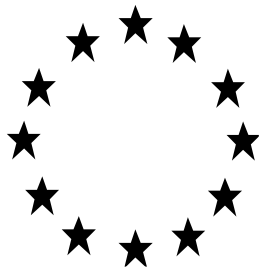
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

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

(submitted by the evaluating Competent Authority)



HG tegen kruipend ongedierte

Product type 18

Permethrin as included in the Union list of approved active substances

Asset Number

Evaluating Competent Authority: NL

Date: February 2023

Table of Contents

1 CONCLUSION

APCP:

The BPF 'HG tegen kruipend ongedierte' is a permethrin based biocidal product family and consists of a single meta-SPC. The biocidal products within the BPF are AE formulations and are packed in a PET/ALU/OPA/PP bag-on-valve within the spray can. The spray can is used with actuator with straw connected.
All corresponding products are clear colourless liquids with a slight fruity odour.
A long term ambient storage stability study indicated the product to be stable in it's commercial packaging for 2 years.

All products in MetaSPC 1 - Spray can : HG tegen kruipend ongedierte aerosol are classified category 3 aerosol and therefore the hazard phrase - H229 (Pressurized container: may burst if heated) should be added to the label.
No other physical hazards are assigned to HG tegen kruipend ongedierte.
The analytical HPLC-PDA method used to determine the content of active substance is considered sufficiently validated.

Efficacy:

HG tegen kruipend ongedierte can be used by non-professional users. Based on the provided efficacy tests authorisation can be granted against crawling insects, (including cockroaches, ants and silverfish) for use by non-professional users indoor via a crack and crevice treatment and against outdoor ant nests around buildings. For indoor use: Apply 25 ml per m2 (corresponding with 25 seconds of spraying). Treat up to a maximum of 2 m^2 which equals 10 meter plinth/cracks/crevices (2.5 seconds spraying per meter plinth/cracks/crevices). For outdoor use: Apply 12.5 ml into the nest (corresponding with 12.5 seconds of spraying).

Human Health:

No adverse health effects are expected for the unprotected non-professional user or the general public when products included in the BPF HG tegen kruipend ongedierte are used in compliance with the SPC.

Environment:

The risks to the aquatic compartment are considered not acceptable for the indoor uses of the products in the BPF HG tegen kruipend ongedierte for the control of crawling insects when applied 3-11 times per year (as was applied for).

At CG, however, certain products were authorized by reducing the packaging size, use of designed spray lance for cracks and crevice treatment, and in combination with a number of instructions and restrictions on the SPC/label.
When this approach is extrapolated to HG tegen kruipend ongedierte the following adaptations need to be applied to the products:

- The package size is reduced to 100 ml, representing 2 times spot crack and crevices treatment of 2 m2;

- The packaging is provided only with a designed spray nozzle/lance for cracks and crevice treatment;
- the following instructions and restrictions on the SPC/label:
  "Do not apply more than 50 mL solution/application when treating a private house."
  "Only apply on restricted areas in cracks and crevices."
  "If you suspect that after two applications the product is not effective, contact a pest control company."

For the authorized use concerning outdoor use (terraces) – nest treatment, with the risk mitigation measure:

"Do not apply the product in areas with a drain."

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product family

Identifier[1]	**Country (if relevant)**
	The Netherlands

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	HG International BV
	Address	PJ Oudweg 41 1314 CJ Almere The Netherlands
Authorisation number	NL-0021235-0000	
Date of the authorisation	5 mei 2023	
Expiry date of the authorisation	5 mei 2033	

2.1.1.3 Manufacturer(s) of the products of the family

Name of manufacturer	HG International BV
Address of manufacturer	PJ Oudweg 41 1314 CJ Almere The Netherlands
Location of manufacturing sites	BiB Production & Packaging Randweg 7 6045 JK Roermond

2.1.1.4 Manufacturer(s) of the active substance(s)

Active substance	Permethrin
Name of manufacturer	Tagros Chemicals India Ltd Substances supplier: Limaru NV (acting for Tagros Chemicals India Private Limited)
Address of manufacturer	Tagros Chemicals India Ltd "Jhaver Centre", Rajah Annamalai Building, IV Floor, 72, Marshalls Road, Egmore, Chennai-600 008, India Telephone number: +91-44-42007400 E-mail: info@tagros.com

[1] Please fill in here the identifying product name from R4BP.

Location of manufacturing sites	Tagros Chemicals India Ltd A-4/1&2, Sipcot Industrial Complex Pachayankuppam, Cuddalore – 607 005 Tamilnadu India

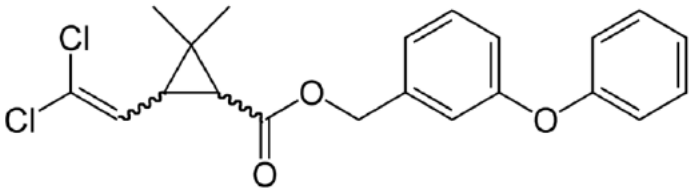
2.1.2 Product (family) composition and formulation

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

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

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

	Main constituent(s)
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	≥ 93.0%
Structural formula	

2.1.2.2 Candidate(s) for substitution

For permethrin, the criteria for candidate for substitution are not met.

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product family[2]

The biocidal product family (BPF) named "HG tegen kruipend ongedierte"
consists of one meta-SPC:
MetaSPC 1 - Spray can (AE formulation) : HG tegen kruipend ongedierte aerosol

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**	
					Min	**Max**
Permethrin	3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate	Active substance	52645-53-1	258-067-9	0.215 (0.2 pure)	0.215 (0.2 pure)
Confidential business information	Confidential business information	Non-active substance[2]	Confidential business information	Confidential business information		

2.1.2.4 Information on technical equivalence

Not applicable since the manufacturer of the acticle substance is a reference source.

2.1.2.5 Information on the substance(s) of concern

Products included in the BPF HG tegen kruipend ongedierte do not contain a substance of concern. Details can be found in Confidential Annex 3.6.

2.1.2.6 Type of formulation

MetaSPC 1 - Spray can : HG tegen kruipend ongedierte aerosol

AE

[2] Non-active substance(s), of which knowledge is essential for proper use of the product. In the SPC in the application the applicant shall indicate also the exact function (e.g. solvent, deterrent, preservative, pigment, etc.). In the SPC which will be disseminated this information will not be provided but limited to the name of non-active substance.

2.1.3 Hazard and precautionary statements

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

MetaSPC 1 - Spray can : HG tegen kruipend ongedierte aerosol

Classification	
Hazard category	Aerosol Category 3 Aquatic Chronic Category 1
Hazard statement	H229 Pressurized container: may burst if heated H410 Very toxic to aquatic life with long lasting effects
Labelling	
Signal words	GHS09 Signal word: warning
Hazard statements	H229 Pressurized container: may burst if heated H410 Very toxic to aquatic life with long lasting effects
Precautionary statements	P101 If medical advice is needed, have product container or label at hand. P102 Keep out of reach of children. P210 Keep away from heat/sparks/open flames/hot surfaces. – No smoking. P251 Pressurized container: Do not pierce or burn, even after use. P273 Avoid release to the environment P391 Collect spillage. P410 + P412 Protect from sunlight. Do not expose to temperatures exceeding 50°C / 122° F. P501 Dispose of contents/container to hazardous or special waste collection point.
Note	EUH208 Contains permethrin. May produce an allergic reaction.

2.1.4 Authorised use(s)

The biocidal product family (BPF) named "HG tegen kruipend ongedierte"
consists of
MetaSPC 1 - Spray can : HG tegen kruipend ongedierte aerosol

This family consists of 3 products with each a separate use in MetaSPC1 due to the names of the products which are not applicable for all three uses. There are differences between the use specific instructions and the use specific mitigation measures for the different target species and therefore, the use decriptions are split over the relevant uses. This is in line with the current SPC proposal.

2.1.4.1 Use description

MetaSPC 1 - Spray can : HG tegen kruipend ongedierte aerosol

Table 1. Use # 1.1 – Crawling insects – Indoor – cracks and crevices

Product Type	PT 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: *Blattodea* – Cockroaches – Nymphs and adults *Formicidae* - Ants – Larvae, adults, queens, nests *Lepismatidae* – Silverfish – Adults
Field of use	Indoor cracks and crevices RTU Aerosol spray can with straw
Application method(s)	Spraying
Application rate(s) and frequency	Rate: Apply 25 ml per m^2 (corresponding with 25 seconds of spraying). Do not apply more than 50 mL solution/application when treating a private house. Frequency: Maximum use frequency is 2 times per year. In case needed, the first treatment can be repeated once after 6 weeks
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	Aerosol in bag inside spray can: The product is packaged in a bag on valve system aerosol system, consisting of an aluminium, tin plated, PET aerosol can with valve and PET/ALU/OPA/PP bag. The net product volume is 100 ml. The spray can is sold without actuator attached. An actuator with (PP) straw connected is provided with the spray can which has to be mounted on the valve before it can be used.

2.1.4.2 Use-specific instructions for use

Crawling insects: Hold or direct the straw onto the cracks and crevices to be treated and apply 25 ml per m^2, being 25 seconds spraying (being a quantity until these areas are visibly moist). Treat all hiding places behind and under cabinets, refrigerators, radiators and equipment. Do not apply more than 50 mL product/application when treating a private house

2.1.4.3 Use-specific risk mitigation measures

The product will continue to work up to 6 weeks after spraying. For a good effect against most insects, a certain duration of action is needed. Therefore, the treated areas should be skipped as much as possible during cleaning. Ventilate the room/area in which the treatment took place. See also under general directions for use.

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

see the general directions for use

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

see the general directions for use

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

see the general directions for use

Table 2. Use # 1.2 – Silverfish – Indoor – cracks and crevices

Product Type	PT 18 - Insecticides, acaricides and products to control other arthropods
Where relevant, an exact description of the authorised use	Insecticide
Target organism (including development stage)	*Lepismatidae* – Silverfish – Adults
Field of use	Indoor cracks and crevices RTU Aerosol spray can with straw
Application method(s)	Spraying
Application rate(s) and frequency	Rate: Apply 25 ml per m^2 (corresponding with 25 seconds of spraying). Treat up to a maximum of 2 m^2. Do not apply

	more than 50 mL product/application when treating a private house Frequency: Maximum use frequency is 2 times per year. In case needed, the first treatment can be repeated once after 6 weeks
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	Aerosol in bag inside spray can: The product is packaged in a bag on valve system aerosol system, consisting of an aluminium, tin plated, PET aerosol can with valve and PET/ALU/OPA/PP bag. The net product volume is 100 ml. The spray can is sold without actuator attached. An actuator with (PP) straw connected is provided with the spray can which has to be mounted on the valve before it can be used.

2.1.4.7 Use-specific instructions for use

Silverfish: Hold or direct the straw onto the cracks and crevices to be treated and apply 25 ml per m^2, being 25 seconds spraying (being a quantity until these areas are visibly moist). Treat all hiding places behind and under cabinets, refrigerators, radiators and equipment. Do not apply more than 50 mL product/application when treating a private house

2.1.4.8 Use-specific risk mitigation measures

The product will continue to work up to 6 weeks after spraying. For a good effect against most insects, a certain duration of action is needed. Therefore, the treated areas should be skipped as much as possible during cleaning.

Ventilate the room/area in which the treatment took place.
See also under general directions for use.

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

see the general directions for use of Meta SPC1

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

see the general directions for use of Meta SPC1

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

see the general directions for use of Meta SPC1

Table 3. Use # 1.3 – Ants- indoor (cracks and crevices) and Outdoor (around buildings) - Nest treatment

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods
Where relevant, an exact description of the authorised use	Insecticide
Target organism(s) (including development stage)	*Formicidae* – Ants – Larvae, adults, queens, nests
Field(s) of use	Outdoor use Only allowed for nest treatment around buildings Indoor use – cracks and crevices Ready-To-Use Aerosol spray can
Application method(s)	Spraying
Application rate(s) and frequency	Outdoor Rate: Apply 12.5 ml into the nest (corresponding with 12.5 seconds of spraying). Indoor: Rate: Apply 25 ml per m^2 (corresponding with 25 seconds of spraying). Do not apply more than 50 mL product/application when treating a private house. Frequency: Maximum use frequency is 2 times per year. In case needed, the first treatment can be repeated once after 6 weeks
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	Aerosol in bag inside spray can: The product is packaged in a bag on valve system aerosol system, consisting of an aluminium, tin plated, PET aerosol can with valve and PET/ALU/OPA/PP bag. The net product volume is 100 ml. The spray can is sold without actuator attached. An actuator with (PP) straw connected is provided with the spray can which has to be mounted on the valve before it can be used.

2.1.4.12 Use-specific instructions for use

Ants outdoor: Hold or direct the tube of the nozzle into nest opening and apply 12.5 ml into the nest being 12.5 seconds spraying.

Ants indoor: Hold or direct the straw onto the cracks and crevices to be treated and apply 25 ml per m^2 (corresponding with 25 seconds of spraying). Do not apply more than 50 mL product/application when treating a private house.

Be aware that this biocidal product contains permethrin which is dangerous to bees.

2.1.4.13 Use-specific risk mitigation measures

see the general directions for use

Indoor: The product will continue to work up to 6 weeks after spraying. For a good effect against most insects, a certain duration of action is needed. Therefore, the treated areas should be skipped as much as possible during cleaning.

Ventilate the room/area in which the treatment took place.

Outdoor: do not apply this product in areas with a drain.

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

see the general directions for use

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

see the general directions for use

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

see the general directions for use

2.1.5 General Directions for use

MetaSPC 1 - Spray can : HG tegen kruipend ongedierte aerosol

2.1.5.1 Instructions for use

Comply with the instructions for use. Shake before use.
Place the actuator with straw on the valve without applying unnecessary pressure.
Spray cracks and crevices using an actuator with straw connected. Check the effect and, if necessary, repeat the treatment after six weeks.
If you suspect that after two applications the product is not effective, contact a pest control company.

2.1.5.2 Risk mitigation measures

Do not apply on (pet) animals and plants.

The product should be applied where children and pets do not come in contact with the product.
Unprotected persons and animals should be kept away during application.

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

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.

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

Direct or indirect effects: not reported.

First aid instructions:
IF ON SKIN: Take off all contaminated clothing and wash it before reuse. Wash skin with water.If skin irritation or rash occur: Get medical advice.
IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.
IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.
IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.
If medical advice is needed, have product container or label at hand.

Emergency measures to protect the environment: Avoid release to the environment.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Dispose of contents/container to hazardous or special waste collection point.

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

Keep in frost free area.
Protect from sunlight. Do not expose to temperatures exceeding 50º C / 122º F.
Shelf life: 2 years
Keep out of reach of children and non-target animals/pets

2.1.6 Other information

-

2.1.7 Packaging of the biocidal product

MetaSPC 1 - Spray can : HG tegen kruipend ongedierte aerosol

The aerosol packaging is a so-called bag-on-valve aerosol. The aerosol can consist of aluminium, tin plate or PET. In the aerosol can a bag-on-valve is filled with the recipe "HG tegen kruipend ongedierte". The bag used is made of four layers of foil. From outside to inside the foils are Polypropylene (PP), Oriented Polyamide (OPA), Aluminum (ALU), and Polyethylene Terephthalate (PET). The "HG tegen kruipend ongedierte" only comes in contact with the PET inner foil of the bag. The aerosol is air-pressurized.
During filling, the aerosol can is pre-pressurized with compressed air and the valve is fitted on the can. After fitting the valve on the can the bag is filled with the recipe. Due to this principle the recipe is not mixed with the propellant and is the 100% recipe described in the SPC. The spray can is sold without actuator attached. An actuator with (PP) straw connected is provided with the spray can which has to be mounted on the valve before it can be used.
The Aluminum can and the tin plate can are completely non-translucent. A PET can is colored white or is transparent with a coloured sleeve or label.
The bag-on-valve itself is completely non-translucent due to the aluminum foil. The active substance is not exposed to light.

The net product volume is 100 ml.

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)
Aerosol can (bag-on-valve)	100 ml	Can: Aluminium, tin plated, or PET; Bag: PET/ALU/ OPA/PP	Valve plus Aerosol actuator / extension tube combination, both made from polypropylene	Non-professional	Yes *

*See information on shelf life

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

See Annex 3.1 with the reference of the product data.

2.1.8.2 Access to documentation

A letter of access to the EU assessment dossier of permethrin is available.

2.2 Assessment of the biocidal product (family)

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

The uses below are the ones originally applied for by the applicant, without any changes by the e-CA. These uses are assessed in the following chapters.

Please note: Use #1.2, 1.3, 1.5 and 1.6 of Meta SPC 1 and all uses of Meta SPC2 are no longer applied for by the applicant.

See 2.1.4 for the authorised uses, after assessment of the dossier.

The most worst-case for the products is surface spraying, compared to target spot or cracks and crevices (the latter having the lowest exposure).
For environmental risk assessment all indoor uses are considered together, only the outdoor ant use is having a different environmental exposure scenario.
In scenario 1.1, and 1.4 a tube/lance is connected to the spray can which will reduce human exposure to a minimum (negligible) and which will therefore reduce the indirect environmental exposure of surface water via STP (via washing clothes) to zero.

