Scenarios 3 and 8b as well.

Groundwater				
Scenario	3-PBA		DCVC	
	PECsoil [mg/kg]	PECgroundwater [µg/l]	PECsoil [mg/kg]	PECgroundwater [µg/l]
Scenario 1-Tier 2	3.03E-05	7.65E-03	2.96E-05	2.53E-02
Scenario 2	2.60E-05	6.56E-03	2.54E-05	2.17E-02

Scenario 3	2.42E-02	6.11	2.36E-02	20.23
Scenario 7	2.88E-02	7.27	2.81E-02	24.10
Scenario 8A	5.30E-05	1.34E-02	5.17E-05	4.43E-02
Scenario 8B	5.09E-03	1.29	4.97E-03	4.26

FOCUS PEARL calculations

Emission to groundwater has been assessed using the latest version of FOCUS PEARL (version 5.5.5.) by applying the metabolite's physical-chemical parameters as presented in the table below.

Since scenario 7 concerns direct application to ant nest outdoors (direct emission to soil), the selection of application schemes (timelines and crops) was based on ENV 157-groundwater assessment for outdoor applications. FOCUS PEARL was performed for all nine FOCUS scenarios for grass/alfalfa crop. Concerning the application timing, ants will most probably occur during spring and summer months, thus five applications between April and September were considered. Crop interception was set to zero.

The application rate (kg/ha) of the active substance was calculated considering application of the product to one nest and 16 domestic premises per hectare. The application rate (kg/ha) of each metabolite was calculated from the app.rate of the a.s. multiplied by the ratio of molecular weights.

Parameters for groundwater modelling			
Input	Value	Unit	Remarks
Molecular weight	214.22	g/mol	3-PBA
	209.07	g/mol	DCVC
Water solubility (at 25°C)	16.91	mg/l	3-PBA
	127.6	mg/l	DCVC
Molar enthalpy of dissolution	27	kJ/mol	Default
Vapour pressure (at 25°C)	0.000421	Pa	3-PBA
	0.26	Pa	DCVC
Molar enthalpy of vaporisation	95	kJ/mol	Default
Diffusion coefficient in water	4.3E-05	m ² /d	Default
Gas diffusion coefficient	0.43	m ² /d	Default
Reference temperature to degradation, vaporization and dissolution	20	°C	Default
Exponent for the effect of liquid (degradation moisture relationship)	0.7	-	Default
K _{oc}	217.8	l/kg	3-PBA
	59.47	l/kg	DCVC
DT ₅₀ for degradation in soil*	15.8	days (at 20°C)	3-PBA
	30.9	days (at 20°C)	DCVC
Arrhenius activation energy	65.4	kJ/mol	Default
Freundlich exponent (1/n)	0.9	-	
Application type	To the soil surface	-	
Crop type	Grass/alfalfa	-	
Application time	29.04	-	
	05.06		
	11.07		

	17.08 22.09		
Application rate	0.000108	Kg/ha	3-PBA
	0.000106	Kg/ha	DCVC
* The degradation rate value is required at 20°C for modelling purposes (the model applies temperature correction as part of its internal routines). DT50 values reported at BCP-35 Harmonised list of endpoints for RA were used.			

The predicted 80th percentile concentration for Cypermethrin metabolites for each scenario calculated considering application at 22.09 (worst-case values) are presented in the following table.

PECgroundwater - Output (FOCUS PEARL [vs 5.5.5]) in µg/L		
	Application time: 22.09	
Location	3-PBA	DCVC
Chateaudun	0	0.000011
Hamburg	0	0.000001
Jokioinen	0	0.000005
Kremsmunster	0	0.000016
Okehampton	0	0.000019
Piacenza	0	0.000009
Porto	0	0.000000
Sevilla	0	0.000001
Thiva	0	0.000011

The results of the higher tier modelling indicate negligible groundwater concentrations in all FOCUS scenarios. All groundwater concentrations of Cypermethrin metabolites are below the EU trigger value of 0.1 µg/L.

Primary and secondary poisoning

Primary poisoning

According to OECD Emission Scenario Document for PT18 primary poisoning for birds or mammals, i.e. the direct consumption of insecticide by birds or mammals may mainly occur in the following cases:

- insecticides are applied together with food attractant, or
- insecticides are applied as granular formulation.

Furthermore in ESD PT 18 it is reported that "it is not believed that powder, gels or any other sort of insecticides are in a form that could be sufficiently appetent to bird or mammals so they would be at risk".

Therefore, for FREE LAND DUST primary poisoning assessment for birds or mammals is not relevant.

Regarding the bioaccumulation by terrestrial organisms, Cypermethrin has a high Koc value which ranges from 80653 to 574360 (Covance report 1669/015), which indicate that the active would adhere to soil/sediment making it very difficult for organisms to uptake and accumulate it. Conversely, the active may also absorb to biological surface such as skin which may lead to toxic effects in higher organisms after biomagnification.

Secondary poisoning

A predicted no effect oral concentration (PNEC_{oral}) can be calculated based on the results of the mammalian and avian repeat dose toxicity tests. The result of this calculation gives a predicted no-effect concentration in food that should be protective to other mammalian and avian species.

According to the Technical Guidance Document on Risk Assessment Part II (p. 128), secondary poisoning effects on bird populations rarely occurs over the short-term. Therefore, results from long-term studies are strongly preferred, such as NOECs for mortality, reproduction or growth.

PNEC oral, bird

The PNEC_{oral} for secondary poisoning of birds is derived by applying an assessment factor of 30 to the chronic NOEC of 1000 mg/Kg feed, resulting in a **PNEC_{oral,bird} of 33.3 mg/Kg feed**.

PNEC_{oral},mammals

The PNEC_{oral} for secondary poisoning of mamal is derived by applying an assessment factor of 30 to the chronic rat study (McAusland, Butterworth, Hunt, 1978) NOEC of 5 mg/Kg bw/d, resulting in a **PNEC_{oral,mammals} of 3.3 mg/Kg food**.

According to the TGD (EC, 2003) a calculation for PEC_{oral,predator} should be conducted if the a.s. shows a potential for bioaccumulation, indicated by a log Kow value >3. Since Cypermethrin has a slight potential for bioaccumulation (log Kow of 5.45) the calculation of a possible risk to man via the food chain was conducted according to the TGD (EC, 2003).

The concentration of a contaminant in food (fish) of fish-eating predators (PEC_{oral,predator}) is derived from the PEC for surface water, the measured BCF for fish and the biomagnification factor (BMF). Since the log Kow of Cypermethrin is 5.45 and a measured

BCF for Cypermethrin in the test OECD guideline (1981) part 305E was reported at 373 ± 45 L/kg the default BMF of 10 is used in the calculation (Table 23: Default BMF values for organic substances - Guidance on BPR: Vol IV Environment Parts B+C Version 2.0 October 2017). The calculation of $PEC_{oral,predator}$ is presented below.

Regarding Scenario 1, only the TIER 2 (dry cleaning of treated surfaces) is relevant and is taken into consideration for the risk characterization.

Aquatic Compartment (including Risk characterisation for fish eating organisms)

All calculations below were performed only for **Scenario 8a** since it represents the worst case in term of Predicted Exposure Concentration.

Calculating Risk to Fish Eating Predator – Cypermethrin - Scenario 1- Industrial use - Tier 1 (worst case)

$$PEC_{oral, fish-eating predator} = PEC_{water} \times BCF_{fish} \times BMF$$

Where:

Variable/parameter (unit)	Symbol	Unit	Value	Source
Predicted Environmental Concentration in fish-eating predators	$PEC_{oral, fish-eating predator}$	[mg.kg _{wet fish} ⁻¹]	1.00×10^{-3}	Output
Predicted Environmental Concentration in water (1)	PEC_{water}	[mg.L ⁻¹]	2.41×10^{-7}	Input
Bioconcentration Factor for fish on wet weight basis (2)	BCF_{fish}	[L.kg _{wet fish} ⁻¹]	373 ± 45 L/kg	Input
Biomagnification factor in fish (3)	BMF	[-]	10	Default

¹ $PEC_{water} = 2.55 \times 10^{-7}$ mg.L⁻¹ for Scenario 1- Industrial use - Tier 1

² According to Cypermethrin CAR.

