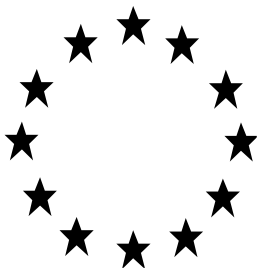
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

DRAFT RISK ASSESSMENT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATION



Neopermin

Product type 18

Active substance: Permethrin

Evaluating Competent Authority: The Netherlands

Date: December 2020

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1 CONCLUSION

The dustable powder Neopermin containing 0.5% permethrin is used indoors by non-professionals and (trained) professionals for spot and crack and crevice treatment against crawling insects such as ants and cockroaches. The product is used at a dose rate of 1 g of product per m^2 on spots where the crawling insects are or where they could come into the house or in empty storage spaces. The product can be used on wood, concrete and smooth surfaces (glass, ceramic etc.).

The product is not meant to be co-applied with other substances or products.

The product contains 0.5% permethrin and a carrier. It is a fine white powder at room temperature and pressure. It has a tap density of 0.67-0.83 g/ml. It is stable at room temperature for at least 2 years at 25° C and for at least 2 weeks at 54° C with no indication of any significant change to any of the physical, chemical or technical properties of the product or the packaging during these storage periods and temperatures.

Data gap for renewal:
A storage stability study should be provided that addresses the active substance content of the material that is retained on the 75µm sieve in the dry sieve test, according to the requirements of the BPR guidance (version 2.0, May 2018).

The product is considered to have no physical hazards. It is considered to be relatively inert, with no expected explosive, flammable, oxidising, self-heating, self-reacting or self-ignition hazards. Laboratory, simulated-use and field studies were provided to demonstrate the efficacy of the product against ants (*Lasius niger*) and cockroaches (*Blatella germanica*, *Blatta orientalis*).

No adverse health effects are expected to the unprotected professional worker and the unprotected non-professional user from exposure to permethrin in the Neopermin product when used in accordance with instructions described in the SPC.

Two substances are identified as substances of concern as for these two substances Dutch OEL values are available, for which an risk assessment is included in the Confidential Annex of the PAR.

No adverse health effects are expected to the unprotected professional worker from inhalation exposure to components for which Dutch OEL values are available in the Neopermin product during application when used in accordance with instructions described in the SPC. However, adverse health effects from the exposure to a component for which a Dutch OEL value is available cannot be excluded when the product is transferred from a large container containing up to 25 kg product to a small container by professionals. The use of respiratory protective equipment (RPE) of protection factor 4 or higher is prescribed during the loading operation.

For non-professionals, the loading operation is not expected because the product is packaged in 50-300 g shaker bottle. No adverse health effects are expected to the unprotected non-professional user from inhalation exposure to components for which Dutch OEL values are available in the Neopermin product when used in accordance with the label instructions.

No adverse health effects are expected to the general public including children and animals from indirect exposure to permethrin from the use of the biocidal product.

Accumulation and transport in air can be excluded and no exposure of the atmosphere is expected.

There is no concern to the STP or the terrestrial compartment from use of the Neopermin product in accordance with label instructions.

There is concern to the aquatic compartment from use of the Neopermin product in accordance with label instructions as PNECs for permethrin for the water and sediment compartments are exceeded taking an application frequency of once a day into account. According to the applicant, the product has residual activity for at least 3 weeks which is equal to an application frequency of once per 3-4 weeks. Based on this application frequency, the risks for the water and sediment compartments are acceptable as the PEC/PNECs for these compartments are below 1.

There is no concern to groundwater from use of the Neopermin product in accordance with label instructions as the concentrations in groundwater for permethrin and metabolites DCVA and PBA are well below the drinking water limit of 0.1 µg/L.

There is no concern from primary or secondary poisoning of birds or mammals from use of Neopermin in accordance with the use instructions.

eCA note: The cleaning efficiency of 0.03 for RTU aerosols applied in the environmental risk assessment was not supported by all icMSs. By using the cleaning efficiency of 0.25 for sprays in cracks and crevices an unacceptable risk for the aquatic environment would be identified. However, this unacceptable risk can be mitigated by the risk mitigation measures included in the PAR and SPC. This was agreed in the 44th meeting of the Coordination Group of November 2020.

2: Assessment report

2.1: Summary of product assessment

2.1.1: Administrative information

Table 1: Trade names of the product

Trade name	Country (if relevant)
Neopermin, AMEISEN STREU-UND GIESSMITTEL, EFFECT Neopermin, AMEISENMITTEL	Austria
Ефект пудра срещу мравки; Neopermin	Bulgaria
Biotoll insekticidní prášek proti mravencům; Neopermin	Czech Republic
Biotoll - prášek proti vosám	Czech Republic
Biotoll Neopermin / Effect Sipelga pulber; Neopermin	Estonia
Sipelgate tõrjepulber; Neopermin	Estonia
Effect σκόνη μυρμήγκι; Neopermin	Greece
BIOTOLL NEOPERMIN; Neopermin	Croatia
Pulveris skudru iznīcināšanai; Neopermin	Latvia
TARIN PLUS	Latvia
Insekticidiniai skruzdėlių milteliai; Neopermin	Lithuania
TARIN PLUS	Lithuania
Neo-permin Biotoll csótány- es hangyairtó porozószer	Hungary
EFFECT PROFESSIONAL Neopermin; Neopermin	Germany
AMEISEN STREU-UND GIESSMITTEL	Germany
AMEISENMITTEL	Germany
Perm-EX – Schädlingsfrei gegen Schaben, Ameisen, Silberfischchen und kriechende Insekten	Germany
Perm-EX – Ameisen Streu- und Giessmittel	Germany
Neopermin	Norway
Myggolf Maurmiddel Strøpulver	Norway
EFFECT- środek owadobójczy przeciw mrówkom; Neopermin	Poland
BIOTOLL - pylisty preparat na osy	Poland
Biotoll powder against ants/ Biotoll insekticídny prášok proti mravcom; Neopermin	Slovakia
Biotoll powder against wasps/ Biotoll insekticídny prášok proti osám a na zneškodnenie osích hniezd	Slovakia
INSEKTICIDNO PRAŠIVO BIOTOLL PROTI MRAVLJAM; Neopermin	Slovenia
NEO-PERMIN	Slovenia
NEO-PERMIN; Neopermin	Romania
EFFECT ANT POWDER	Romania
Effect pulvere pentru furnici	Romania
Neopermin	Netherlands

Table 2: Authorisation holder

Name and address of the authorisation holder	Name	UNICHEM D.O.O.
	Address	Sinja Gorica 2, 1360 Vrhnika, Slovenia
Authorisation number	NL-0016477-0000	
Date of the authorisation	5 February 2021	

Expiry date of the authorisation	5 February 2031

Table 3: Manufacturer(s) of the product

Name of manufacturer	UNICHEM D.O.O.
Address of manufacturer	Sinja Gorica 2, 1360 Vrhnika, Slovenia
Location of manufacturing sites	Sinja Gorica 2, 1360 Vrhnika, Slovenia

Table 4: Manufacturer(s) of the active substance(s)

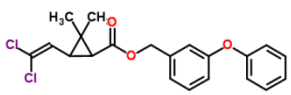
Active substance	Permethrin
Name of manufacturer	Tagros Chemicals India Ltd.
Address of manufacturer	Jhaver Centre", Rajah Annamalai Building, IV Floor, 72, Marshalls Road, Egmore, Chennai-600 008, India
Location of manufacturing sites	Tagros Chemicals India Ltd. A-4/1&2, Sipcot Industrial Complex Pachayankuppam Cuddalore - 607 005, Tamilnadu India

2.1.2: Product composition and formulation

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)	
ISO name	Permethrin
IUPAC or EC name	3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate
EC number	258-067-9
CAS number	52645-53-1
Index number in Annex VI of CLP	613-058-00-2
Minimum purity / content	93% (w/w)
Structural formula	

	Permethrin has four stereoisomers: 1R*cis*, 1S*cis*, 1R*trans*, and 1S*trans*. Two pairs of diastereomers (each consisting of a nonracemic pair of enantiomers) are present in a ratio of ca. 25:75 (*cis*:*trans*).

2.1.2.2: Candidate(s) for substitution

The following information is provided in the Assessment Report for Permethrin:

Permethrin (various isomer mixtures) is not a PBT candidate nor are its individual constituent isomers.

Permethrin is considered to fulfil the T criteria, but does not fulfil the B criteria. However, permethrin could also be considered as potentially persistent based on a constituent of permethrin (the *cis* isomer) and therefore fulfil the P criteria.

Guidance on PBT assessment (ECHA Guidance: Chapter R.11: PBT Assessment, v.1.1, November 2012) indicates that since the *cis* isomer constituent is present within permethrin at amounts ≥ 0.1 % w/w then the multi-constituent substance, permethrin, should also be treated as potentially persistent. In this situation permethrin may potentially fulfil the persistency criteria and, hence, fulfil two out of the three PBT criteria. Due to this borderline status and to the difficulties pertaining to the determination of the P classification, permethrin is currently assessed by the ECHA PBT working group. Depending on the outcome of the ECHA PBT working group there may be a requirement for the substance to be considered as a candidate for substitution as identified in the provisions of Article 10 of Regulation (EU) No 528/2012.

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 (%)
Permethrin	3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate	Active substance	52645-53-1	258-067-9	0.8% (TK) 0.5% (TC, purity 93%))

2.1.2.4: Information on technical equivalence

The manufacturer (Tagros) of the active substance used in the biocidal product is the same as the applicant that submitted the active substance dossier under the Biocides existing review program (refer to the permethrin Assessment report). The active produced by Tagros and the other applicant were declared as technically equivalent to each other and treated as the same active for the purpose of the active assessment and ultimate approval onto the Union List of actives. Therefore, the product contains permethrin that has already been reviewed and approved.

2.1.2.5: Information on the substance(s) of concern

Two substances are identified as substances of concern as for these two substances Dutch OEL values are available. For more information see the Confidential Annex.

There is no concern for endocrine disruptors found in the product.

2.1.2.6: Type of formulation

Dustable powder (DP)

2.1.3: Hazard and precautionary statements

Table 5: Classification and labelling 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	
Signal words	Warning
Hazard statements	H410: Very toxic to aquatic life with long lasting effects EUH208 Contains Permethrin. May produce an allergic reaction.
Precautionary statements	P102: Keep out of reach of children P501: Dispose of contents/container in accordance with local regulation
Note	-

2.1.4: Authorised use(s)

Table 6: Use 1. – Spot and crack and crevice treatment - Professionals

Product Type	Product Type 18: Insecticides, acaricides and products to control other arthropods
Where relevant, an exact description of the authorised use	Insecticide.
Target organism (including development stage)	Crawling insects, including: Cockroaches – *Blattodea* – nymphs and adults Ants – *Formicidae* – adults
Field of use	Indoor
Application method(s)	Manual application Dustable powder applied to surfaces (wood, concrete, smooth surfaces (glass, ceramic etc.)) indoors for spot and crack and crevice treatment only.
Application rate(s) and frequency	1 g of product per m^2. Without cleaning of the surface the product can stay active for 3 weeks. The product may not be applied more than once per month per application site.
Category(ies) of users	Professional Trained professional

Pack sizes and packaging material	5 - 25 kg natron bag (paper/plastic (PE/PP) foil/paper). 1 - 10 kg buckets (HDPE, PE, PP). 50 - 300 g containers (HDPE) (shaker bottle) 50- 300 g cardboard container (PAP) with Al layer inside (shaker bottle).

Use 2 – Spot and crack and crevice treatment – Non-professionals

Product Type	Product Type 18: Insecticides, acaricides and products to control other arthropods
Where relevant, an exact description of the authorised use	Insecticide.
Target organism (including development stage)	Crawling insects, including: Cockroaches – *Blattodea* – nymphs and adults Ants – *Formicidae* – adults
Field of use	Indoor
Application method(s)	Manual application Dustable powder applied to surfaces (wood, concrete, smooth surfaces (glass, ceramic etc.)) indoors for spot and crack and crevice treatment only.
Application rate(s) and frequency	1 g of product per m^2. Without cleaning of the surface the product can stay active for 3 weeks. The product may not be applied more than once per month per application site.
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	50 - 300 g plastic container (HDPE) shaker bottle 50 - 300 g cardboard container (PAP) with Al layer inside (shaker bottle)

2.1.5: General Directions for use

2.1.5.1: Instructions for use

The biocidal product is a ready-to-use powder sold in a variety of packagings dependent on the end user. Professionals may wish, for convenience, to transfer a small amount of product from a larger container to a small container - appropriately labelled by the professional to identify the contents - prior to leaving their workplace, rather than carry buckets and bags around.

Neopermin is an insecticide with contact action and is used for the control of crawling insects including ants (such as *Lasius niger*) and cockroaches (such as *Blatella germanica*, *Blatta orientalis*). The product should be used only as a spot and crack and crevice treatment in places where crawling insects are, or could come into the house, storage room or building, at a dose rate of 1 g of product per m^2. The product can be used on wood, concrete and smooth surfaces (glass, ceramic etc.) and should be applied in places which are difficult for children and animals to access (such as under, between and behind cabinets and in cracks and crevices around the edge of a room). Use a brush to distribute the product into cracks and crevices This product has a residual efficacy and without cleaning can stay active for 3 weeks. Any remaining product or product spills removed from the treated or adjacent surface must not be washed to a drain. Only dry clean by using a vacuum cleaner (preferably) or very carefully brush any remaining powder and dispose into dry waste.

In order to ensure correct dosing, users should use a ¼ teaspoon measuring spoon/spatula to apply 1 g, which is sufficient to treat 1 m^2. In the absence of such a measuring spoon, a normal teaspoon should be used. When the product is measured from the shaker bottle or cardboard container, powder should be applied onto a teaspoon by gently tapping the shaker/container.

The product may be applied not more than once per month per application site.

Do not mix with other products.

Do not rinse used equipment with water. Reuse or dispose of in a safe way

2.1.5.2: Risk mitigation measures

The product should be applied where children and pets do not come in contact with the product.

Contains permethrin (pyrethroids), may be lethal to cats. No access of cats to treated areas.

If the product is transferred to another container by a professional, the container must be appropriately labelled so that the contents can be clearly identified. Respiratory protective equipment (RPE) of protection factor 4 or higher is required when the product is transferred to another container.

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 animals.

Do not store near food, drink and animal feedingstuff.

Unprotected persons and animals should be kept away during application.

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

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

First aid instructions:

Skin contact: Immediately remove contaminated clothing. Wash thoroughly with plenty of water and soap. If feeling unwell seek medical help.

Eye contact: Immediately flush eyes with running water for at least 15 minutes, keeping eyelids open. Check for and remove any contact lenses. If irritation persists, seek professional medical attention

Inhalation: Remove patient to fresh air-move out of dangerous area. If symptoms persist seek medical attention.

Ingestion: Do not provoke vomiting, seek medical advice first. Rinse mouth with water. Immediately consult a specialist. Show the physician the Safety Data Sheet or label.

Emergency measures to protect the environment:

Do not allow product to reach water/drains/sewage systems or permeable soil. If accidental entry into water or ground occurs, inform responsible authorities. For accidental spillage take up mechanically and collect in suitable container and dispose according to current regulations. Clean contaminated area with water and detergent.

2.1.5.4: Instructions for safe disposal of the product and its packaging

For waste chemical disposal must be made according to official regulations: to leave it to authorized collector/remover/transformer of hazardous waste. The product should not be allowed to reach drains/sewage systems.

For packaging the completely emptied container should be disposed of according to regulations. Unclean containers are classified as hazardous waste and should be handled the same as the waste chemical.

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

The product should be stored in a dry place and protected from direct sunlight. The shelf life of the product is 2 years.

2.1.6: Other information

Resistance management measures

1. Where an extended period of control is required, treatments should be alternated with products with different modes of action.

2. Levels of effectiveness should be monitored and instances of reduced effectiveness should be investigated for possible evidence of resistance. In this case, an alternative treatment to overcome the resistance should be used.

3. Products should always be used in accordance with the label recommendations.

4. Complete elimination of insect pests should be attempted in infested areas

5. Hygienic measures (e.g. removal of food sources) should be followed in order to reduce the number of insects attracted into the home/building and hence help reduce both the infestation and the risk of resistance occurring.

6. No cleaning (dry or wet) of the treated area during periods of insect activity. However, since this product would be placed into areas that would be difficult to clean (e.g. under and behind cabinets and in cracks and crevices around the edge of a room), this is not expected to prevent the cleaning of the majority of the floor surface area in a room.

2.1.7: Packaging of the biocidal product

Table 7: Packaging of the biocidal product

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)
Natron bag,	5 - 25 kg	Paper/plastic(PE/PP) foil/paper	Hot sealed or glued bag	Professional only	Yes
Bucket	1 - 10 kg	HDPE, PE, PP	HDPE, PE, PP lid	Professional only	Yes
*Plastic (HDPE) bottle (shaker)	50 - 300 g	HDPE	HDPE, PE or PP sieve with additional HDPE, PE or PP cover/lid	Non-professional/ professional	Yes
*Cardboard container with Al layer inside (shaker)	50 - 300 g	PAP (cardboard) outer with Aluminium inner layer	HDPE, PE or PP rotating cover with integrated sieve.	Non-professional/ professional	Yes

*Note: Both the HDPE bottle and cardboard container are 'shaker' bottles.