MetaSPC 1 - Spray can : HGX tegen vliegend en kruipend ongedierte aerosol

Table 1. Use # 1.1 – crawling insects

Product Type	18
Where relevant, an exact description of the authorised use	
Target organism(s) (including development stage)	Crawling insects, including but not limited to: • Cockroaches: German *Blattella germanica* + oriental *Blatta orientalis*. Adults and nymphs • Ants: *Lasius niger,* • Silverfish: *Lepisma saccharina* Adults and nymphs • Litter beetle Adults and larvae (crawling)
Field(s) of use	Indoor use – cracks and crevices
Application method(s)	RTU Aerosol spray can
Application rate(s) and frequency	Rate: use the amount that is needed to wet the area to be treated = apply 25 ml per m^2 being 25 seconds spraying. Frequency: intermittent for a max of 1 m^2 and for 3-4 events per year; in case needed treatment can be repeated after 6 weeks
Category(ies) of users	Non-Professional
Pack sizes and packaging material	Aerosol in PET bag inside spray can: The product is packaged in a bag on valve system aerosol system, consisting of an aluminium, tin plated, PET aerosol can with valve and PET/ALU/OPA/PP bag. The net product volumes are: 100, 150, 200, 250, 300, 400 and 500 ml.

Table 1. Use # 1.2 – Fleas

Product Type	18
Where relevant, an exact description of the authorised use	
Target organism(s) (including development stage)	Fleas: cat flea *Ctenocephalides felis*. Adults and nymphs
Field(s) of use	Indoor use – target spot application
Application method(s)	RTU Aerosol spray can
Application rate(s) and frequency	Rate: use the amount that is needed to wet the area to be treated = apply 25 ml per m^2 being 25 seconds spraying. Frequency: intermittent for a max of 1 m^2 and for 3-4 events per year; in case needed treatment can be repeated after 6 weeks
Category(ies) of users	Non-Professional
Pack sizes and packaging material	Aerosol in PET bag inside spray can: The product is packaged in a bag on valve system aerosol system, consisting of an aluminium, tin plated, PET aerosol can with valve and PET/ALU/OPA/PP bag. The net product volumes are: 100, 150, 200, 250, 300, 400 and 500 ml.

Table 3. Use # 1.3 – Spiders indoor

Product Type	18
Where relevant, an exact description of the authorised use	
Target organism(s) (including development stage)	Spiders:house spiders: *Tegenaria domestica.Adults*
Field(s) of use	Indoor use – cracks and crevices
Application method(s)	RTU Aerosol spray can
Application rate(s) and frequency	Rate: use the amount that is needed to wet the area to be treated = apply 25 ml per m^2 being 25 seconds spraying. Frequency: intermittent for a max of 1 m^2 and for 3-4 events per year; in case needed treatment can be repeated after 6 weeks
Category(ies) of users	Non-Professional
Pack sizes and packaging material	Aerosol in PET bag inside spray can: The product is packaged in a bag on valve system aerosol system, consisting of an aluminium, tin plated, PET aerosol can with valve and PET/ALU/OPA/PP bag. The net product volumes are: 100, 150, 200, 250, 300, 400 and 500 ml.

Table 4. Use # 1.4 – Ants outdoor

Product Type	18
Where relevant, an exact description of the authorised use	
Target organism(s) (including development stage)	Ants: *Lasius niger*
Field(s) of use	Outdoor use –only allowed around buildings, nest treatment
Application method(s)	RTU Aerosol spray can
Application rate(s) and frequency	Rate: Apply 12.5 ml into the nest being 12.5 seconds spraying. Frequency: intermittent for 1-2 events per year; in case needed treatment can be repeated after 6 weeks
Category(ies) of users	Non-Professional
Pack sizes and packaging material	Aerosol in PET bag inside spray can: The product is packaged in a bag on valve system aerosol system, consisting of an aluminium, tin plated, PET aerosol can with valve and PET/ALU/OPA/PP bag. The net product volumes are: 100, 150, 200, 250, 300, 400 and 500 ml.

Table 5. Use # 1.5 – flying insects

Product Type	18
Where relevant, an exact description of the authorised use	
Target organism(s) (including development stage)	Flying insects, including but not limited to: • Clothes moth adults and nymps • Flies: *Musca domestica* Adults • Mosquitoes: *Aedes aegypti* and *Culex quinquefasciatus*
Field(s) of use	Indoor use – surface application - don't treat total walls
Application method(s)	RTU Aerosol spray can
Application rate(s) and frequency	Rate: Apply 25 ml per m2 being 25 seconds spraying Frequency: seasonal. for a max of 1 m^2 and for 3-4 events per year; in case needed treatment can be repeated after 6 weeks
Category(ies) of users	Non-Professional
Pack sizes and packaging material	Aerosol in PET bag inside spray can: The product is packaged in a bag on valve system aerosol system, consisting of an aluminium, tin plated, PET aerosol can with valve and PET/ALU/OPA/PP bag. The net product volumes are: 100, 150, 200, 250, 300, 400 and 500 ml.

Table 6. Use # 1.6 – Wasps

Product Type	18
Where relevant, an exact description of the authorised use	
Target organism(s) (including development stage)	Wasps, all stages (treatment of nests) • Wasps: *Vespula vulgaris.*
Field(s) of use	Indoor use – targeted spot (nest in wall cavities)
Application method(s)	RTU Aerosol spray can
Application rate(s) and frequency	Efficacy is demonstrated at an application of 25 ml/m^2 Frequency: incidental and occur <1 times per year per household
Category(ies) of users	Non-Professional
Pack sizes and packaging material	Aerosol in PET bag inside spray can: The product is packaged in a bag on valve system aerosol system, consisting of an aluminium, tin plated, PET aerosol can with valve and PET/ALU/OPA/PP bag. The net product volumes are: 100, 150, 200, 250, 300, 400 and 500 ml.

MetaSPC 2 – RTU Trigger spray: HGX tegen vliegend en kruipend ongedierte

Table 1. Use # 2.1 – crawling insects

Product Type	18
Where relevant, an exact description of the authorised use	
Target organism(s) (including development stage)	Crawling insects, including but not limited to: • Cockroaches: German *Blattella germanica* + oriental *Blatta oreintalis*. Adults and nymphs • Ants: *Lasius niger,* • Silverfish: *Lepisma saccharina* Adults and nymphs • Litter beetle Adults and larvae (crawling)
Field(s) of use	Indoor use – cracks and crevices
Application method(s)	RTU Trigger spray
Application rate(s) and frequency	Rate: use the amount that is needed to wet the area to be treated = apply 25 ml per m^2 being 16x spraying. Frequency: intermittent for a max of 1 m^2 and for 3-4 events per year; in case needed treatment can be repeated after 6 weeks
Category(ies) of users	Non-Professional
Pack sizes and packaging material	The product is packaged in a HDPE, PET bottle with trigger sprayer. The net product volumes are: 150, 250, 500 and 650 ml.

Table 2. Use # 2.2 – Fleas

Product Type	18
Where relevant, an exact description of the authorised use	
Target organism(s) (including development stage)	Fleas: cat flea *Ctenocephalides felis*. Adults and nymphs
Field(s) of use	Indoor use – target spot
Application method(s)	RTU Trigger spray
Application rate(s) and frequency	Rate: use the amount that is needed to wet the area to be treated = apply 25 ml per m^2 being 16 times spraying. Frequency: intermittent for a max of 1 m^2 and for events per year; in case needed treatment can be repeated after 6 weeks
Category(ies) of users	Non-Professional
Pack sizes and packaging material	The product is packaged in a HDPE, PET bottle with trigger sprayer. The net product volumes are: 150, 250, 500 and 650 ml.

Table 3. Use # 2.3 – Spiders

Product Type	PT18
Where relevant, an exact description of the authorised use	
Target organism(s) (including development stage)	Spiders :house spiders: Tegenaria domestica. Adults
Field(s) of use	Indoor use - cracks and cervices
Application method(s)	RTU Trigger spray
Application rate(s) and frequency	Rate: use the amount that is needed to wet the area to be treated = apply 25 ml per m^2 being 16 times spraying. Frequency: intermittent for a max of 1 m^2 and for events per year; in case needed treatment can be repeated after 6 weeks
Category(ies) of users	Non-Professional
Pack sizes and packaging material	The product is packaged in a HDPE, PET bottle with trigger sprayer. The net product volumes are: 150, 250, 500 and 650 ml.

Table 4. Use # 2.4 – Ants outdoor

Product Type	18
Where relevant, an exact description of the authorised use	
Target organism(s) (including development stage)	Ants: *Lasius niger*
Field(s) of use	Outdoor use –only allowed around buildings, nest treatment
Application method(s)	RTU Trigger spray

Application rate(s) and frequency	Rate: Apply 12.5 ml into the nest being 8 times spraying. Frequency: intermittent for 1-2 events per year; in case needed treatment can be repeated after 6 weeks
Category(ies) of users	Non-Professional
Pack sizes and packaging material	The product is packaged in a HDPE, PET bottle with trigger sprayer. The net product volumes are: 150, 250, 500 and 650 ml.

Table 5. Use # 2.5 – flying insects

Product Type	18
Where relevant, an exact description of the authorised use	
Target organism(s) (including development stage)	Flying insects, including but not limited to: • Clothes moth adults and nymps • Flies: *Musca domestica* Adults • Mosquitoes: *Aedes aegypti* and *Culex quinquefasciatus*
Field(s) of use	Indoor use – surface application / spot application / don't treat total walls
Application method(s)	RTU Trigger spray
Application rate(s) and frequency	Rate: Apply 25 ml per m^2 being 16 times spraying Frequency: seasonal. for a max of 1 m^2 and for 3-4 events per year; in case needed treatment can be repeated after 6 weeks
Category(ies) of users	Non-Professional
Pack sizes and packaging material	The product is packaged in a HDPE, PET bottle with trigger sprayer. The net product volumes are: 150, 250, 500 and 650 ml.

Table 6. Use # 2.6 – Wasps

Product Type	18
Where relevant, an exact description of the authorised use	
Target organism(s) (including development stage)	Wasps (treatment of nests) • Wasps: *Vespula vulgaris.*
Field(s) of use	Indoor use – targeted spot (nest in wall cavities)
Application method(s)	RTU Trigger spray
Application rate(s) and frequency	Efficacy is demonstrated at an application of 25 ml/m^2 Frequency: incidental and occur <1 times per year per household
Category(ies) of users	Non-Professional
Pack sizes and packaging material	The product is packaged in a HDPE, PET bottle with trigger sprayer. The net product volumes are: 150, 250, 500 and 650 ml.

2.2.2 Physical, chemical and technical properties

The biocidal product family (BPF) named "HG tegen kruipend ongedierte" consists of
MetaSPC 1 - Spray can : HG tegen kruipend ongedierte aerosol.

It should be noted that during the evaluation, part of the originally intended uses are no longer supported, as a result, the name of the products, metaSPC and product family has changed. The product itself has not changed. HGX tegen vliegend en kruipend ongedierte has the same product composition as HG tegen kruipend ongedierte (aerosol). All test results are still valid.

MetaSPC 1 - Spray can : HG tegen kruipend ongedierte aerosol

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Observation	HGX tegen vliegend en kruipend ongedierte, 0.2 % w/w permethrin	Clear liquid	[redacted] 2018b IUCLID 3.1
Colour at 20 °C and 101.3 kPa	Observation	HGX tegen vliegend en kruipend ongedierte, 0.2 % w/w permethrin	Colourless	[redacted] 2018b IUCLID 3.1
Odour at 20 °C and 101.3 kPa	Observation	HGX tegen vliegend en kruipend ongedierte, 0.2 % w/w permethrin	Fruity (slight)	[redacted] 2018b IUCLID 3.1
Acidity / alkalinity	OECD method 122	HGX tegen vliegend en kruipend ongedierte, 0.2 % w/w permethrin	Neat product: pH = 7.5 Acidity/alkalinity determination is not applicable as pH is between 4 and 10	[redacted], 2018a, 2021a IUCLID 3.0 summary [redacted] 2018c IUCLID 3.2
Relative density / bulk density	OECD method 109	HGX tegen vliegend en kruipend ongedierte,0.2 % w/w permethrin	The relative density of HGX tegen vliegend en kruipend ongedierte is 1.000 at 20°C and 101.3 kPa.	[redacted] 2018d IUCLID 3.3

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Storage stability test – **accelerated storage**	CIPAC method MT 46.3; 2 weeks at 54°C (method of analysis: HPLC/UV, see 2.2.4)	HGX tegen vliegend en kruipend ongedierte, 0.2 % w/w permethrin	A fresh made sample of 200 ml "HGX tegen vliegend en kruipend ongedierte" (0.2 % w/w) was tested in a new 200 ml glass jar with a new polypropylene screw cap with HPDE insert to prevent evaporation at 54 ± 2°C in an oven for 2 weeks. No changes were observed in odour, colour and density. Colour: Before storage: colourless. After storage: colourless. Odour: Before storage: Fruity (slight). After storage: Fruity (slight). Density: Before storage: 1.001 g/mL. After storage: 1.001 g/mL. The weight of the jar was slightly decreased from 407.69 to 407.63 g (-0.01%). The active substance content decreased with 0.01 w/w% (-5%) from 0.20 w/w% to 0.19 w/w% during two weeks 54°C which is acceptable because it is less than the maximum allowed decrease of 10% according the BPR.	[redacted] 2018e IUCLID 3.4.1.1

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Storage stability test – **accelerated storage test in commercial packaging**	CIPAC method MT 46.3; 2 weeks at 54°C in the worst case commercial packages. (method of analysis: HPLC/UV, see 2.2.4)	HGX tegen vliegend en kruipend ongedierte, 0.2 % w/w permethrin	A fresh made sample of "HGX tegen vliegend en kruipend ongedierte" was tested in the worst case commercial packages in an oven at 54° ± 2°C for 2 weeks. These packages were: - 3 White tin plated 520 ml aerosol cans with Bag-On-Valve (BOV = bag made of PP/ALU/OPA/PET foil from outside to inside) - 3 White HDPE 500 ml bottles with white Polypropylene triggers sprayer - 3 White PET 500 ml bottles with white Polypropylene trigger sprayer No changes were observed in odour, colour and density. Colour (all packs): Before storage: colourless. After storage: colourless. Odour (all packs): Before storage: Fruity (slight). After storage: Fruity (slight). Density (all packs): Before storage: 1.001 g/mL. After storage: 1.001 g/mL. No significant changes in pack weight: BOV-aerosol (3 packs): Before storage: 346.98-348.01 g. After storage: 346.95-348.00 g.	[redacted] 2019b IUCLID 3.4.1.1

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Mean weight loss 0.005%. No significant changes in pack weight: HDPE bottle (3 bottles): Before storage: 577.25-578.41 g. After storage: 577.01-578.22 g. Mean weight loss 0.04%. PET bottle (3 bottles): Before storage: 569.77-571.54 g. After storage: 569.59-571.36 g. Mean weight loss 0.03%. No phase separation and sedimentation: All packs): Before storage: No phase separation, no sedimentation. After storage: No phase separation, no sedimentation. No significant changes in pH (neat): BOV-aerosol: Before storage: pH 7.46. After storage: pH 7.26. HDPE bottle: Before storage: pH 7.46. After storage: pH 7.28. PET bottle: Before storage: pH 7.46. After storage: pH 7.22. No significant change in pressure at 20°C and 30°C of BOV-aerosol: Pack 1/2/3, before storage: 30°C: 9.3/9.2/9.4 bar	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			20°C: 9.0/8.8/9.1 bar Pack 1/2/3, after storage: 30°C: 9.2/9.0/9.2 bar 20°C: 8.8/8.7/9.0 bar No significant changes in sprayability (even flow and without dripping, determined visually), spray pattern (FEA method 644), amount of spray (mean of 10 sprays, 3 replicate determinations), nozzle blockage (visually): BOV-aerosol: Sprayability: Before storage: Even flow spray, no dripping. After storage: Even flow spray, no dripping. Spray pattern: Before storage: Circular, ø 23 cm. After storage: Circular, ø 23 cm. Amount of spray: Before storage: 1.00 g/sec. After storage: 1.00 g/sec. Nozzle blockage: Before storage: No blockage. After storage: No blockage. HDPE bottle: Sprayability: Before storage: Even flow spray, no dripping. After storage: Even flow spray, no dripping. Spray pattern: Before storage: Circular, ø 18 cm. After storage:	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Circular, ø 18 cm. Amount of spray: Before storage: 1.50 g/sec. After storage: 1.50 g/sec. Nozzle blockage: Before storage: No blockage. After storage: No blockage. PET bottle: Sprayability: Before storage: Even flow spray, no dripping. After storage: Even flow spray, no dripping. Spray pattern: Before storage: Circular, ø 18 cm. After storage: Circular, ø 18 cm. Amount of spray: Before storage: 1.49 g/sec. After storage: 1.48 g/sec. Nozzle blockage: Before storage: No blockage. After storage: No blockage. The packs were stable: BOV-aerosol: Before storage: No leakage, no ballooning, no panelling, no deformation. After storage: No leakage, no ballooning, no panelling, no deformation. HDPE bottle: Before storage: No leakage, no ballooning, no panelling, no deformation. After storage:	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			No leakage, no ballooning, no panelling, no deformation. PET bottle: Before storage: No leakage, no ballooning, no panelling, no deformation. After storage: No leakage, no ballooning, no panelling, no deformation. The active substance in the BOV-aerosol decreased with 0.01 w/w % (5%) from 0.20 to 0.19 w/w/% during 2 weeks at 54°C, which is acceptable because it is less than the maximum allowed decrease of 10% according the BPR. The active substance in the HDPE bottle with trigger sprayer decreased with 0.01 w/w % (5%) from 0.20 to 0.19 w/w/% during 2 weeks at 54°C, which is acceptable because it is less than the maximum allowed decrease of 10% according the BPR. The active substance in the PET bottle with trigger sprayer decreased with 0.01 w/w % (5%) from 0.20 to 0.19 w/w/% during 2 weeks at 54°C, which is acceptable because it is less than the maximum allowed decrease of 10% according the BPR. The generated accelerated storage data of HG tegen vliegend en	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			kruipend ongedierte after two weeks 54°C show a stable formulation and indicate that the HGX tegen vliegend en kruipend ongedierte will be stable during 2 years at ambient temperature.	
Storage stability test – **long term storage at ambient temperature**	The tests are set up according the Manual on development and use of FAO and WHO specifications for pesticides November 2010, GIFAP Technical Monograph n°17 2010 and the Guidance on the Biocidal Products Regulation; Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C Version 2.0 May 2018.	HGX tegen vliegend en kruipend ongedierte, 0.2 % w/w permethrin	MetaSPC1: HGX tegen vliegend en kruipend ongedierte in bag-on-valve aerosol was started in de standard packaging of 520 ml tin plated cans with PET/ALU/OPA/PP bag-on-valves filled with 250 ml of product. Other packages like aluminum and PET cans were not tested while the formulation is in de bag-on-valve and will not be in contact with the cans. The commercial packaging of 100ml is packed in the same bag-on-valve under same pressure. The quality of the bag-on-valve will be the same only the volume differs. The tests are performed at ambient temperature (18°C – 22°C). The study was started (t=0) at 18-10-2018. 2-years results: The long term storage test of the HG tegen kruipend ongedierte in bag-on-valve aerosol was started in the packaging of 520 ml tin plated cans with 4 layer	[redacted] 2018f IUCLID 3.4.1.2 [redacted] 2021c (interim report after 2 years)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			bag-on-valves filled with 250 ml of product. The results after 24 months show no changes in colour, oudour and density. The pH slightly decreased. The sprayability is OK, there are no changes in spray pattern, amount of spray, pressure, nozzle blockage The packaging remains stable as well, no leakage, ballooning, paneling or deformation is observed. The weight slightly decreased. The amount of active substance also slightly decreased from 0.2% to 0.19% which is within acceptable ranges (maximum allowed decrease of 10% according the BPR). A shelflife of 2 years is supported. Final results of the long term ambient storage stability study will be available in 2023 after 5 years of storage.	
	eCA remark: In the long term ambient storage stability study, no MMAD before and after storage was determined. The eCA agrees on this approach and does not consider the determination of the MMAD as arequirement in this case, since the product is not to be applied as an aerosol but as a liquid (through actuator with straw connected).			
Storage stability test – **low temperature stability test for liquids**	CIPAC method MT 39.3; 7 days at 0°C	HGX tegen vliegend en kruipend ongedierte 0.2 % w/w permethrin	A fresh made sample of 200 ml "HGX tegen vliegend en kruipend ongedierte" was tested in a new 200 ml glass jar fitted with a new polypropylene screw cap	[redacted] 2018g IUCLID 3.4.1.2