³ According to Cypermethrin CAR and Table 23 of ECHA Guidance on the BPR (Volume IV Environment –Version 2.0, October 2017)

Based on the above, the Predicted Environmental Concentrations in fish-eating predators are presented in the following table.

Summary table on estimated theoretical exposition values (ETE) via food chain	
Scenario	$PEC_{oral, fish-eating predator}$
1 -Industrial use - Tier 1	1.00×10^{-3}

PEC/PNEC ratio for fish eating birds:

Compartment	$PEC_{oral predator}$ (mg/kg)	$PNEC_{oral}$ (mg/kg)	PEC/PNEC
Biota	1.00×10^{-3}	33.3	3.02×10^{-5}

PEC/PNEC ratio for fish eating mammals:

Compartment	$PEC_{oral predator}$ (mg/kg)	$PNEC_{oral}$ (µg/kg)	PEC/PNEC
Biota	1.00×10^{-3}	3.3	3.05×10^{-4}

Conclusion:

By comparing the $PEC_{oral,predator}$ with the respective PNECs, PEC/PNEC ratios are below one for birds and mammals, indicating acceptable risk of secondary poisoning through the aquatic food-chain via fish.

Terrestrial Compartment (including risk characterisation for earthworm eating organisms)

Calculated Risk to Worm Eating Predators

It is accepted that substances adsorbed to soil particles can be ingested and may bioaccumulate in worms. Since birds and mammals consume worms and the gut of earthworms can contain substantial amounts of soil, the exposure of the predators may be affected by the quantity of active substance that is present in this soil.

The total concentration in an entire worm can be calculated as the weighted average of the worm's tissues (through BCF and pore water) and guts contents (through soil concentration). A quantitative risk characterisation for secondary poisoning in the terrestrial compartment (for the food chain soil → earthworm → worm-eating birds or mammals) has been performed below for completeness sake.

PEC_{oral, bird} of 33.3 mg/Kg feed.
PEC_{oral, mammals} of 3.3 mg/Kg food.

Cypermethrin

All calculations below were performed only for Scenario 7 since it represent the worst case in term of Predicted Exposure Concentration.

PEC_{oral, predator} derivation:

The calculation method described in the TGD was used to determine the PEC_{oral, predator} for earthworm eating predators as:

Based on the following equation, the concentration of Cypermethrin in an entire worm is:

$$C_{\text{earthworm}} = [(BCF_{\text{earthworm}} \times C_{\text{porewater}}) + (C_{\text{soil}} \times F_{\text{gut}} \times CONV_{\text{soil}})] / [1 + (F_{\text{gut}} \times CONV_{\text{soil}})]$$

BCF_{earthworm}

Bioconcentration can be described as a hydrophobic partitioning between the pore water and the phases inside the organism and can be modelled according to the following equation as described by Jager (1998):

$$BCF_{\text{earthworm}} = (0.84 + 0.012Kow) / RHO_{\text{earthworm}}$$

where for RHO_{earthworm} by default a value of 1 (kgwwt.L⁻¹) can be assumed.

Guidance on BPR: Vol IV Environment Parts B+C Version 2.0 October 2017 (Equation 104d)

$$BCF_{\text{earthworm}} = 3382,9 \text{ L/kg}$$

$$C_{\text{porewater}} = 5.49 \times 10^{-6} \text{ mg/L (EUSES 2.2.0)}$$

$$C_{\text{soil}} = 5.60 \times 10^{-2} \text{ mg/kg wwt soil corresponding to local PEC in agricultural soil.}$$

$$F_{\text{gut}} = 0.1 \text{ (TGD on Risk Assessment page 132)}$$

$$CONV_{\text{soil}} = RHO_{\text{soil}} / (F_{\text{solid}} \times RHO_{\text{solid}}) = 1700 / (0.6 \times 2500) = 1.13.$$

$$\text{Cypermethrin PEC}_{\text{oral, predator}} = 2.43 \times 10^{-2} \text{ mg/kg wet earthworm (C}_{\text{earthworm}})$$

Risk characterisation for earthworm-eating birds:

The risk to the earthworm-eating birds is calculated as the ratio between the concentration in their food ($PEC_{oral, predator}$) and the no-effect-concentration for oral intake ($PNEC_{oral}$) as follows:

$$PEC_{oral, predator} / PNEC_{oral} = 2.43 \times 10^{-2} / 33.3 = 7.28 \times 10^{-4}$$

Risk characterisation for earthworm-eating mammals:

The risk to the earthworm-eating mammals is calculated as the ratio between the concentration in their food ($PEC_{oral, predator}$) and the no-effect-concentration for oral intake ($PNEC_{oral}$) as follows:

$$PEC_{oral, predator} / PNEC_{oral} = 2.43 \times 10^{-2} / 3.3 = 7.35 \times 10^{-3}$$

Conclusion:

The predicted concentrations of FREE LAND DUST in the environment from use in PT18 suggests no unacceptable risk of toxicity to birds and mammals from Cypermethrin, indicating an acceptable risk of secondary poisoning through the terrestrial food-chain via earthworm.

Overall conclusion:

Scenario	Concentration	$PEC_{oral, predator}$	PEC/PNEC birds	PEC/PNEC mammals
Scenario: Application, Aquatic compartment	$PEC_{surface\ water}$ (mg/L)	(mg/kg wet fish)		
Cypermethrin	2.41×10^{-7}	1.00×10^{-3}	3.02×10^{-5}	3.05×10^{-4}
Scenario: Application, Terrestrial compartment	$PEC_{porewater}$ (mg/L)	(mg/kg wet earthworm)		
Cypermethrin	5.49×10^{-6}	2.43×10^{-2}	7.28×10^{-4}	7.35×10^{-3}

Conclusion:

The log Kow of Cypermethrin was calculated as 5.45, with a potential to bioconcentrate following uptake via water/porewater (e.g. in fish/worms) leading to secondary poisoning. The Bioconcentration factors measured in the test OECD guideline (1981) part 305E was reported at 373 ± 45 L/kg.

All $PEC_{oral, predator}/PNEC_{oral}$ ratios determined indicate that there is no unacceptable risk of secondary poisoning following the appropriate use of FREE LAND DUST.

Mixture toxicity

Mixture toxicity is not relevant for FREE LAND DUST.

Aggregated exposure (combined for relevant emission sources)

Aggregated exposure is not relevant, based on the decision scheme developed by UBA for the following reasons.

1. Cypermethrin is approved in EU as a biocide in 2 PTs: (i) PT 8 and (ii) PT18; however, as a result of the uses of these products, there is no overlap in time and space in Europe, since in PT 8 Cypermethrin is used in industrial preventive wood preservation applied in automated spraying, vacuum pressure, double vacuum pressure, flow coating or dipping treatment plants.
2. The main constituent of a.s. is not part of other a.s., and a.s. is not a relevant metabolite of other a.s. (and *vice versa*), and there are no other active substances that form the same relevant metabolites.

Therefore, according to the decision scheme developed by UBA, no aggregated exposure estimation is required.

Overall conclusion on the risk assessment for the environment of the product
<p>As regards the environment, the risk assessment was performed considering Cypermethrin as active substance of FREE LAND DUST;</p> <p>Risks were acceptable for sediment dwelling organisms and terrestrial environment. Cypermethrin concentration in groundwater proved to be lower than the trigger value set by DWD.</p> <p>For surface water and sediment, the risk characterization ratios calculated for cypermethrin proved to be below 1, which indicates the absence of unacceptable risks when the product is used according to label instructions.</p> <p>No unacceptable risks of secondary poisoning via the food chain were identified, when following the label instructions of FREE LAND DUST.</p>

2.2.9 Measures to protect man, animals and the environment

Open and handle containers with care, avoid contact with skin and eyes. Ensure the work area is well ventilated. Do not eat, drink or smoke or apply cosmetics in work area. Always wash after handling product.