2.1.8: Documentation

2.1.8.1: Data submitted in relation to product application

No new data on the active substance has been submitted by the applicant or by the supplier of its permethrin involved in the existing active review program. All data on the product has been summarised in the submitted IUCLID dossier.

2.1.8.2: Access to documentation

Unichem has a letter of access to the active dossier which has been provided with the application.

2.2: Assessment of the biocidal product

2.2.1: Intended use(s) as applied for by the applicant

Table 8: Use 1 – spot and crack and crevice treatment- Professionals

Product Type	Product Type 18: Insecticides, acaricides and products to control other arthropods
Where relevant, an exact description of the authorised use	Insecticide.
Target organism (including development stage)	Crawling insects, including: Cockroaches – *Blattodea* – nymphs and adults Ants – *Formicidae* – adults
Field of use	Indoor
Application method(s)	Manual application

	Dustable powder applied to surfaces (wood, concrete, smooth surfaces (glass, ceramic etc.)) indoors for spot and crack and crevice treatment only.
Application rate(s) and frequency	1 g of product per m^2. Without cleaning of the surface the product can stay active for 3 weeks
Category(ies) of users	Professional
Pack sizes and packaging material	5 - 25 kg natron bag (paper/plastic (PE/PP) foil/paper). 1 - 10 kg buckets (HDPE, PE, PP). 50 - 300 g containers (HDPE) (shaker bottle) 50 - 300 g cardboard container (PAP) with Al layer inside (shaker bottle).

Table 9: Use 2 – spot and crack and crevice treatment– Non-Professionals

Product Type	Product Type 18: Insecticides, acaricides and products to control other arthropods
Where relevant, an exact description of the authorised use	Insecticide.
Target organism (including development stage)	Crawling insects, including: Cockroaches – *Blattodea* – nymphs and adults Ants – *Formicidae* – adults
Field of use	Indoor
Application method(s)	Manual application Dustable powder applied to surfaces (wood, concrete, smooth surfaces (glass, ceramic etc.)) indoors for spot and crack and crevice treatment only.
Application rate(s) and frequency	1 g of product per m^2, without cleaning of the surface the product can stay active for 3 weeks
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	50 - 300 g plastic container (HDPE) shaker bottle 50 - 300 g cardboard container (PAP) with Al layer inside (shaker bottle)

Assessment of the biocidal product

2.2.2: Physical, chemical and technical properties

Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**
Physical state at 20°C and 101.3 kPa	Visual examination	Product containing 0.5% w/w permethrin	Solid (powder)	[redacted]
Colour at 20°C and 101.3 kPa	Visual examination	Product containing 0.5% w/w permethrin	White	
Odour	Data waiver	-	It is not considered safe for laboratory staff to deliberately sniff a biocidal powder product in order to assess its odour. Therefore, on grounds of health and	

			safety this test is considered unnecessary. **eCA remark** Acceptable, as the odour is a non-critical endpoint.	
Acidity/alkalinity	Data waiver	-	The product formulation is a dustable powder and will therefore not be used in combination with water. Acidity/alkalinity data is therefore not relevant.	
Relative density / bulk density	CIPAC MT 33	Product containing 0.5% w/w permethrin	0.67 – 0.83 g/mL (Tap density)	[redacted]
Storage stability test – accelerated storage @ 54°C for 2 weeks	CIPAC MT 46.3 Appearance of test item, packaging weight loss (%) and content of active substance assessed at T0 and T24.	Product containing 0.5% w/w permethrin	Tested during 2 weeks at 54°C in HDPE. **Before storage:** Appearance: White powder Packaging: White HDPE bottle with a cover with holes Active substance content: 0.52% w/w **After storage:** Appearance: White powder Packaging: unchanged Weight loss: 0.18% w/w Active substance content: 0.48% w/w	[redacted]
Storage stability test – long term storage at ambient temperature	-	-	Test for 2 years at 25°C/60%RH in HDPE **Before storage:** Appearance: White powder Packaging: White HDPE bottle with holes in the top and a cover Active substance content: 0.515% w/w **After storage** Appearance: White powder Packaging: Unchanged Weight loss:- 0.227% Active substance content: 0.474% w/w	[redacted]
Storage stability test – **low temperature stability test for liquids**	-	-	-	
Tap density	CIPAC MT 33	Product containing	**Before storage** : Di=0.67 g/ml, Df = 0.87 g/ml (30.4% increase)	[redacted]

		0.5% w/w permethrin	**After storage** : Di=0.57 g/ml, Df = 0.83 g/ml (45.8% increase)	
Wet sieve analysis and dry sieve test	CIPAC MT 59.1	Product containing 0.5% w/w permethrin	Dry sieve test: **Before storage**; Recovery 84.7%Distribution; 5.5%>125 µm 75 µm <0.0%<125 µm 45 µm<11.7%<75 µm 32 µm <14.1%<45 µm 68.6% <32 µm **After storage**: Recovery 96.4%Distribution; 1%>125 µm 75 µm <16.7%<125 µm 45 µm<19.3%<75 µm 32 µm <10.0%<45 µm 49.4% <32 µm.	[redacted]
eCA remark: According to the BPR guidance (version 2.0, May 2018) the active substance content should be determined on the material that is retained on the 75µm sieve. This requirement is to ensure that the active substance is not separated from the carrier. The applicant indicated that this is not relevant for the product Neopermin because the openings of the commercial bottle are much larger, i.e. approximately 2.41 mm. In addition, the active substance content that is determined after the long term storage stability study indicates that the active substance is not retained in the commercial HDPE bottles. The eCA would like to add the following: From the dry sieve test results it can be concluded that indeed more than the allowed 5% of product is retained on the 75µm sieve after storage. However, the percentage of product that is retained on the 125µm sieve actually decreased after storage. Overall the size distribution remained fairly constant during storage. In addition, from the particle size distribution it can be concluded that the actual particle size does not change during storage (refer to particle size distribution). The difference in size distribution between dry sieve test and particle size distribution test is therefore likely caused by different sample preparations dictated by the appropriate CIPAC methods. The eCA is of the opinion that the explanation of the applicant in combination with the test results is acceptable and that no problems are to be expected regarding the use of the product Neopermin. However, the BPR guidance indicates that the active substance content must be determined on the material that is retained on the 75µm sieve if this is more than 5%. Therefore, the eCA sets a data gap for renewal. For the renewal the applicant should provide a study that addresses the active substance content of the material that is retained on the 75µm sieve. **Data gap for renewal:** A storage stability study should be provided that addresses the active substance content of the material that is retained on the 75µm sieve in the dry sieve test, according to the requirements of the BPR guidance (version 2.0, May 2018).				
Particle size distribution, content of dust/fines, attrition, friability	CIPAC MT 187/ISO 13320:2009 -laser diffraction	Product containing 0.5% w/w permethrin	Particle size distribution: **Before storage**: 10%<3.501 µm 50% < 16.920 µm 90%<48.285 µm **After storage**: 10% <3.75 µm 50% < 17.94 µm 90%<51.39 µm. Refer to dry sieve test results for content of dust/fines.	[redacted]

Light	Data waiver	-	The powder is not exposed to light during storage. Therefore this study is not required.	-
eCA remark: A light stability study was not performed. Therefore the sentence 'protect from direct sunlight' will be included on the label.				
Temperature and humidity	-	-	Temperature effect (54°C) is covered by accelerated storage stability study and in 2 years storage stability study (25°C). Humidity is assessed at 60%RH in the 2 years storage stability study. Refer to results for storage stability test – long term storage at ambient temperature and individual results in this table.	[redacted]
Reactivity towards container material	-	-	See results for storage stability test – long term storage at ambient temperature	[redacted]
Wettability	Data waiver	-	The product will not be dispersed in water but instead will be used as a dustable powder. Wettability data is therefore not required.	-
Suspensibility, spontaneity and dispersion stability	Data waiver	-	Not applicable for a RTU formulation. The product is not intended to be suspended in water.	-
Emulsifiability, re-emulsifiability and emulsion stability	Data waiver	-	This data is not required as the product is not used as an emulsion.	-
Disintegration time	Data waiver	-	This data is not required for a dustable powder. The product will not be dissolved in a solvent.	-
Persistent foaming	Data waiver	-	This data is not relevant as the product will not be applied in water for use.	-
Flowability/Pourability/Dustability	Data waiver	-	According to the BPR guidance (section 3.6.5.8, Volume I Parts A+B+C Version 2.0 May 2018) a flowability test is required on granular materials. The product is not granular, therefore no test needed.	-

			In the same guidance, a pourability test is stated as required for suspension concentrates, capsule suspensions and suspoemulsions. This is not applicable for this product, therefore not required. For dustability, the relevant test method is CIPAC MT 34 which is not readily available. Alternatively, it suffices to prove that no compaction or cracking occurs following a heat test under pressure. Since, the product is incredibly soft and easy to break up and very difficult to compress, it is very likely the product will remain a fine powder when tapped from the shaker bottles onto the spoon, prior to application.	
Burning rate — smoke generators	Data waiver	-	No data provided because the product is not intended to be used as a smoke generator.	
Burning completeness — smoke generators	Data waiver	-	No data provided because the product is not intended to be used as a smoke generator.	
Composition of smoke — smoke generators	Data waiver	-	No data provided because the product is not intended to be used as a smoke generator.	
Spraying pattern — aerosols	Data waiver	-	No data provided because the product will not be used as an aerosol.	
Physical compatibility	Data waiver	-	No data available, the product is not intended to be used in combination with other products.	
Chemical compatibility	Data waiver	-	No data available, the product is not intended to be used in combination with other products.	
Degree of dissolution and dilution stability	Data waiver	-	No data available because the product is not a water-soluble product.	
Surface tension	Data waiver	-	According to the guidance on the BPR: Volume I, Part A, this test is not required since is the product is a solid.	
Viscosity	Data waiver	-	According to the guidance on the BPR: Volume I,	

			Part A, a study on viscosity is not required as the product is a solid.	

According to the Guidance on the BPR (Volume I. Part A Chapter III: Requirements for Biocidal Products Version 1.1 November 2014), for solid preparations, "extrapolation to all types of packaging is acceptable except to more flexible packs. For solid formulations sold in flexible packs the effects of stacking on the packaging and the physical and chemical properties must be investigated. The stacking undertaken must reflect those encountered in commercial practice".

For further information on the stacking test refer to confidential annex as the information is based on compositional information.

Conclusion on the physical, chemical and technical properties of the product

The product contains approximately 0.5% permethrin. It is a fine white powder at room temperature and pressure. It has a tap density of 0.67-0.83 g/ml. It is stable at room temperature for at least 2 years at 25° C and for at least 2 weeks at 54° C with no indication of any significant change to any of the physical, chemical or technical properties of the product or the packaging during these storage periods and temperatures.

Data gap for renewal:
A storage stability study should be provided that addresses the active substance content of the material that is retained on the 75µm sieve in the dry sieve test, according to the requirements of the BPR guidance (version 2.0, May 2018).

2.2.3: Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	Data waiver	-	None of the components contain chemical groups associated with explosive properties as indicated in Appendix 6 of the UN-MTC. Therefore a study	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			is scientifically unjustified.	
Flammable gases	Data waiver	-	The study does not need to be conducted because the product is a solid. Therefore, a test is scientifically unnecessary.	
Flammable aerosols	Data waiver	-	The study does not need to be conducted because the product is a solid. Therefore, a test is scientifically unnecessary.	
Oxidising gases	Data waiver	-	The study does not need to be conducted because the product is a solid. Therefore it is scientifically unnecessary.	
Gases under pressure	Data waiver	-	The study does not need to be conducted because the product is a solid. Therefore it is scientifically unnecessary.	
Flammable liquids	Data waiver	-	The study does not need to be conducted because the flash point is only relevant to liquids and low melting point	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			solids. Therefore it is scientifically unnecessary.	
Flammable solids	Data waiver	-	The CLP criteria states that for inorganic materials, -testing may be waived where the substance is commonly known to be not flammable. The main component (inorganic) of the product is is commonly known to be not flammable. Therefore a test is scientifically unnecessary.	
Self-reactive substances and mixtures	Data waiver	-	The study does not need to be conducted because there are no chemical groups present in the molecule which are associated with explosive or self-reactive properties according to Appendix 6, Section 5.1 of the UN-MTC and hence, the classification procedure does not	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			need to be applied (study scientifically unnecessary).	
Pyrophoric liquids	Data waiver	-	The product is a solid, therefore a test is not scientifically necessary.	
Pyrophoric solids	Data waiver	-	According to the additional classification considerations in CLP Annex I, 2.10.4, the classification procedure for pyrophoric solids need not be applied when experience in manufacture or handling shows that the substance or mixture does not ignite spontaneously on coming into contact with air at normal temperatures (i.e. the substance or mixture is known to be stable at room temperature for prolonged periods of time (days)).The main component of the product fulfils this	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			criteria, so pyrophoric tests are not scientifically necessary	
Self-heating substances and mixtures	Data waiver		It is considered that for this product self-heating (caused by reaction of components with oxygen in the air) is highly unlikely. Therefore a study is scientifically unnecessary.	
Substances and mixtures which in contact with water emit flammable gases	Data waiver		From common use the main component of the product is known not to emit flames on contact with water. Therefore this test is scientifically unnecessary	
Oxidising liquids	Data waiver		The study does not need to be conducted because the product is a solid. Therefore it is scientifically unnecessary.	
Oxidising solids	Data waiver		The components in the product are not oxidising.	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Therefore testing is not required.	
Organic peroxides	Data waiver		The study does not need to be conducted because the substance does not fall under the definition of organic peroxides according to GHS and the relevant UN Manual of tests and criteria	
Corrosive to metals	Data waiver		The product is not a liquid or a solid that may become liquid during transport. Therefore the data is scientifically unnecessary.	
Auto-ignition temperatures of products (liquids and gases)	Data waiver		This study is required for liquids and gases. The product is a solid therefore this study is scientifically unnecessary.	
Relative self-ignition temperature for solids	Data waiver		The main component of the product is an inorganic material commonly known not to be flammable and therefore it is highly likely that	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			the product will not self-ignite. Therefore a study is scientifically unnecessary.	
Dust explosion hazard	Data waiver		Materials that cannot be oxidised are exempt from testing. As the product meets this criterion a test is scientifically unnecessary.	

Conclusion on the physical hazards and respective characteristics of the product

The product is considered to have no physical hazards. It is considered to be relatively inert, with no expected explosive, flammable, oxidising, self-heating, self-reacting or self-ignition hazards.

2.2.4: Methods for detection and identification

Table 10: Analytical methods for the analysis of the product as such including the active substance, impurities and residues

Analyte	Analytical method	Number of measurements	Linearity	Specificity	Recovery rate (%)			Reference
					Range	Mean	RSD	
Permethrin (active substance) The cis : trans isomers are present in the ratio 25 : 75	GC-FID	For linearity: 5 concentrations corresponding to 50%, 75%, 100%, 125% and 150% of the active ingredient concentration	r^2 = 0.9988 Equation: Y =17926x – 0.0059 Linearity range: 0.024 mg permethrin/ml to 0.071 mg	Method proved to be specific.	50% 100% 150%	100.3% 100.25% 100.42%	1.59%	[redacted]

		For accuracy (recovery) 6 measurements (2 at each fortification level of 50,100 and 150%) For precision: 6 samples.	permethrin/ml (equivalent to 0.25%-0.75% w/w permethrin in product) LOQ = 0.024 mg permethrin/ml.					

eCA remark: No analytical method for the SoC [redacted] has been provided. This is considered acceptable since [redacted] are not part of an equilibrium and the amount is therefore not likely to increase due to a shift in the equilibrium. Neither are the SoC a degradation product of a non-stabile substance.

Sample preparation

Permethrin standard solution: Permethrin raw material is dissolved in acetone. An aliquot of this solution is further diluted with acetone and the suspension sonicated for 10 minutes and centrifuged for 10 minutes at 3000 rpm.

Permethrin reference standard solution: Permethrin reference standard is dissolved in acetone. An aliquot of this solution was transferred in to another flask and diluted with acetone.

Dibutyl phthalate internal standard solution: Dibutyl phthalate was dissolved in acetone. An aliquot of this was transferred to a volumetric flask and diluted with acetone.

Test sample solution: About 1 g of test product (0.5% permethrin) was dissolved in 100 ml acetone. The suspension was sonicated for 10 minutes and centrifuged for 10 minutes at 3000 rpm.