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			with HPDE insert to prevent evaporation at 0 ± 2°C in a refrigerator for 7 days. The active substance content increased with 0.01 w/w% (+5%) from 0.20 w/w% to 0.21 w/w% during 7 days 0°C, which is acceptable because the change is less than the maximum allowed decrease of 10% according the BPR. No changes were observed in odour, colour and density. Colour: Before storage: colourless. After storage: colourless. Odour: Before storage: Fruity (slight). After storage: Fruity (slight). Density: Before storage: 1.001 g/mL. After storage: 1.001 g/mL. No phase separation: Before storage: No phase separation. After storage: No phase separation. The weight of the jar was slightly decreased from 409.15 to 409.09 g (-0.01%). HGX tegen vliegend en kruipend ongedierte is stable after 7 days storage at 0°C.	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			No freeze/thaw cycles were investigated. On the label the phrase "Keep in a frost free area" must be mentioned.	
Storage stability test – **low temperature stability test for liquids in commercial packaging**	CIPAC method MT 39.3	HGX tegen vliegend en kruipend ongedierte, 0.2 % w/w permethrin	A fresh made sample of HGX tegen vliegend en kruipend ongedierte was tested in the worst case commercial packages in a refrigerator for 7 days at 0° ± 2°C. These packages were: - 3 White tin plated 520 ml aerosol can with Bag-On-Valve (BOV = bag made of PP/ALU/OPA/PET foil from outside to inside) - 3 White HDPE 500 ml bottle with white Polypropylene trigger sprayer - 3 White PET 500 ml bottle with white Polypropylene trigger sprayer. No phase separation and sedimentation: All packs): Before storage: No phase separation, no sedimentation. After storage: No phase separation, no sedimentation. No changes were observed in odour, colour and density. Colour (all packs): Before storage: colourless. After storage: colourless. Odour (all packs): Before storage: Fruity (slight).	[redacted] 2019a IUCLID 3.4.1.2

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			After storage: Fruity (slight). Density (all packs): Before storage: 1.001 g/mL. After storage: 1.001 g/mL. No significant changes in pack weight: BOV-aerosol (3 packs): Before storage: 345.66-346.04 g. After storage: 345.66-346.05 g. Mean weight loss -0.001%. No significant changes in pack weight: HDPE bottle (3 bottles): Before storage: 575.87-577.03 g. After storage: 575.82-577.04 g. Mean weight loss 0.006%. PET bottle (3 bottles): Before storage: 567.56-569.78 g. After storage: 567.57-569.73 g. Mean weight loss 0.004%. No significant changes in pH (neat): BOV-aerosol: Before storage: pH 7.46. After storage: pH 7.41. HDPE bottle: Before storage: pH 7.46. After storage: pH 7.39. PET bottle: Before storage: pH 7.46. After storage:	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			pH 7.40. No significant change in pressure at 20°C and 30°C of BOV-aerosol: Pack 1/2/3, before storage: 30°C: 9.2/9.4/9.2 bar 20°C: 8.9/9.1/8.9 bar Pack 1/2/3, after storage: 30°C: 9.1/9.4/9.2 bar 20°C: 8.9/9.0/8.9 bar No significant changes in sprayability (even flow and without dripping, determined visually), spray pattern (FEA method 644), amount of spray (mean of 10 sprays, 3 replicate determinations), nozzle blockage (visually): BOV-aerosol: Sprayability: Before storage: Even flow spray, no dripping. After storage: Even flow spray, no dripping. Spray pattern: Before storage: Circular, ø 23 cm. After storage: Circular, ø 23 cm. Amount of spray: Before storage: 0.98 g/sec. After storage: 0.96 g/sec. Nozzle blockage: Before storage: No blockage. After storage: No blockage. HDPE bottle: Sprayability: Before storage:	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Even flow spray, no dripping. After storage: Even flow spray, no dripping. Spray pattern: Before storage: Circular, ø 18 cm. After storage: Circular, ø 18 cm. Amount of spray: Before storage: 1.49 g/sec. After storage: 1.50 g/sec. Nozzle blockage: Before storage: No blockage. After storage: No blockage. PET bottle: Sprayability: Before storage: Even flow spray, no dripping. After storage: Even flow spray, no dripping. Spray pattern: Before storage: Circular, ø 18 cm. After storage: Circular, ø 18 cm. Amount of spray: Before storage: 1.48 g/sec. After storage: 1.48 g/sec. Nozzle blockage: Before storage: No blockage. After storage: No blockage. The packs were stable: BOV-aerosol: Before storage: No leakage, no ballooning, no panelling, no deformation. After storage:	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			No leakage, no ballooning, no panelling, no deformation. HDPE bottle: Before storage: No leakage, no ballooning, no panelling, no deformation. After storage: No leakage, no ballooning, no panelling, no deformation. PET bottle: Before storage: No leakage, no ballooning, no panelling, no deformation. After storage: No leakage, no ballooning, no panelling, no deformation. The active substance in the BOV-aerosol decreased with 0.01 w/w % (5%) from 0.20 to 0.19 w/w/% during 2 weeks at 54°C, which is acceptable because it is less than the maximum allowed decrease of 10% according the BPR. The active substance in the BOV-aerosol did not change during 7 days at 0°C and remained 0.20 w/w %. The active substance in the HDPE bottle with trigger sprayer decreased with 0.01 w/w % (5%) from 0.20 to 0.19 w/w/% during 7 days at 0°C. This is compliant with the specification of 0.20 ± 0.2 w/w %. The active substance in the PET bottle with trigger sprayer increased	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			with 0.01 w/w % (5%) from 0.20 to 0.21 w/w/% during 7 days at 0°C. This is acceptable because the change is less than the maximum allowed decrease of 10% according the BPR. HGX tegen vliegend en kruipend ongedierte is stable after 7 days storage at 0°C. No freeze/thaw cycles were investigated. On the label the phrase "Keep in a frost free area" must be mentioned.	
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	waiver	HGX tegen vliegend en kruipend ongedierte, 0.2 % w/w permethrin	The effect of light is not applicable for the HGX tegen vliegend en kruipend ongedierte because the formulation will not be exposed to light because the packages are not translucent.	[redacted] 2018a IUCLID 3.0 summary
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	waiver	HGX tegen vliegend en kruipend ongedierte, 0.2 % w/w permethrin	The effect of humidity is not applicable for the HGX tegen vliegend en kruipend ongedierte because the formulation is water based.	[redacted] 2018a IUCLID 3.0 summary
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards**	Part of ambient storage stability test	MetaSPC1- spray can HGX tegen vliegend en kruipend ongedierte, 0.2 % w/w permethrin	For the aerosol this is the standard packaging of 520 ml tin plated can with PET/ALU/OPA/PP bag-on-valve filled with 250 ml of product. Other packages like aluminum and PET cans were not tested while the formulation is in de bag-on-valve and will not be	[redacted] 2018a, 2021c IUCLID 3.0 summary

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
container material			in contact with the cans. The commercial packaging of 100 ml is packed in the same bag-on-valve under same pressure. The quality of the bag-on-valve will be the same only the volume differs. During the ambient storage test the appearance of the packages are observed and weight change of the packages is assessed. The 2 year results (see above) show that the packaging remains stable, no leakage, ballooning, panelling or deformation is opbsreved.	
Wettability	n.a.	n.a.	Not required for an AE formulation type	
Suspensibility, spontaneity and dispersion stability	n.a.	n.a.	Not required for an AE formulation type	
Wet sieve analysis and dry sieve test	n.a.	n.a.	Not required for an AE formulation type	
Emulsifiability, re-emulsifiability and emulsion stability	n.a.	n.a.	Not required for an AE formulation type	
Disintegration time	n.a.	n.a.	Not required for an AE formulation type	
Particle size distribution, content of dust/fines, attrition, friability	n.a.	n.a.	The particle size distribution, content of dust/fines attrition, friability is not applicable because HGX tegen vliegend en kruipend ongedierte is a water based formulation and not a powder.	[redacted], 2018a IUCLID 3.0 summary
Persistent foaming	n.a.	n.a.	Not required for formulation type / ready	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			to use products spray can and trigger spray	
Flowability/Pourability/Dustability	n.a.	n.a.	Not required for an AE formulation type	
Burning rate — smoke generators	n.a.	n.a.	Not required for an AE formulation type	
Burning completeness — smoke generators	n.a.	n.a.	Not required for an AE formulation type	
Composition of smoke — smoke generators	n.a.	n.a.	Not required for an AE formulation type	
Spraying pattern — aerosols	According to FEA method 644 (Filled Aerosols Packs – Evaluation of Aerosol Spray Patterns)	metaSPC1 HGX tegen vliegend en kruipend ongedierte in aerosol 250 ml (0.2 % w/w) permethrin	The spraying pattern for the HGX tegen vliegend en kruipend ongedierte in aerosol at 30 cm distance was determined to be circular with a diameter of 23 cm. This information has become obsolete since the currently intended uses are all with actuator with straw connected The spraying pattern of HGX tegen vliegend en kruipend ongedierte with nozzle with a straw was not determined since the straw does not give a pattern – no aerosol - just a solid jet of liquid product.	[redacted], 2018h IUCLID 3.5.12
Droplet size distribution	Laser diffraction spectroscopy	metaSPC1 HGX tegen vliegend en kruipend ongedierte aerosol, 0.2% w/w permethrin	Dx(10) (µm) = 43.58, 36.53, 40.83 Dx(50) (µm) = 75.89, 70.65, 73.57 Dx(90) (µm) = 126.01, 125.81, 126.39 **eCA remark:** This information has become obsolete since the currently intended uses are all applied through actuator with	[redacted] (2018) IUCLID 3.5.12

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			straw connected and therefore do not produce aerosols or droplets.	
Physical compatibility	n.a.	n.a.	Not required; Product RTU and not intended for use together with other products	
Chemical compatibility	n.a.	n.a.	Not required; Product is RTU and not intended for use together with other products	
Degree of dissolution and dilution stability	n.a.	n.a.	Not required for RTU product	
Surface tension	EU Test Method A.5 and OECD Test Guideline 115 (Surface Tension Aqueous Solutions, ring tensiometer)	HGX tegen vliegend en kruipend ongedierte (HGX180830) 0.2 % w/w permethrin	The surface tension of the neat product "HGX tegen vliegend en kruipend ongedierte" was determined to be 19.9 mN/m at 20°C and 101.3 kPa.	[redacted] 2018i IUCLID 3.8
Viscosity	OECD Test Guideline 114 (Viscosity of Liquids)	HGX tegen vliegend en kruipend ongedierte, 0.2 % w/w permethrin	It was concluded that the neat product "HGX tegen vliegend en kruipend ongedierte" has a kinematic viscosity of 10.11 seconds using a Din 4 mm flow cup at 20°C. This corresponds to 2.61 mm^2/s.	[redacted] 2018j IUCLID 3.9
	OECD test guideline 114 Viscosity of liquids using a rotational viscometer (Brookfield).	HG tegen kruipend ongedierte, 0.2 % w/w permethrin	The dynamic viscosity of HG tegen kruipend ongedierte is in the range of 15-19 m Pa.s at 20°C for shear rates of 150 – 250 rpm. At 40°C the dynamic viscosity is in the range of 11-15 m Pa.s for shear rates of 150 – 250 rpm	[redacted] 2021d

Conclusion on the physical, chemical and technical properties of the product
The BPF 'HG tegen kruipend ongedierte', including metaSPC1 is an AE formulation packed in a PET/ALU/OPA/PP bag-on-valves within the spray can. The spray can is used with actuator with straw connected. All corresponding products are clear colourless liquids with a slight fruity odour. The pH of the neat product is determined at 7.5, the relative density is 1.000 at 20°C and 101.3 kPa. The products in this BPF are not to be mixed with another product. The spraying pattern for 'HG tegen kruipend ongedierte' in aerosol at 30 cm distance was determined to be a conical aerosol with a circular shape and with a diameter of 23 cm, The droplet size distribution shows the droplet size to be large for the aerosol (median droplet diameter 73 and 128 µm). This is not relevant for the currently intended uses with the straw connected. The surface tension of the neat product was determined at 19.9 mN/m at 20°C and 101.3 kPa. The dynamic viscosity of HG tegen kruipend ongedierte is in the range of 15-19 m Pa.s at 20°C for shear rates of 150 – 250 rpm. At 40°C the dynamic viscosity is in the range of 11-15 m Pa.s for shear rates of 150 – 250 rpm. HG tegen kruipend ongedierte is stable after 7 days storage at 0°C. No freeze/thaw cycles were investigated. On the label the phrase "Keep in a frost free area" must be mentioned. The complete BPF has an shelf life of 2 years at ambient storage conditions based on the results of the available accelerated storage stability study and interim results of the 2 years stability study, performed in the claimed commercial packs (White tin plated aerosol cans with Bag-On-Valve). The packaging remains stable as well, no leakage, ballooning, paneling or deformation is observed .