Avoid contamination of drains or bodies of water.

Store upright in the original tightly closed container. Store in a cool, well ventilated, bunded area, away from heat and ignition sources such as smoking and open flames. Keep away from direct sunlight and protect against frost. Store away from strong oxidizing agents.

Store away from food and animal feed.

UN number




ADR / RID, IMDG, IATA:	3077
ADR / RID:	In accordance with Special Provision 375, this product, when is packed in receptacles of a capacity ≤ 5Kg or 5L, is not submitted to ADR provisions.
IMDG:	In accordance with Section 2.10.2.7 of IMDG Code, this product, when is packed in receptacles of a capacity ≤ 5Kg or 5L, is not submitted to IMDG Code provisions.

IATA:	In accordance with SP A197, this product, when is packed in receptacles of a capacity ≤ 5Kg or 5L, is not submitted to IATA dangerous goods regulations.
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UN proper shipping name

ADR / RID:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Cipermetrina)
IMDG:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Cipermetrina)
IATA:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Cipermetrina)




Transport hazard class(es)

ADR / RID:	Class: 9	Label: 9	
IMDG:	Class: 9	Label: 9	
IATA:	Class: 9	Label: 9	

Packaging group

ADR / RID, IMDG, IATA:	III
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Environmental hazards

ADR / RID:	Environmentally Hazardous	
IMDG:	Marine Pollutant	
IATA:	Environmentally Hazardous	

Special precautions for user

ADR / RID:	HIN - Kemler: 90	Limited Quantities: 5 kg	Tunnel restriction code: (-)
	Special Provision: -		
IMDG:	EMS: F-A, S- F	Limited Quantities: 5 kg	
IATA:	Cargo:	Maximum quantity: 400 Kg	Packaging instructions: 956
	Pass.:	Maximum quantity: 400 Kg	Packaging instructions: 956
	Special Instructions:	A97, A158, A179, A197	

Suitable Extinguishing Media

DO NOT use water stream. : Use class B extinguishing devices: CO2, foam, chemical powder, sand, earth, nebulized water

In case of fire, nature of reaction products, combustion gases, etc.*Specific Hazards*

Carbon monoxide might be formed in fire.

Fire fighting advice

Individual protection devices equipped with oxygen respirator. Use water stream only to cool surfaces of containers exposed to fire.

Use water spray or fog, dry chemical carbon dioxide.

Do not use water jets.

Use appropriate containment equipment to avoid environmental contaminations especially watercourses and drainage systems.

Smoke from fires is toxic, take precautions to protect personnel from exposure. Wear positive breathing apparatus.

Emergency measures in case of an accident

Direct or indirect effects: Pyrethroids, like Cypermethrin, may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice.

First aid instructions are detailed below.

If inhaled:

Remove affected person to fresh air and apply artificial respiration if required. Seek medical advice if specific symptomatic reactions are observed.

If swallowed:

Immediately call a poison control centre or doctor for treatment advice. Do not give any liquid to the person. Do not induce vomiting. If vomiting occurs spontaneously, keep head below hips to prevent aspiration. Do not give anything by mouth to an unconscious person.

If on skin or hair:

Remove contaminated clothing and wash with soap and running water. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control centre or doctor for treatment advice if irritation persists.

If in eyes:

Remove contact lenses, if present. Hold eyelids apart and flush eye continuously with running water for 15 – 20 minutes. Call a poison control centre or doctor for treatment advice or if irritation persists.

In the event of a leak or spillage:

- Shut off the source of the leak if it is safe to do so

Immediate actions:

- Contain the product to avoid environmental contamination.
- Recover product where possible.

Clean up-actions:

- Absorb spillage in earth, sand or sawdust or other inert material.
- Place in appropriate metal or plastic containers.

- Seal the containers and label them.
 - Remove the contaminated material to a safe location for subsequent disposal.
- If contamination of drainage systems or watercourses is unavoidable, immediately inform the appropriate authorities.

Possibility of destruction or decontamination following release in or on the following: air, water, including drinking water and soil

Contamination of water may occur in the case of leakage at the manufacturing plant. Should any contamination of water occur outside the plant, the contaminated water should be collected or contained with clean-up via suction and filtering.

If surface waters are contaminated, Cypermethrin will be durably bound to the sediment where it is susceptible to biotic and abiotic degradation. The buffer capacity of sediment can be enhanced by addition of organic matter. Sediments can also be dredged and removed to an approved dumping site.

If the product is spilled in soil, Cypermethrin will be durably bound to the soil where it is susceptible to biotic and abiotic degradation. Soil could also be collected and removed to an incineration plant or approved landfill site.

Prevent the product from flowing into sewers or contaminating surface waterways. Soak up spills with inert absorbent material. Contaminated waters should be isolated where possible to limit the extent of contamination. Expert advice should be sought to establish the degree of contamination and the feasibility of available treatment techniques such as flocculation, carbon adsorption, etc. Where relevant the appropriate authorities should be notified. Wear appropriate personal protective equipment during any cleanup operations.

Procedures for waste management of the active substance for industry or professional users

For industrial users waste and contaminated materials are hazardous waste and can be disposed of by incineration.

The product is supplied to professional and non-professional users in a range of packaging sizes. Empty containers must not be used for any other purpose. They should be punctured and disposed of according to national waste disposal requirements.

Ventilate area. Collect leaking and spilled liquid in sealable containers (heavy duty plastic drums). Absorb remaining liquid in sand or inert absorbent and transfer to sealable containers for disposal. Wash area thoroughly with water and detergent, preventing runoff from entering drains. Wear chemical resistant goggles, gloves and boots, light protective clothing and self-contained breathing apparatus if contaminated area is not well ventilated. If material enters drains advise emergency services.

Solid absorbent material collected from spillage incidents should be disposed of at approved landfill sites. Triple- (or preferably) pressure-rinse containers before disposal. Do not dispose of undiluted chemicals on-site. Do not wash product or spillages into waterways, drains or sewers.

Possibility of re-use or recycling

None.

Conditions for controlled discharge including leachate qualities on disposal

Under Hazardous Waste Directive (91/689/EEC) surplus Cypermethrin and contaminated materials (including sawdust) must be classified a "Special Waste".

Disposal must be in accordance with these regulations and requirements set out in the Integrated Pollution Prevention and Control Directive.

The active substance can be disposed to an approved landfill site as specified by the local or county authorities. Due to the high binding capacity of Cypermethrin to soil any release from an approved landfill site would not leach significantly into surrounding soil.

Observations on undesirable or unintended side-effects e.g. on beneficial and other non-target organisms

The products containing Cypermethrin are likely to be extremely dangerous to fish and other aquatic life.

Identification of any substances falling within the scope of List I or List II of the Annex to Directive 80/68/EEC on the protection of groundwater against pollution caused by certain dangerous substances

Cypermethrin falls within the scope of List I of the Annex to Directive 80/68/EEC on the protection of groundwater against pollution caused by certain dangerous substance.

2.2.10 Assessment of a combination of biocidal products

FREE LAND DUST is not intended to be authorised for the use in combination with other biocidal products.

2.2.11 Comparative assessment

Please refer to section 2.1.2.2. of this document.

3 ANNEXES

3.1 List of studies for the biocidal product

In relation to the product application, the following data on product are submitted:

- Physical state, color and odor
- pH value
- Density
- Dustiness
- Particle size distribution
- Flammability of Solids
- Explosivity Properties
- Oxidising Properties of Solids
- Methods for detection and identification
- Accelerated Storage Stability and Corrosion Characteristics
- Efficacy against target organisms.