Placebo solution: About 995 mg placebo was dissolved in 100 ml acetone and the suspension sonicated for 10 minutes then centrifuged for 10 minutes at 3000 rpm

GC-FID conditions:

Column	**Restek Rtx-1 – 30 m x 0.25 mm x 25.0 µm**
Injector temperature	**270° C; Split 20:1**
Injection volume	**1.0 µl**
Flow	**Helium, 1.5 ml/min**
GC oven program	**230°C for 2 min, rate 10°C/min to 270°C for 5 min**
Detection	**FID, 290°C**

General method description

Preparations for the analytical determination of permethrin in the product, were dissolved in Acetone, quantified against an internal standard (dibutyl phthalate) and investigated by capillary column and GC-FID technique. Specificity was tested by separately injecting solvent, test sample, placebo, permethrin raw material, permethrin reference standard, diethyl phthalate internal standard and dibutyl phthalate internal standard. A GC/MS-SCAN mode confirmatory technique was used to demonstrate the method selectivity. Linearity was tested on 5 points corresponding to 50,75,100,125 and 150% of the active in the sample. Each concentration level was prepared once. Accuracy was performed on reconstituted samples (active ingredient in the presence of placebo). Two different preparations at three different concentrations of the active ingredient in the sample were tested. Precision was performed on 6 sample preparations. A system suitability test was used to show the system was acceptable (≤ 2% variation between response factors of two standard solutions (containing 100% analyte) and ≤ 2% variation in their percentage recovery). Cis-trans-permethrin isomers were separated with ramping chromatographic run and capillary non-polar column.

Conclusion: The analytical method was specific, linear, precise and accurate and was successfully validated. An analytical method for the SoC [redacted] are not considered necessary since the amount is not expected to increase.

Analytical methods for residues in soil, water, air and body tissue and fluids

Reference can be made to the active substance dossier for analytical methods to determine permethrin in these compartments, where relevant.

2.2.5: Efficacy against target organisms

2.2.5.1: Function and field of use

The product Neopermin is intended to be used as a dustable powder insecticide (PT18) by professional and non-professional users.

2.2.5.2: Organisms to be controlled and products, organisms or object to be protected

Neopermin is intended to control crawling insects including ants (*Lasius niger)* and cockroaches (*Blatella germanica, Blatta orientalis*). Humans are the organisms to be protected as cockroaches are potential carriers of transmittable disease if they come into contact with food and ants may bite causing pain. Structures (foundation) around the house and potentially wiring inside the house are objects to be protected from ants.

2.2.5.3: Effects on target organisms, including unacceptable suffering

The active substance permethrin causes knockdown and mortality in insects. The target organisms are not considered to feel pain, and no unacceptable suffering is considered to occur between exposure to the product and death.

2.2.5.4: Mode of action, including time delay

Mode of action

Permethrin affects neuron membranes by prolonging sodium channel activation. Voltage-Gated Sodium Channel (VGSC) inactivation and deactivation leads to a prolonged VGSC open time. The clustering of kdr and six super-kdr mutations in DIIS4-S5 linker, DIIS5 and DIIS6 suggest that these regions [in the VGSC] are part of the pyrethroid-binding site. After modification by pyrethroids the channels remain open as the insecticide impedes channel closing either by inactivation or deactivation, and the sodium channels retain the ability to conduct Na. However, the membrane potential is shifted so that the nerve cells function in a new, and relatively stable, state of abnormal hyper-excitability. In insects this produces an incapacitating, but sublethal effect, known as 'knockdown'. The amplitude of the sodium current continues undiminished until the level of hyperexcitability overwhelms the capacity of the cell to maintain the activity of the sodium pump and eventually causes paralysis.

Experimental data on the efficacy of the biocidal product against target organism(s)

2.2.5.5: Efficacy data

<table>
<tr><th>Function</th><th>Field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test method</th><th>Test system / concentrations applied / exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr><td>Insecticide</td><td>Indoor

Professional and non-professional use</td><td>Neopermin permethrin powder – 0.5% permethrin</td><td>Crawling insects:
Blattella germanica (adult and nymph)

Blatta orientalis (adult and nymphs)

Lasius niger (adults)</td><td>C.E.B. method No. 135 / 159

Laboratory test.</td><td>Insecticide was applied to plasterboard and ceramic tiles.
Dose rate = 1g/m^2
Exposure time = 1 hour
Persistence was measured after 1, 2 and 3 weeks.</td><td>Direct contact trial: treatment led to fast knockdown (30 seconds) on all target organisms and the efficacy is complete (100% mortality after 24 hours = no recovery).

Residual surface trial: treatment led to total, final mortality (no recovery after 24 hours) up to 3 weeks after treatment of the materials.

The results are summarised in the tables below:

Direct spray test/immediate knockdown effect (+ mortality):
<table>
<tr><th>TRIAL</th><th>Test species</th><th>KT100 (secs)</th><th>% Mortality 24 h</th></tr>
<tr><td rowspan="3">Direct spray test</td><td>Blattella germanica</td><td>30</td><td>100</td></tr>
<tr><td>Blatta orientalis</td><td>30</td><td>100</td></tr>
<tr><td>Lasius niger</td><td>30</td><td>100</td></tr>
</table>
KT100 = time from the beginning of the experiment required to knockdown/kill 100% of the insects.

Residue surface trial

Knockdown summary for the data in KT100 (time from the beginning of the experiment - including the 1 ’hour exposure time of the insects onto the treated surfaces - required to knockdown/kill 100% of the insects)</td><td>[redacted]</td></tr>
</table>

Date	Test species	Plasterboard panel	Ceramic tiles
Day 0 + 1 week	*Blattella germanic*	15 min	15 min
	Blatta orientalis	15 min	15 min
	Lasius niger	15 min	15 min
Day 0 + 2 weeks	*Blattella germanic*	15 min	15 min
	Blatta orientalis	15 min	15 min
	Lasius niger	15 min	15 min
Day 0 + 3 weeks	*Blattella germanic*	15 min	15 min
	Blatta orientalis	30 min	30 min
	Lasius niger	15 min	15 min

Mortality summary of the data in % of death 24 hours after exposure

Date	Test species	Plasterboard panel	Ceramic tiles
Day 0 + 1 week	*Blattella germanica*	100%	100%
	Blatta orientalis	100%	100%
	Lasius niger	100%	100%
Day 0 + 2 weeks	*Blattella germanica*	100%	100%
	Blatta orientalis	100%	100%
	Lasius niger	100%	100%
Day 0 + 3 weeks	*Blattella germanica*	100%	100%

						Blatta orientalis	100%	100%
						Lasius niger	100%	100%
Insecticide	Indoor	Neopermin permethrin powder – 0.5% permethrin	*Blatela germanica* (German cockroach); adults + nymphs *Blatta orientalis* (oriental cockroach); adults + nymphs *Lasius niger* (black ant); adults	Simulated use trial. Choice test Transitional Guidance on Efficacy assessment for Product Type 18, Insecticide, Acaricides & other Biocidal Products against Arthropods and Product Type 19, Repellents & Attractants – September 2016 - ECHA	**Dose:** 1 g/m^2= 3 g on treated area, i.e. onto half of the 6m2 floor, which equals 3m2. Single application. Room (6m^2 floor): Floor made of ceramic tiles and walls made of non-sorbent epoxide panels. Ceramic and cement tiles were placed on the floor. Water and food and cardboard harbourages are available. Half of the surface area was treated. Residual efficacy measured by % mortality after 24 hours exposure directly after treatment and 24 hours exposure 3 weeks after treatment. 4 replicates per species per time, also for the control. 25 insects per replicate. Environmental conditions	For all species and all life stages measured, 100% mortality occurred after 24 hours exposure directly after treatment and after 3 weeks. The untreated control experienced 0% mortality. **Results for treated surface after 24 hours exposure:**								[redacted]

		Time after treatment					
		0			3 weeks		
Target	Rep	D	A	%M	D	A	%M
Blatella germanica ADULTS	1	25	0	100	25	0	100
	2	25	0	100	25	0	100
	3	25	0	100	25	0	100
	4	25	0	100	25	0	100
	Mean			**100**			**100**
Blatella germanica NYMPHS	1	25	0	100	25	0	100
	2	25	0	100	25	0	100
	3	25	0	100	25	0	100
	4	25	0	100	25	0	100
	Mean			**100**			**100**
Blatella orientalis ADULTS	1	25	0	100	25	0	100
	2	25	0	100	25	0	100
	3	25	0	100	25	0	100
	4	25	0	100	25	0	100
	Mean			**100**			**100**
Blatella orientalis NYMPHS	1	25	0	100	25	0	100
	2	25	0	100	25	0	100
	3	25	0	100	25	0	100
	4	25	0	100	25	0	100
	Mean			**100**			**100**
Lasius niger ADULTS	1	25	0	100	25	0	100
	2	25	0	100	25	0	100
	3	25	0	100	25	0	100
	4	25	0	100	25	0	100
	Mean			**100**			**100**

D=dead, A=alive, %M = %mortality, rep=replicate

Results for untreated control after 24 hrs exposure:

		Time after treatment	
		0	3 weeks

					The test chambers were kept at a temperature of 22°C + 1°C, a relative humidity of 60% + 5% and 8 hours light per day (800 lux) during the period of testing.		

Target	Rep	D	A	%M	D	A	%M
Blatella germanica ADULTS	1	0	25	0	0	25	0
	2	0	25	0	0	25	0
	3	0	25	0	0	25	0
	4	0	25	0	0	25	0
	Mean			**0**			**0**
Blatella germanica NYMPHS	1	0	25	0	0	25	0
	2	0	25	0	0	25	0
	3	0	25	0	0	25	0
	4	0	25	0	0	25	0
	Mean			**0**			**0**
Blatella orientalis ADULTS	1	0	25	0	0	25	0
	2	0	25	0	0	25	0
	3	0	25	0	0	25	0
	4	0	25	0	0	25	0
	Mean			**0**			**0**
Blatella orientalis NYMPHS	1	0	25	0	0	25	0
	2	0	25	0	0	25	0
	3	0	25	0	0	25	0
	4	0	25	0	0	25	0
	Mean			**0**			**0**
Lasius niger ADULTS	1	0	25	0	0	25	0
	2	0	25	0	0	25	0
	3	0	25	0	0	25	0
	4	0	25	0	0	25	0
	Mean			**0**			**0**

D=dead, A=alive, %M = %mortality, rep=replicate

Insecticide	Indoor	Neopermin permethrin powder – 0.5% permethrin	*Blatela germanica* (german cockroach); all life stages *Blatta orientalis* (oriental cockroach); all life stages	Field trial natural infestations in multi-family public housing. CA-DEC12-Doc.6.2.a-FINAL: guidance document to	1 g product per m^2 (=5 mg/m^2 permethrin). Single application in the kitchenarea (12m2). Crack and crevice treatment. To evaluate the cockroach populations sticky trapping was done. Trapped insects counted before and	Percentages of reduction of cockroaches' populations after treatment: **Blattella germanica** No. days after treatment: 1 / 7 / 14 / 21 Test product: 87.2 / 94.1 / 98.5 / 99.5	[redacted]

<table>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>replace part of Appendices to chapter 7 on the TNsG on Product evaluation; Product Type 18 and 19</td>
<td>1, 7, 14 & 21 days after treatment.

5 replicates per target species, also 5 control replicates per target species.

Environmental conditions:
The test was conducted in an occupied multi-family accommodation building with stable temperature of 20±2°C during trial.

Test period: 24th Oct-14th Nov 2016</td>
<td>
<table>
<tr><td>Untreated control</td><td>5.2</td><td>-4.2</td><td>-12.8</td><td>-2.6</td></tr>
</table>
Blatta orientalis
<table>
<tr><td>No. days after treatment</td><td>1</td><td>7</td><td>14</td><td>21</td></tr>
<tr><td>Test product</td><td>77.7</td><td>91.4</td><td>97.4</td><td>99.3</td></tr>
<tr><td>Untreated control</td><td>1.2</td><td>5.6</td><td>3.8</td><td>-2.7</td></tr>
</table>
> 90% reduction in the cockroach population after 7 days and > 99% reduction 3 weeks after application
</td>
<td></td>
</tr>
<tr>
<td>Insecticide</td>
<td>Indoor</td>
<td>Neopermin permethrin powder – 0.5% permethrin</td>
<td>Lasius niger (black ant); all life stages</td>
<td>Field trial

nests</td>
<td>1 g product per m2 and per nest (=5 mg permethrin/nest entry = 5 mg/m2 permethrin) Single application on entries of nest and on area of 1m2 around entrances.

Efficacy was measured by counting number of ants moving along a trial (=FCS) (always same on place at same time of day). Assessment was done before and 1,3,7,14,21,& 28 days after treatment.

After 28 days nests were opened.</td>
<td>
Mean % of reduction of FCS
<table>
<tr><td>No days after treatment</td><td>1</td><td>3</td><td>7</td><td>14</td><td>21</td><td>28</td></tr>
<tr><td>Test product</td><td>81.2</td><td>94.5</td><td>95.5</td><td>99.4</td><td>100.0</td><td>100.0</td></tr>
<tr><td>Untreated control</td><td>-6.8</td><td>7.4</td><td>6.2</td><td>9.3</td><td>17.4</td><td>13.0</td></tr>
</table>
Final count:
No ants alive after 28 days in treated nests.
</td>
<td></td>
</tr>
</table>

					5 replicates, also for the control. Environmental conditions: (data source: MeteoFrance) Average temperature: November –October 14.6-15.6°C. Maximum temperature (Nov-Oct) 24.0-25.1°C. Minimum temperature 11.1-11.3°C. Rain: October 48 mm. November 321.9 mm. Hours of sun: October 149 hrs, November 95 hrs Test period: Oct 12th –Nov 9th 2016		

Conclusion on the efficacy of the product:

Laboratory, simulated-use and field studies were provided to demonstrate the efficacy of the product against ants and cockroaches. See section 2.3.1.2: Evaluation of the label claims.

2.2.5.6: Occurrence of resistance and resistance management

Literature search for cases of resistance to permethrin where used against crawling insects

The search was performed against the representative target organisms for the 'control of crawling insect' claim

1. Species/orders/family were input into the Arthropod Pesticide Resistance Database (www.pesticideresistance.org) and the following output was observed:

Species/groups claimed against	**Resistance observed**
German cockroach (Blattodea)	*Yes. 14 cases indicated around various locations around the world.
Oriental cockroach (Blattellidae)	No.
Common black ants (Formicidae)	No resistance indicated for formicidae family.

* note: during subsequent searching for resistance against the oriental cockroach, hits were also returned for the German cockroach, and it became very obvious that German cockroaches in particular, are a problem with regards to developing resistance to insecticides in general, but particularly to pyrethrins such as cypermethrin and permethrin.

2.3: General internet search for resistance

Search strategy

Since the search in the table above has already indicated resistance has been observed for permethrin in some of the target organisms, these are not included in the second search. There is little reason to include them, since the conclusion that resistance has been observed will not change.

The following search terms were used:

a) common name, resistance, permethrin

b) scientific name as indicated in brackets in table below, resistance, permethrin

Species/groups claimed against	**Resistance observed**
Oriental cockroach (Blattellidae)	www.who.int/water_sanitation_health/resources/vector288to301.pdf indicated no resistance observed. In general no obvious hits with stated resistance were found.
Common black ants (Formicidae)	No hits obtained with any obvious resistance

Conclusions

Several incidences of resistance have been reported for the German Cockroach. It is clear that this species is particularly problematic with respect to its ability to develop resistance to permethrin.

No incidences of resistance were found for the Oriental Cockroach (although this cannot be excluded, given the close biological relationship to the German Cockroach) or ants.

It is clear from the search, that a general awareness of the possibility of resistance to permethrin is required from the professional use of Neopermin for the control of 'crawling insects'.Resistance Management Measures must be in place for situations when the user (particularly the professional user) observes a reduction in the expected control level for the product.

Resistance Management

It is clear from the search, that a general awareness for resistance is required from the professional. Therefore the following resistance management measures/strategies should be followed:

1. Where an extended period of control is required, treatments should be alternated with products with different modes of action.

2. Levels of effectiveness should be monitored and instances of reduced effectiveness should be investigated for possible evidence of resistance. In this case, an alternative treatment to overcome the resistance should be used.

3. Products should always be used in accordance with the label recommendations.

4. Complete elimination of insect pests should be attempted in infested areas

5. Hygienic measures (e.g. removal of food sources) should be followed in order to reduce the number of insects attracted into the home/building and hence help reduce both the infestation and the risk of resistance occurring.

6. No cleaning (dry or wet) of the treated area during periods of insect activity. However, since this product would be placed into areas that would be difficult to clean (e.g. under and behind cabinets and in cracks and crevices around the edge of a room), this is not expected to prevent the cleaning of the majority of the floor surface area in a room.

2.3.1.1: Known limitations

No cleaning (dry or wet) of the treated area during periods of insect activity. However, since this product would be placed into areas that would be difficult to clean (e.g. under and behind cabinets and in cracks and crevices around the edge of a room), this is not expected to prevent the cleaning of the majority of the floor surface area in a room.

2.3.1.2: Evaluation of the label claims

The biocidal product, Neopermin, is used indoors for the control of crawling insects such as ants (*Lasius niger*) and cockroaches (*Blatella germanica, Blatta orientalis*) . The product is used as a spot

and crack and crevice treatment at a dose rate of 1 g of product per m^2 on spots where the crawling insects are or where they could come into the house or in empty storage spaces. The product can be used on wood, concrete and smooth surfaces (glass, ceramic etc.).