2.2.3 Physical hazards and respective characteristics

The biocidal product family (BPF) named "HG tegen kruipend ongedierte" consists of :
MetaSPC 1 - Spray can : HG tegen kruipend ongedierte aerosol

MetaSPC 1 - Spray can : HG tegen kruipend ongedierte aerosol

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	Waiver, Assessment individual components according the UN Manual of Tests and Criteria Rev. 7 2019, Appendix 6, A6.3	HG tegen kruipend ongedierte, 0.2 % w/w permethrin	HG tegen kruipend ongedierte and the ingredients are not classified as explosive according the criteria for explosives as described in the section 2.1 of Annex 1 to the CLP regulation and in line with the UN Manual (2019, A6.3). Further justification is presented in the Confidential Annex of this document.	[redacted] 2018a, 2021a IUCLID 3.0 summary
	eCA remark: Considering the composition of the biocidal product family, no explosive properties are to be expected. A full theoretical screening of all components within the formulation is presented in the confidential annex of the PAR. Therefore, the eCA agrees that the endpoint *Explosive* is sufficiently addressed.			
Flammable gases	Waiver		Not applicable for an AE formulation type.	
Flammable aerosols	Waiver	HGX tegen vliegend en kruipend ongedierte, 0.2 % w/w permethrin	HGX tegen vliegend en kruipend ongedierte contains <1% flammable ingredients in the recipe. The product is an air-pressurised bag-on-valve aerosol Therefore, according the criteria for flammable aerosols described in the section 2.36 of Annex I to the CLP Regulation, the products within meta-SPC1 are classified as a category 3 aerosol.	[redacted] 2018a, 2021a IUCLID 3.0 summary
Oxidising gases	n.a.		Not applicable for an AE formulation type	
Gases under pressure	Waiver		Not applicable for an AE formulation type	[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
				[redacted] 2018a, 2021a IUCLID 3.0 summary
Flammable liquids	EU test method A.9 and ISO 2719:2016 for flash point determination (non-equilibrium method).	HGX tegen vliegend en kruipend ongedierte, 0.2 % w/w permethrin	The flash point determination according to the closed cup / Pensky-Martens principle, was carried out on a 100 ml sample of fresh made HGX tegen vliegend en kruipend ongedierte. It was concluded that HGX tegen vliegend en kruipend ongedierte has no flash point ≤ 100°C. Also, the products within mats-SPC are classified as cat 3 aerosols and therefore do not have to be classified as flammable liquid in addition.	[redacted] 2018k IUCLID 4.6
Flammable solids	n.a.		Not required for an AE formulation type	
Self-reactive substances and mixtures	Waiver Assessment individual components according the UN Manual of Tests and Criteria Rev. 7 2019, Appendix 6, A6.3	HGX tegen vliegend en kruipend ongedierte, 0.2 % w/w permethrin	HGX tegen vliegend en kruipend ongedierte does not contain self-reactive substances and the mixture does not have to be classified according the criteria for self-reactive substances and mixtures described in the section 2.8 of Annex I to the CLP Regulation and in line with the UN Manual (2019, A6.3 Further justification is presented in the Confidential Annex of this document.	[redacted] 2018a, 2021a IUCLID 3.0 summary
	eCA remark: Considering the composition of the biocidal product family, no self reactive properties are to be expected. A full theoretical screening of all components within the formulation is presented in the confidential annex of the PAR. Therefore, the eCA agrees that the endpoint *Self reactive substances and mixtures* is sufficiently addressed.			
Pyrophoric liquids	Waiver	HGX tegen vliegend en kruipend ongedierte, 0.2 % w/w permethrin	From long term experience it is known that HG tegen kruipende insecten is stable in contact with air and it does not spontaneously ignite.	[redacted] 2018a, 2021a IUCLID 3.0 summary

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Therefore it can be concluded that HG tegen kruipende insecten lacks pyrophoric properties.	
Pyrophoric solids	n.a.	n.a.	Not required for an AE formulation type	
Self-heating substances and mixtures	Waiver	HGX tegen vliegend en kruipend ongedierte, 0.2 % w/w permethrin	According the Guidance on application of CLP, section 2.11.4.2, HG tegen kruipend ongedierte does not have to be classified as a self-heating mixture because the phenomenom of self-heating applies only to solids and the surface of liquids is not large enough for reaction with air. Also, the HGtegen kruipend ongedierte is not applied and adsorbed on a large surface (e.g. on powder particles) so a self-heating hazard is not needed to be considered.	[redacted] 2018a, 2021a IUCLID 3.0 summary
Substances and mixtures which in contact with water emit flammable gases	Waiver	HGX tegen vliegend en kruipend ongedierte, 0.2 % w/w permethrin	HGX tegen vliegend en kruipend ongedierte does not contain substances which in contact with water emit flammable gases because the product is water based. The mixture does not have to classified according the criteria for substances and mixtures which in contact with water emit flammable gases described in section 2.12 of Annex I to the CLP Regulation.	[redacted] 2018a, 2021a IUCLID 3.0 summary
Oxidising liquids	Waiver Assessment individual components according the UN Manual of Tests and Criteria Rev. 7 2019, Appendix 6, A6.3	HGX tegen vliegend en kruipend ongedierte, 0.2 % w/w permethrin	HGX tegen vliegend en kruipend ongedierte does not contain oxidising substances and does not have to be classified according the criteria for oxidising liquids described in the section 2.13 of Annex I to the CLP Regulation and in line with the UN Manual (2019, A6.3.	[redacted] 2018a, 2021a IUCLID 3.0 summary

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			An elaborate justification is presented in the Confidential Annex of this document.	
Oxidising solids	n.a.		Not required for an AE formulation type	
Organic peroxides	n.a.		Not applicable, the product contains no organic peroxides.	
Corrosive to metals	UN Transport of Dangerous Goods Manual 2009 Section 37 Class 8	HG against crawling pest 0.2 % w/w permethrin	A corrosion test has been performed by COT bv and the HG tegen kruipend ongedierte For both the steel and the aluminium, 3 sets of 3 panels have been used for exposure to the biocidal product for 7 days at 57°C, fully immersed, half immersed and exposed to the gas phase. All steel panels show uniform corrosion and a mass loss of <1 % for total immersion, halfway immersion, and gas phase. All aluminium panels show uniform corrosion and a mass loss of < 0.1% for total immersion, halfway immersion, and gas phase. Therefore, HG against crawling pests) is classified according to Part III, section 37 of UN 2009, Transport of dangerous goods, Class B, as noncorrosive	[redacted] COT BV, 2021
Auto-ignition temperatures of products (liquids and gases)	EU Test Method A.15	HGX tegen vliegend en kruipend ongedierte, 0.2 % w/w permethrin	No auto-ignition of the test substance occurred up to a temperature of 650°C	[redacted], 2018 IUCLID 4.17
Relative self-ignition temperature for solids	n.a.		Not required for an AE formulation type	
Dust explosion hazard	n.a.		Not required for an AE formulation type	

Conclusion on the physical hazards and respective characteristics of the product
All products in MetaSPC 1 - Spray can : HG tegen kruipend ongedierte aerosol are classified category 3 aerosol and therefore the hazard phrase H229 (Pressurized container: may burst if heated) should be added to the label. HG tegen kruipend ongedierte has no flash point up to 100°C. No auto-ignition of the test substance occurred up to a temperature of 650°C. The products of BPF 'HG tegen kruipend ongedierte' are not explosive or oxidizing. Neither do they have self-reactive, self-heating properties or pyrophoric properties. The test on corrosiveness to metals shows HG tegen kruipend ongedierte is non-corrosive.

2.2.4 Methods for detection and identification

The product HG spraycan contains permethrin as active substance, which has been included in the current Union List of authorized active substances; an EU Assessment Report is available. Applicant has a Letter of Access to the Union List inclusion dossier for permethrin. For analytical methods, reference is made to the permethrin Assessment Report.

The HPLC-PDA method (HG Method W265) used to determine the permethrin concentration in the product in the accelerated storage stability study was validated in a separate study. The validation study (see summary in IUCLID section 5) showed linearity, specificity, accuracy, repeatability and precision of the analytical method to be acceptable (see table below).
For determination of linearity of detector response for permethrin six concentration levels were assessed ranging from 5 – 50 mg/L.
The blank formulation shows no interfering or co-eluting peaks during the elution time of the analysis at the specified wavelength. Samples of blank formulation spiked with technical permethrin show eluting peaks at the expected retention times and in the same ratio trans- and cis-permetrhin.
For determination of accuracy (recovery) aliquots of formulation blank were spiked with permethrin at 0.2 mg/L (=100%) (in duplo) and injected in duplicate.
For determination of repeatability, three samples were measured (each sample injected twice) giving < 0.3% RSD measured on a concentration level of 0.2% permethrin.
For verification of system precision, one sample was measured five times (5 injections). The determined method precision is < 0.3% RSD. The results meets the acceptance criterion RSD < 3.41 (maximum relative standard deviation calculated according to the modified Horwitz equation).

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Precision**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		

Permethrin	HPLC-PDA (272 nm)	(A) Three different samples each injectes twice: mean 0.2019%, RSD 0.29% RSD <Horwitz RSDr (3.41%) (B) One sample injectes five times: mean 0.2017%, RSD 0.22% RSD <Horwitz RSDr (3.41%)	Y = 0.5144 + 2.58796 x R^2 = 0.99998 Linearity range: 5-50 mg/L, equivalent to 25-250% of nominal, 6 concentration levels	No interference from matrix (formulation blank)	Fortification level a.s. 0.2% (n=4): Recovery 96.1-99.1%	97.6 %	1.44 %	Not applicable	 2018 L Appendix 1 – results, Appendix 2- calculation and Appendix 3 – CoA permethrin

Analytical methods for monitoring residues in food of plant and animal origin are not relevant for this specific non-crop use and/or reference is made to the methods presented in the EU assessment report.

An acceptable validated HPLC-MS/MS method for residues of permethrin in soil (LOQ 5.0 µg/kg) was presented in the EU assessment report.

Acceptable validated methods were provided for residues of permethrin in air (lowest LOQ 0.1 µg/m^3 air).

Acceptable validated methods were provided for residues of permethrin in drinking water and surface water (LOQ 0.05 µg/L for drinking water and surface water).

Conclusion on the methods for detection and identification of the product
The analytical method, HPLC-PDA, is considered sufficiently validated in order to determine the active substance permethrin in the biocidal product. Acceptable validated method are presented in the EU assessment report for determination of residues of permethrin in soil (LOQ 5.0 µg/kg), air (lowest LOQ 0.1 µg/m^3 air) and water (LOQ 0.05 µg/L for drinking water and surface water).

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

HG tegen kruipend ongedierte is a biocidal product family (BPF) with one Meta SPC containing insecticidal products for the non-professional use against crawling insects. The products are based on the active substance permethrin.

The product is exclusively intended for:
Indoor cracks and crevices application against crawling insects, outdoor cracks and crevices application (ant nests) .

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

The products are used for control of crawling insects, including the following organisms:

Scientific name: Blattodea
Common name: Cockroaches
Development stage: adults and nymphs

Scientific name: Formicidae
Common name: ants
Development stage: all stages

Scientific name: Lepismatidae:
Common name: Silverfishes
Development stage: adults

The products are used for the protection of humans against nuisance pests.

2.2.5.3 Effects on target organisms, including unacceptable suffering

HG tegen kruipend ongedierte contains the active ingredient permethrin.

Permethrin is a contact insecticide which is primarily taken up through the extremities. Permethrin affects both the peripheral and central nervous systems of target insects, causing convulsions, paralysis and ultimately death in target organisms.

2.2.5.4 Mode of action, including time delay

The primary insecticidal mode of action of permethrin is interference with the voltage-gated sodium channels of insects. Closure of the sodium channels is delayed during depolarization, thereby initiating repetitive discharges in motor and sensory axons. The effects of the axon hyperexcitation are characterised by progressive fine whole body tremor, exaggerated start response, uncoordinated muscle twitching, hyperexcitability and eventually death. Permethrin also induces hepatic microsomal enzymes.

As a type I axonic poison, it has a negative temperature correlation; the lower the surrounding temperature the more toxic it becomes to insects. This negative temperature dependence is one of the contributing factors to permethin's high potency and selectivity for insects over mammals.

Besides being an effective insecticide, permethrin also exhibits a mild contact repellent effect. This contact repellence effect is known as the "hot-foot effect" and may be relevant for some arthropods. The repellent effect is dose related and for insecticidal products the repellent effect of permethrin is considered as a side effect, since the toxic response of the insect is a delayed kill (insecticidal) effect.

2.2.5.5 Efficacy data

An overview of all efficacy tests which are performed is given below.

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

Indoors &outdoors: Non-professional</td><td>HGX Insecticide Spray Aerosol

0.2% permethrin w/w

(Meta 1)</td><td>Lasius niger (Black garden ant)</td><td>Field test

According to Guidance on the Biocidal Products Regulation-Volume II Efficacy Parts B&C – version 3.0 April 2018 ECHA, C.E.B method MG1 and No196

Location: Lawns/gardens, grass/meadow and pavement/industrial areas in Anglet, Macay, Bayonne, Tamos, Biarritz and Mendionde in the south of of France.

Test period: September 17th 2018 – October 29th 2018

Application rate: 0 (untreated) and 12.5 ml/nest (25mg/ permethrin per nest) , Application frequency: one application on T=0 days.

Treated area: the nestopening of the nest</td><td>
<table>
<tr><th>Days after application</th><th>FCS reduction - Untreated control</th><th>FCS reduction - Test product at 12.5 ml/m^2</th></tr>
<tr><td>1</td><td>1.7</td><td>91.7</td></tr>
<tr><td>3</td><td>-3.2</td><td>95.3</td></tr>
<tr><td>7</td><td>1.5</td><td>97.7</td></tr>
<tr><td>14</td><td>-4.5</td><td>100</td></tr>
<tr><td>28</td><td>-2.2</td><td>100</td></tr>
<tr><td>42</td><td>3.4</td><td>100</td></tr>
</table>
At the final observations (after 6 weeks) the treated nests were opened. No alive larvae, adults or queens were observed in the treated nests.
</td><td>[redacted] 2018f. Field trial of the efficacy of an insecticidal product against ants.

2389f-aeosol-LN/0918</td></tr>
</table>

<table>
<tr><th>Function and Field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test Method/Test sytem/concentrations applied/exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>Frequency of Crossing in Surface (FCS) was assessed in the morning and always at the same hour of the day at T= -1, 1, 3, 7, 14, 28 and 42 days after application.

Replicates: 5 nests (+ 5 untreated controls)</td><td></td><td></td></tr>
<tr><td>Insecticide

Indoors &outdoors: Non-professional</td><td>HGX Insecticide Spray Aerosol

0.2% permethrin w/w

(Meta 1)</td><td>Lasius niger (black garden ant) – 25 adult workers per replicate</td><td>Simulated-use test

Guidance on the Biocidal Products Regulation-Volume II Efficacy Parts B&C –version 3.0 April 2018 ECHA

Application rate: 0 (untreated control) and 25 ml/m^2 (=50 mg permethrin per m^2), single application at the start of the treatment.

Test room: 3 x 2 x 2 m chamber (12 m^3) with walls made of non-sorbent epoxide panels and a ceramic tile floor. Some panels (2 m^2) of materials treated with the product were set on the half of the floor. A few cardboards (to give harborages to the insects) and water + food sources (4 each) were set on the floor of the test chamber. The water and food sources were not located on the treated panels.</td><td>Knockdown (time required to achieve 100% knockdown):

<table><tr><td>Lasius niger</td><td>Cement</td><td>Ceramic tile</td></tr><tr><td>KD day 0</td><td>4 h</td><td>4 h</td></tr><tr><td>KD 6 weeks</td><td>4 h</td><td>4 h</td></tr></table>
Mortality (after 24h exposure):

<table><tr><td>Lasius niger</td><td>Cement</td><td>Ceramic tile</td></tr><tr><td>Mortality day 0</td><td>100%</td><td>100%</td></tr><tr><td>Mortality Day 0 + 6 weeks</td><td>100%</td><td>100%</td></tr></table>
The mortality in the untreated controls was 0%.</td><td>2018d. Simulated-use trial of the efficacy of an insecticidal product against various pests.

2389d aeosol-SIMUSE/0918</td></tr>
</table>

<table>
<tr><th>Function and Field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test Method/Test sytem/concentrations applied/exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>Exposure time: 24 hours, knockdown was assessed after 4 hours, mortality was observed after 24 hours.

Replicates: 5 (+ 5 for the untreated control), 25 insects per replicate

2 types of treated surfaces:

porous:
-cement

non-porous:
-ceramic tile

Residual efficacy tested after 6 weeks.

Environmental conditions:
22°C +/- 1°C, relative humidity: 60 +/- 5% and 8 hours light per day of 800 lux, <1 m^3/h ventilation</td><td></td><td></td></tr>
<tr><td>Insecticide

Indoors &outdoors: Non-professional</td><td>HGX Insecticide Spray Aerosol

0.2% permethrin w/w

(Meta 1)</td><td>Lasius niger (black garden ant) - 25 adult workers per replicate</td><td>Laboratory test – no choice trial

According to Guidance on the Biocidal Products Regulation-Volume II Efficacy Parts B&C – version 3.0 April 2018 ECHA and C.E.B method No135/159

Application rate: 0 (untreated control) and 25 ml/m^2 (=50 mg permethrin per m^2),</td><td>Knockdown (time required to achieve 100% knockdown):
<table><tr><th>Ants</th><th>Concrete</th><th>Wood</th><th>Ceramic tile</th><th>Steel</th></tr><tr><td>KD day 0</td><td>1 hour</td><td>1 hour</td><td>1 hour</td><td>1 hour</td></tr><tr><td>KD 6 weeks</td><td>1 hour</td><td>1 hour</td><td>1 hour</td><td>1 hour</td></tr></table></td><td>2018c. Laboratory trial of the efficacy of a insecticidal product against various flying and crawling target organisms (German and oriental cockroaches, ants,</td></tr>
</table>

<table>
<tr><th>Function and Field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test Method/Test sytem/concentrations applied/exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>single application at the start of the treatment.

Exposure time: 1 hour, knockdown and mortality observed up to 24 hours after exposure.

Replicates: 5 (+ 5 for the untreated control), 25 insects per replicate

4 types of treated surfaces (15X15 cm, covered by a petri dish of 14 cm diameter):

porous:
-concrete
-unpainted wood

non-porous:
-ceramic tiles
-steel

Residual efficacy tested after 6 weeks.

Environmental conditions:
22°C +/- 2°C, relative humidity: 70 +/- 5%,
stored and 16 hours light per day of 1200 lux, ventilation 1 m3/h.</td><td>Mortality (24h after exposure):

<table><tr><th>Ants</th><th>Concrete</th><th>Wood</th><th>Ceramic tile</th><th>Steel</th></tr><tr><td>Mortality day 0</td><td>100 %</td><td>100 %</td><td>100 %</td><td>100 %</td></tr><tr><td>Mortality Day 0 + 6 weeks</td><td>100 %</td><td>100 %</td><td>100 %</td><td>100 %</td></tr></table>
The mortality in the untreated controls was less than 5%.</td><td>fleas, silverfishes, flies, mosquitoes, wasps, clothes moths, spiders, litter beetles).