Reference List – Biocidal Product FREE LAND DUST

Section No	Year	Title	Data protection claimed (Y/N)	Owner of data
Section 3, Physical and Chemical Properties - Physical state, color and odor	2020	FREE LAND DUST: Determination of the Physico-chemical Properties - Study No. CH – 0008/2020 March 26, 2020 GLP/GEP: yes	Y	Activa S.r.l.
Section 3, Physical and Chemical Properties - pH value	2020	FREE LAND DUST: Determination of the Physico-chemical Properties - Study No. CH – 0008/2020 March 26, 2020 GLP/GEP: yes	Y	Activa S.r.l.
Section 3, Physical and Chemical Properties - Bulk density	2020	FREE LAND DUST: Determination of the Physico-chemical Properties - Study No. CH – 0008/2020 March 26, 2020 GLP/GEP: yes	Y	Activa S.r.l.
Section 3, Physical and Chemical Properties - Dustiness	2020	FREE LAND DUST: Determination of the Physico-chemical Properties - Study No. CH – 0008/2020 March 26, 2020 GLP/GEP: yes	Y	Activa S.r.l.
Section 3, Physical and Chemical Properties - Particle size distribution	2020	FREE LAND DUST: Determination of the Physico-chemical Properties - Study No. CH – 0008/2020 March 26, 2020 GLP/GEP: yes	Y	Activa S.r.l.

Section 4, Flammability of Solids	2020	Free LAND DUST - Regulatory Testing - Report number S3016007067BR1/2020 - 2nd March 2020 GLP/GEP: yes	Y	Activa S.r.l.
Section 4, Explosivity Properties	2020	Free LAND DUST - Regulatory Testing - Report number S3016007067BR1/2020 - 2nd March 2020 GLP/GEP: yes	Y	Activa S.r.l.
Section 4, Oxidising Properties of Solids	2020	Free LAND DUST - Regulatory Testing - Report number S3016007067BR1/2020 - 2nd March 2020 GLP/GEP: yes	Y	Activa S.r.l.
Section 4, Oxidising Properties of Solids	2020	FREE LAND DUST: Determination of the Accelerated Storage Stability and Corrosion Characteristics - Study No. CH - 0010/2020 March 26, 2020 GLP/GEP: yes	Y	Activa S.r.l.
Section 4, Thermal Stability Testing	2020	Free Land Dust - Thermal Stability number S3016007747R1/2020 - 24th June 2020 GLP/GEP: yes	Y	Activa S.r.l.
Section 5, Methods of detection and identification - HPLC Analysis	2020	FREE LAND DUST: Validation of the Analytical Method for the Determination of the Active Ingredient Content - Study No. CH - 0009/2020 March 03, 2020 GLP/GEP: yes	Y	Activa S.r.l.
Section 6.7, Efficacy data	2020	SIMULATED-USE TRIAL OF THE EFFICACY OF THE PRODUCT "FREE LAND DUST" AGAINST ORIENTAL COCKROACHES Cracks and crevices application - MARCH 2020 - Report No. 2532a/0120 GLP/GEP: yes	Y	Activa S.r.l.
Section 6.7, Efficacy data	2020	SIMULATED-USE TRIAL OF THE EFFICACY OF THE PRODUCT "FREE LAND DUST" AGAINST ORIENTAL COCKROACHES spot application - MARCH 2020 - Report No. 2532b/0120 GLP/GEP: yes	Y	Activa S.r.l.
Section 6.7, Efficacy data	2019	EVALUATION OF THE EFFICACY OF "FREE LAND DUST" AGAINST BLATTELLA GERMANICA, PERIPLANETA AMERICANA AND LASIUS NIGER - October 10, 2019 -	Y	Activa S.r.l.

		Report code : ACTPOL1 80719 – 02 GLP/GEP: yes		
Efficacy data, Section 6.7	2020	FIELD TRIAL TO TEST THE EFFICACY OF THE PRODUCT "Free Land Dust" AGAINST ANTS' NESTS - 2020-06-25 - Test n. 2532h-FIELD-ANT/0120	Y	Activa S.r.l.
Efficacy data, Section 6.7	2020	FIELD TRIAL TO TEST THE EFFICACY OF THE PRODUCT "Free Land Dust" AGAINST WASPS' NESTS - 2020-07-13 - Test No. 2532j-FIELD-WASP/0120	Y	Activa S.r.l.
Efficacy data, Section 6.7	2020	EFFICACY EVALUATION OF "FREE LAND DUST" AGAINST BLATTA ORIENTALIS (FIELD TEST) - July 28, 2020 - Report code : Q086-20-01	Y	Activa S.r.l.
Efficacy data, Section 6.7	2020	EFFICACY EVALUATION OF "FREE LAND DUST" AGAINST BLATTELLA GERMANICA (FIELD TEST) - July 28, 2020 - Report code : Q087-20-01	Y	Activa S.r.l.
Efficacy data, Section 6.7	2021	FIELD TRIAL TO TEST THE EFFICACY OF THE PRODUCT "Free Land Dust" AGAINST ANTS IN AN INDOOR AREA Study code: Protocol	-	Activa S.r.l.
Efficacy data, Section 6.7	2019	EVALUATION OF THE EFFICACY OF "FREE LAND DUST" AGAINST VESPULA GERMANICA (TILE TEST) – Study code ACTPOL180719-03	Y	Activa S.r.l.

3.2 Output tables from exposure assessment tools

HUMAN HEALTH



Human health
exposure calculator

ENVIRONMENT**SCENARIO 1 - Barrier Application against Crawling insects - TIER 1**

Section/parameter	Actual value	Unit	Stat
STUDY			
STUDY IDENTIFICATION			
Study name	FREE LAND DUST- Use 1		S
Study description	barrier treatment		S
SUBSTANCE			
SUBSTANCE IDENTIFICATION			
General name	Cypermethrin		S
Description	PT18		S
CAS-No	52315-07-8		S
EC-notification no.	257-842-9		S
EINECS no.			D
PHYSICO-CHEMICAL PROPERTIES			
Molecular weight	416.3	[g.mol ⁻¹]	S
Melting point	41.2	[°C]	S
Boiling point	??	[°C]	D
Vapour pressure at 20 [°C]	4.25E-07	[Pa]	O
Vapour pressure at 25 [°C]	6.00E-07	[Pa]	S
Water solubility at 20 [°C]	4	[µg.l ⁻¹]	S
Water solubility at 25 [°C]	4.28E-03	[mg.l ⁻¹]	O
Octanol-water partition coefficient	5.45	[log ₁₀]	S
PARTITION COEFFICIENTS AND BIOCONCENTRATION FACTORS			
SOLIDS-WATER			
Organic carbon-water partition coefficient	5.75E+05	[l.kg ⁻¹]	S
AIR-WATER			
Henry's law constant at test temperature	0.024	[Pa.m ³ .mol ⁻¹]	S
Temperature at which Henry's law constant was measured	20	[°C]	S
DEGRADATION AND TRANSFORMATION RATES			
AIR			

Rate constant for degradation in air	0.749	[d] (DT50)	S
SOIL			
Rate constant for biodegradation in bulk soil	17.2	[d] (DT50,12[oC])	S
Total rate constant for degradation in bulk soil	17.2	[d] (DT50,12[oC])	S
REMOVAL RATE CONSTANTS SOIL			
Total rate constant for degradation in bulk soil	17.2	[d] (DT50,12[oC])	S
RELEASE ESTIMATION			
BIOCIDE SCENARIO INPUT DATA			
Usage/production title	Scenario 1		S
Scenario choice for biocides	(18) Insecticides, acaricides and products to control other arthropods		S
Additional scenario information	(18.2.1) Indoor, spray application		S
GENERAL INPUT			
Select formulation/use	Spray - crack and crevice		S
Fraction of substance in commercial product	2.63E-03	[-]	S
Cover mixing/loading?	No		S
Select pest	Cockroaches		S
Select treatment	Barrier, cracks and crevices		S
APPLICATION			
Quantity of commercial product applied per m2	8	[g.m-2]	S
Number of applications per day in a standard house	1	[d-1]	S
Number of applications per day in a large building	1	[d-1]	S
Frequency of application in standard houses	1-2 times a year		S
Frequency of application in large buildings	1-2 times a year		S
Fraction emitted to applicator	0	[-]	S
Fraction emitted to floor	0.18	[-]	S
Fraction emitted to treated surfaces	0.8	[-]	S