To demonstrate efficacy of the product, laboratory tests on both porous and non-porous surfaces, simulated-use tests and field tests were provided with : *Lasius niger, Blattella germanica and Blatta orientalis.*

Lasius niger:

-The lab test showed 100% knockdown in 30 seconds and 100% mortality after 24 hours. Residual efficacy after 3 weeks was demonstrated to be 100% knockdown within 15 minutes and 100% mortality after 24 hours at an application rate of 1 g/m^2.

-The simulated-use test demonstrated total mortality (100% within 24 hr) directly after treatment and 3 weeks after treatment on both porous and non-porous surfaces at an application rate of $1g/m^2$.

- The field test demonstrated 94.5% reduction in the number of ants within 3 days, and 100% reduction within 3 weeks. After 4 weeks the nests were opened and all ants in the nests were killed. Although the field test was performed on ant nests outside, instead of the use inside for which the applicant applied, the test was considered as acceptable for the intended use as the product dose used is identical to the product claim and the additional exposure to wind and rain make the test-conditions worst-case compared to a similar test indoors.

Blatella germanica & *Blatta orientalis*

-The lab test showed 100% knockdown in 30 seconds and 100% mortality after 24 hours. Residual efficacy after 3 weeks was shown by a 100% knockdown within 15 minutes for *Blattela germanica* and within 30 min for *Blatta orientalis* and for both species 100% mortality after 24 hours at an application rate of 1 g/m^2.

-The simulated-use test demonstrated total mortality (100% within 24 hr) directly after treatment and 3 weeks after treatment on both porous and non-porous surfaces at an application rate of $1g/m^2$.

- The field tests demonstrated a 94.1% reduction in the number of *Blatella germanica* cockroaches within 1 week, and 99.5% reduction within 3 weeks, relative to the non-treated areas. For *Blatta orientalis* a 91.4 % reduction was achieved within 1 week and 97.4% within 3 weeks.

Conclusions:

The efficacy studies demonstrated that the product was effective against small and large cockroaches and ants and demonstrated residual efficacy up to 3 weeks after application.

The laboratory study demonstrated knockdown of cockroaches and ants after direct application of powder (100% within 30 seconds) and 3 weeks after treatment (100% within 15 or 30 minutes) on both porous and non-porous surfaces at an application rate of $1g/m^2$.

The simulated-use tests demonstrated total mortality (100% within 24 hr) of both cockroaches and ants directly after treatment and 3 weeks after treatment on both porous and non-porous surfaces at an application rate of 1g/m^2.

-The field tests for both cockroach species was representative for the intended use of the product and sufficient efficacy was shown (> 90% reduction in the number of cockroaches within 1 week, and > 99% reduction within 3 weeks). For ants a field test was provided with outdoor ant nests. This test demonstrated > 90% reduction in the number of ants within 3 days, and 100% kill of all ants within the nest, 4 weeks after treatment. The outdoor test conditions can be considered to be a more difficult challenge than controlling the number of ants indoors (i.e. outdoor is worst-case, as indoors there is less exposure to weather conditions (bright sunlight (slow photolysis potential for 10-20% loss of permethrin over 28 day test duration, based on DT50 in assessment report), wind (potential for blowing powder away from nest), rain (potential for washing away from nest) and a higher chance of repopulation from nearby nests). The outdoor field test is therefore considered as sufficient proof of efficacy against ants for use inside.

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

The product is not intended to be used with other biocidal products.

2.3.2: Risk assessment for human health

2.3.2.1: Assessment of effects on human health

There are no new studies available for Neopermin.

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not skin corrosive/irritant
Justification for the value/conclusion	See justification in the table below
Classification of the product according to CLP	No classification

Data waiving	
Information requirement	Skin corrosion and irritation
Justification	According to column 3 of the data requirements for biocidal products, specific rules for adaptation state that: 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), and synergistic effects between any of the components are not expected. None of the components of the formulation is classified for skin irritating properties. Since there are valid data available on each component to allow classification of the product and synergistic effects between any of the components are not expected, it is considered that it is not scientifically justified to conduct this study.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Not eye damaging/irritant
Justification for the value/conclusion	See justification in the table below
Classification of the product according to CLP	No classification

Data waiving	
Information requirement	Eye irritation
Justification	According to column 3 of the data requirements for biocidal products, specific rules for adaptation state that: 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), and synergistic effects between any of the components are not expected. None of the components of the formulation is classified for eye irritating properties. Since there are valid data available on each component to allow classification of the product and synergistic effects between any of the components are not expected, it is considered that it is not scientifically justified to conduct this study.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	There is no substance with this classification contained in the product
Classification of the product according to CLP	No classification

Data waiving	
Information requirement	Respiratory tract irritation
Justification	In accordance with BPR guidance, testing for respiratory irritation is not required under the BPR.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not skin sensitising
Justification for the value/conclusion	See justification below
Classification of the product according to CLP	EUH 208 “Contains permethrin. May produce an allergic reaction” is required.

Data waiving	
Information requirement	Skin sensitisation
Justification	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 to allow classification of the mixture according to the rules laid down in and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. According to the agreed list of endpoints for permethrin, permethrin is sensitising. In the assessment report, Skin sens. Cat. 1B has been proposed. Therefore, taking this proposed classification and the nominal concentration of permethrin as 0.5%, the rules laid down in 1272/2008 are followed. According to regulation 1272/2008, for a category 1B skin

	sensitiser present at ≥ 1%, H317 is needed for the product. As the concentration of permethrin is < 1%, but above 0.1%, EUH 208 "Contains permethrin. May produce an allergic reaction" is required. None of the other components are classified for skin sensitising properties. Since there are valid data available on each component to allow classification of the product and synergistic effects between any of the components are not expected, it is considered that it is not scientifically justified to conduct this study.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not respiratory sensitising
Justification for the value/conclusion	See justification in the table below
Classification of the product according to CLP	No classification

Data waiving	
Information requirement	Respiratory sensitisation
Justification	According to column 3 of the data requirements for biocidal products, specific rules for adaptation state that: 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 Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. None of the components are classified as a respiratory sensitiser. Since there are valid data available on each component to allow classification of the product and synergistic effects between any of the components are not expected, it is considered that it is not scientifically justified to conduct this study.

Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	LD50 >2000 mg/kg bw
Justification for the selected value	See justification in the table below
Classification of the product according to CLP	No classification

Data waiving	
Information requirement	Acute toxicity by oral route
Justification	According to column 3 of the data requirements for biocidal products, specific rules for adaptation state that: 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), and synergistic effects between any of the components are not expected. Considering the con-formulants, only the active substance is classified for acute oral toxicity. According to the assessment report, permethrin is proposed as acute tox.4. Since the concentration in the product is less than the generic cut-off of 1%, the product is not classified. Since there are valid data available on each component to allow classification of the product and synergistic effects between any of the components are not expected, it is considered that it is not scientifically justified to conduct this study.

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	LD50 >1.5 mg/L (dust and mist)
Justification for the selected value	See justification in the table below
Classification of the product according to CLP	No classification

Data waiving	
Information requirement	Acute toxicity by inhalation
Justification	According to column 3 of the data requirements for biocidal products, specific rules for adaptation state that: 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), and synergistic effects between any of the components are not expected. Considering the con-formulants, only the active substance is classified for acute inhalation toxicity. According to the assessment report, permethrin is proposed as acute tox.4. Since the concentration in the product is less than the generic cut-off of 1%, the product is not classified. Since there are valid data available on each component to allow classification of the product and synergistic effects between any of the components are not expected, it is considered that it is not scientifically justified to conduct this study.

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	LD50 > 2000 mg/kg bw
Justification for the selected value	See justification in the table below
Classification of the product according to CLP	No classification

Data waiving	
Information requirement	Acute toxicity by dermal route
Justification	According to column 3 of the data requirements for biocidal products, specific rules for adaptation state that: 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), and synergistic effects between any of the components are not expected. None of the formulants of the product are classified for acute dermal toxicity.Since there are valid data available on each component to allow classification of the product and synergistic effects

	between any of the components are not expected, it is considered that it is not scientifically justified to conduct this study.

Dermal absorption

Table 11: Value used in the risk assessment – Dermal absorption

Substance	Permethrin
Value(s)	3%
Justification for the selected value(s)	Data from the Assessment Report for permethrin indicates that the dermal absorption of permethrin is 3% within 120 h. The 3% value was obtained from a test in human volunteers using radiolabelled permethrin in isopropanol with non-occlusive patches. It is likely that the isopropanol would have evaporated leaving the permethrin only, on the skin surface. In the case of Neopermin, the product contains a carrier of the permethrin, and the worst that could happen is that permethrin could potentially migrate off the carrier onto the skin. This is not likely to result in a greater absorption than the value in the list of endpoints. In reality the permethrin is likely to stay on the carrier and the carrier will not go through the skin due to its inorganic structure and lack of solubility, so in fact the absorption is likely to be less than the value in the list of endpoints. For specific information on the carrier, see product composition as included in the confidential Annex In conclusion, it is therefore justified to use the dermal absorption of 3% for Neopermin as the dermal absorption study in the permethrin Assessment Report represents a worse case than Neopermin.

Available toxicological data on non-active substance(s) (i.e. substance(s) of concern)

Based on the criteria for other grounds of concern as defined in the SoC guidance document (CA-Nov14-Doc.5.11) two substances are identified as substances of concern as for these two substances Dutch OEL values are available. For more information see the Confidential Annex.

Available toxicological data relating to a mixture

There are no relevant toxicological data available.

Other

<u>Endocrine Disruptor assessment</u>

To examine if any of the co-formulants contained in the product Neopermin may possess ED properties, a screening was performed by examining the co-formulants are

- Classified as CMR or PBT;

- Identified as ED in the DG Santé's Impact Assessment study on Screening of available evidence on chemical substances for the identification of endocrine disruptors;
- Identified as ED in the EU list of potential endocrine disruptors; or
- Listed in CoRAP linked to ED concerns.

None of the co-formulants triggered an alert for ED property from this screening. Therefore ED potency of co-formulants contained in Neopermin was not examined further.

Additionally, for the active substance permethrin, was concluded not to have ED properties. Therefore, it is concluded that Neopermin does not have ED properties.

2.3.2.2: Exposure assessment

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

Table 12: Summary table: Relevant paths of potential human exposure

Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	***Industrial use**	**Professional use**	**Non-professional use**	***Industrial use**	**Professional use**	**General public**	**Via food**
Inhalation	No	Yes	Yes	No	No	Yes	No
Dermal	No	Yes	Yes	No	No	Yes	No
Oral	No	No	No	No	No	Yes	No

**any use-pattern involving manufacture of the active and formulation of the product is considered to be covered by other chemical legislation controlling exposure of workers.*

Summary of exposure scenarios

Table 13: 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.	Loading	Primary exposure: Professional worker may, for convenience, transfer some biocidal product from natron bags (5-25 kg) or bucket (1-10 kg) into a smaller appropriately labelled container prior to leaving their place of work to visit the place to be treated.	Professionals
2	Application	Primary exposure: Professionals apply the biocidal product using a measuring spoon to surfaces at a rate of 1 g/m^2. The product is used indoors only.	Professionals
3.	Post application	Post application: A professional could be required to clean-up product residues from treated surfaces following application.	Professionals
4.	Application	Primary exposure: Non-professionals apply the biocidal product to surfaces with the use of a shaker (HDPE bottle or small cardboard container) using a measuring/tea spoon to surfaces at a rate of 1 g/m^2. The product is used indoors only.	Non-professionals
5.	Post application	Post application exposure: Dry cleaning of the treated area using a vacuum cleaner (preferred) or brush would need to be performed after application of the product.	Non-professionals
6.	Indirect exposure	Secondary exposure: The general public can be exposed to the biocidal product following treatment via contact with treated surfaces.	General public (infants)
7.	Bystanders	Bystanders (adults and children) could be present whilst a non-professional is using the biocidal product.	General public

Industrial exposure

There are no industrial uses of the biocidal product.

Professional exposure

Scenarios 1-3

Scenario 1-3-primary exposure during application and post-application (cleaning)

Scenario 1*:** Loading - ***Transfer of powder to smaller container

The biocidal product is packaged ready-to-use in a variety of packaging dependent on the end user. Since the amount used each day is expected to be low, professionals may wish, for convenience, to transfer a small amount of product from a larger container to a small container - appropriately labelled by the professional to identify the contents - prior to leaving their workplace, rather than carry buckets and bags around.

During loading the professional users may be exposed to the product via dermal and inhalation route. The exposure will be assessed using Mixing and Loading Model 7 (solid/powder), as the worst case.

Scenario 2: application of product

NeoPermin is an insecticide with contact action and is used for the control of crawling insects such as ants (*Lasius niger*) and cockroach (*Blatella germanica, Blatta orientalis*). The product should be used indoor only as a spot and crack and crevice treatment where crawling insects are, or could come into the house, storage room or building, at a dose rate of 1 g of product per m^2. The product can be used on wood, concrete and smooth surfaces (glass, ceramic etc.) and should be applied in places which are difficult to access (such as under, between and behind cabinets and in cracks and crevices around the edge of a room). This product works very quickly and also has a residual action therefore repeat applications are only necessary after 3 weeks, if needed.

In order to ensure correct dosing, a measuring spoon should be used. Professionals should use a 1/4 teaspoon measuring spoon/spatula to apply 1 g, which is sufficient to treat 1 m^2. From the shaker (HDPE bottle or cardboard container), powder should be applied onto a teaspoon by gently tapping the shaker.

As the worst-case exposure scenario, an unprotected professional user taps Neopermin onto a measuring spoon from a shaker (HDPE bottle or cardboard container) before being scattered to the area to be treated.

Inhalation exposure will occur when the product is tapped onto a spoon. According to the HEAd hoc recommendation no.6 (page 33), the indicative inhalation exposure is 2.47 mg/m^3 (scattering powder against ants from a hand held flexible duster/hand held canister by consumers and professionals). An exposure duration of 1 hr is also indicated. See Annex I for the calculation.

Regarding dermal exposure, the use of model for scattering powder against ants from a hand held flexible duster/hand held canister (HEAd hoc recommendation no.6, page 33), or Hand-held dusting applicator pack for crack and crevice ([redacted], p.198) may lead to underestimation in exposure levels, because the product will be transferred from the container to a spoon held in a hand before scattering. As the worst case, the entire surface of a hand (both palm and back) is assumed to be covered by a thin layer (0.01 cm) of the product.

Oral exposure would be negligible as professionals would adhere to strict industrial and personal hygiene and safety practice. Professional workers would ensure their hands are washed at breaks and when finished working with the product and that they do not eat, drink or smoke whilst working.

Scenario 3: Post-application

If any, remaining product is removed using a vacuum cleaner (preferred) or brush and disposed into dry waste. Dermal and inhalation exposure is considered to be the same (or less than) for application of the product since the hands would be much further away from the product.

Description of Scenario [1] Loading

During loading the professional users may be exposed to the product via dermal and inhalation route. The exposure will be assessed using Mixing and Loading Model 7 (solid/powder), as the worst case.

	Parameters	Value
Tier 1	Concentration of permethrin in product	0.5% w/w
	Dermal exposure rate (no gloves)	305 mg/min
	Inhalation exposure	7.2 mg/m^3
	Exposure duration	10 minutes
	*Dermal penetration (active)	3%
	Body weight	60 kg
	Inhalation rate	1.25 m^3/hr

*Derived in the Permethrin Assessment report (2014) and stated in the agreed list of endpoints

Description of Scenario [2] Application
The product should be used indoor only as a spot and crack and crevice treatment where crawling insects are, or could come into the house, storage room or building applied at 1 g/m^2. As the worstcase exposure scenario, an unprotected professional user taps Neopermin onto a measuring spoon from a shaker (HDPE bottle or cardboard container) before being scattered to the area to be treated. Inhalation exposure will occur when the product is tapped onto a spoon. Regarding dermal exposure, the use of the model for scattering powder against ants from a hand held flexible duster/hand held canister (HEAd hoc recommendation no.6, page 33), or Hand-held dusting applicator pack for crack and crevice ([redacted], p.198) may lead to underestimation in exposure levels, because the product will be transferred from the container to a spoon held in a hand before scattering. Therefore, as the worst case, the entire surface of a hand (both palm and back) is assumed to be covered by a thin layer (0.01 cm) of the product. Oral exposure would be negligible as professionals would adhere to strict industrial and personal hygiene and safety practice.

	Parameters	Value
Tier 1	Concentration of permethrin in product	0.5% w/w
	**Inhalation exposure (product)	2.47 mg/m^3
	**Exposure duration	1 hr
	Inhalation rate	1.25 m^3/hr
	*Dermal penetration	3%
	***Area of hand	410 cm^2
	****Thickness of product layer on hand	0.01 cm
	Body weight	60 kg

*Derived in the Permethrin Assessment report (2014) and stated in the agreed list of endpoints
** HEAd hoc recommendation no.6, page 33., Scattering powder against ants from a hand held flexible duster/hand held canister
*** HEAd hoc. Recommendation 14.
**** TGD default, page 223, part II.

Calculations for scenarios 1-3

Please refer to Annex 1 for the relevant calculations.