2389c aeosol-LAB/0918</td></tr>
<tr><td>Insecticide

Indoor</td><td>HGX Insecticide Spray</td><td>Blattella germanica (German</td><td>Simulated-use test

Guidance on the Biocidal</td><td>Blatella germanica

Knockdown (time required to achieve</td><td>[redacted] 2018d. Simulated-use trial of the</td></tr>
</table>

<table>
<tr><th>Function and Field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test Method/Test sytem/concentrations applied/exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr>
<td>Non-professional</td>
<td>Aerosol

0.2% permethrin w/w

(Meta 1)</td>
<td>cockroach)– 10 males + 10 virgin females + 5 second stage juveniles per replicate

Blatta oreintalis (oriental cockroach)– 10 males + 10 virgin females + 5 second stage juveniles per replicate</td>
<td>Products Regulation-Volume II Efficacy Parts B&C –version 3.0 April 2018 ECHA

Application rate: 0 (untreated control) and 25 ml/m^2 (=50 mg permethrin per m^2),
single application at the start of the treatment.

Test room: 3 x 2 x 2 m chamber (12 m^3) with walls made of non-sorbent epoxide panels and a ceramic tile floor. Some panels (2 m^2) of materials treated with the product were set on the half of the floor. A few cardboards (to give harborages to the insects) and water + food sources (4 each) were set on the floor of the test chamber. The water and food sources were not located on the treated panels.

Exposure time: 24 hours, knockdown was assessed after 4 hours, mortality was observed after 24 hours.

Replicates: 5 (including 5 for the untreated control), 25 insects per replicate

4 types of treated surfaces

porous:</td>
<td>100% knockdown):
<table>
<tr><td>Adult</td><td>Cement</td><td>Ceramic tile</td></tr>
<tr><td>KD day 0</td><td>4 h</td><td>4 h</td></tr>
<tr><td>KD 6 weeks</td><td>4 h</td><td>4 h</td></tr>
</table>
<table>
<tr><td>Nymph</td><td>Cement</td><td>Ceramic tile</td></tr>
<tr><td>KD day 0</td><td>4 h</td><td>4 h</td></tr>
<tr><td>KD 6 weeks</td><td>4 h</td><td>4 h</td></tr>
</table>
Mortality (after 24h exposure):
<table>
<tr><td>Adult</td><td>Cement</td><td>Ceramic tile</td></tr>
<tr><td>Mortality day 0</td><td>100%</td><td>100%</td></tr>
<tr><td>Mortality Day 0 + 6 weeks</td><td>100%</td><td>100%</td></tr>
</table>
<table>
<tr><td>Nymph</td><td>Cement</td><td>Ceramic tile</td></tr>
<tr><td>Mortality day 0</td><td>100%</td><td>100%</td></tr>
<tr><td>Mortality Day 0 + 6 weeks</td><td>100%</td><td>100%</td></tr>
</table>
The mortality in the untreated controls was 0%.

Blatta orientalis</td>
<td>efficacy of an insecticidal product against various pests.

2389d aeosol-SIMUSE/0918</td>
</tr>
</table>

<table>
<tr><th>Function and Field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test Method/Test sytem/concentrations applied/exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>-cement

non-porous:
-ceramic tile

Residual efficacy tested after 6 weeks.

Environmental conditions:
22°C +/- 2°C, relative humidity: 60 +/- 5% and 8 hours light per day of 800 lux, <1 m^3/h ventilation</td><td>Knockdown (time required to achieve 100% knockdown):
<table>
<tr><td>Adult</td><td>Cement</td><td>Ceramic tile</td></tr>
<tr><td>KD day 0</td><td>4 h</td><td>4 h</td></tr>
<tr><td>KD 6 weeks</td><td>4 h</td><td>4 h</td></tr>
</table>
<table>
<tr><td>Nymph</td><td>Cement</td><td>Ceramic tile</td></tr>
<tr><td>KD day 0</td><td>4 h</td><td>4 h</td></tr>
<tr><td>KD 6 weeks</td><td>4 h</td><td>4 h</td></tr>
</table>
Mortality (after 24h exposure):
<table>
<tr><td>Adult</td><td>Cement</td><td>Ceramic tile</td></tr>
<tr><td>Mortality day 0</td><td>100%</td><td>100%</td></tr>
<tr><td>Mortality Day 0 + 6 weeks</td><td>100%</td><td>100%</td></tr>
</table>
<table>
<tr><td>Nymph</td><td>Cement</td><td>Ceramic tile</td></tr>
<tr><td>Mortality day 0</td><td>100%</td><td>100%</td></tr>
<tr><td>Mortality Day 0 + 6 weeks</td><td>100%</td><td>100%</td></tr>
</table>
The mortality in the untreated controls was 0%.</td><td></td></tr>
<tr><td>Insecticide</td><td>HGX</td><td>Blattella</td><td>Laboratory test – no choice trial</td><td>Blatella germanica</td><td></td></tr>
</table>

<table>
<tr><th>Function and Field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test Method/Test sytem/concentrations applied/exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr>
<td>Indoor Non-professional</td>
<td>Insecticide Spray Aerosol

0.2% permethrin w/w

(Meta 1)</td>
<td>germanica (German cockroach) – 10 males + 10 virgin females + 5 second stage juveniles per replicate

Blatta oreintalis (oriental cockroach) – 10 males + 10 virgin females + 5 second stage juveniles per replicate</td>
<td>According to Guidance on the Biocidal Products Regulation-Volume II Efficacy Parts B&C – version 3.0 April 2018 ECHA and C.E.B method No135/159

Application rate: 0 (untreated control) and 25 ml/m^2 (=50 mg permethrin per m^2), single application at the start of the treatment.

Exposure time: 1 hour, knockdown and mortality observed up to 24 hours after exposure.

Replicates: 5 (including 5 for the untreated control), 25 insects per replicate

4 types of treated surfaces (15X15 cm, covered by a petri dish of 14 cm diameter):

porous:
-concrete
-unpainted wood

non-porous:
-ceramic tiles
-steel

Residual efficacy tested after 6 weeks.</td>
<td>Knockdown (time required to achieve 100% knockdown):

<table>
<tr><td>Adult</td><td>Concrete</td><td>Wood</td><td>Ceramic tile</td><td>Steel</td></tr>
<tr><td>KD day 0</td><td>1 h</td><td>1 h</td><td>1 h</td><td>1 h</td></tr>
<tr><td>KD 6 weeks</td><td>2 h</td><td>2 h</td><td>1 h</td><td>1 h</td></tr>
</table>

<table>
<tr><td>Nymph</td><td>Concrete</td><td>Wood</td><td>Ceramic tile</td><td>Steel</td></tr>
<tr><td>KD day 0</td><td>1 h</td><td>1 h</td><td>1 h</td><td>1 h</td></tr>
<tr><td>KD 6 weeks</td><td>1 h</td><td>1 h</td><td>1 h</td><td>1 h</td></tr>
</table>

Mortality (24h after exposure):

<table>
<tr><td>Adult</td><td>Concrete</td><td>Wood</td><td>Ceramic tile</td><td>Steel</td></tr>
<tr><td>Mortality day 0</td><td>100 %</td><td>100 %</td><td>100 %</td><td>100 %</td></tr>
<tr><td>Mortality Day 0 + 6 weeks</td><td>100 %</td><td>100 %</td><td>100 %</td><td>100 %</td></tr>
</table>

<table>
<tr><td>Nymph</td><td>Concrete</td><td>Wood</td><td>Ceramic tile</td><td>Steel</td></tr>
<tr><td>Mortality day 0</td><td>100 %</td><td>100 %</td><td>100 %</td><td>100 %</td></tr>
<tr><td>Mortality Day 0 +</td><td>100 %</td><td>100 %</td><td>100 %</td><td>100 %</td></tr>
</table>
</td>
<td>2018c. Laboratory trial of the efficacy of a insecticidal product against various flying and crawling target organisms (German and oriental cockroaches, ants, fleas, silverfishes, flies, mosquitoes, wasps, clothes moths, spiders, litter beetles).

2389c aeosol-LAB/0918</td>
</tr>
</table>

<table>
<tr><th>Function and Field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test Method/Test sytem/concentrations applied/exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>Environmental conditions:
22°C +/- 2°C, relative humidity: 70 +/- 5%,
stored and 16 hours light per day of 1200 lux, ventilation 1 m^3/h.</td><td>
<table>
<tr><td>6 weeks</td><td></td><td></td><td></td><td></td></tr>
</table>

The mortality in the untreated controls was less than 5%.

Blatta orientalis

Knockdown (time required to achieve 100% knockdown):
<table>
<tr><td>Adult</td><td>Concrete</td><td>Wood</td><td>Ceramic tile</td><td>Steel</td></tr>
<tr><td>KD day 0</td><td>1 h</td><td>1 h</td><td>1 h</td><td>1 h</td></tr>
<tr><td>KD 6 weeks</td><td>4 h</td><td>4 h</td><td>1 h</td><td>1 h</td></tr>
</table>

<table>
<tr><td>Nymph</td><td>Concrete</td><td>Wood</td><td>Ceramic tile</td><td>Steel</td></tr>
<tr><td>KD day 0</td><td>1 h</td><td>1 h</td><td>1 h</td><td>1 h</td></tr>
<tr><td>KD 6 weeks</td><td>1 h</td><td>1 h</td><td>1 h</td><td>1 h</td></tr>
</table>

Mortality (24h after exposure):
<table>
<tr><td>Adult</td><td>Concrete</td><td>Wood</td><td>Ceramic tile</td><td>Steel</td></tr>
<tr><td>Mortality day 0</td><td>100 %</td><td>100 %</td><td>100 %</td><td>100 %</td></tr>
<tr><td>Mortality Day 0 + 6 weeks</td><td>100 %</td><td>100 %</td><td>100 %</td><td>100 %</td></tr>
</table>

<table>
<tr><td>Nymph</td><td>Conc</td><td>Woo</td><td>Cera</td><td>Steel</td></tr>
</table>
</td><td></td></tr>
</table>

<table>
<tr><th>Function and Field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test Method/Test sytem/concentrations applied/exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td></td><td>
<table>
<tr><td></td><td>rete</td><td>d</td><td>mic tile</td><td></td></tr>
<tr><td>Mortality day 0</td><td>100 %</td><td>100 %</td><td>100 %</td><td>100 %</td></tr>
<tr><td>Mortality Day 0 + 6 weeks</td><td>100 %</td><td>100 %</td><td>100 %</td><td>100 %</td></tr>
</table>
The mortality in the untreated controls was less than 5%.
</td><td></td></tr>
<tr><td>Insecticide

Indoor Non-professional</td><td>HGX Insecticide Spray Aerosol

0.2% permethrin w/w

(Meta 1)</td><td>Lepisma saccharina (silverfish) - 25 adults per replicate</td><td>Laboratory test – no choice trial

According to Guidance on the Biocidal Products Regulation-Volume II Efficacy Parts B&C – version 3.0 April 2018 ECHA and C.E.B method No135/159

Application rate: 0 (untreated control) and 25 ml/m^2 (=50 mg permethrin per m^2), single application at the start of the treatment.

Exposure time: 1 hour, knockdown and mortality observed up to 24 hours after exposure.

Replicates: 5 (including 5 for the untreated control), 25 insects per replicate

4 types of treated surfaces (15X15 cm, covered by a petri dish of 14 cm diameter):</td><td>Knockdown (time required to achieve 100% knockdown):
<table>
<tr><th>Lepisma saccharina</th><th>Concrete</th><th>Wood</th><th>Ceramic tile</th><th>Steel</th></tr>
<tr><td>KD day 0</td><td>1 hour</td><td>1 hour</td><td>1 hour</td><td>1 hour</td></tr>
<tr><td>KD 6 weeks</td><td>1 hour</td><td>1 hour</td><td>1 hour</td><td>1 hour</td></tr>
</table>
Mortality (24h after exposure):
<table>
<tr><th>Lepisma saccharina</th><th>Concrete</th><th>Wood</th><th>Ceramic tile</th><th>Steel</th></tr>
<tr><td>Mortality day 0</td><td>100 %</td><td>100 %</td><td>100 %</td><td>100 %</td></tr>
<tr><td>Mortality Day 0 + 6 weeks</td><td>100 %</td><td>100 %</td><td>100 %</td><td>100 %</td></tr>
</table>
The mortality in the untreated controls was less than 5%.</td><td>[redacted] 2018c. Laboratory trial of the efficacy of a insecticidal product against various flying and crawling target organisms (German and oriental cockroaches, ants, fleas, silverfishes, flies, mosquitoes, wasps, clothes moths, spiders, litter beetles).

2389c aeosol-LAB/0918</td></tr>
</table>

<table>
<tr><th>Function and Field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test Method/Test sytem/concentrations applied/exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>porous:
-concrete
-unpainted wood

non-porous:
-ceramic tiles
-steel

Residual efficacy tested after 6 weeks.

Environmental conditions:
22°C +/- 2°C, relative humidity: 70 +/- 5%,
stored and 16 hours light per day of 1200 lux, ventilation 1 m^3/h</td><td></td><td></td></tr>
<tr><td>Insecticide

Indoor Non-professional</td><td>HG against crawling insects

Aerosol 0.2% permethrin w/w

(Meta 1)</td><td>Lasius niger (black garden ant) - 60 adult workers per replicate</td><td>Simulated-use test

Guidance on the Biocidal Products Regulation-Volume II Efficacy Parts B&C –version 3.0 April 2018 ECHA
Application rate: 0 (untreated control) and 25 ml/m2 (=50 mg permethrin per m2), single application at the start of the treatment

Test room: 3 x 2 x 2 m chamber (12 m3) is 6 m² surface
The test chambers walls are made of non-sorbent epoxide panels and the floor is made of ceramic tiles. A “furniture” is built to represent the</td><td>TABLE I: % of mortality of the target organisms in the test chamber after 24 hours of exposure – POROUS MATERIAL
<table>
<tr><th>TREATMENT</th><th>TARGET ORGANISM</th><th>AGE OF THE TREATMENT</th><th>Mortality Mean %</th><th>Standard deviation</th></tr>
<tr><td>HG against crawling insects</td><td>Lasius niger</td><td>0</td><td>100%</td><td>0.0</td></tr>
<tr><td>HG against crawling insects</td><td>Lasius niger</td><td>+6 weeks</td><td>100%</td><td>0.0</td></tr>
</table></td><td>EFFICACY OF AN INSECTICIDAL PRODUCT CRACKS AND CREVICES TREATMENT CRAWLING INSECTS Study TEC number 2628/1120</td></tr>
</table>

<table>
<tr><th>Function and Field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test Method/Test sytem/concentrations applied/exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>reality of cracks and crevices but only the first visible part is treated, to simulate the real conditions of application. The “furniture” is a pile of 5 non-porous lacquer wood boards of 1 m x 1 m (usual dimensions of kitchen furniture), assembled together but letting a 3 cm space between each other in order to create the cracks/crevices. On the first 15 cm of these cracks/crevice (entry of the "furniture"), 16 ceramic tiles of 15 cm x 15 cm are set of the material to be claimed but only 2/3 of its surface is treated (first 10 cm are treated and 5 cm are not treated). In total, 0.24 m2 treated surface per test chamber.
They are set on their porous side. Four water + food sources are set in the corners of the test chamber and the insects are able to reach it without being in contact with the product. - water source (4 x 25 cm long water vials with a cotton</td><td>
<table>
<tr><td>TREATMENT</td><td>TARGET ORGANISM</td><td>AGE OF THE TREATMENT</td><td>Mortality Mean %</td><td>Standard deviation</td></tr>
<tr><td>Untreated control</td><td>Lasius niger</td><td>0</td><td>0.7</td><td>0.9</td></tr>
<tr><td>Untreated control</td><td>Lasius niger</td><td>+6 weeks</td><td>0.0</td><td>0.0</td></tr>
</table>
TABLE II: % of mortality of the target organisms in the test chamber after 24 hours of exposure – NON-POROUS MATERIAL
<table>
<tr><td>TREATMENT</td><td>TARGET ORGANISM</td><td>AGE OF THE TREATMENT</td><td>Mortality Mean %</td><td>Standard devi attion</td></tr>
<tr><td>HG against crawling insects</td><td>Lasius niger</td><td>0</td><td>100%</td><td>0.0</td></tr>
<tr><td>HG against crawling insects</td><td>Lasius niger</td><td>6 weeks</td><td>100%</td><td>0.0</td></tr>
</table>
</td><td></td></tr>
</table>

<table>
<tr><th>Function and Field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test Method/Test sytem/concentrations applied/exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>wick) - food source (4 Petri dishes with pet food biscuit) → food and water sources are not on the treated surfaces

Exposure time: 24 hours, knockdown was assessed after 4 hours, mortality was observed after 24 hours.

Replicates: 5 (including 5 for the untreated control), 60 insects per replicate

2 types of treated surfaces 16 tiles of (15X15 cm, of which is treated 10x15 cm):

porous:
ceramic tile porous side

non-porous:
-ceramic tile

Residual efficacy tested after 6 weeks.