CLEANING			
Washable coveralls or disposable coveralls?	Washable coveralls		S
Dry or wet cleaning of treated surfaces?	Wet cleaning of treated surfaces		S
OUTPUT			
CLEANING EMISSIONS FROM MIXING/LOADING			
STANDARD HOUSES			
Local emission to wastewater from washing applicator's coveralls	0	[kg.d-1]	S
Local emission to wastewater from wet cleaning the floor	0	[kg.d-1]	S
LARGE BUILDINGS			
Local emission to wastewater from washing applicator's coveralls	0	[kg.d-1]	S
Local emission to wastewater from wet cleaning the floor	0	[kg.d-1]	S
PRIVATE USE			
GENERAL INPUT			
Select formulation/use	Spray - crack and crevice		S
Fraction of substance in commercial product	2.63E-03	[-]	S
Cover mixing/loading?	No		S
Select pest	Cockroaches		S
Select treatment	Barrier, cracks and crevices		S
APPLICATION			
Quantity of commercial product applied per m2	8	[g.m-2]	S
Frequency of application in standard houses	1-2 times a year		S
Fraction emitted to applicator	0	[-]	S
Fraction emitted to floor	0.18	[-]	S
Fraction emitted to treated surfaces	0.8	[-]	S
CLEANING			
Washable coveralls or disposable coveralls?	Washable coveralls		S
Dry or wet cleaning of treated surfaces?	Wet cleaning of treated surfaces		S
OUTPUT			

CLEANING EMISSIONS FROM MIXING/LOADING			
Local emission to wastewater from washing applicator's coveralls	0	[kg.d-1]	S
Local emission to wastewater from wet cleaning the floor	0	[kg.d-1]	S
DISTRIBUTION			
LIFE CYCLE STEPS			
LOCAL PECS [INDUSTRIAL USE]			
RELEASE VIA STP			
AIR			
Annual average local PEC in air (total)	2.12E-08	[mg.m-3]	O
WATER, SEDIMENT			
Local PEC in surface water during emission episode (dissolved)	7.49E-07	[mg.l-1]	O
Qualitative assessment might be needed (TGD Part II, 5.6)	No		O
Annual average local PEC in surface water (dissolved)	6.15E-07	[mg.l-1]	O
Local PEC in freshwater sediment during emission episode	9.36E-03	[mg.kgwwt-1]	O
Local PEC in seawater during emission episode (dissolved)	8.96E-07	[mg.l-1]	O
Qualitative assessment might be needed (TGD Part II, 5.6)	No		O
Annual average local PEC in seawater (dissolved)	7.36E-07	[mg.l-1]	O
Local PEC in marine sediment during emission episode	0.011198	[mg.kgwwt-1]	O
SOIL, GROUNDWATER			
Local PEC in agric. soil (total) averaged over 30 days	3.20E-04	[mg.kgwwt-1]	O
Local PEC in agric. soil (total) averaged over 180 days	7.61E-05	[mg.kgwwt-1]	O
Local PEC in grassland (total) averaged over 180 days	3.05E-05	[mg.kgwwt-1]	O
Local PEC in pore water of agricultural soil	7.50E-09	[mg.l-1]	O
Local PEC in pore water of grassland	3.01E-09	[mg.l-1]	O
Local PEC in groundwater under agricultural soil	7.50E-09	[mg.l-1]	O
LOCAL PECS [PRIVATE USE]			
RELEASE VIA STP			

AIR			
Annual average local PEC in air (total)	1.91E-08	[mg.m-3]	0
WATER, SEDIMENT			
Local PEC in surface water during emission episode (dissolved)	5.57E-07	[mg.l-1]	0
Qualitative assessment might be needed (TGD Part II, 5.6)	No		0
Annual average local PEC in surface water (dissolved)	5.57E-07	[mg.l-1]	0
Local PEC in freshwater sediment during emission episode	6.97E-03	[mg.kgwwt-1]	0
Local PEC in seawater during emission episode (dissolved)	6.67E-07	[mg.l-1]	0
Qualitative assessment might be needed (TGD Part II, 5.6)	No		0
Annual average local PEC in seawater (dissolved)	6.67E-07	[mg.l-1]	0
Local PEC in marine sediment during emission episode	8.34E-03	[mg.kgwwt-1]	0
SOIL, GROUNDWATER			
Local PEC in agric. soil (total) averaged over 30 days	2.38E-04	[mg.kgwwt-1]	0
Local PEC in agric. soil (total) averaged over 180 days	5.66E-05	[mg.kgwwt-1]	0
Local PEC in grassland (total) averaged over 180 days	2.27E-05	[mg.kgwwt-1]	0
Local PEC in pore water of agricultural soil	5.58E-09	[mg.l-1]	0
Local PEC in pore water of grassland	2.24E-09	[mg.l-1]	0
Local PEC in groundwater under agricultural soil	5.58E-09	[mg.l-1]	0

SCENARIO 1 - Barrier Application against Crawling insects - TIER 2

Section/parameter	Actual value	Unit	Stat
STUDY			
STUDY IDENTIFICATION			
Study name	FREE LAND DUST- Use 1-dry		S
Study description	barrier treatment-dry		S
SUBSTANCE			
SUBSTANCE IDENTIFICATION			
General name	Cypermethrin		S

Description	PT18		S
CAS-No	52315-07-8		S
EC-notification no.	257-842-9		S
EINECS no.			D
PHYSICO-CHEMICAL PROPERTIES			
Molecular weight	416.3	[g.mol ⁻¹]	S
Melting point	41.2	[°C]	S
Boiling point	??	[°C]	D
Vapour pressure at 20 [°C]	4.25E-07	[Pa]	O
Vapour pressure at 25 [°C]	6.00E-07	[Pa]	S
Water solubility at 20 [°C]	4	[µg.l ⁻¹]	S
Water solubility at 25 [°C]	4.28E-03	[mg.l ⁻¹]	O
Octanol-water partition coefficient	5.45	[log10]	S
PARTITION COEFFICIENTS AND BIOCONCENTRATION FACTORS			
SOLIDS-WATER			
Organic carbon-water partition coefficient	5.75E+05	[l.kg ⁻¹]	S
AIR-WATER			
Henry's law constant at test temperature	0.024	[Pa.m ³ .mol ⁻¹]	S
Temperature at which Henry's law constant was measured	20	[°C]	S
DEGRADATION AND TRANSFORMATION RATES			
AIR			
Rate constant for degradation in air	0.749	[d] (DT50)	S
SOIL			
Rate constant for biodegradation in bulk soil	17.2	[d] (DT50,12[°C])	S
Total rate constant for degradation in bulk soil	17.2	[d] (DT50,12[°C])	S
REMOVAL RATE CONSTANTS SOIL			
Total rate constant for degradation in bulk soil	17.2	[d] (DT50,12[°C])	S

)	
RELEASE ESTIMATION			
BIOCIDE SCENARIO INPUT DATA			
Usage/production title	Scenario 1		S
Scenario choice for biocides	(18) Insecticides, acaricides and products to control other arthropods		S
Additional scenario information	(18.2.1) Indoor, spray application		S
GENERAL INPUT			
Select formulation/use	Spray - crack and crevice		S
Fraction of substance in commercial product	2.63E-03	[-]	S
Cover mixing/loading?	No		S
Select pest	Cockroaches		S
Select treatment	Barrier, cracks and crevices		S
APPLICATION			
Quantity of commercial product applied per m2	8	[g.m-2]	S
Number of applications per day in a standard house	1	[d-1]	S
Number of applications per day in a large building	1	[d-1]	S
Frequency of application in standard houses	1-2 times a year		S
Frequency of application in large buildings	1-2 times a year		S
Fraction emitted to applicator	0	[-]	S
Fraction emitted to floor	0.18	[-]	S
Fraction emitted to treated surfaces	0.8	[-]	S
CLEANING			
Washable coveralls or disposable coveralls?	Washable coveralls		S
Dry or wet cleaning of treated surfaces?	Dry cleaning of treated surfaces		S
OUTPUT			
CLEANING EMISSIONS FROM MIXING/LOADING STANDARD HOUSES			
Local emission to wastewater from washing applicator's coveralls	0	[kg.d-1]	S