Table 14: Summary table: estimated systemic exposure from professional uses

Exposure scenario	Tier/PPE	Estimated inhalation uptake (mg/kg bw/day)	Estimated dermal uptake (mg/kg bw/day)	Estimated oral uptake (mg/kg bw/day)	Estimated total uptake (mg/kg bw/day)
Scenario 1 – loading	Tier 1- No PPE	0.000125	0.007625	Negligible	0.00775
Scenario 2- application using a spoon	Tier 1 – No PPE	0.00026	0.0089	Negligible	0.00916
Scenario 3-post application	Tier 1 – No PPE	<0.00026	<0.0089	Negligible	<0.00916

Further information and considerations on scenarios 1-3

The biocidal product is labelled as EUH208 (Contains Permethrin. May produce an allergic reaction).

Combined scenarios

It is possible that a professional worker could be exposed to permethrin on a daily basis as a result of application of the product and cleaning up the product following application.

Table 15: Summary table: combined systemic exposure from professional uses (worst case)

Exposure scenarios combined	Tier/PPE	Estimated inhalation uptake (mg/kg bw/day)	Estimated dermal uptake (mg/kg bw/day)	Estimated oral uptake (mg/kg bw/day)	Estimated total uptake (mg/kg bw/day)
Scenarios 1+2+3	Tier 1 – No PPE	0.000645	0.025425	negligible	0.02607

Non-professional exposure

Scenarios 4-5

Table 16: Non-professional use of dusting powders

Scenario 4: Application of the product

For non-professionals Neopermin is sold in small containers up to 300 g and non-professionals are not expected to transfer the content to another container. Therefore no loading step needs to be considered in the exposure assessment.

In order to ensure correct dosing, a measuring spoon should be used. In the absence of a measuring spoon, the non-professional should use 1/4 of a standard teaspoon of the product in order to measure 1 g, which is sufficient to treat 1 m^2. For the shaker (HDPE bottle or cardboard container, powder should be applied onto a teaspoon by gently tapping the shaker. A total of approximately 1/4 - 1/2 of a standard teaspoon would provide sufficient for spot/crack and crevice treatment in the house.

For the purpose of assessing the risk, it is assumed that the product is used once per month over the summer which equates to roughly 5 times per year.

Non-professionals will be potentially exposed via the dermal and inhalation routes. However, the exposure level is considered to be lower than that for a professional user, based on less frequent use, less volume used per day shorter exposure duration (<1 h per day) and the same application method as professionals using a spoon. Considering the application method, direct oral exposure for the non-professional user is unlikely.

Scenario 5: Post-application cleaning

After a specified contact time following application of the product, non-professionals may need to remove product residues from the treated surfaces. The exposure level for a non-professional user is considered to be lower than that for a professional user, considering lower frequency, and less volume to be cleaned, and the same method for cleaning (using vacuum cleaner or brush).

Calculations for scenarios 4-5

Please refer to Annex 1 for the calculations, where relevant.

Table 17: Summary table: estimated systemic exposure from non-professional use

Exposure scenario	**Tier/PPE**	**Mean event concentration (mg a.i./m3)**	**Estimated <u>acute</u> inhalation uptake (mg/kg bw/day)**	**Estimated <u>acute</u> dermal uptake (mg/kg bw/day)**	**Estimated oral uptake (mg/kg bw/day)**	**Estimated total <u>acute</u> uptake (mg/kg bw/day)**
Scenario 4-application using spoon	Tier 1 – No PPE	Exposure will be lower than for primary exposure for the unprotected professional user (Scenario 2)				
Scenario 5-post-application (cleaning)	Tier 1 – No PPE	Exposure will be lower than for primary exposure for the unprotected professional user (Scenario 3)				

Combined scenarios

It is possible that a non-professional might clean the product from treated areas prior to a new treatment. It is assumed that the dose from cleaning will be equal to application.

Table 18: Summary table: combined **<u>acute</u>** systemic exposure for non-professional

Exposure scenarios combined	**Estimated inhalation uptake (mg/kg bw/day)**	**Estimated dermal uptake (mg/kg bw/day)**	**Estimated oral uptake (mg/kg bw/day)**	**Estimated total uptake (mg/kg bw/day)**
Scenario 4 + 5 (cleaning followed by application)	<0.00052	<0.0178	Negligible	<0.01836

Exposure of the general public Scenario 6-7

Indirect exposure – Scenario 6:

Following application, indirect exposure of children is possible. As the worst case an infant (8 kg) crawling over the treated area for 1 hour (CAR permethrin, PT18) is assumed for the exposure assessment. Oral exposure may also occur as a result of hand-mouth contact. Indirect exposure to adults can also occur but due to the differences in bodyweight, the exposure to infants will be the worst case.

Model for Scenario 6:

The calculations are based on the use rate of 1 g product per m^2 of treated area, and transfer coefficient of 2100 cm^2/hour (HEAd hoc recommendation No. 12). For oral exposure due to hand-to-mouth contact, it is assumed that 10% of the amount of product that deposits on the infant skin is ingested (CAR permethrin, PT18).

Bystanders – Scenario 7:

Bystanders (both adults and children) might be present whilst the biocidal product is being used by the non-professional users. In this case the bystanders will be respiratory exposed to permethrin contained in Neopermin.

Although adults using the products should ensure that children and infants will not be in the vicinity when the product is being applied, according to the instruction, children may be accidentally present in the same room. Exposure level of an infant is therefore calculated, by converting the exposure of the non-professional users using the lower bodyweight of 8 kg for an infant, as the worst case. See Annex I for the calculations.

The exposures of adults will be less than those calculated for the primary exposure of the unprotected non-professional users.

Scenario 6 - Indirect exposure to infant crawling on treated surfaces		
Tier 1	*Dermal exposure – rubbing off model*	
	Exposure frequency	1/day
	Body weight of infant (default in HEAd hoc. Recommendation 14)	8 kg
	Surface Transfer coefficient (HEAd hoc recommendation no. 12)	0.21 m^2/h
	Dislodgeable amount	1 g/m^2
	Transfer coefficient (Dislodgeable residues), powder from stainless steel ((TNsG, 2007)	70%
	Contact time (CAR permethrin, PT18)	60 minutes
	Dermal absorption[1]	3%
	Oral exposure – constant rate	
	Oral absorption	100%
	Amount ingested	10% of product deposited on skin
Scenario 7 – Bystander exposure		
Tier 1	*Inhalation exposure*	
	Body weight of infant (default in HEAd hoc. Recommendation 14)	8 kg
	Indicative inhalation exposure…	2.47 mg/m^3
	Duration of exposure per day	1 hr
	Concentration of permethrin	0.5%
	Inhalation rate	0.84 m^3/hr

Calculations for scenarios 6-7

Please refer to Annex 1 for the calculations, where relevant.

Table 19: Summary table: estimated systemic exposure to the general public

Exposure scenario	**Tier/PPE**	**Mean event concentration (mg a.i./m3)**	**Estimated acute inhalation uptake (mg/kg bw/day)**	**Estimated acute dermal uptake (mg/kg bw/day)**	**Estimated oral uptake (mg/kg bw/day)**	**Estimated total acute uptake (mg/kg bw/day)**
Scenario 6- indirect exposure (infant crawling)	Tier 1 – No PPE	-	-	0.0025	0.0092	0.0117
Scenario 7 – Infant (bystander)	Tier 1 – No PPE	-	0.0013	-	-	0.0013

Combined scenarios

It is possible that an infant might be present during the treatment and subsequently crawl surface where the product is applied.

Table 21: Summary table: combined **acute** systemic exposure for an infant

Exposure scenarios combined	**Estimated inhalation uptake (mg/kg bw/day)**	**Estimated dermal uptake (mg/kg bw/day)**	**Estimated oral uptake (mg/kg bw/day)**	**Estimated total uptake (mg/kg bw/day)**
Scenario 6 + 7 (cleaning followed by application)	0.0013	0.0025	0.0092	0.013

Monitoring data

Information on surveys or monitoring studies with the biocidal product is not available.

Dietary exposure

Dietary exposure following use of the biocidal product will not occur as one of the risk-mitigation measures states that "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 animals.". In addition, the product is applied in places which are difficult for children and animals to access (such as under, between and behind cabinets and in cracks and crevices around the edge of a room), according to the use instruction, reducing accidental contact of the product with food/feed. Therefore, contact of the biocidal product with food is not expected and hence a dietary exposure assessment is not required.

Estimating livestock exposure to active substances used in biocidal products

Livestock exposure to permethrin is not foreseen from use of the biocidal product.

Exposure associated with production, formulation and disposal of the biocidal product

This is covered by other legislation and therefore does not need to be discussed as part of this risk assessment.

2.3.2.3: Risk characterisation for human health

Table 22: Reference values to be used in risk characterisation

Reference	Study	NOAEL (LOAEL)	AF	Correction for oral absorption	Value
AELshort-term	90 day inhalation study in rats	NOAEL 50 mg/kg bw/day	100	None applied as an oral study gave a very similar AEL	0.5 mg/kg bw/day
AELmedium-term	12 month oral study in dogs	NOAEL 5 mg/kg bw/day	100	Not applicable	0.05 mg/kg bw/day
AELlong-term	12 month oral study in dogs	NOAEL 5 mg/kg bw/day	100	Not applicable	0.05 mg/kg bw/day
ARfD	90 day inhalation study in rats	NOAEL 50 mg/kg bw/day	100	None applied as an oral study gave a very similar AEL	0.5 mg/kg bw/day
ADI	Chronic study in rats	NOAEL 5 mg/kg bw/day	100	Not applicable	0.05 mg/kg bw/day

Maximum residue limits or equivalent

Permethrin is not approved under the PPP regulation, MRLs were set in Regulation (EC) No 396/2005 at the lower limit of analytical quantification.

Additionally, is permethrin also used in veterinary medicinal products, MRL were set in Regulation (EU) 37/2010: Bovine: 50 µg/kg muscle/liver/kidney/milk and 500 µg/kg fat. For milk further provisions in Commission Directive98/82/EC are to be observed.

Risk for professional users

Professional users will be using the biocidal product on a regular basis and are therefore considered to be chronically exposed. The systemic exposures are therefore compared to the long-term AEL derived in the Assessment Report for Permethrin (2014). Combined exposure is also assessed by adding the exposure from each of the relevant scenarios as shown in the table below. It should be mentioned that the PSD (particle size distribution) data for the product of approximately 47% respirable particles (Report No. 2015/133AM) (< 15 µm) are not taken into account and the exposure calculation can be considered to be worst case.

Table 23: Systemic effects for professional exposure during use of the biocidal product

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)

Scenario 1 – loading	Tier 1 – No PPE	5	0.05	0.00775	16	Yes
Scenario 2- application using a spoon	Tier 1 – No PPE	5	0.05	0.00916	18	Yes
Scenario 3 – Post-application	Tier 1 – No PPE	5	0.05	<0.00916	<18	Yes
Scenario 1+2+3	Tier 1 – No PPE	5	0.05	<0.02611	<52	Yes

Local effects

The biocidal product is not classified for local effects. It is labelled as EUH208 (Contains Permethrin. May produce an allergic reaction).

Conclusion

There are **no adverse health effects expected** to the unprotected professional worker from exposure to permethrin in the Neopermin product when used in accordance with instructions described in the SPC. However, adverse health effects from the exposure to components for which a Dutch OEL value is available cannot be excluded during loading operation by professionals (see confidential Annex). The use of respiratory protective equipment (RPE) of protection factor 4 or higher is prescribed during the loading operation.

Risk for non-professional users

Non-professionals are expected to use the biocidal product only intermittently for a few events per year (once per month over the summer, i.e. around 5 times per year). Considering that the product needs to be applied as a spot and crack and crevice treatment only, and to be applied in places which are difficult to access (such as under, between and behind cabinets and in cracks and crevices around the edge of a room) reducing accidental contact to the product we think that the possible exposure after treatment (of up to 3 weeks) is not that frequent that an AELmedium term should be used. Therefore, comparison of the exposure values to the AEL for acute exposure is considered most applicable for the assessment of the non-professional user of this product.

Table 24: Systemic effects for non-professionals

Task/ Scenario	**Tier**	**Systemic NOAEL mg/kg bw/d**	**AEL mg/kg bw/d**	**Estimated uptake mg/kg bw/d**	**Estimated uptake/ AEL (%)**	**Acceptable (yes/no)**
Scenario 4 – application using spoon	Tier 1- No PPE	50	0.5	<0.00916	<2	Yes
Scenario 5 – Post-application (cleaning)	Tier 1- No PPE	50	0.5	<0.00916	<2	Yes

Scenario 4+5	Tier 1- No PPE	50	0.5	<0.01832	<4	Yes

Local effects

The biocidal product is not classified for local effects. It is labelled as EUH208 (Contains Permethrin. May produce an allergic reaction).

Conclusion

There are **no adverse health effects expected** to the unprotected non-professional user from exposure to permethrin in the Neopermin product when used in accordance with label instructions.

Risk for the general public

The general public will be indirectly exposed to the biocidal product following contact with treated surfaces and as a bystander. Exposure is expected to be intermittently as the product is only used a few times per year (once per month over the summer, i.e. around 5 times per year). As a result, comparison of the exposure values to the AEL for acute exposure is considered to be a more reasonable approach.

Table 25: Systemic effects for indirect exposure to the general public

Task/ Scenario	**Tier**	**Systemic NOAEL mg/kg bw/d**	**AEL mg/kg bw/d**	**Estimated uptake mg/kg bw/d**	**Estimated uptake/ AEL (%)**	**Acceptable (yes/no)**
Scenario 6 – Indirect exposure to infants	Tier 1	50	0.5	< 0.0117	< 2	Yes
Scenario 7 – Bystander (infants)	Tier 1	50	0.5	< 0.0013	< 1	Yes
Scenario 6+7	Tier 1	50	0.5	< 0.013	< 3	Yes

Local effects

The biocidal product is not classified for local effects. It is labelled as EUH208 (Contains Permethrin. May produce an allergic reaction).

Conclusion

There are no adverse health effects expected to the general public including children from indirect exposure to permethrin from the use of the biocidal product.

Risk for consumers via residues in food

Permethrin is not approved under the PPP regulation, MRLs were set in Regulation (EC) No 396/2005 at the lower limit of analytical quantification. Additionally, is permethrin also used in veterinary medicinal products, no MRL set.

Dietary exposure following use of the biocidal product is not expected as one of the risk-mitigation measures states that "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 animals.". In addition, the product is applied in places which are difficult for children and animals to access (such as under, between and behind cabinets and in cracks and crevices around the edge of a room), according to the use instruction, reducing accidental contact of the product with food/feed. Therefore, contact of the biocidal product with food is not expected and hence a dietary risk assessment, including a comparison to the existing MRL is not required.

2.3.3: Risk assessment for animal health

The biocidal products are used indoor only and hence there will be no direct exposure of wild animals to permethrin due to the use of Neopermin. However, the exposure of domestic animals cannot be excluded, and especially cats are known to be sensitive to permethrin due to slow metabolisation. In order to prevent exposure of domestic animals, the following sentence is included in the risk mitigation measures: *the product should be applied where children and pets do not come in contact with the product* and *Contains permethrin (pyrethroids), may be lethal to cats. No access of cats to treated areas.*.

2.3.4: Risk assessment for the environment

There are no ecotoxicological data available on the biocidal product itself. Therefore, information on the active substance, permethrin, can be used to predict the ecotoxicological effects and environmental fate of the biocidal product.

2.3.4.1: Effects assessment on the environment

According to the Assessment Report for permethrin (2014) and the update of the PNECsoil (conclusion of an e-consultation dated 13th March 2017 and agreed at CG-22) the following PNECs are stated and will be used in this risk assessment:

Permethrin:

$PNEC_{surfacewater}$ = 0.00047 µg a.s/L (equivalent to 4.7E-07 mg a.s./L)

$PNEC_{micro\text{-}organisms}$ (STP) = 0.00495 mg a.s/L

$PNEC_{soil\ (wet\ weight)}$ = 0.175 mg a.s/kg $soil_{wwt}$

$PNEC_{sediment}$ = 0.001mg/kg_{dwt} (2.17E-04 mg/kg_{wwt})

$PNEC_{oral\ bird}$ = 16.7 mg a.s/kg food

$PNEC_{oral\ small\ mammal}$= 120 mg a.s/kg food

DCVA:

$PNEC_{surfacewater}$ = 0.015 mg/L

$PNEC_{soil\ (wet\ weight)}$ = 4.6 mg/kg_{wwt}

$PNEC_{sediment}$ = 0.055 mg/kg_{dwt} (0.012 mg/kg_{wwt})

PBA:

$PNEC_{surfacewater}$ = 0.010 mg/L

$PNEC_{soil\ (wet\ weight)}$ = 1.44 mg/kg_{wwt}

$PNEC_{sediment}$ = 0.042mg/kg_{dwt} (0.009 mg/kg_{wwt})

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

Refer to data waiver for further ecotoxicological studies below.

Further Ecotoxicological studies

No further ecotoxicological studies have been conducted by Tagros on the permethrin active or the permethrin dust product supported in this document.