Environmental conditions:
22°C +/- 2°C, relative humidity: 60 +/- 5% and 8 hours light per day of 800 lux, <1 m3/h ventilation</td><td><table><tr><td></td><td></td><td></td><td></td><td></td></tr></table>
<table><tr><td>TREATMENT</td><td>TARGET ORGANISM</td><td>AGE OF THE TREATMENT</td><td>Mortality Mean %</td><td>Standard deviation</td></tr><tr><td>Untreated control</td><td>Lasius niger</td><td>0</td><td>0</td><td>0</td></tr><tr><td>Untreated control</td><td>Lasius niger</td><td>+6 weeks</td><td>0</td><td>0</td></tr></table></td><td></td></tr>
<tr><td>Insecticide

Indoor</td><td>HG against crawling insects</td><td>Blattella germanica (German</td><td>Simulated-use test

Guidance on the Biocidal</td><td>TABLE I: % of mortality of the target organisms in the test chamber after</td><td>EFFICACY OF AN INSECTICIDAL</td></tr>
</table>

<table>
<tr><th>Function and Field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test Method/Test sytem/concentrations applied/exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr><td>Non-professional</td><td>Aerosol 0.2% permethrin w/w

(Meta 1)</td><td>cockroach) – 20 males + 20 virgin females + 20 second stage juveniles per replicate

Blatta oreintalis (oriental cockroach) – 20 males +20 virgin females + 5 second stage juveniles per replicate</td><td>Products Regulation-Volume II Efficacy Parts B&C –version 3.0 April 2018 ECHA
Application rate: 0 (untreated control) and 25 ml/m2 (=50 mg permethrin per m2), single application at the start of the treatment

Test room: 3 x 2 x 2 m chamber (12 m3) is 6 m² surface
The test chambers walls are made of non-sorbent epoxide panels and the floor is made of ceramic tiles. A “furniture” is built to represent the reality of cracks and crevices but only the first visible part is treated, to simulate the real conditions of application. The “furniture” is a pile of 5 non-porous lacquer wood boards of 1 m x 1 m (usual dimensions of kitchen furniture), assembled together but letting a 3 cm space between each other in order to create the cracks/crevices. On the first 15 cm of these cracks/crevice (entry of the "furniture"), 16 ceramic tiles of 15 cm x 15 cm are set of</td><td>24 hours of exposure -POROUS MATERIAL
<table><tr><th>TREATMENT</th><th>TARGET ORGANISM</th><th>AGE OF THE TREATMENT</th><th>Mortality Mean %</th><th>Standard deviation</th></tr><tr><td>HG against crawling insects</td><td>Blattella germanica adults</td><td>0</td><td>100%</td><td>0.0</td></tr><tr><td>HG against crawling insects</td><td>Blatta oreintalis l adults</td><td>0</td><td>100%</td><td>0.0</td></tr><tr><td>HG against crawling insects</td><td>Blattella germanica Adults</td><td>+6 weeks</td><td>100%</td><td>0.0</td></tr><tr><td>HG against crawling insects</td><td>Blatta oreintalis adults</td><td>+6 weeks</td><td>100%</td><td>0.0</td></tr><tr><td>HG against crawling insects</td><td>Blattella germanica Nymphs</td><td>0</td><td>100%</td><td>0.0</td></tr><tr><td>HG against</td><td>Blatta oreint</td><td>0</td><td>100%</td><td>0.0</td></tr></table></td><td>PRODUCT CRACKS AND CREVICES TREATMENT CRAWLING INSECTS Study TEC number 2628/1120</td></tr>
</table>

<table>
<tr><th>Function and Field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test Method/Test sytem/concentrations applied/exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>the material to be claimed but only 2/3 of its surface is treated (first 10 cm are treated and 5 cm are not treated). In total, 0.24 m2 treated surface per test chamber.
They are set on their porous side. Four water + food sources are set in the corners of the test chamber and the insects are able to reach it without being in contact with the product. - water source (4 x 25 cm long water vials with a cotton wick) - food source (4 Petri dishes with pet food biscuit) → food and water sources are not on the treated surfaces

Exposure time: 24 hours, knockdown was assessed after 4 hours, mortality was observed after 24 hours.

Replicates: 5 (including 5 for the untreated control), 60 insects per replicate

2 types of treated surfaces 16 tiles of (15X15 cm, of which is treated 10x15 cm):</td>
<td>
<table>
<tr><td>crawling insects</td><td>alis Nymphs</td><td></td><td></td><td></td></tr>
<tr><td>HG against crawling insects</td><td>Blattella germanica Nymphs</td><td>+6 weeks</td><td>100%</td><td>0.0</td></tr>
<tr><td>HG against crawling insects</td><td>Blatta oreintalis oriental Nymphs</td><td>+6 weeks</td><td>100%</td><td>0.0</td></tr>
</table>
<table>
<tr><th>TREATMENT</th><th>TARGET ORGANISM</th><th>AGE OF THE TREATMENT</th><th>Mortality Mean %</th><th>Standa deviatic</th></tr>
<tr><td>Untreated control</td><td>Blattella germanica adults</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>Untreated control</td><td>Blatta oreintalis adults</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>Untreated control</td><td>Blattella germanica adults</td><td>+6 weeks</td><td>0</td><td>0</td></tr>
</table>
</td>
<td></td>
</tr>
</table>

<table>
<tr><th>Function and Field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test Method/Test sytem/concentrations applied/exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>porous:
ceramic tile porous side

non-porous:
-ceramic tile

Residual efficacy tested after 6 weeks.

Environmental conditions:
22°C +/- 2°C, relative humidity: 60 +/- 5% and 8 hours light per day of 800 lux, <1 m3/h ventilation</td><td>
<table>
<tr><td>Untreated control</td><td>Blatta oreintalis adults</td><td>+6 weeks</td><td>0</td><td>0</td><td></td></tr>
<tr><td>Untreated control</td><td>Blattella germanica Nymps</td><td>0</td><td>0.7</td><td>0.9</td><td></td></tr>
<tr><td>Untreated control</td><td>Blatta oreintalis Nymps</td><td>0</td><td>0</td><td>0</td><td></td></tr>
<tr><td>Untreated control</td><td>Blattella germanica Nymps</td><td>+6 weeks</td><td>0</td><td>0</td><td></td></tr>
<tr><td>Untreated control</td><td>Blatta oreintalis Nymps</td><td>+6 weeks</td><td>0</td><td>0</td><td></td></tr>
</table>

TABLE II: % of mortality of the target organisms in the test chamber after 24 hours of exposure– NON – POROUS MATERIAL
<table>
<tr><th>TREATMENT</th><th>TARGET ORGANISM</th><th>AGE OF THE TREATMENT</th><th>Mortality Mean %</th><th>Standard deviation</th></tr>
<tr><td>HG against crawling insects</td><td>Blattella germanica adults</td><td>0</td><td>100%</td><td>0</td></tr>
<tr><td>HG</td><td>Blatta</td><td>0</td><td>100%</td><td>0</td></tr>
</table>
</td><td></td></tr>
</table>

Function and Field of use envisaged	Test substance	Test organism(s)	Test Method/Test sytem/concentrations applied/exposure time	Test results: effects					Reference
				against crawling insects	*oreintalis* adults				
				HG against crawling insects	*Blattella germanica* adults	+6 weeks	100%	0	
				HG against crawling insects	*Blatta oreintalis* adults	+6 weeks	100%	0	
				HG against crawling insects	*Blattella germanica* Nymps	0	100%	0	
				HG against crawling insects	*Blatta oreintalis* Nymps	0	100%	0	
				HG against crawling insects	*Blattella germanica* Nymps	+6 weeks	100%	0	
				HG against crawling	*Blatta oreintalis* Nymps	+6 weeks	100%	0	

<table>
<tr><th>Function and Field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test Method/Test sytem/concentrations applied/exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td></td><td>
<table>
<tr><td>insects</td><td></td><td></td><td></td><td></td></tr>
</table>
<table>
<tr><td>TREATMENT</td><td>TARGET ORGANISM</td><td>AGE OF THE TREATMENT</td><td>Mortality Mean %</td><td>Standard deviation</td></tr>
<tr><td>Untreated control</td><td>Blattella germanica adults</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>Untreated control</td><td>Blatta oreintalis adults</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>Untreated control</td><td>Blattella germanica Nymphs</td><td>+6 weeks</td><td>0</td><td>0</td></tr>
<tr><td>Untreated control</td><td>Blatta oreintalis Nymps</td><td>+6 weeks</td><td>0</td><td>0</td></tr>
<tr><td>Untreated control</td><td>Blattella germanica Nymphs</td><td>0</td><td>0.3</td><td>0.7</td></tr>
<tr><td>Untreated control</td><td>Blatta oreintalis adults</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>Untreated control</td><td>Blattella germanica Nymphs</td><td>+6 weeks</td><td>0</td><td>0</td></tr>
</table>
</td><td></td></tr>
</table>

<table>
<tr><th>Function and Field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test Method/Test sytem/concentrations applied/exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td></td><td>
<table>
<tr><td>Untreated control</td><td>Blatta oreintalis Nymps</td><td>+6 weeks</td><td>0</td><td>0</td></tr>
</table>
xx
</td><td></td></tr>
<tr><td>Insecticide

Indoor Non-professional</td><td>HG against crawling insects

Aerosol 0.2% permethrin w/w

(Meta 1)</td><td>Lepisma saccharina (silverfish) - 60 adults per replicate mixed sex</td><td>Simulated-use test

Guidance on the Biocidal Products Regulation-Volume II Efficacy Parts B&C –version 3.0 April 2018 ECHA
Application rate: 0 (untreated control) and 25 ml/m2 (=50 mg permethrin per m2), single application at the start of the treatment

Test room: 3 x 2 x 2 m chamber (12 m3) is 6 m² surface
The test chambers walls are made of non-sorbent epoxide panels and the floor is made of ceramic tiles. A “furniture” is built to represent the reality of cracks and crevices but only the first visible part is treated, to simulate the real conditions of application. The “furniture” is a pile of 5 non-porous lacquer wood boards of 1 m x 1 m (usual dimensions of kitchen furniture), assembled together but letting a 3 cm</td><td>TABLE I: % of mortality of the target organisms in the test chamber after 24 hours of exposure -POROUS MATERIAL
<table>
<tr><th>TREATMENT</th><th>TARGET ORGANISM</th><th>AGE OF THE TREATMENT</th><th>Mortality Mean %</th><th>Standard deviation</th></tr>
<tr><td>HG against crawling insects</td><td>Lepisma saccharina</td><td>0</td><td>100%</td><td>0.0</td></tr>
<tr><td>HG against crawling insects</td><td>Lepisma saccharina</td><td>+6 weeks</td><td>100%</td><td>0.0</td></tr>
</table>
<table>
<tr><th>TREATMENT</th><th>TARGET ORGANISM</th><th>AGE OF THE TREATMENT</th><th>Mortality Mean %</th><th>Standard deviation</th></tr>
<tr><td>Untreated control</td><td>Lepisma saccharina</td><td>0</td><td>0.3</td><td>0.7</td></tr>
<tr><td>Untreated control</td><td>Lepisma saccharina</td><td>+6 weeks</td><td>0</td><td>0</td></tr>
</table>
</td><td>EFFICACY OF AN INSECTICIDAL PRODUCT CRACKS AND CREVICES TREATMENT CRAWLING INSECTS Study TEC number 2628/1120</td></tr>
</table>

<table>
<tr><th>Function and Field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test Method/Test sytem/concentrations applied/exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>space between each other in order to create the cracks/crevices. On the first 15 cm of these cracks/crevice (entry of the "furniture"), 16 ceramic tiles of 15 cm x 15 cm are set of the material to be claimed but only
2/3 of its surface is treated (first 10 cm are treated and 5 cm are not treated). In total, 0.24 m2 treated surface per test chamber. They are set on their porous side. Four water + food sources are set in the corners of the test chamber and the insects are able to reach it without being in contact with the product. - water source (4 x 25 cm long water vials with a cotton wick) - food source (4 Petri dishes with pet food biscuit) → food and water sources are not on the treated surfaces

Exposure time: 24 hours, knockdown was assessed after 4 hours, mortality was observed after 24 hours.</td><td>TABLE II: % of mortality of the target organisms in the test chamber after 24 hours of exposure– NON – POROUS MATERIAL

<table><tr><th>TREATMENT</th><th>TARGET ORGANISM</th><th>AGE OF THE TREATMENT</th><th>Mortality Mean %</th><th>Standard deviation</th></tr><tr><td>HG against crawling insects</td><td>Lepisma saccharina</td><td>0</td><td>100%</td><td>0.0</td></tr><tr><td>HG against crawling insects</td><td>Lepisma saccharina</td><td>+6 weeks</td><td>100%</td><td>0.0</td></tr></table>
<table><tr><th>TREATMENT</th><th>TARGET ORGANISM</th><th>AGE OF THE TREATMENT</th><th>Mortality Mean %</th><th>Standard deviation</th></tr><tr><td>Untreated control</td><td>Lepisma saccharina</td><td>0</td><td>0.3</td><td>0.7</td></tr><tr><td>Untreated control</td><td>Lepisma saccharina</td><td>+6 weeks</td><td>0.3</td><td>0.7</td></tr></table></td><td></td></tr>
</table>

Function and Field of use envisaged	Test substance	Test organism(s)	Test Method/Test sytem/concentrations applied/exposure time	Test results: effects	Reference
			Replicates: 5 (including 5 for the untreated control), 60 insects per replicate 2 types of treated surfaces 16 tiles of(15X15 cm, of which is treated 10x15 cm): porous: ceramic tile porous side non-porous: -ceramic tile Residual efficacy tested after 6 weeks. Environmental conditions: 22°C +/- 2°C, relative humidity: 60 +/- 5% and 8 hours light per day of 800 lux, <1 m3/h ventilation		

Conclusion on the efficacy of the product

To demonstrate efficacy of the products in the biocidal product family 'HG tegen kruipend ongedierte' laboratory, simulated-use and field tests were provided. These tests were performed with HGX Insecticide Spray Aerosol, the composition of which is identical to the products in Meta SPC 1. Seperately, a crack and crevices test has been done with HG tegen kruipend ongedierte (HG against crawling insects). The tested products contain the same inert ingredients. The concentration of the active ingredient is the same in all tests.
For the indoor uses, an application rate of 25 ml of the product/m^2 (50 mg permethrin per m^2) is used and for the outdoor use against ant nests, the application rate is 12.5 ml per nest (= 12.5 ml/m^2 (25 mg permethrin per m^2)) .
Based on the provided efficacy tests authorisation can be granted against crawling insects, including cockroaches, ants and silverfish for use by non-professional users indoor via a crack and crevice treatment and against outdoor ant nests around buildings.

For a more elaborate evaluation of the label claims, see section 2.2.5.8.

2.2.5.6 Occurrence of resistance and resistance management

Due to extensive use in the agrochemical industry, pyrethroid resistance is emerging despite early optimism that because of its rapid toxicological action it would not lead to the development of resistance.

Literature search for cases of resistance to permethrin when used against crawling insects. The search was performed against the representative target organisms for the 'control of crawling insect' .
Species/orders/family were input into the Arthropod Pesticide Resistance Database (www.pesticideresistance.org) and the following output was observed:

Species/groups claimed against which Resistance was observed.

-German cockroach (Blattodea) *Yes. 14 cases indicated around various locations around the world.
-Oriental cockroach (Blattellidae) No resistance
-Common black ants (Formicidae) No resistance

During subsequent searching for resistance against the oriental cockroach, hits were also returned for the German cockroach, and it became very clear that German cockroaches in particular, can be a problem with regards to developing resistance to insecticides in general, but particularly to pyrethroids such as cypermethrin and permethrin.

General internet search for resistance Search strategy

In the first seach it was already indicated resistance has been observed for permethrin in some of the target organisms. w This has not been included in the second search. There is no practical 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.

The resistance management measures:
If biocides containing permethrin are used for only a limited period this will not contribute very much to the development of resistance in the target organisms. To prevent resistance development in target organisms it is recommended to alternate with other products based on active substances from another chemical group (no pyrethroids).

2.2.5.7 Known limitations

No limitations on efficacy have been observed during testing.

2.2.5.8 Evaluation of the label claims

Meta SPC 1

All tests for this Meta SPC were performed with HGX Insecticide Spray Aerosol and HG tegen kruipend ongedierte (HG against crawling insects).
The tested products both contain the same inert ingredients and the concentration of the active ingredients are the same in all tests.

Ants

To demonstrate efficacy against ants, one laboratory test, two simulated-use tests and one field test with *Lasius niger* were provided.

In the laboratory study [redacted] 2018c) 100% knockdown within 1 hour was demonstrated directly after application and after 6 weeks on both porous and non-porous surfaces at an application rate of 25 ml/m^2. A mortality of 100% within 24 hours was demonstrated directly after application and after 6 weeks on both porous (concrete and unpainted wood) and non-porous (ceramic tiles, steel) surfaces at an application rate of 25 ml/m^2. For the nest treatment use (at an application rate of 12.5 ml/nest) the 25 ml/m^2 application rate in the laboratory test is considered to be sufficiently representative as it demonstrates the basic insecticidal potential of the product.

In the simulated-use study [redacted] 2018d) 100% knockdown within 4 hours was demonstrated directly after application and after 6 weeks at an application rate of 25 ml/m^2 and a treated surface of 2 m^2. A mortality of 100% within 24 hours was demonstrated directly after application and after 6 weeks at an application rate of 25 ml/m^2 and a treated surface of 2 m^2. As both porous and non-porous surfaces were tested simultaneously it cannot be concluded on which of these surfaces the product is (and remained) efficaceous. For this latter reason, and because the maximum treated area in the simulated-use test exceeds the maximum treated area prescribed in the use instructions (crack and crevices treatment), this study is disregarded for the efficacy evaluation.

In the simulated-use study EFFICACY OF AN INSECTICIDAL PRODUCT CRACKS AND CREVICES TREATMENT CRAWLING INSECTS Study TEC number 2628/1120a mortality of 100% within 24 hours was demonstrated directly after application and after 6 weeks at an application rate of 25 ml/m^2 of in total 0.24 m^2 of treated surface. Both porous and non-porous surfaces were tested separately. This simulated use test used a test design which is representative of crack and crevice treatment.