Local emission to wastewater from wet cleaning the floor	0	[kg.d-1]	S
LARGE BUILDINGS			
Local emission to wastewater from washing applicator's coveralls	0	[kg.d-1]	S
Local emission to wastewater from wet cleaning the floor	0	[kg.d-1]	S
PRIVATE USE			
GENERAL INPUT			
Select formulation/use	Spray - crack and crevice		S
Fraction of substance in commercial product	2.63E-03	[-]	S
Cover mixing/loading?	No		S
Select pest	Cockroaches		S
Select treatment	Barrier, cracks and crevices		S
APPLICATION			
Quantity of commercial product applied per m2	8	[g.m-2]	S
Frequency of application in standard houses	1-2 times a year		S
Fraction emitted to applicator	0	[-]	S
Fraction emitted to floor	0.18	[-]	S
Fraction emitted to treated surfaces	0.8	[-]	S
CLEANING			
Washable coveralls or disposable coveralls?	Washable coveralls		S
Dry or wet cleaning of treated surfaces?	Dry cleaning of treated surfaces		S
OUTPUT			
CLEANING EMISSIONS FROM MIXING/LOADING			
Local emission to wastewater from washing applicator's coveralls	0	[kg.d-1]	S
Local emission to wastewater from wet cleaning the floor	0	[kg.d-1]	S
DISTRIBUTION			
LIFE CYCLE STEPS			
LOCAL PECS [INDUSTRIAL USE]			
RELEASE VIA STP			

AIR			
Annual average local PEC in air (total)	2.12E-08	[mg.m-3]	0
WATER, SEDIMENT			
Local PEC in surface water during emission episode (dissolved)	1.37E-07	[mg.l-1]	0
Qualitative assessment might be needed (TGD Part II, 5.6)	No		0
Annual average local PEC in surface water (dissolved)	1.13E-07	[mg.l-1]	0
Local PEC in freshwater sediment during emission episode	1.72E-03	[mg.kgwwt-1]	0
Local PEC in seawater during emission episode (dissolved)	1.65E-07	[mg.l-1]	0
Qualitative assessment might be needed (TGD Part II, 5.6)	No		0
Annual average local PEC in seawater (dissolved)	1.35E-07	[mg.l-1]	0
Local PEC in marine sediment during emission episode	2.06E-03	[mg.kgwwt-1]	0
SOIL, GROUNDWATER			
Local PEC in agric. soil (total) averaged over 30 days	5.89E-05	[mg.kgwwt-1]	0
Local PEC in agric. soil (total) averaged over 180 days	1.40E-05	[mg.kgwwt-1]	0
Local PEC in grassland (total) averaged over 180 days	5.70E-06	[mg.kgwwt-1]	0
Local PEC in pore water of agricultural soil	1.38E-09	[mg.l-1]	0
Local PEC in pore water of grassland	5.61E-10	[mg.l-1]	0
Local PEC in groundwater under agricultural soil	1.38E-09	[mg.l-1]	0
LOCAL PECS [PRIVATE USE]			
RELEASE VIA STP			
AIR			
Annual average local PEC in air (total)	1.91E-08	[mg.m-3]	0
WATER, SEDIMENT			
Local PEC in surface water during emission episode (dissolved)	1.02E-07	[mg.l-1]	0
Qualitative assessment might be needed (TGD Part II, 5.6)	No		0
Annual average local PEC in surface water (dissolved)	1.02E-07	[mg.l-1]	0
Local PEC in freshwater sediment	1.28E-03	[mg.kgwwt-1]	0

during emission episode			
Local PEC in seawater during emission episode (dissolved)	1.22E-07	[mg.l-1]	O
Qualitative assessment might be needed (TGD Part II, 5.6)	No		O
Annual average local PEC in seawater (dissolved)	1.22E-07	[mg.l-1]	O
Local PEC in marine sediment during emission episode	1.53E-03	[mg.kgwwt-1]	O
SOIL, GROUNDWATER			
Local PEC in agric. soil (total) averaged over 30 days	4.38E-05	[mg.kgwwt-1]	O
Local PEC in agric. soil (total) averaged over 180 days	1.04E-05	[mg.kgwwt-1]	O
Local PEC in grassland (total) averaged over 180 days	4.26E-06	[mg.kgwwt-1]	O
Local PEC in pore water of agricultural soil	1.03E-09	[mg.l-1]	O
Local PEC in pore water of grassland	4.20E-10	[mg.l-1]	O
Local PEC in groundwater under agricultural soil	1.03E-09	[mg.l-1]	O

SCENARIO 2 - Wasp nest - Indoor

Section/parameter	Actual value	Unit	Stat
STUDY IDENTIFICATION			
Study name	2021-07-FREE LAND DUST-Use 2		S
Study description	Indoor wasp nest professional		S
SUBSTANCE			
SUBSTANCE IDENTIFICATION			
General name	Cypermethrin		S
Description			D
CAS-No	52315-07-8		S
EC-notification no.			D
EINECS no.	257-842-9		S
PHYSICO-CHEMICAL PROPERTIES			
Molecular weight	416	[g.mol-1]	S
Melting point	47	[oC]	S
Boiling point	??	[oC]	D
Vapour pressure at 20 [oC]	4,25E-07	[Pa]	O
Vapour pressure at 25 [oC]	6,00E-07	[Pa]	S
Water solubility at 20 [oC]	4	[µg.l-1]	S
Water solubility at 25 [oC]	4,28E-03	[mg.l-1]	O

Octanol-water partition coefficient	5,45	[log10]	S
PARTITION COEFFICIENTS AND BIOCONCENTRATION FACTORS			
SOLIDS-WATER			
Organic carbon-water partition coefficient	5,75E+05	[l.kg-1]	S
AIR-WATER			
Henry's law constant at test temperature	0,024	[Pa.m3.mol-1]	S
Temperature at which Henry's law constant was measured	20	[oC]	S
DEGRADATION AND TRANSFORMATION RATES			
CHARACTERIZATION			
Characterization of biodegradability	Not biodegradable		S
STP			
Select biodegradation test method	Method 1: estimated from standardized biodegradability tests (OECD 301 series, 310, 302 series)		S
SOIL			
Rate constant for biodegradation in bulk soil	17,2	[d] (DT50,12[oC])	S
RELEASE ESTIMATION			
BIOCIDES SCENARIO INPUT DATA			
Usage/production title	Cypermethrin Powder indoor wasp nest		S
Scenario choice for biocides	(18) Insecticides, acaricides and products to control other arthropods		S
Additional scenario information	(18.2.1) Indoor, spray application		S
PRIVATE USE			
Emission scenario			D
INTERMEDIATE RESULTS			
RELEASE FRACTIONS AND EMISSION DAYS			
PRIVATE USE			
GENERAL INPUT			
Select formulation/use	Spray - surface		S
Fraction of substance in commercial product	2,63E-03	[-]	S
Cover mixing/loading?	No		S
Select pest	Wasps/hornets		S
Select treatment	Spot, surface		S
Total area treated in a standard house	2	[m2]	S
Wet cleaning zone in a standard house (leading to releases to the STP)	2	[m2]	S