Data waiving	
Information requirement	Further ecotoxicological studies, specifically; short-term toxicity test on fish; short-term toxicity to aquatic invertebrates; growth inhibition study on algae; inhibition of microbial activity; long-term toxicity testing on fish; long-term toxicity testing on invertebrates; bioconcentration; bioaccumulation in an appropriate aquatic species; studies on sediment dwelling organisms; effects on aquatic macrophytes; effects on soil micro-organisms; effects on earthworms or other soil-dwelling non-target invertebrates; acute toxicity to plants; reproduction study with earthworms or other soil-dwelling non-target invertebrates; effects on birds; effects on arthropods, bioconcentration terrestrial; bioaccumulation terrestrial.
Justification	According to the BPR data requirements: Further studies chosen from among the endpoints referred to in Section 9 of Annex II for relevant

	components of the biocidal product or the biocidal product itself may be required if the data on the active substance cannot give sufficient information and if there are indications of risk due to specific properties of the biocidal product. It is considered that the data on permethrin as given in the assessment report, is sufficient to classify the biocidal product. The co-formulants are not expected to have any ecotoxic effect at the concentration present. Synergistic effects between the components and permethrin are not expected. Permethrin will dominate the ecotoxicity hazard of the product. Therefore, the ecotoxicity hazard of the product can be based on the active concentration. There is no justification to perform further ecotoxicity studies on the product, as it is easy to predict the likely effect of exposure to this product based on the concentration of the permethrin present and the lack of synergism expected. Additional justification for data waiver for tests on birds; arthropods; bioconcentration terrestrial; bioaccumulation terrestrial; The product is not applied outdoors so direct exposure to birds or arthropods is not likely.

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

Data waiving	
Information requirement	Effect on other non-target, non-aquatic organisms; effects on any other specific, non-target organisms (flora and fauna) believed to be at risk
Justification	According to the BPR data requirements: Further studies chosen from among the endpoints referred to in Section 9 of Annex II for relevant components of the biocidal product or the biocidal product itself may be required if the data on the active substance cannot give sufficient information and if there are indications of risk due to specific properties of the biocidal product. It is considered that the data on permethrin as given in the assessment report, is sufficient to classify the biocidal product. The co-formulants are not expected to have any ecotoxic effect at the concentration present. Synergistic effects between the components and permethrin are not expected. Permethrin will dominate the ecotoxicity hazard of the product. Therefore, the ecotoxicity hazard of the product can be based on the active concentration. The general effect on contact of the product with arthropods is easy to predict without further studies. The mode of action of the active is insecticidal. Therefore any non-target arthropod (such as the honeybee) will not react well to exposure to this product! Exposure should therefore be avoided where possible. A test on one arthropod (bee) has already indicated the high toxicity of the active and the likely effect of contact with the product. Additionally, there is no outdoor application for this product. There is no justification to perform further studies on other non-target arthropods.

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

Data waiving	
Information requirement	Supervised trials to assess risks to non-target organisms under field conditions
Justification	Refer to the justifications for "further ecotoxicological studies" and "Effect on other non-target, non-aquatic organisms; effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)". These two sets of justifications cover the data waiver for this information requirement. Additional justification: the product is not in the form of bait or granules.

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

Data waiving	
Information requirement	Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk
Justification	Refer to the justifications for "further ecotoxicological studies" and "Effect on other non-target, non-aquatic organisms; effects on any other specific, non-target organisms (flora and fauna) believed to be at risk" (ADS). These two sets of justifications cover the data waiver for this information requirement. Additional justification: the product is not in the form of bait or granules.

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

Not relevant

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

Envisaged use concerns indoor spot and crack and crevice treatment, which will not result in direct release to the environment. Indirect emission via the STP to the environment, however, will occur due to wet cleaning of the contaminated floor and treated areas and due to wet cleaning of the

contaminated clothes of the applicator. In the event that the product enters the waste water system, there will be release to surface water and spreading of contaminated sewage sludge on agricultural land. In view of the latter route emission to soil and groundwater occurs. Volatilisation to the atmosphere following normal biocidal use of the product is limited due to the very low vapour pressure (2.16×10^{-6} Pa at 20°C). Accumulation in air does not occur due to the low air photolysis DT50 of 0.701 days (based on a 24-hour day and hydroxyl radical concentration of 5×10^5 radicals/cm^3). Thus, accumulation and long-range transport via air can be excluded.

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

Data waiving	
Information requirement	Further studies on fate and behaviour in the environment
Justification	It is not considered that further studies on the fate and behaviour are required. A large amount of data already exists for the active in the list of endpoints, and is sufficient to cover the product. The other components are not substances of concern. The product is not used outside. There is no justification to perform fate and behaviour studies on the components in the product.

Leaching behaviour (ADS)

Data waiving	
Information requirement	Leaching behaviour
Justification	There is no need to assess leaching behaviour for the active and sufficient data is already available (specifically Koc, water solubility) to assess the likelihood for the active. The product is not used outside and therefore there is no likelihood of exposure to rain. There is risk reduction measures stated on the label to prevent release to drain from indoor use. In the unlikely event (i.e. label instructions not being followed) that emission was to occur from indoor use, assessment of release to groundwater could be made with the available data on Koc/water solubility/DT50. Therefore there is no justification to perform this study.

Testing for distribution and dissipation in soil (ADS)

No data is available

Data waiving

Information requirement	Testing for distribution in soil
Justification	Permethrin already has data in the list of endpoints which indicate its likely distribution and dissipation, specifically adsorption/desorption and soil degradation studies to cover soil. No further studies are considered justified.

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

No data is available

Data waiving	
Information requirement	Testing for distribution in water and sediment
Justification	Permethrin already has data in the list of endpoints which indicate its likely distribution and dissipation, specifically adsorption/desorption and soil degradation studies to cover water and sediment. No further studies are considered justified.

Testing for distribution and dissipation in air (ADS)

No data is available

Data waiving	
Information requirement	Testing for distribution and dissipation in air
Justification	Permethrin already has data in the list of endpoints which indicate its likely distribution and dissipation, specifically water solubility/vapour pressure to cover air. No further studies are considered justified.

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)

Data waiving	
Information requirement	Overspray study to assess risks to aquatic organisms or plants under field conditions
Justification	Refer to data waiver for "further studies on fate and behaviour in the environment" (ADS).

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)

Data waiving	
Information requirement	Overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions
Justification	Refer to data waiver for "further studies on fate and behaviour in the environment" (ADS).

2.3.4.2: Exposure assessment

Table 20: General information

Assessed PT	**PT 18**
Assessed scenarios	Monthly application of the product (targeted application) by professionals and non-professionals, cleaning up product residues by **wet cleaning methods** and using **washable clothing**.
ESD(s) used	Emission Scenario Document for Insecticides, Acaricides and Products to Control other Arthropods for Household and Professional Uses, July 2008
Approach	For all scenarios, the approach was based on actual product use information and default values indicated in the ESD.
Distribution in the environment	Calculated based on Guidance on BPR Vol IV Part B+C (2017) and SimpleTreat version 3.1
Groundwater simulation	No simulation for leaching to groundwater using a higher tier model was performed.
Confidential Annexes	No
Life cycle steps assessed	Production: No Formulation No Use: Yes Service life: No End of service life: Yes
Remarks	None

Emission estimation

The label instructions indicate that the worst-case treatment rate is 1 g permethrin dust per 1 m^2 of treated surface by spot and crack and crevice application.

The environmental risk assessment for the product is based on the ESD for PT 18 (2008) as well as on the Guidance on Biocidal Products Regulations Volume IV Environment Part B+C (Guidance on BPR IV/B+C, 2017)[1] and the Technical Agreements for Biocides (TAB, August 2017[2]).

1 Guidance on the Biocidal Product Regulation. Volume IV: Environment - Part B+C: Assessment and Evaluation. European Chemicals Agency, Report no. ECHA-17-G-23-EN, Helsinki, Finland, 2017.

2 Technical Agreements for Biocides, European Chemicals Agency – ECHA, 2017.

Physico-chemical data of the active substance and used for the calculations was taken from the List of Endpoints in the Assessment Report for permethrin (2014).

Table 21: Physico-chemical and degradation rate input parameters for permethrin for calculating the local emission

Input	**Value**	**Unit**	**Remarks**
Molecular weight	391.29	g/mol	
Melting point	35	°C	
Boiling point	305	°C	
Vapour pressure (at 20°C)	2.155E-06	Pa	
Water solubility (at 20°C)	0.00495	mg/L	
Log Octanol/water partition coefficient	4.67	Log 10	
Organic carbon/water partition coefficient (Koc)	26930	L/kg	Mean Koc (for n=10)
Henry's Law Constant	4.6E-03	$Pa/m^3/mol$	A range was cited, but the lowest value is taken for the worst-case with respect to minimising volatility
Biodegradability	Not ready biodegradable	-	
DT_{50} for degradation in sediment	-	-	No value reported
DT_{50} for degradation in soil	106	d (at 12 °C)	(geometric mean, n = 5)
Bioconcentration factor (fish)	570	L/kg fish	Measured value
Bioconcentration factor (worms)	15108	L/kg worm	Estimated value (according to the method described by Jager (1998)
Biomagnification factor	1	-	Based on BCF fish < 2000 L/kg in accordance with guidance

The fate of permethrin in a sewage treatment plant (STP) is calculated with SimpleTreat version 3.1 and is given in the next table:

Calculated fate and distribution in the STP		
Compartment	Percentage [%]	Remarks
Air	negligible	-
Water	27.6	-
Sludge	72.4	-
Degraded in STP	0	-

Table 22: Use specific input parameters

Input	**Value**	**Unit**	**Remarks**
Fraction of active ingredient in product	0.5	%	Product information
Application scope	Spot and crack and crevice	-	Chosen as most applicable use as the product is not expected to be

			used for surface broadcast treatment.
Treatment rate	1	g/m^2	Application rate, based on efficacious dose rate (from studies)
Area of treated surface, house (targeted applications)	2	m^2	Default in ESD & Technical Agreements for Biocides (TAB)
Area of treated surface, larger building	9.3	m^2	Default in TAB for large building, targeted application.
Number of preparations per day, house	1	-	Default in ESD. In order to ensure correct dosing, users should use a ¼ teaspoon measuring spoon/spatula to apply 1 g, which is sufficient to treat 1 m^2. In the absence of such a measuring spoon, a normal teaspoon should be used. When the product is measured from the shaker bottle or cardboard container, powder should be applied onto a teaspoon by gently tapping the shaker/container.
Number of preparations per day, building	3	-	Default in ESD. In order to ensure correct dosing, users should use a ¼ teaspoon measuring spoon/spatula to apply 1 g, which is sufficient to treat 1 m^2. In the absence of such a measuring spoon, a normal teaspoon should be used. When the product is measured from the shaker bottle or cardboard container, powder should be applied by gently tapping the shaker/container.
Quantity of product used per application, per house	2	g	Based on 1 g/m^2 x 2 m^2
Quantity of product used per application, per building	9.3	g	Based on 1 g/m^2 x 9.3 m^2
Washable/ disposable applicators	-	-	Both scenarios are considered
Cleaning method for treated surfaces	Wet cleaning	-	
Cleaning efficiency	0.03 (3%)		*The default of 0.5 the fraction of the product that can be removed by cleaning (dust/powder-surfaces) is an overestimation. The ESD gives a fraction of 0.03 to 0.2 for RTU aerosols into cracks of crevices or onto surfaces (page 64 of ESD). A %CE of 3% is proposed on the basis that the product will be applied to places that will be hard to clean such as behind and under cabinets and other fixed objects. In order to ensure correct dosing, users should use a ¼ teaspoon measuring spoon/spatula to apply 1 g, which is sufficient to treat 1 m^2. In the absence of such a measuring spoon, a normal

			teaspoon should be used. When the product is measured from the shaker bottle or cardboard container, powder should be applied by gently tapping the shaker/container. So, this is considered a controlled placement of the product with less likelihood of the product landing onto areas that will be wet-cleaned.
Number of houses per STP	4000	-	Default in TAB (2016)
Number of larger buildings per STP	300	-	Default in TAB (2016)
Simultaneity factor (daily application)	Tier 1: 0.0552 Tier 2: 0.0138	-	ESD. Note that for similar uses it was agreed in the EU to use a higher simultaneity factor of 0.0552 (application frequency once per day) and therefore this simultaneity factor was applied as tier 1. According to the applicant, the product has residual activity for at least 3 weeks. The application frequency will therefore be once per 3-4 weeks which equals a simultaneity factor of 0.0138 (tier 2). Please refer to the position paper included in Annex 3 of this PAR.

Metabolites

According to the assessment report for permethrin the major metabolites are 3-(2, 2-dichlorovinyl)-2,2-dimethyl-(1-cyclopropane) carboxylate (DCVA) and 3-phenoxybenzoic acid (PBA).

The assessment report states that DCVA and PBA are far less toxic to aquatic organisms than permethrin and DVCA displays low toxicity to soil dwelling arthropods. Overall, it is reasonable to assume that toxicity of the metabolites to birds and mammals is not likely to be greater than the parent. Therefore the PNECs of permethrin for birds and mammals are considered acceptable for use for the assessment of secondary poisoning as no PNECs for birds and mammals exposed to the metabolites are available.

The approach used to calculate the PECs for these is based on the assumption that 100% of the parent PEC is converted to metabolite PEC taking into account the relative molar masses (as described on page 39 of the Assessment Report). The values will be worst case since degradation studies indicate less than 100% conversion to these metabolites.

The molecular weight of DCVA and PBA is 209.1 and 214.2 respectively (based on doc IIB of the final draft CAR for permethrin PT18 of 2014). The molecular weight of permethrin is 391.3. The PECs for each are calculated using these ratios.

For DCVA, PEC = $PEC_{permethrin}$ * 209.1/391.3 = $PEC_{permethrin}$ * 0.53

For PBA, PEC = $PEC_{permethrin}$ * 214.2/391.3 = $PEC_{permethrin}$ * 0.55

Use of Neopermin in houses and buildings:

According to the ESD for PT 18 (2008), emissions to the STP from indoor spot and crack and crevice treatment occur due to wet cleaning of the floor/treated area and due to wet cleaning of the clothes of the applicator. In relation with the form of the product and the way of application, it is stated in the ESD that the fraction emitted to the applicator during a powder broadcast is negligible.

Taking the default parameters for RTU aerosols into cracks of crevices or onto surfaces described in the ESD into account, the use of the product results in the following emissions during the application step.

Table 23: Emissions during application for spot and crack and crevice treatment in houses and large buildings

Compartment	**Local emission [kg/d]**	
	houses	Large buildings
Air	Negligible and not further assessed	
Applicator	Negligible and not further assessed	
Floor	1.80E-06	8.37E-06
Treated surface	8.00E-06	3.72E-05

Taking a cleaning efficiency of 0.03 into account, the following emissions to wastewater during wet cleaning can be calculated.

Table 24: Emissions to wastewater during cleaning for spot and crack and crevice treatment in houses and large buildings

Compartment	**Local emission [kg/d]**	
	houses	Large buildings
Air	Negligible and not further assessed	
Applicator	Negligible and not further assessed	
Floor/treated surface	2.97E-07	1.41E-06

The emissions to STP are calculated using a simultaneity factor of 5.52% (tier 1) and 4000 treated private houses and 300 large buildings. This results in a total emission from both types of buildings of **8.90E-05 kg/d**.

The resulting PECs for permethrin and metabolites DCVA and PBA are shown in the table below.

Table 25: Calculated PEC values for Permethrin and metabolites DCVA and PBA using a simultaneity factor of 5.52% (tier 1)

Floor/treated surface	**PEC_{STP} (mg/L)**	**PECwater (mg/L)**	**PECsed (mg/kg wwt)**	**PECsoil[a] (mg/kg wwt)**	**PEC_{GW}[b] (µg/L)**
Permethrin	1.23E-05	1.18E-06	6.92E-04	1.32E-04	0.00025
DCVA	6.51E-06	6.26E-07	3.67E-04	7.00E-05	1.34E-04
PBA	6.76E-06	6.49E-07	3.81E-04	7.26E-05	1.39E-04

[a] Concentration in top soil after ten successive sludge applications - initial concentration.
[b] Concentration is averaged over 30 days after the 10th sludge application.

According to the applicant, the product has residual activity for at least 3 weeks. The application frequency will therefore be per 3-4 weeks which equals a simultaneity factor of 0.0138 (tier 2). This results in a total emission from both types of buildings of **2.22E-05 kg/d**.

The resulting PECs for permethrin and metabolites DCVA and PBA are shown in the table below.

Table 26: Calculated PEC values for Permethrin and metabolites DCVA and PBA using a simultaneity factor of 1.38% (tier 2)

Floor/treated surface	**PEC_{STP} (mg/L)**	**PECwater (mg/L)**	**PECsed (mg/kg wwt)**	**PECsoil[a] (mg/kg wwt)**	**PEC_{GW}[b] (µg/L)**
Permethrin	3.06E-06	2.94E-07	1.73E-04	3.30E-05	6.29E-05
DCVA	1.62E-06	1.56E-07	9.15E-05	1.75E-05	3.34E-05
PBA	1.69E-06	1.62E-07	9.49E-05	1.81E-05	3.46E-05

[a] Concentration in top soil after ten successive sludge applications - initial concentration.
[b] Concentration is averaged over 30 days after the 10th sludge application.