In the field test [redacted] 2018f) to show efficacy for the nest treatment of *Lasius niger* nests a reduction of 100% was demonstrated after 2 weeks (remaining up to 6 weeks), with no live larvae, adults or queen remaining in the nests. The test was performed at an application rate of 12.5 ml per nest. The field test was performed in outdoor areas and areas around buildings, this is considered to be sufficient to cover nest treatment use around buildings.

Based on the results from the laboratory study, simulated field test and field test, authorization can be granted for indoor use against ants for the use by non-professionals with a crack and crevice treatment with 25 ml/m² and for outside use around buildings and nest treatment at an application rate of 12.5 ml/nest. For both treatments residual efficacy is 6 weeks.

Cockroaches

To demonstrate efficacy against cockroaches, one laboratory test and two simulated-use tests with *Blatella germanica* and *Blatta orientalis* were provided.

In the laboratory study [redacted] 2018c) 100% knockdown within 1 hour (2 hours for adults of *Blatella germanica* on wood and concrete after 6 weeks; 4 hours for adults of *Blatta orientalis* on wood and concrete after 6 weeks) was demonstrated for adults and nymphs of both species directly after application and after 6 weeks on both porous (concrete and wood) and non-porous (ceramic and steel) surfaces at an application rate of 25 ml/m². A mortality of 100% within 24 hours was demonstrated for both species directly after application and after 6 weeks on both porous and non-porous surfaces at an application rate of 25 ml/m².

In the simulated-use study [redacted], 2018d) 100% knockdown within 4 hours was demonstrated for nymphs and adults of both species directly after application and after 6 weeks at an application rate of 25 ml/m² and a treated surface of 2 m². A mortality of 100% within 24 hours was demonstrated for nymphs and adults of both species directly after application and after 6 weeks at an application rate of 25 ml/m² and a treated surface of 2 m². As both porous and non-porous surfaces were tested simultaneously it cannot be concluded on which of these surfaces the product is (and remained) efficaceous. For this latter reason, and because the maximum treated area in the simulated-use test exceeds the maximum treated area prescribed in the use instructions, this study is disregarded for the efficacy evaluation.

In the simulated-use study EFFICACY OF AN INSECTICIDAL PRODUCT CRACKS AND CREVICES TREATMENT CRAWLING INSECTS Study TEC number 2628/1120, a mortality of 100% within 24 hours was demonstrated directly after application and after 6 weeks at an application rate of 25 ml/m² of in total 0.24 m² of treated surface. Both porous and non-porous surfaces were tested separately. This simulated use test used a test design which is representative of crack and crevice treatment.

Based on the results from the laboratory study and simulated field tests, authorization can be granted for indoor use against cockroaches for the use by non-professionals with a crack and crevice treatment with 25 ml/m². Residual efficacy is 6 weeks.

Silverfish

To demonstrate efficacy against silverfish one laboratory test and one simulated use test with *Lepisma saccharina* were provided.

In the laboratory study ([redacted], 2018c) 100% knockdown within 1 hour was demonstrated directly after application and after 6 weeks on both porous (concrete and wood) and non-porous (ceramic and steel) surfaces at an application rate of 25 ml/m². A mortality of 100% within 24 hours was demonstrated directly after application and after 6 weeks on both porous and non-porous surfaces at an application rate of 25 ml/m².

In the simulated-use study EFFICACY OF AN INSECTICIDAL PRODUCT CRACKS AND CREVICES TREATMENT CRAWLING INSECTS Study TEC number 2628/1120 a mortality of 100% within 24 hours was demonstrated directly after application and after 6 weeks at an application rate of 25 ml/m^2 of in total 0.24 m^2 of treated surface. Both porous and non-porous surfaces were tested separately. This simulated use test used a test design which is representative of crack and crevice treatment.

For use against silverfish no specific requirements are listed in the efficacy guidance document part B/C. In such cases, the requirements will depend on the claim of the product. For direct spray-on products a no-choice laboratory test is considered sufficient. Additionally, a simulated use test was provided demonstrating the efficacy of the application method.

Based on the results from the laboratory study and simulated field test, authorization can be granted for indoor use against silverfish for the use by non-professionals with a crack and crevice treatment with 25 ml/m^2. Residual efficacy is 6 weeks.

General crawling insect claim:

For a general crawling insect claim efficacy tests should be provided with cockroaches and ants. As this has indeed been provided, a general crawling insect claim is possible. Based on the results from these tests authorization can be granted for indoor use against crawling insects for the use by non-professionals with a crack and crevice treatment with 25 ml/m^2. Residual efficacy is 6 weeks.

Other target species

Although originally part of the application, use against fleas, spiders, litter beetles, wasps and other flying insects is no longer applied for by the applicant.

Uses to be authorised:

Based on the efficacy data provided the following uses can be authorized:

Meta SPC 1
Use 1
Crawling insects (including cockroaches, ants and silverfish) – indoor – cracks and crevices
Use 2
Silverfish – indoor – cracks and crevices
Use 3
Ants – indoor – cracks and crevices
Ants – outdoor (around buildings) – Nest treatment

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

The products in this biocidal product family are not intended to be used in combination with other biocidal products.

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

No toxicological data are available with the products in the BPF 'HG tegen kruipend ongedierte'. The classification is based on the CLP calculation method described in Annex I of Regulation 1272/2008/EC.

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	None of the metaSPCs included in the BPF 'HG tegen kruipend ongedierte' have to be classified as skin irritant.
Justification for the value/conclusion	According to the CLP Criteria a mixture does not have to be classified for skin irritation hazard if the total content of category 2 skin irritants <10% and the total content of skin corrosive components is < 1%. Based on the compostion as explained in detail in the confidential part (Annex 3.6), the meta SPCs of 'HG tegen kruipend ongedierte' do not have to be classified as skin irritant or as corrosive to the skin. More specific information is included in the confidential Annex, section Information on classification based on the calculation rules.
Classification of the product according to CLP	Meta SPC 1:Not required.

Data waiving	
Information requirement	IUCLID section 8.1
Justification	With the meta SPCs in BPF 'HG tegen kruipend ongedierte' no tests for skin irritation or corrosion have been performed. The classification and labelling of the product has been prepared based on the ingredients and the calculation method described in Annex I of Regulation 1272/2008/EC.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	None of the metaSPCs included in the BPF 'HG tegen kruipend ongedierte' have to be classified as eye irritant.
Justification for the value/conclusion	According to the CLP Criteria a mixture does not have to be classified for eye irritation hazard if the total content of category 1 eye irritants is >3%. Based on the compostion as explained in detail in the confidential part (Annex 3.6), the metaSPCs of 'HG tegen kruipend ongedierte' do not have to be classified as eye irritant. More specific information is included in the confidential Annex, section Information on classification based on the calculation rules.
Classification of the product according to CLP	MetaSPC1: Not required.

Data waiving	
Information requirement	IUCLID section 8.2
Justification	With the metaSPCs in BPF 'HG tegen kruipend ongedierte' no tests for eye irritation have been performed. The classification and labelling of the product has been prepared based on the ingredients and the calculation method described in Annex I of Regulation 1272/2008/EC.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
	Not applicable.
Justification for the conclusion	There are currently no standard tests and no OECD TG available for respiratory irritation and there is no testing requirement for respiratory irritation under the Biocides Regulation. None of the formulants are classified for respiratory irritation.
Classification of the product according to CLP	MetaSPC1: Not required.

Data waiving	
Information requirement	Not in IUCLID
Justification	With the metaSPCs in BPF 'HG tegen kruipend ongedierte' no tests for respiratory tract irritation have been performed. The classification and labelling of the product has been prepared based on the ingredients

	and the calculation method described in Annex I of Regulation 1272/2008/EC.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	None of the metaSPCs included in the BPF 'HG tegen kruipend ongedierte' have to be classified as skin sensitizer.
Justification for the value/conclusion	Among the formulants only the active substance Permethrin (0.2% = 2 g/L) is classified for sensitizing properties (cat 1B), however it does not exceed the 1% and the metaSPCs do not have to be classified. In the EU, the special hazard phrase EUH208, intended to protect persons previously sensitized to certain substances, is required for a mixture containing at least one substance classified as sensitising and present in a concentration equal to or greater than 0.1% or in a concentration equal to or greater than that specified under a specific note for the substance in part 3 of Annex VI and the label (SDS) shall bear the statement: "Contains permethrin. May produce an allergic reaction."
Classification of the product according to CLP	MetaSPC1: Classification is not required, but labelling with EUH208: "Contains permethrin. May produce an allergic reaction" is required.

Data waiving	
Information requirement	IUCLID section 8.3
Justification	With the metaSPCs in BPF 'HG tegen kruipend ongedierte' no tests for skin sensitization have been performed. The classification and labelling of the product has been prepared based on the ingredients and the calculation method described in Annex I of Regulation 1272/2008/EC.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	None of the metaSPCs included in the BPF 'HG tegen kruipend ongedierte' have to be classified as respiratory sensitizer.
Justification for the value/conclusion	The metaSPC1 'HG tegen kruipend ongedierte' does not contain formulants which are classified for respiratory sensitisation (H334).
Classification of the product according to CLP	MetaSPC1: Not required.

Data waiving

Information requirement	IUCLID section 8.4
Justification	Not applicable as it is 'additional information'.

Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	None of the metaSPCs included in the BPF 'HG tegen kruipend ongedierte' have to be classified for acute oral toxicity.
Justification for the selected value	The metaSPCs included in the BPF 'HG tegen kruipend ongedierte' do not contain relevant amounts of co-formulants which are classified for acute oral toxicity. The active substance permethrin is H302, but based on the calculation rules and the compostion as explained in detail in the confidential part (Annex 3.6), metaSPC1 'HG tegen kruipend ongedierte' does not have to be classified for acute oral toxicity. More specific information is included in the confidential Annex, section Information on classification based on the calculation rules.
Classification of the product according to CLP	MetaSPC1: Not required

Data waiving	
Information requirement	IUCLID section 8.5.1
Justification	With the metaSPC in BPF 'HG tegen kruipend ongedierte" no tests for acute oral toxicity have been performed. The classification and labelling of the product has been prepared based on the ingredients and the calculation method described in Annex I of Regulation 1272/2008/EC.

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	None of the metaSPCs included in the BPF 'HG tegen kruipend ongedierte' have to be classified for acute inhalation toxicity.
Justification for the selected value	The metaSPCs included in the BPF 'HG tegen kruipend ongedierte' do not contain relevant amounts of co-formulants which are classified for acute inhalation toxicity. The active substance permethrin is H332, but based on the calculation rules and the compostion as explained in detail in the confidential part (Annex 3.6), the metaSPCs in BPF 'HG tegen kruipend ongedierte' do not have to be classified for acute inhalation toxicity.

Classification of the product according to CLP	Not required.

Data waiving	
Information requirement	IUCLID section 8.5.2
Justification	With the metaSPCs in BPF 'HG tegen kruipend ongedierte' no tests for acute inhalation toxicity have been performed. The classification and labelling of the product has been prepared based on the ingredients and the calculation method described in Annex I of Regulation 1272/2008/EC.

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	None of the metaSPCs included in the BPF 'HGX tegen vliegend en kruipend ongedierte' have to be classified for acute dermal toxicity.
Justification for the selected value	The metaSPCs included in the BPF 'HG tegen kruipend ongedierte' do not contain relevant amounts of co-formulants which are classified for acute dermal toxicity. The active substance permethrin is not classified for acute dermal toxicity. More specific information is included in the confidential Annex, section Information on classification based on the calculation rules.
Classification of the product according to CLP	Not required.

Data waiving	
Information requirement	IUCLID section 8.5.3
Justification	With the metaSPCs in BPF 'HG tegen kruipend ongedierte' no tests for acute dermal toxicity have been performed. The classification and labelling of the product has been prepared based on the ingredients and the calculation method described in Annex I of Regulation 1272/2008/EC.

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Permethrin
Value(s)*	50%
Justification for the selected value(s)	Default value in-use concentrations containing < 5% a.s. of water based formulations based on the EFSA guidance (2017), see justification as included in the table below

Data waiving	
Information requirement	IUCLID section 8.6
Justification	With the products in the BPF 'HG tegen kruipend ongedierte' no tests for dermal absorption of permethrin have been performed. Details on the dermal absorption of permethrin can be found in the EU assessment of the active substance permethrin. The value of 3% dermal absorption set in the EU assessment report (AR), is derived from a human volunteer study. In this study, a dilution of permethrin in isopropanol is applied on the human skin. The meta SPCs in BPF 'HG tegen kruipend ongedierte' are water based products (>95%) and are not considered to be a 'similar' formulation as the co-formulants are different. However, the permethrin in isopropanol applied to the skin of human voluntiers under non-occlusive conditions, might result in vapouration of isopronanol, leaving the permethrin on the skin, in a non-solvent environment, which is more comparable to the water-based HG products if they come onto the skin. As such the value of 3% could be supported as well. Furthermore, the EFSA 2017 guidance on dermal absorption supports a value of 50% for waterbased products in dilution and a value of 10% of concentrated waterbased products. Concentrated products are considered to have a concentration of 5% active substance while an in-use dilution contains a concentration of a.s. lower than or equal to 5% (SANTE/2018/10591 rev.1), which implies that the current HG products (0.2%) could be considered as waterbased dilution and the value of 50%, according to EFSA 2017, is supported. This value has been used for a conservative risk assessment.

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

As mentioned in 2.1.2.5 and explained in detail in Confidential Annex 3.6, there are no substances of concern to be considered and no hazard information is to be included for risk assessment purposes.

See Annex 3.6 for further details.

Available toxicological data relating to a mixture

Not applicable as there are no mixtures containing substances of concern.

Other

Endocrine disrupting properties

Value used in the Risk Assessment – Endocrine disrupting properties	
Value	no effects
Justification for the selected value	Based on the available information on its components, the products in the BPF 'HG tegen kruipend ongedierte' are not expected to have endocrine disrupting (ED) properties. The BPC opinion on permethrin states: *permethrin is not considered to have endocrine disrupting properties* The mode of action (efficacy) of permethrin is not via the endocrine system. Furthermore, there are no relevant metabolites or degradation products to be considered. Recent document (CA-March18-Doc.7.3.b-final) indicates that all formulants of the biocidal product (family) should be considered for possible ED properties. As requested, also the screening in line with the 2019 guidance has been added to the confidential Annex. Details on assessment for ED alerts for the formulants are confidential and can be found in Annex 3.6. It can be concluded that the biocidal products of the BPF 'HG tegen kruipend ongedierte' do not have to be considered for having endocrine disrupting properties.
Classification of the product according to CLP	No classification for endocrine disrupting properties is required for the the biocidal products in the BPF 'HG tegen kruipend ongedierte'.

2.2.6.2 Exposure assessment

A non-professional will apply the RTU products of BPF 'HG tegen kruipend ongedierte' using an aerosol spray can with straw. Oral exposure is not relevant for adult users, the relevant exposure routes are dermal and inhalation exposure. Considering the possible secondary exposure, the general public can be exposed by touching treated spots or crawling on treated surfaces (worst-case for small children).
Exposure via food is not considered relevant as the use instructions have a restriction (RMM) not to use in areas were food/feed is present.

As mentioned under 2.1.2.5, 2.2.6.1 and explained in detail in confidential Annex 3.6, there is no SoC that needs to be considered for risk assessment. See Annex 3.6 for further details.

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

Summary table: relevant paths of human exposure for BPF HG tegen kruipend ongedierte							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Industrial use	**Professional use**	**Non-professional use**	**Industrial use**	**Professional use**	**General public**	**Via food**
Inhalation	n.a.	n.a.	Yes	n.a.	n.a.	Yes	No
Dermal	n.a	n.a	Yes	n.a	n.a	Yes	No
Oral	n.a.	n.a.	n.a.	n.a.	n.a.	Yes	No

List of scenarios

The intended uses are the same for the MetaSPC 1- Spray can. In all cases, the product is applied with a spray can connected to a straw.

MetaSPC 1 - Spray can : HG tegen kruipend ongedierte aerosol

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)
All scenarios	Mixing/loading	Not applicable since all supported products are RTU formulations in end-use packaging.	Non-professional
1.1 crawling insects	spraying	Indoor - cracks and crevices spraying against crawling insects with aerosol can using a straw , 25 ml/m2; no more than 2 m2 per treatment .	Non-professional
1.2 silverfish	spraying	Indoor - cracks and crevices spraying against silverfish with aerosol can using a straw, 25 ml/m2; no more than 2 m2 per treatment .	Non-professional
1.3 ants	spraying	Outdoor – nest treatment with aerosol can using a straw, ants 12.5 ml/nest . Indoor - cracks and crevices spraying against ants with aerosol can using a straw, 25 ml/m2; no more than 2 m2 per treatment .	Non-professional
All scenarios	cleaning	No cleaning of equipment needed. RTU products	Non-professional
All scenarios	Dermal (oral)	Secondary: touching treated surfaces (crawling infant as worst-case)	Bystanders

As products included in metaSPC1 are spray cans for which the application is limited to cracks and crevices treatment and to be applied with a straw. There will be no spray drift, inhalation exposure of by-stander during the use of product will be negligible Moreover, a RMM is included that animals and other persons should not be present during use. Therefore, inhalation exposure to by-standers is considered covered an is not separately assessed.

Industrial exposure

Not applicable for this biocidal product family.

Professional exposure

Not applicable for this biocidal product family.

Non-professional exposure

For the non-professional user both dermal and inhalation exposure is considered following the use of the RTU aerosol spray can with straw.
As the products in the BPF 'HG tegen kruipend ongedierte' are all RTU formulations in end-use packaging, there are no mixing and loading activities or cleaning of equipment, and consequently no M&L or cleanup exposure. Exposure will only occur during actual application: spraying with the aerosol spray can with tube.