APPLICATION			
Quantity of commercial product applied per m2		5 [g.m-2]	S
Frequency of application in standard houses	1-2 times a year		S
Fraction emitted to applicator		0 [-]	S
Fraction emitted to floor		0,18 [-]	S
Fraction emitted to treated surfaces		0,8 [-]	S
CLEANING			
Cleaning efficiency (of treated surfaces and floor from application)		0,25 [-]	S
Washable coveralls or disposable coveralls?	Washable coveralls		S
Dry or wet cleaning of treated surfaces?	Wet cleaning of treated surfaces		S
OUTPUT			
CLEANING EMISSIONS FROM MIXING/LOADING			
Local emission to wastewater from washing applicator's coveralls		0 [kg.d-1]	S
Local emission to wastewater from wet cleaning the floor		0 [kg.d-1]	S
DISTRIBUTION			
SEWAGE TREATMENT			
[PRIVATE USE]			
INPUT AND CONFIGURATION [PRIVATE USE]			
INPUT			
Use or bypass STP (local freshwater assessment)	Use STP		S
LOCAL PECS [PRIVATE USE]			
RELEASE VIA STP			
AIR			
Annual average local PEC in air (total)		1,19E-09 [mg.m-3]	O
WATER, SEDIMENT			
Local PEC in surface water during emission episode (dissolved)		1,18E-07 [mg.l-1]	O
Qualitative assessment might be needed (TGD Part II, 5.6)	No		O
Annual average local PEC in surface water (dissolved)		1,18E-07 [mg.l-1]	O
Local PEC in freshwater sediment during emission episode		1,48E-03 [mg.kgwwt-1]	O
Local PEC in seawater during emission episode (dissolved)		1,41E-07 [mg.l-1]	O
Qualitative assessment might be needed (TGD Part II, 5.6)	No		O
Annual average local PEC in seawater (dissolved)		1,41E-07 [mg.l-1]	O
Local PEC in marine sediment during emission episode		1,77E-03 [mg.kgwwt-1]	O
SOIL, GROUNDWATER			

Local PEC in agric. soil (total) averaged over 30 days	5,05E-05	[mg.kgwwt-1]	O
Local PEC in agric. soil (total) averaged over 180 days	1,20E-05	[mg.kgwwt-1]	O
Local PEC in grassland (total) averaged over 180 days	4,80E-06	[mg.kgwwt-1]	O
Local PEC in pore water of agricultural soil	1,18E-09	[mg.l-1]	O
Local PEC in pore water of grassland	4,73E-10	[mg.l-1]	O
Local PEC in groundwater under agricultural soil	1,18E-09	[mg.l-1]	O

SCENARIO 3 - Wasp nest - Outdoor

Section/parameter	Actual value	Unit	Status
STUDY			
STUDY IDENTIFICATION			
Study name	2021-07-FREE LAND DUST-Use 3		S
Study description	Outdoor wasp nest professional		S
PHYSICO-CHEMICAL PROPERTIES			
Molecular weight	416	[g.mol-1]	S
Melting point	47	[oC]	S
Boiling point	??	[oC]	D
Vapour pressure at 20 [oC]	4,25E-07	[Pa]	O
Vapour pressure at 25 [oC]	6,00E-07	[Pa]	S
Water solubility at 20 [oC]	4	[µg.l-1]	S
Water solubility at 25 [oC]	4,28E-03	[mg.l-1]	O
Octanol-water partition coefficient	5,45	[log10]	S
PARTITION COEFFICIENTS AND BIOCONCENTRATION FACTORS			
SOLIDS-WATER			
Organic carbon-water partition coefficient	5,75E+05	[l.kg-1]	S
AIR-WATER			
Henry's law constant at test temperature	0,024	[Pa.m3.mol-1]	S
Temperature at which Henry's law constant was measured	20	[oC]	S
DEGRADATION AND TRANSFORMATION RATES			
CHARACTERIZATION			
Characterization of biodegradability	Not biodegradable		S
STP			
Select biodegradation test method	Method 1: estimated from standardized biodegradability tests		S

	(OECD 301 series, 310, 302 series)		
AIR			
Rate constant for degradation in air	0,749	[d-1]	S
SOIL			
Rate constant for biodegradation in bulk soil	17,2	[d] (DT50,12 [oC])	S
RELEASE ESTIMATION			
BIOCIDE SCENARIO INPUT DATA			
Usage/production title	Cypermethrin Powder outdoor Ant nest		S
Scenario choice for biocides	(18) Insecticides, acaricides and products to control other arthropods		S
Additional scenario information	(18.3.3) Outdoor, nest spraying		S
INDUSTRIAL USE			
Emission scenario			D
INTERMEDIATE RESULTS			
RELEASE FRACTIONS AND EMISSION DAYS			
INDUSTRIAL USE			
GENERAL INPUT			
Quantity of commercial product applied per nest	10	[g]	S
Fraction of substance in commercial product	2,63E-03	[-]	S
DISTRIBUTION			
LIFE CYCLE STEPS			
LOCAL PECS [INDUSTRIAL USE]			
DIRECT RELEASE			
SOIL			
Local PEC during application	0,047275	[mg.kgw wt-1]	O
GROUNDWATER			
Local PEC during application	4,66E-06	[mg.l-1]	O

SCENARIO 7 - Outdoor ant nest

Section/parameter	Actual value	Unit	Stat
STUDY IDENTIFICATION			
Study name	2021-07-FREE LAND DUST-		S
SUBSTANCE IDENTIFICATION			
General name	Cypermethrin		S
CAS-No	52315-07-8		S
EC-notification no.			D

EINECS no.	257-842-9		S
PHYSICO-CHEMICAL PROPERTIES			
Molecular weight	416	[g.mol-1]	S
Melting point	47	[oC]	S
Boiling point	??	[oC]	D
Vapour pressure at 20 [oC]	4,25E-07	[Pa]	O
Vapour pressure at 25 [oC]	6,00E-07	[Pa]	S
Water solubility at 20 [oC]	4	[µg.l-1]	S
Water solubility at 25 [oC]	4,28E-03	[mg.l-1]	O
Octanol-water partition coefficient	5,45	[log10]	S
PARTITION COEFFICIENTS AND BIOCONCENTRATION FACTORS			
SOLIDS-WATER			
Organic carbon-water partition coefficient	5,75E+05	[l.kg-1]	S
AIR-WATER			
Henry's law constant at test temperature	0,024	[Pa.m3.mol-1]	S
Temperature at which Henry's law constant was measured	20	[oC]	S
DEGRADATION AND TRANSFORMATION RATES			
CHARACTERIZATION			
Characterization of biodegradability	Not biodegradable		S
STP			
Select biodegradation test method	Method 1: estimated from standardized biodegradability tests (OECD 301 series, 310, 302 series)		S
AIR			
Rate constant for degradation in air	0,749	[d-1]	S
SOIL			
Rate constant for biodegradation in bulk soil	17,2	[d] (DT50,12[oC])	S
RELEASE ESTIMATION			
BIOCIDE SCENARIO INPUT DATA			
Usage/production title	Cypermethrin Powder outdoor Ant nest		S
Scenario choice for biocides	(18) Insecticides, acaricides and products to control other arthropods		S
Additional scenario information	(18.3.4) Outdoor, spot application		S
INDUSTRIAL USE			
Emission scenario			D
INTERMEDIATE RESULTS			
RELEASE FRACTIONS AND EMISSION DAYS			

INDUSTRIAL USE			
GENERAL INPUT			
Quantity of commercial product applied	5	[g]	S
Fraction of substance in commercial product	2,63E-03	[-]	S
Type of spot application	Powder		S
Number of application sites	1	[-]	S
Number of applications during a campaign	1	[-]	S
SECONDARY POISONING			
Repeated applications by spraying?	No		S
DISTRIBUTION			
LIFE CYCLE STEPS			
LOCAL PECS [INDUSTRIAL USE]			
DIRECT RELEASE			
SOIL			
Local PEC due to a campaign	0,055694	[mg.kg wwt-1]	O
GROUNDWATER			
Local PEC due to a campaign	5,49E-06	[mg.l-1]	O

SCENARIO 8a Around building against *Blatta orientalis* (Urban)

Section/parameter	Actual value	Unit	Stat
STUDY			
STUDY IDENTIFICATION			
Study name	FREE LAND DUST- 8aURBAN		S
SUBSTANCE			
SUBSTANCE IDENTIFICATION			
General name	Cypermethrin		S
CAS-No	52315-07-8		S
EC-notification no.			D
EINECS no.	257-842-9		S
PHYSICO-CHEMICAL PROPERTIES			
Molecular weight	416	[g.mol-1]	S
Melting point	47	[oC]	S
Boiling point	??	[oC]	D
Vapour pressure at 20 [oC]	4,25E-07	[Pa]	O
Vapour pressure at 25 [oC]	6,00E-07	[Pa]	S
Water solubility at 20 [oC]	4	[µg.l-1]	S
Water solubility at 25 [oC]	4,28E-03	[mg.l-1]	O
Octanol-water partition coefficient	5,45	[log10]	S
PARTITION COEFFICIENTS AND BIOCONCENTRATION FACTORS			