Atmospheric compartment:

Volatilisation to the atmosphere following normal biocidal use of the product is limited due to the very low vapour pressure (2.16×10^{-6} Pa at 20°C). Accumulation in air does not occur due to the low air photolysis DT50 of 0.701 days (based on a 24-hour day and hydroxyl radical concentration of 5×10^5 radicals/cm^3). Thus, accumulation and transport in air can be excluded and no exposure of the atmosphere is expected.

Primary and secondary poisoning

Primary poisoning

Birds

According to data available in the assessment report, permethrin has low acute toxicity to birds (LD50 > 460 mg/kg bw) and very low dietary toxicity (LC50 > 10000 ppm). Also, for indoor use, it is considered unlikely that birds will enter the buildings and unlikely that they would eat the powder product.

Mammals

According to the assessment report, permethrin may be hazardous to small mammals following acute exposure. In domestic homes and large buildings, the most likely non-target mammal at risk to the product would be the cat, because cats are known to be particularly sensitive to permethrin and are usually smaller than dogs, which are also likely to be inside treated properties.

The instructions for use will control the amount and placement of the product so that it will be difficult for cats to access (cracks/crevices, under and behind cabinets) so the probability of exposure is considered very low when the product is used in accordance with the label instructions.

Note: the ESD for PT18 states that for primary poisoning, it is not believed that powder is a form that could be sufficiently appetizing to birds or mammals that there they would be a risk.

Secondary poisoning

According to the assessment report, permethrin has the potential to bioaccumulate based on its log Pow of 4.67 and a bioconcentration factor of 500-570 L/kg from a 28-day bioconcentration study in bluegill fish, although the rapid depuration (50% in 4.7 days) indicates that any permethrin taken up by aquatic or terrestrial organisms will be rapidly eliminated once exposure ceases, which mitigates potential for biomagnification up the food chain.

A BCF fish of 570 L/kg and a BCF earthworm of 15108 L/kg_{wwt} was applied in the assessment of secondary poisoning through the consumption of fish or earthworms by birds and mammals.

The relevant secondary poisoning PECs required for the risk characterisation are shown in the tables below:

Aquatic

Table 27: PECs for permethrin and metabolites DCVA and PBA in fish for secondary poisoning of birds and mammals

	PECoral predator (mg/kg wet fish)	
	Tier 1[a]	**Tier 2[b]**
Permethrin	3.36E-04	8.38E-05
DCVA	1.78E-04	4.45E-05
PBA	1.85E-04	4.62E-05

a Tier 1: simultaneity factor of 0.0552 based on an application frequency of once per day.

b Tier 2: simultaneity factor of 0.0138 based on an application frequency of once per 3-4 weeks.

Terrestrial

Table 28: PECs for permethrin and metabolites DCVA and PBA in earthworms for secondary poisoning of birds and mammals

	PECoral predator (mg/kg wet earthworm)	
	Tier 1[a]	**Tier 2[b]**
Permethrin	1.70E-03	4.26E-04
DCVA	9.03E-04	2.26E-04
PBA	9.37E-04	2.34E-04

a Tier 1: simultaneity factor of 0.0552 based on an application frequency of once per day.

b Tier 2: simultaneity factor of 0.0138 based on an application frequency of once per 3-4 weeks.

2.3.4.3: Risk characterisation

As a worst-case, the PNECs of permethrin are used for metabolites DCVA and PBA in the risk assessment.

Atmosphere

Volatilisation to the atmosphere following normal biocidal use of the product is limited due to the very low vapour pressure (2.16×10^{-6} Pa at 20°C). Accumulation in air does not occur due to the low air photolysis DT50 of 0.701 days (based on a 24-hour day and hydroxyl radical concentration of 5×10^5 radicals/cm^3).

Conclusion: accumulation and transport in air can be excluded and no exposure of the atmosphere is expected.

Sewage treatment plant (STP)

Table 29: PEC/PNEC values

	PEC_{STP} (mg/L)	**$PNEC_{STP}$ (mg/L)**	**$PEC/PNEC_{STP}$**
Tier 1[a]			
Permethrin	1.23E-05	0.00495	0.002
DCVA	6.51E-06	0.00495	0.001
PBA	6.76E-06	0.00495	0.001
Tier 2[b]			
Permethrin	3.06E-06	0.00495	0.001
DCVA	1.62E-06	0.00495	0.0003
PBA	1.69E-06	0.00495	0.0003

[a] Tier 1: simultaneity factor of 0.0552 based on an application frequency of once per day.

[b] Tier 2: simultaneity factor of 0.0138 based on an application frequency of once per 3-4 weeks.

Conclusion: There is **no concern** to the STP compartment from use of the Neopermin product in accordance with label instructions.

Aquatic compartment

Table 30: PEC/PNEC values using a simultaneity factor of 5.52% (tier 1)

	PEC_{water} (mg/L)	**$PNEC_{water}$ (mg/L)**	**$PEC/PNEC_{water}$**
Permethrin	1.18E-06	4.70E-07	**2.51**
DCVA	6.26E-07	0.015	4.17E-05
PBA	6.49E-07	0.01	6.49E-05
	PEC_{sed} (mg/kg wwt)	**$PNEC_{sed}$ (mg/kg wwt)**	**$PEC/PNEC_{sed}$**
Permethrin	6.92E-04	2.17E-04	**3.19**
DCVA	3.67E-04	0.012	3.06E-02
PBA	3.81E-04	0.009	4.23E-02

Table 31: PEC/PNEC values using a simultaneity factor of 1.38% (tier 2)

	PEC_{water} (mg/L)	**$PNEC_{water}$ (mg/L)**	**$PEC/PNEC_{water}$**
Permethrin	2.94E-07	4.70E-07	6.26E-01
DCVA	1.56E-07	0.015	1.04E-05
PBA	1.62E-07	0.01	1.62E-05
	PEC_{sed} (mg/kg wwt)	**$PNEC_{sed}$ (mg/kg wwt)**	**$PEC/PNEC_{sed}$**
Permethrin	1.73E-04	2.17E-04	7.97E-01
DCVA	9.15E-05	0.012	7.63E-03

PBA	9.49E-05	0.009	1.05E-02

Conclusion: There is **concern** to the aquatic compartment from use of the Neopermin product in accordance with label instructions as PNECs for permethrin for the water and sediment compartments are exceeded taking an application frequency of once a day into account. According to the applicant, the product has residual activity for at least 3 weeks which is equal to an application frequency of once per 3-4 weeks. Based on this application frequency, the risks for the water and sediment compartments are **acceptable** as the PEC/PNECs for these compartments are below 1.

Terrestrial compartment

Table 32: PEC/PNEC values

	PEC_{soil} (mg/kg wwt)	**$PNEC_{soil}$ (mg/kg wwt)**	**$PEC/PNEC_{soil}$**
Tier 1[a]			
Permethrin	1.32E-04	0.175	7.54E-04
DCVA	7.00E-05	4.6	1.52E-05
PBA	7.26E-05	1.44	5.04E-05
Tier 2[b]			
Permethrin	3.30E-05	0.175	1.89E-04
DCVA	1.75E-05	4.6	3.80E-06
PBA	1.81E-05	1.44	1.26E-05

a Tier 1: simultaneity factor of 0.0552 based on an application frequency of once per day.

b Tier 2: simultaneity factor of 0.0138 based on an application frequency of once per 3-4 weeks.

Conclusion

There is **no concern** to the terrestrial compartment from use of the Neopermin product in accordance with label instructions.

Groundwater

Table 33: PEC values

	PEC_{gw} (µg/L)	
	Tier 1[a]	**Tier 2[b]**
Permethrin	2.50E-04	6.29E-05
DCVA	1.34E-04	3.34E-05
PBA	1.39E-04	3.46E-05

a Tier 1: simultaneity factor of 0.0552 based on an application frequency of once per day.

b Tier 2: simultaneity factor of 0.0138 based on an application frequency of once per 3-4 weeks.

Conclusion: there is **no concern** to groundwater from use of the Neopermin product in accordance with label instructions as the concentrations in groundwater for permethrin and metabolites DCVA and PBA are well below the drinking water limit of 0.1 µg/L.

Primary and secondary poisoning

Primary poisoning

Birds

According to data available in the assessment report, permethrin has low acute toxicity to birds (LD50 > 460 mg/kg bw) and very low dietary toxicity (LC50 > 10000 ppm). Also, for indoor use, it is considered unlikely that birds will enter the buildings and unlikely that they would eat the powder product.

Conclusion: based on the assessment in 2.3.3, there is **no concern** from primary poisoning of birds from use of Neopermin in accordance with the use instructions.

Mammals

According to the assessment report, permethrin may be hazardous to small mammals following acute exposure. In domestic homes and large buildings, the most likely non-target mammal to be exposed to the product would be the cat. Cats are also known to be particularly sensitive to permethrin.

Conclusion: based on the assessment in 2.3.3, there is **no concern** from primary poisoning to mammals from the use of Neopermin in accordance with the use instructions.

Secondary poisoning

According to the Guidance for BPR: Volume IV Part B, the risk to the fish-eating predators (mammals and/or birds) is calculated as the **ratio** between the concentration in their food (**PECoral**, **predator**) and the no-effect-concentration for oral intake (**PNECoral**).

Aquatic

Table 34: PEC/PNECs for permethrin and metabolites DCVA and PBA in fish for secondary poisoning of birds and mammals

	PEC oral (mg/kgwwt fish)	**PNECoral, bird** (mg a.s/kg food)	**PNECoral, small mammal** (mg a.s/kg food)	**PEC/PNECbirds**	**PEC/PNECsmall mammal**
Tier 1[a]					
Permethrin	3.36E-04	16.7	120	2.01E-05	2.80E-06
DCVA	1.78E-04	16.7	120	1.07E-05	1.48E-06
PBA	1.85E-04	16.7	120	1.11E-05	1.54E-06
Tier 2[b]					
Permethrin	8.38E-05	16.7	120	5.03E-06	6.98E-07
DCVA	4.45E-05	16.7	120	2.67E-06	3.71E-07
PBA	4.62E-05	16.7	120	2.77E-06	3.85E-07

a Tier 1: simultaneity factor of 0.0552 based on an application frequency of once per day.

b Tier 2: simultaneity factor of 0.0138 based on an application frequency of once per 3-4 weeks.

Conclusion: there is **no concern** for secondary poisoning from permethrin and metabolites DCVA and PBA to birds or mammals from use of the product in accordance with the use instructions.

Terrestrial

Table 35: PEC/PNECs for permethrin and metabolites DCVA and PBA in earthworms for secondary poisoning of birds and mammals

	PECoral (mg/kg)	PNECoral, bird (mg a.s/kg food)	PNECoral, small mammal (mg a.s/kg food)	PEC/PNECbirds	PEC/PNECsmall mammal
Tier 1[a]					
Permethrin	1.70E-03	16.7	120	1.02E-04	1.42E-05
DCVA	9.03E-04	16.7	120	5.41E-05	7.53E-06
PBA	9.37E-04	16.7	120	5.61E-05	7.81E-06
Tier 2[b]					
Permethrin	4.26E-04	16.7	120	2.55E-05	3.55E-06
DCVA	2.26E-04	16.7	120	1.35E-05	1.88E-06
PBA	2.34E-04	16.7	120	1.40E-05	1.95E-06

a Tier 1: simultaneity factor of 0.0552 based on an application frequency of once per day.

b Tier 2: simultaneity factor of 0.0138 based on an application frequency of once per 3-4 weeks.

Conclusion: there is **no concern** for secondary poisoning from permethrin and metabolites DCVA and PBA to birds or mammals from use of the product in accordance with the use instructions.

Overall conclusion on the risk assessment for the environment for the product

In the draft SPC the following instructions for use and risk mitigation measures for the environment are included:

- Any remaining product or product spills removed from the treated or adjacent surface must not be washed to a drain. Only dry clean by using a vacuum cleaner (preferably) or very carefully brush any remaining powder and dispose into dry waste.
- Do not rinse used equipment with water. Reuse or dispose of in a safe way. Do not allow product to reach water/drains/sewage systems or permeable soil. If accidental entry into water or ground occurs, inform responsible authorities. For cleaning up take up mechanically and collect in suitable container and dispose according to current regulations. Clean contaminated area with water and detergent.
- Disposal of the unused quantities of the product and the packaging: Waste chemical: Disposal must be made according to official regulations: to leave it to authorized collector/remover/transformer of hazardous waste. Do not allow product to reach drains/sewage systems. Ensure that waste is in compliance with local and national requirements.
- The product may be applied not more than once per month per application site.

eCA note: The cleaning efficiency of 0.03 for RTU aerosols applied in the environmental risk assessment was not supported by all icMSs. By using the cleaning efficiency of 0.25 for sprays in cracks and crevices an unacceptable risk for the aquatic environment would be identified. However, this unacceptable risk can be mitigated by the risk mitigation measures included in the PAR and SPC. This was agreed in the 44th meeting of the Coordination Group of November 2020.

Mixture toxicity

An assessment of mixture toxicity is not required since none of the non-active components are classified for ecotoxicological effects and they are not expected to enhance the toxicity of the active substance.

Aggregated exposure (combined for relevant emission sources)

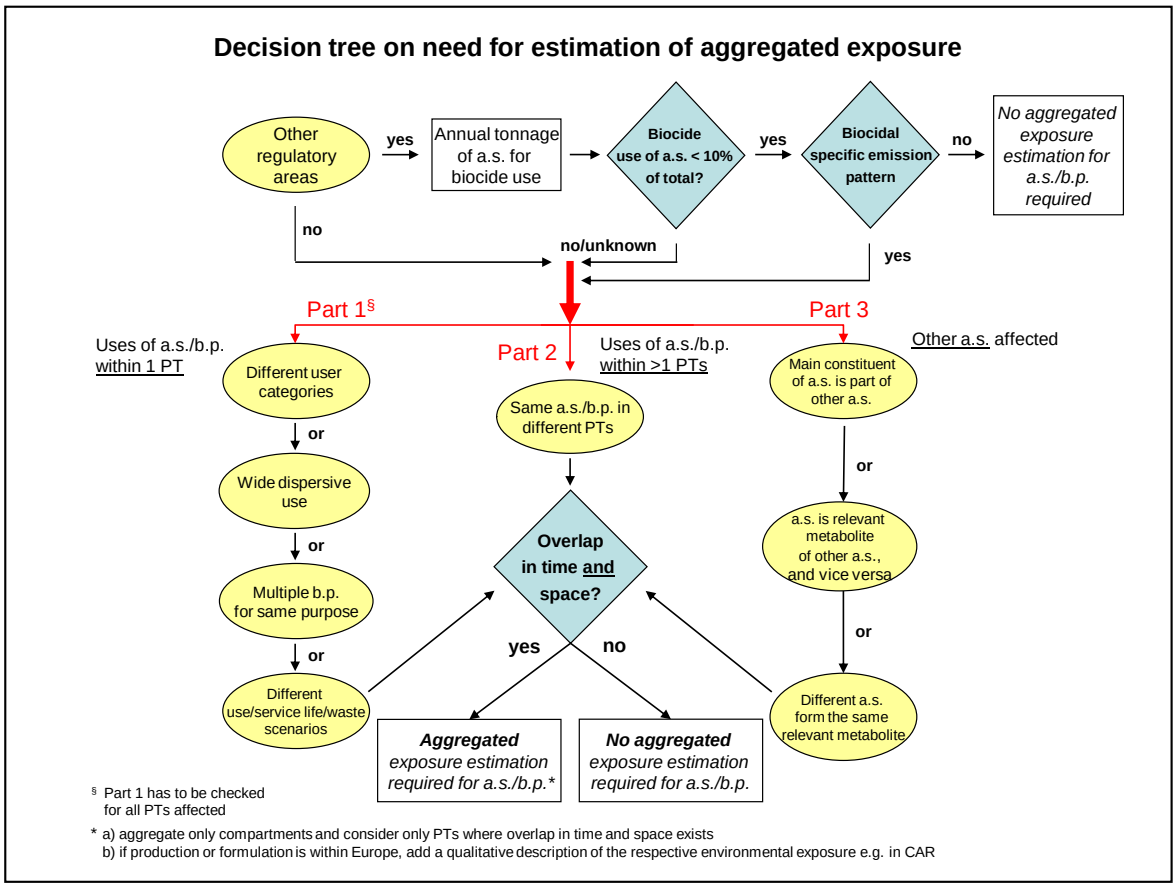


Figure 1: Decision tree on the need for estimation of aggregated exposure

There is currently no finalised guidance to conduct an aggregated exposure scenario. However, this product is not used in other Product Types, therefore the only exposure to the environment comes from use of this product.

2.3.5: Measures to protect man, animals and the environment

For the measures to protect animals and the environment we refer to sections 2.3.3 and 2.3.4 and the SPC.

2.3.6: Assessment of a combination of biocidal products

The biocidal products are not intended to be authorised for use with other biocidal products.

2.3.7: Comparative assessment

A comparative assessment is not required for this product.