SOLIDS-WATER			
Organic carbon-water partition coefficient	5,75E+05	[l.kg-1]	S
AIR-WATER			
Henry's law constant at test temperature	0,024	[Pa.m3.mol-1]	S
Temperature at which Henry's law constant was measured	20	[oC]	S
DEGRADATION AND TRANSFORMATION RATES			
CHARACTERIZATION			
Characterization of biodegradability	Not biodegradable		S
STP			
Select biodegradation test method	Method 1: estimated from standardized biodegradability tests (OECD 301 series, 310, 302 series)		S
AIR			
Rate constant for degradation in air	0,749	[d-1]	S
SOIL			
Rate constant for biodegradation in bulk soil	17,2	[d] (DT50,12[oC])	S
RELEASE ESTIMATION			
BIOCIDE SCENARIO INPUT DATA			
Usage/production title	Cypermethrin Powder outdoor		S
Scenario choice for biocides	(18) Insecticides, acaricides and products to control other arthropods		S
Additional scenario information	(18.3.2) Outdoor, crawling insects		S
PRIVATE USE			
Emission scenario			D
INTERMEDIATE RESULTS			
RELEASE FRACTIONS AND EMISSION DAYS			
PRIVATE USE			
GENERAL INPUT			
Fraction of substance in commercial product	2,69E-03	[-]	S
Location of the treated surface	Urban area		S
Cover mixing/loading?	No		S
APPLICATION			
Area treated	Crawling space		S
Quantity of commercial product applied per m2	8	[g.m-2]	S
Frequency of application in standard houses	1-2 times a year		S

CRAWLING SPACE			
Area of walls and ceiling (crawling space) treated per day	0	[m2]	S
Area of soil (crawling space) treated per day	1	[m2]	S
Fraction emitted to soil during application on walls and ceiling	0	[-]	S
Fraction emitted to soil during application on soil	0,9	[-]	S
LOCAL			
[PRIVATE USE]			
RELEASE VIA STP			
Intermittent release	Yes		S
DISTRIBUTION			
LIFE CYCLE STEPS			
LOCAL PECS [PRIVATE USE]			
RELEASE VIA STP			
AIR			
Annual average local PEC in air (total)	1,50E-13	[mg.m-3]	O
WATER, SEDIMENT			
Local PEC in surface water during emission episode (dissolved)	2,22E-07	[mg.l-1]	O
Qualitative assessment might be needed (TGD Part II, 5.6)	No		O
Annual average local PEC in surface water (dissolved)	2,22E-07	[mg.l-1]	O
Local PEC in freshwater sediment during emission episode	2,77E-03	[mg.kgwwt-1]	O
Local PEC in seawater during emission episode (dissolved)	2,65E-07	[mg.l-1]	O
Qualitative assessment might be needed (TGD Part II, 5.6)	No		O
Annual average local PEC in seawater (dissolved)	2,65E-07	[mg.l-1]	O
Local PEC in marine sediment during emission episode	3,32E-03	[mg.kgwwt-1]	O
SOIL, GROUNDWATER			
Local PEC in agric. soil (total) averaged over 30 days	9,49E-05	[mg.kgwwt-1]	O
Local PEC in agric. soil (total) averaged over 180 days	2,25E-05	[mg.kgwwt-1]	O
Local PEC in grassland (total) averaged over 180 days	9,01E-06	[mg.kgwwt-1]	O
Local PEC in pore water of agricultural soil	2,22E-09	[mg.l-1]	O
Local PEC in pore water of grassland	8,88E-10	[mg.l-1]	O
Local PEC in groundwater under	2,22E-09	[mg.l-1]	O

agricultural soil

SCENARIO 8b Around building against Blatta orientalis – RURAL

Section/parameter	Actual value	Unit	Stat
SUBSTANCE IDENTIFICATION			
General name	Cypermethrin		S
CAS-No	52315-07-8		S
EC-notification no.			D
EINECS no.	257-842-9		S
PHYSICO-CHEMICAL PROPERTIES			
Molecular weight	416	[g.mol ⁻¹]	S
Melting point	47	[oC]	S
Boiling point	??	[oC]	D
Vapour pressure at 20 [oC]	4,25E-07	[Pa]	O
Vapour pressure at 25 [oC]	6,00E-07	[Pa]	S
Water solubility at 20 [oC]	4	[µg.l ⁻¹]	S
Water solubility at 25 [oC]	4,28E-03	[mg.l ⁻¹]	O
Octanol-water partition coefficient	5,45	[log10]	S
PARTITION COEFFICIENTS AND BIOCONCENTRATION FACTORS			
SOLIDS-WATER			
Organic carbon-water partition coefficient	5,75E+05	[l.kg ⁻¹]	S
AIR-WATER			
Henry's law constant at test temperature	0,024	[Pa.m ³ .mol ⁻¹]	S
Temperature at which Henry's law constant was measured	20	[oC]	S
DEGRADATION AND TRANSFORMATION RATES			
CHARACTERIZATION			
Characterization of biodegradability	Not biodegradable		S
STP			
Select biodegradation test method	Method 1: estimated from standardized biodegradability tests (OECD 301 series, 310, 302 series)		S
AIR			
Rate constant for degradation in air	0,749	[d ⁻¹]	S
SOIL			
Rate constant for biodegradation in bulk soil	17,2	[d] (DT50,12[oC])	S

RELEASE ESTIMATION			
BIOCIDE SCENARIO INPUT DATA			
Usage/production title	Cypermethrin Powder outdoor Ant nest		S
Scenario choice for biocides	(18) Insecticides, acaricides and products to control other arthropods		S
Additional scenario information	(18.3.2) Outdoor, crawling insects		S
PRIVATE USE			
Emission scenario			D
INTERMEDIATE RESULTS			
RELEASE FRACTIONS AND EMISSION DAYS			
PRIVATE USE			
GENERAL INPUT			
Fraction of substance in commercial product	2,69E-03	[-]	S
Location of the treated surface	Rural area		S
Cover mixing/loading?	No		S
APPLICATION			
Area treated	Crawling space		S
Quantity of commercial product applied per m ²	8	[g.m ⁻²]	S
Frequency of application in standard houses	1-2 times a year		S
CRAWLING SPACE			
Area of walls and ceiling (crawling space) treated per day	0	[m ²]	S
Area of soil (crawling space) treated per day	2	[m ²]	S
Soil volume for application and deposition, treated	2,5	[m ³]	S
Fraction emitted to soil during application on walls and ceiling	0	[-]	S
Fraction emitted to soil during application on soil	0,9	[-]	S
DISTRIBUTION			
LIFE CYCLE STEPS			
LOCAL PECS [PRIVATE USE]			
DIRECT RELEASE			
SOIL			
Local PEC, treated area/crawling space	9,11E-03	[mg.kgwwt-1]	O
Local PEC, untreated area	??	[mg.kgwwt-1]	O
GROUNDWATER			

Local PEC, treated area/crawling space	8,98E-04	[µg.l-1]	0
Local PEC, untreated area	??	[µg.l-1]	0

3.3 New information on the active substance

New information on the active substance is not available.

3.4 Residue behaviour

No residues of FREE LAND DUST in food or feed occur.

3.5 Summaries of the efficacy studies (B.5.10.1-xx)

Cypermethrin is a contact insecticide. i.e. 0.263% w/w technical material, to be applied indoor and outdoor by professional and non-professional users. *FREE LAND DUST* is a powder formulation and is used under PT18 for targeted spot application on crawling insects, and for eradication of wasp nest and ants nest.

Test organisms in efficacy studies are detailed below.

- *Blattella germanica*
- *Lasius niger* (black garden ants)
- *Blatta orientalis*
- *Vespula spp* (German wasp)

3.6 Confidential annex

Please refer to separate file.

3.7 Other