Annexes

List of studies for the biocidal product

Used for the evaluation of:	Author	Year	Title	Test facility GLP status, published or not
Efficacy	[redacted]	[redacted]	laboratory measurement of the effectiveness of an insecticide speciality intended for the destruction of crawling and flying insects in household environment	[redacted]
Efficacy	[redacted]	[redacted]	simulated-use trial of the efficacy of an insecticidal product	[redacted]
Efficacy	[redacted]	[redacted]	field trial of the efficacy of neopermin 0.5% permethrin powder as a residual treatment to control german and oriental cockroaches	[redacted]
Efficacy	[redacted]	[redacted]	field trial of the efficacy of an insecticide product intended for the destruction of ants	[redacted]

Annex 1: **Calculations for human health assessment**

Professional use of the biocidal product: Scenario 1: Transfer of powder to smaller container

Inhalation

Indicative inhalation exposure = 7.2 mg/m^3

Duration of exposure = 10 min

Inhalation rate = 1.25 m^3/hr (default)

Concentration of permethrin = 0.5%

Body weight = 60 kg (default)

Therefore, amount of permethrin inhaled = 7.2 mg/m3 * 0.5% * 1.25 m3/hr *10/60 hr = 0.0075 mg

Systemic dose = 0.0075 mg/60 kg = 0.000125 mg/kg

Dermal

Indicative dermal exposure = 305 mg product/min

Dermal penetration = 3%

Therefore amount of permethrin absorbed = 305 mg/min*10 min*0.5%*3% = 0.4575 mg

Sytemic dose = 0.4575 mg/60 kg = 0.007625 mg/kg

Total systemic dose = 0.000125 + 0.007625 = 0.00775 mg/kg.

Professional use of the biocidal product: Scenario 2: *application of product*

Inhalation

For tapping of a shaker bottle/cardboard container, the following calculation is performed:

Indicative inhalation exposure = 2.47 mg/m^3

Duration of exposure per day = 1 hr

Concentration of permethrin = 0.5%

Inhalation rate – 1.25 m^3/hr (default)

Body weight (adult) = 60 kg (default)

Therefore, amount of permethrin inhaled = 2.47 mg/m3 * 0.5% * 1.25 m3/hr = 0.015 mg

Systemic dose = 0.015 mg/60 kg bw = 0.00026 mg/kg bw/day

Dermal

A worst-case would be coating of the entire hand with powder

The area of the hand is approximately 410 cm2 (HEAd hoc. Recommendation 14). A thin layer of dust is assumed to be 0.01 cm thick (TGD default, page 223, part II).

Weight of coating = 410 cm2 * 0.01 cm * 0.87 g/cm3 = 3.567 g = **3567 mg**

Systemic dose = (3567 mg/day * 0.5% * 3%)/60 kg bw = 0.0089 mg/kg bw/day

Professional use of the biocidal product: Scenario 3: post-application

Both inhalation and dermal exposure are not expected to be higher than that for application. Therefore, refer to those calculations.

Indirect exposure to infant crawling on treated surface: Scenario 6:

Oral exposure

The external dermal dose of permethrin is:

0.21 m^2/hour (transfer coefficient) x 1hour x 1 g b.p./m^2 x 0.5 % a.s. x 70% (transfer coefficient, dislodgeable residues) = 0.735 mg permethrin

Therefore, if 10% of the external dermal dose of permethrin is ingested by the infant then the oral dose is:

0.735 mg x 10% = 0.0735 mg = 0.0092 mg/kg bw

Dermal exposure

Using calculation above, amount of external dermal dose = 0.735 mg permethrin

10% of this is assumed to be ingested by mouthing, as calculated above.

This leaves 0.735 – 0.0735 = 0.6615 mg permethrin available for absorption

Dermal absorption = 3%

Therefore, permethrin absorbed = 0.6615 x 3% = 0.0198 mg

Systemic dose = 0.0198 mg a.i./8kg = 0.00248 mg/kg

Professional use of the biocidal product: Scenario 7: ***bystander exposure during application of product***

Inhalation

Indicative inhalation exposure = 2.47 mg/m^3

Duration of exposure per day = 1 hr

Concentration of permethrin = 0.5%

Inhalation rate – 0.84 m^3/hr (default)

Body weight (infant) = 8 kg (default)

Therefore, amount of permethrin inhaled = 2.47 mg/m3 * 0.5% * 0.84 m3/hr = 0.010 mg

Systemic dose = 0.010 mg/8 kg bw = 0.00130 mg/kg bw/day

Annex 2: **Confidential annex**

See document Draft PAR Confidential Annex CLEAN

Annex 3: **Position paper to argue case for use of application frequency to allocate simultaneity factor for indoor use.**

The following argument contains extracts from several assessment reports, to support the use of the application frequency (once every 3-4 weeks) to set the simultaneity factor of 1.38% as used by the applicant for the indoor use of Neopermin for spot and crack and crevice treatment only (note: barrier treatment is not requested as a use by Unichem).

A summary of the actives which have assessment reports which clearly show the link between the application frequency and simultaneity factor used is shown below.

Insecticide active	**Frequency of use indoors**	**Simultaneity factor used**
Alpha-cypermethrin	1-2 applications per year	0.00204 (0.204%)
Imiprothrin	**1 application per month**	***0.0138 (1.38%)**
Bendiocarb	6 applications per year	0.82%
Dinotefuran	1 application per week	2.75%
epsilon-Momfluorothrin	Daily default, then refined for 1/month	5.5% daily default 1.38% once/month
Transfluthrin	Daily cleaning – BUT the representative product was designed to emit active on a daily basis into the air (NOT crack and crevice) and the RMS referred to welcoming refinements with frequency and simultaneity.	5.5% (due to daily emission)

*this directly supports the use of 1.38% Sim F for a similar application frequency to that for Neopermin.

Extracts from the alpha-cypermethrin assessment report

2.2.2.3 Environmental exposure assessment

The insecticide product Tenopa (3 % alpha-cypermethrin, 3 % flufenoxuron) is exclusively used for indoor applications against cockroaches and fleas in domestic and public areas. Tenopa is applied on hard surfaces, cracks and crevices, areas behind furnishings and equipment by professional pest-control operators (PCOs).

The main emission route of the product Tenopa is via wastewater in sewage water treatment plants after the cleaning of the treated area or the spraying materials. Therefore,

Simultaneity factor, $F_{simultaneity}$, represents the percentage of houses/buildings which are treated simultaneously (ESD PT18, p. 38-40). Initially, calculations were made with the default F_{sim} of 0.0552, due to lack of other information.

After a meeting with the applicant (7th October 2013) to discuss possible safe-use scenarios, label restrictions were introduced by the applicant to reduce the default simultaneity factor: Only 1 to 2 applications per year are envisaged, resulting in an F_{sim} of 0.00204.
This new proposed factor was discussed during the Environmental BPC-WG-1-2014. Even though some reservations to such a reduction in use was voiced, it was concluded that label restrictions are the applicants responsibility. Therefore, the new simultaneity factor of 0.00204, representing a use restriction of 1 to 2 applications per year, was accepted during the aforementioned working group.

Conclusion: The frequency of application was taken into account in determining the simultaneity factor used in the risk assessment, and accepted by the ENV WG 2014, on the grounds that the label restrictions were the applicant's responsibility. Presumably the BPC also accepted this approach to show safe use of the representative product in order for the active to **ultimately be approved.**

Extracts from Imoprothrin Assessment Report

Based on the OECD ESD for PT18 (5th draft 2008), the main relevant scenarios were identified as:

Scenario 1: Indoor domestic use (crawling insects) - Crack and crevice
Scenario 2: Indoor large building use (crawling insects) - Crack and crevice
Scenario 3: Indoor domestic use (flea and bed bug treatment) - Surface treatment

The representative product for imiprothrin is Pralle®, a pre-pressurised handheld aerosol insecticide spray containing 0.5 % active substance.

The product is for indoor use only and may be used for treatments in domestic or restaurant kitchens and other areas in buildings where small infestations and harbourages of crawling insects may occur. For the control of cockroaches – *Periplaneta americana* (American cockroaches), *Blattella germanica* (German cockroaches) and *Blatta orientalis* (Oriental cockroaches) and other crawling insects – *Cimex lectularius* (bed bugs) and *Ctenocephalides felis* (cat fleas).

PEC input assumptions for assessment of emissions from representative product (Pralle® 0.5 % aerosol)

Input/ Parameter (units)	**Data/ Endpoint**
Number of houses in catchment of STP (-) Domestic/ Large building	4000 / 300
Effluent discharge rate of STP (l d^{-1})	2 x 10^6
Number of applications (-) Crack and Crevice / Surface treatment	1 / 1
Cleaning efficiency (-) Crack and crevice Tier 1/ Crack and crevice Tier 2/ Surface	0.10/ 0.03 / 0.20
Treatment area Domestic/ Large building/ Domestic surface treatment(m)	2 / 9.3/ 5.9
Simultaneity Factor (%)- Monthly application	0.0138

Conclusion:

The frequency of application indoors, was taken into account in determining the simultaneity factor used in the risk assessment and in this case, it was a similar application frequency to the Unichem product. Presumably the BPC accepted this approach to show safe use of the representative product in order for the active to ultimately be approved.

Extracts from Bendiocarb Assessment Report

3.3. Elements to be taken into account by Member States when authorising products

With regard to both environmental exposure and resistance, labelling should indicate that application of products containing bendiocarb should be limited to a maximum of six indoors and one outdoors per year per premises (this leads to simultaneity factors of 0.82 and 0.2 % respectively), unless it can be demonstrated in the application for product authorisation that more frequent use of the product is acceptable.

Table 2.4 PEC input assumptions

Input/Parameter (units)	Data/Endpoint
Local population in catchment of STP (-)	10,000
Daily wastewater flow per inhabitant (l d^{-1} eq^{-1})	200
Effluent discharge rate of STP (l d^{-1})	2 x 10^6
Population per house (-)	2.49
Average number of rooms per house (including bathroom)	6.46
Size of domestic household (m^2)	131
Size of large building (m^2)	609
Default wet cleaned area per household (m^2)	38.5
Default wet cleaned area per large building (m^2)	180
Number of potential houses treated per catchment	4000 (indoor)
	2500 (outdoor)
Number of potential large buildings treated per catchment	300 (indoor)
	300 (outdoor)
Simultaneity Factor (%)	0.82 (indoor)
	0.2 (outdoor)

Conclusion:

The frequency of application indoors, was taken into account in determining the simultaneity factor used in the risk assessment. Presumably the BPC accepted this approach to show safe use of the representative product in order for the active to ultimately be approved.

Extract taken from Dinotefuran assessment report

and seek harbourage. The potential environmental emissions identified are:

Indoor use only

1. Emissions from treated hard surfaces (spot treatment in difficult to access areas or crack and crevice treatment) as a result of wet cleaning resulting in:

Potential environmental releases of dinotefuran resulting from indoor use of the gel bait product by professional operators against cockroach infestations should only be associated with hard surface treatment. The major route of environmental exposure is considered to be that resulting from the wet cleaning of hard surfaces around cracks and crevices or where spots of gel have been applied. Where regular cleaning is essential or customary, it is extremely unlikely that this type of formulation would provide effective control due to potential losses between re-application so use of the product will be limited to difficult to access locations / areas.

Input/Parameter (units)	Data/Endpoint
Local population in catchment of STP (-)	10,000
Daily wastewater flow per inhabitant (l d^{-1} eq^{-1})	200
Effluent discharge rate of STP (l d^{-1})	2 x 10^6
Size of targeted treatment area within each domestic dwelling (m²) *	2.0
Size of targeted treatment area within each larger building (m²) *	9.3
Number of potential houses treated per catchment (-)	4000 (indoor)
Number of potential large buildings treated per catchment (-) *	300 (indoor)
Simultaneity Factor (%) based upon weekly treatment indoors	2.75 (indoor)

Conclusion

The frequency of application was taken into account for the simultaneity factor. Presumably the BPC accepted this approach to show safe use of the representative product in order for the active to ultimately be approved.

Extract from epsilon-Momfluorothrin assessment report

The representative products are both aerosols: *epsilon*-momfluorothrin / Sumithrin OBA (Oil-based Aerosol) and *epsilon*-momfluorothrin / Sumithrin WBA (Water-based Aerosol).

The proposed domestic uses of product are as follows;

- Indoor for the control of crawling or flying insects (e.g. cockroaches, ants, flies or mosquitoes).
- Outdoor for the control of crawling insects (e.g. cockroaches and ants).

Indoor use

Emissions from a space spray application or as a spot treatment in difficult to access areas (crack and crevice treatment) as a result of wet cleaning resulting in:

As detailed in the ESD, in the case of air space treatment there is no direct application on material, and the insecticide particles are suspended in the air with 96 % falling to the floor during the day and subject to wet cleaning. In the case of the crack and crevice application these are likely to be to areas not prone to frequent wet cleaning.

Table 2.8 PEC input assumptions for assessment of emissions from representative products (*epsilon*-momfluorothrin / Sumithrin OBA or WBA)

Input/ Parameter (units)	Data/ Endpoint
Number of houses in catchment of STP (-) Indoor / Outdoor	4000 / 2500
Effluent discharge rate of STP (l d^{-1})	2×10^6
Number of applications (-) Crack and Crevice / Space spray / Outdoor	1 / 4 / 1
Cleaning efficiency (-) Crack and crevice / Space spray	0.03 / 1
Perimeter application width of spray application- Default (foundation height / ground width) (m)	0.5 / 0.5
Simultaneity Factor (%)- Default Crack and crevice / Space spray	0.0275 / 0.055
Simultaneity Factor (%)- Refined Combined assessment# Indoor crack & crevice / Indoor Space spray / Outdoor spray	0.0069/ 0.0138 / 0.0138
Cleaning efficacy (F_{CE}) : crack, crevice and spot treatment to difficult to access areas	0.03
Fraction to water at STP *	77.8
Fraction to sewage sludge at STP *	17.4
Fraction to air at STP *	9.93×10^{-5}
Sludge rate : rate of sewage sludge production at STP (kg d^{-1})	710

* Derived by SimpleTreat 3.1; # Refinement agreed at TM-I-2011

Extract from Transfluthrin assessment report

For the indoor use of Raid Portable Electric, Turbo 4 Seasons and Baygon Mosquito Coil, indirect emission to the environment is considered via discharge of waste water to the Sewage Treatment Plant (STP) upon cleaning of floors to which part of the active substance has deposited. The Predicted Environmental Concentrations (PECs) were calculated with EUSES

Discussion on the aquatic risk assessment

There are a number of arguments (see below) indicating that the risk assessment is based on worst-case assumptions.

1. In the absence of sufficient chronic data, the PNECaquatic is derived applying the highest assessment factor of 1000.
2. In the scenario overestimations are incorporated such as - 10% of the active substance is emitted to the floor after condensation of the vaporised product; - daily cleaning performed and – 100% cleaning efficiency is applied. Raid Portable Electric induces vaporisation of the active substance without heating, and the fraction emitted to the floor is therefore likely to be overestimated.

higher emissions to the environment. It should be emphasised that the ESD does address the frequency and simultaneity in which insecticidal products are used in households. The RMS welcomes it if refined data on use frequency and simultaneity for this type of use become available. Analysis of product sales data over a representative period with an appropriate level of spatial and temporal resolution can be used to improve estimates of emissions to STP. Additionally the removal rate from (contaminated) surfaces could be an important parameter to refine the risk assessment. This information can be provided at the point of product registration.

Conclusion

In this case, it is noted that the RMS was the Netherlands. In the case of Unichem's Neopermin product, the refined data on use frequency and hence simultaneity is based on the label restriction to limit application frequency to only once every 3-4 weeks.

Overall conclusion

There are very clear precedents available from the past approvals of several actives, where the simultaneity factor was set on the basis of the frequency of application as we are requesting for Neopermin risk assessment.

Based on their approval dates, the approval of three of these actives must have passed through the ECHA Environmental Working Groups and Biocidal Products Committee process (i.e. under the BPR) and ultimately EU Commission approval, and the other actives through the previous system of Technical Meetings/Steering Committee etc.

Therefore, it can be concluded that a sufficient majority of experts/CA representatives and the EU Commission have concluded that it is acceptable to connect the frequency of application with the simultaneity factor.

From this, and in the interest of fairness and harmonisation with these active approval decisions, taking into account the extracts taken from the assessment reports, the applicant (Unichem) requests Ctgb, that the simultaneity factor should be based on an application frequency of 3-4 weeks and should be set at 1.38%.

Additional supplemental arguments:

It should also be noted that this is an indoor application, therefore rainfall is not relevant. It is also believed reasonable, that a professional user would not revisit to reapply the product on a daily basis, even if a cleaner was to clean up the same day of application, as they would not know the product had been cleaned up, and any cleaner would be unlikely to tell them and the label instructions would tell them not to reapply daily. In the case of the non-professional, most likely in the domestic home, it is reasonable that they would tell other members of the household not to clean up the areas which have been treated after the product was applied. It is also reasonable to expect that if someone in a household did ignore the message not to clean and then decided to clean in the difficult-to-access areas, that it would become apparent to the non-professional who applied the product, that the cockroaches/ants/crawling insects didn't seem to be getting controlled and they would see that it had been cleaned and tell the family (or any cleaner who cleans their home) to stop cleaning the areas where they had applied the product.