MetaSPC 1 - Spray can : HG tegen kruipend ongedierte aerosol

Scenario [1.1 to 1.3]

Description of Scenario [1.1-1.3]		
Non-professional spraying with RTU aerosol spray can with straw. Indoor use against crawling insects as well as outdoor use against ants – nest treatment. Frequency: once per 6 weeks Duration of exposure: Indoor uses 50 seconds as use instructions indicate 25 mL per m2 (corresponding with 25 seconds of spraying), maximum treatment area is 2 m^2, and spray volume is 1 mL/second. Outdoor – nest treatment with aerosol can using a spray lance/tube, ants 12.5 ml/nest . Calculated with ConsExpo Web using the default scenario for Pest Control Products. (Pest Control Products Fact Sheet. RIVM report 320005002/2006). ConsExpo distinguishes: Cracks and crevices treatment, which covers the intended use scenarios for crawling insects, silverfish and ants (both indoor and outdoor as the indoor use is worst-case for the outdoor use).		
	Parameters[1]	Value
Tier 1	Body weigth	60 kg (HEAdhoc rec 14)
	Use frequency	1-2 times per year (outdoor) 1-2 times per year (indoor) According to use instructions
	Spray duration	1 min (based on use instructions to apply 25 ml/m^2 and spray volume of 1 ml/second results in 50 seconds spraying)
	Exposure duration	240 min (Consexpo)
	Weight fraction compound permethrin	0.2 %
	Inhalation uptake fraction	1
	Inhalation rate	1.25 m^3/h (HEAdhoc rec 14)
	Dermal exposed areas	1949 cm^2 (=two hands plus lower arms, HEEG opinion 17,2013)*
	Dermal uptake permethrin	50 % dermal absorption (default EFSA guidance 2017)
Tier 2	Not needed, PPE not applicable for consumer products	

*NL CA note: Applicant has indicated that the used value for dermal exposure area is very worst case, as there is hardly spray drift when the straw is used, therefore dermal exposure could be limited to the hands only. Considering the straw to be used for the crack and crevice treatment, we agree that hands only could be considered realistic wost case. However, as using a more worst case option does not result in unsafe use for the

unprotected non-professional user (i.e. 2.2% of the AEL), we consider adaptions of the calculation is not necessary.

Calculations for Scenario [1.1 to 1.3]

The details of the calculations can be found in appendix 3.2.

It is noted that the outdoor ant nest application is covered by the more worst-case indoor use on cracks and crevices. In both cases a spraying duration of 1 minute is taken to cover the proposed 12.5 seconds in ant nest or the 50 seconds indoor cracks and crevices.
No additional calculations for the outdoor use are included.

metaSPC 1 - RTU aerosol

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
1.1 to 1.3 with cracks and crevices (ConsExpo)	1 / no PPE 1 minute spraying	0.0094mg/kg bw/day	0.0017 mg/kg bw/day	n.a.	0.011 mg/kg bw/day

Combined scenarios

There are no combined use scenarios.

Exposure of the general public

The secondary exposure following outdoor use in ant-nests is considered negligible as it is assumed that inhalation exposure will hardly occur or at least be much lower than for the user of the product. Dermal secondary touching and or a child crawling into an ant nest outdoor will hardly occur either, if so, possible exposure is expected to be lower than for the indoor crawling scenario as only half of the amount of product is used outdoor.

For the secondary exposure following indoor uses against cracks and crevices, inhalation exposure of bystanders is considered negligible or at least much lower than for the user. The product is applied with a straw, there is hardly spray drift which can be inhaled by bystanders during or after application.

For the dermal secondary exposure, the indirect exposure of a child crawling/touching treated surface is calculated as a worst-case. This worst-case exposure assessment is in line with the EU assessment report (AR) of permethrin. It is further noted that for the intended use on cracks and crevices, also the crawling and touching will be very limited as the treated surfaces are more difficult to reach than in the case of general surface or air spraying which used to be part of the intended uses.

Consexpo presents a default scenario for post application after spraying.

Description of Scenario [2]		
Secondary exposure for child crawling/touching treated surface, representing a worst-case for exposure of the general public Calculated with ConsExpo Web using the default scenario for Pest Control Products. (Pest Control Products Fact Sheet. RIVM report 320005002/2006). Selecting the post-application scenario.		
	Parameters[1]	Value
Tier 1	Exposed body surface toddler	1170 cm2(HEEG opinion 7) has been used, although for cracks and crevices the smaller surface of 499.2 m^2 (hands plus lower arms child, HEEG Opinion 17) could also be supported as the current uses are only relating to cracks and cravices. It is physically hardly possible to crawl with legs/knees in cracks.
	Body weight	8 kg (HEAdhoc recom no. 14)
	Transfer coefficient	0.6 m^2/hour (default Consexpo)
	Dislogable amount*	3.825 g product/m2 (calculation based on use instructions 25 ml product is used on 1 m^2 (maximum per day). 25 ml product is 25 gram product (density product is 1 g/ml). It is assumed that 85% ends up on the floor, being 21.25 gram and 18 % is dislogable, being 3.825 gram product per 1 m^2 surface
	Ingestion rate	3.825 mg product /min (calculation based on 10% ingestion of the total external dermal dose following hand-to mouth contact. 3.825 g/m2 x 0.6 m2/hour (transfer coefficient) / 60 minutes x 10%
	Duration (contact time)	60 minutes for a surface of 2 m2 (default). It should be noted this is a worst-case as a child is not expected to crawl for such a long time in cracks and crevices which are difficult to reach.
	Contacted surface	The 2 m2 default is used, , but as the product is applied along the plint, the contacted surface will be lower as a child will not crawl along the plints. As such the 2 m2 represents a worst-case.

* The dislodgeable amount is calculated based on the Dermal exposure; Rubbing off model as detailed on page 71 of the RIVM pest control products fact sheet, this scenario assumes that 85% of the total amount applied ends up on the floor surface (the airborne fraction is taken to be 15%). Furthermore, 18% dislodgeable residues, from Various types of surface"

(Biocides Human Health Exposure Methodology Table: Transfer coefficients – Dislodgeable residues", p171) is considered.

Calculations for Scenario [secondary exposure child]

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Post-application child	1 / no PPE Worst-case toddler	n.a.	0.290 mg/kg bw/day	0.057 mg/kg bw/day	0.340 mg/kg bw/day

Combined scenarios

No combination of secondary exposure scenarios is relevant.

Monitoring data

Not relevant and no data available.

Dietary exposure

No exposure foreseen as use around food is restricted with risk mitigation measure (RMM).

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

The active substance is not produced by the applicant and covered in the EU assessment. The applicant formulates the product according to standard workplace safety rules and no exposure will take place.

Disposal
It is obliged to dispose of this material and its container to hazardous or special waste collection point. As such no further exposure is expected.
Cleaning of equipment is not applicable as product is in ready-for-use packages which are not re-used.

Aggregated exposure

Not applicable, methodology is under development.

Summary of exposure assessment

metaSPC 1 - RTU areosol

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake**
1.1 to 1.3 one minute	Non-professional	Tier 1 / no PPE	0.011 mg/kg bw (worst-case no straw in model)
Post-applicatio n child	Secondary Bystander (child as worst-case)	Tier 1 / no PPE	0.340 mg/kg bw/day (worst-case as surface treatment is considered in model, not crack-and-crevice treatment)

Risk characterisation for human health

Reference values to be used in Risk Characterisation

Reference	Study	NOAEL (LOAEL)	AF	Correction for oral absorption	Value (mg/kg bw/day)
AEL short-term		0.2201 mg/L (inhalation)or 59 mg/kg bw/day oral	100	no	0.5
AEL medium-term	12 months dog	5 mg/kg bw/day	100	no	0.05
AEL long-term	12 months dog	5 mg/kg bw/day (12 months dog)	100	no	0.05
ARfD		0.2201 mg/L (inhalation)or 59 mg/kg bw/day oral	100	no	0.5
ADI	12 months dog	5 mg/kg bw/day	100	no	0.05

Maximum residue limits or equivalent

Not applicable

Permethrin is not approved under the PPP regulation, MRLs were set in Regulation (EC) No 396/2005 at the lower limit of analytical quantification.
Most recent MRLs for permethrin can be found in Regulation 2017/623. These also includes MRLs for meat and milk (veterinary use).
However, these MRLs are not applicable, as there will be no dietary exposure to residues of permethrin. There is a use restriction not to use the product where food/feed is present.

Specific reference value for groundwater

There is no emission to the groundwater and this is not relevant.

Risk for industrial users

The product is not intended for use by industrial users.

Risk for professional users

The product is not intended for use by professional users.

Risk for non-professional users

MetaSPC 1 - Spray can : HG tegen kruipend ongedierte aerosol

Systemic effects

Task/ Scenario	Tier	Details	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
1.1 to 1.3 one minute	1	Worst-case cracks and crevices spray no straw in model defaults	0.5	0.011 mg/kg bw/day	2.2 %	yes

Combined scenarios

Not applicable.

Local effects

The products in this BPF are not classified for local effects and this is not to be considered for risk assessment. However, BPC opinion points out to consider the EUH208 possible sensitizer issue for non-professionals as a local effect.

Below, the risks will be addressed for the elements indicated in paragraph 4.3.2.5, "(Semi-) Quantitative RC for local respiratory and skin effects" of the Guidance on the Biocidal Products Regulation. Volume III Human Health - Assessment & Evaluation (Parts B+C). Version 4.0, December 2017.

In line with the Table 27: 'Guidance for concluding qualitatively on the acceptability for non-professional exposure', the following qualitative local RA is presented:

BPF

Steps	**Information**
Describe local hazard	EUH208
Assign hazard category	No category, below medium or low hazard
Identity exposure	
-Who is exposed	Non-professionals
-Task/use/process	Spraying with RTU spray can with tube
-Exposure route	Dermal
-Frequency and duration of exposure	Few times per year (1 to up to 4 times per year maximum according to use instructions) Duration is only several seconds or several times spraying (< one minute)
-Degree of potential exposure under best practice conditions	Low exposure with spray can due to the use of tube in all applications
Relevant RMM	RTU products Spray can is sold with tube
Relevant PPE	Not relevant
Conclusion on qualitative risk assessment	Local risk assessment is not required according to the tables in the guidance document, EUH208 is not part of the hazard scheme. However, EUH208: Contains permethrin. May produce an allergic reaction.is important information for sensitized persons and therefore important information for users (i. e. primary exposure). However, considering the use crack and crevice treatment using an aersol can with a straw and infrequent use (max. 2 times per year where necessary treatment can be repeated after six weeks), very low to no direct exposure to the product is expected.

Conclusion

No adverse health effects are expected when using the products in BPF 'HG tegen kruipend ongedierte' according to instructions. The estimated uptake / AELshortterm is 2.2 %.

Risk for the general public

It is noted that the secondary exposure of a child by touching or crawling will only be incidental.
Moreover, for the indoor cracks and crevices scenarios) the treated surfacesare difficult to reach/touch for (small) children. The secondary exposure following outdoor use in ant-nests is considered negligible as it is assumed that inhalation exposure will hardly occur or at least be much lower than for the user of the product. Dermal secondary touching and or a child crawling into an ant nest outdoor will hardly occur either, if so, possible exposure is expected to be lower than for the indoor crawling scenario as only a quarter of the amount of product is used outdoor.
It is also noted that the period in which children display crawling behaviour (which was taken as an indication of worst-case exposure) covers only a small part of total life time. As such this scenario is considered not to represent a prolonged or chronic exposure situation; therefore it is acceptable to compare the exposure with the short term AEL instead of a chronic AEL.

Systemic effects

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)
Secondary-worst-case (child)	1/ no PPE		0.5	0.34 mg/kg bw/day	68.0 %	Yes

Combined scenarios

Not applicable for secondary exposure scenarios.

Local effects

The products in this BPF are not classified for local effects and this is not to be considered for risk assessment. Local risk assessment is not required according to the tables in the guidance document, EUH208 is not part of the hazard scheme. Very low to no secondary exposure is expected due to low frequency of use and considering that the product is applied to places which are not easy to access.

Conclusion

No adverse health effects are expected following secondary exposure (infants representing worst-case scenario) as a result of the use of the products in BPF 'HG tegen kruipend ongedierte' according to instructions.

Furthermore, to avoid exposure of other people than the user of the product, the following RMMs are include in 2.1.5.2 and SPC:

- Unprotected persons and animals should be kept away during application.

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

Risk for consumers via residues in food

Not applicable. Risk mitigation measures (RMM) are prescribed for not using the product in places were food/feed is present or prepared.

The following RMMs are included in 2.1.5.2 and SPC:

- 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.

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

Not applicable. The products in HG tegen kruipend ongedierte contain a single active substance only and no substances of concern. There is no need to consider combined exposure from the product itself. Furthermore, the products are not intended or for that matter foreseen to be used in combination with other products.

2.2.7 Risk assessment for animal health

The products are not intended for use directly on animals, however, as products included are used in houses by non-professional users, pets can be exposed.
The intended indoor use is limited to cracks and crevices with a straw, at difficult to reach areas for pet animals (i.e. hiding places of crawling insects e.g. behind and under cabinets, refrigerators, radiators . Furthermore, frequency of use is low: 1-2 times per year (outdoor), 1-2 times per year (indoor).
The products contain only 0.2% permethrin. Besides biocidal uses, permethrin is also already on the market as active in veterinary medicinal products for pet animals, and as such has been tested for safety under conditions of use as a veterinary medicinal product. It is known that cats are susceptible to permethrin.

The following RMMs are included in 2.1.5.3 and SPC to avoid animal exposure:

- Do not apply on (pet) animals and plants.
- Unprotected persons and animals should be kept away during application.
- The product should be applied where children and pets do not come in contact with the product.
- Keep cats away from treated surfaces. Due to their particular sensitivity to permethrin, the product can cause severe adverse reactions in cats..
- 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.

2.2.8 Risk assessment for the environment

****
The eCA has performed a separate risk assessment to be found in the green section in paragraph 2.2.8.3.
Endpoints have been checked

****

2.2.8.1 Effects assessment on the environment

The PNECs are taken from the EU Assessment report of Permethrin (2014); the updated $PNEC_{soil}$ for permethrin is taken from the Addendum to the EU Assessment report of Permethrin (2017).

Permethrin
PNECsurfacewater = 0.00047 µg a.s/L
PNECmicro-organisms (STP) = 0.00495 mg a.s/L
PNEC soil (wet weight) = 0.175 mg a.s/kg $soil_{wwt}$
PNECsediment = 0.001 mg/kg dwt (2.17×10^{-4} mg/kg_{wwt})
PNECoral bird = 16.7 mg a.s/kg food or 2.09 mg/kg bw
PNECoral small mammal = 120 mg a.s/kg food or 6 mg/kg bw

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

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

Note that permethrin environmental metabolites are less toxic than permethrin itself - an environmental risk assessment that is adequate for permethrin will cover any potential risks of these metabolites, with the exception of groundwater. DCVA and PBA are expected to be more mobile in soil which may result in leaching to the groundwater due to outdoor use or after distribution of sewage sludge. Therefore, the risk for the soil compartment and groundwater is assessed quantitatively for the major metabolite DCVA. Considering that PBA is less persistent and less mobile, the risk assessment for DCVA is considered to cover the risks for PBA.

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

No information is available on ecotoxicity with the product. The products in BPF 'HG tegen kruipend ongedierte' do not contain any substances of concern for the environment. Based

on the CLP calculation rules and the composition of the products, the products in BPF 'HG tegen kruipend ongedierte' are classified with H410 Very toxic to aquatic life with long lasting effects.

Further Ecotoxicological studies

No new data are available.

Endocrine disrupting properties

Value used in the Risk Assessment – Endocrine disrupting properties non target organisms	
Value	no endocrine disrupting indications
Justification for the selected value	The Commission Delegated Regulation (EU) 2017/2100 specifying the scientific criteria for the determination of endocrine-disrupting properties (ED criteria) under Regulation (EU) No 528/2012 (BPR) establishes that the ED criteria become applicable by 7 June 2018 for biocides (https://www.ctgb.nl/onderwerpen/hormoon-verstoorders). No further ecotoxicological studies are available for the products in the BPF 'HG tegen kruipend ongedierte'. The products were not tested for potential endocrine disruption properties. The products in the BPF 'HG tegen kruipend ongedierte' contain the active substance permethrin and various co-formulants (see confidential annex). For permethrin no ED assessment is required because for active substances which have been approved, the EU assessment should be followed. The Assessment Report (April 2014) states that there is no indication for endocrine disrupting properties of the active substance in fish. To examine if any of the co-formulants contained in the BPF may possess ED properties, a screening was performed in line with the harmonised approach for ED alert assessment for co-formulants as agreed in the coordination group ("CG-34-2019-02 AP 16.5 e-consultation ED potential of co-formulants"). Details on assessment for ED alerts for the co-formulants are confidential and can be found in Annex 3.6. It can be concluded that the co-formulants in the biocidal products of the BPF 'HG tegen kruipend ongedierte' do not have an ED alert.

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

No new data are available.

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

No new data are available.

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

No new data are available.

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

Not relevant. The products in the BPF 'HG tegen kruipend ongedierte' are intended for cracks and crevices treatment, not for large scale use.

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

For indoor uses, emission to the environment is indirect only, via wastewater emitted to a Sewage Treatment Plant (STP) due to wet cleaning of the treated or contaminated area or of the applicators clothing. Wastewater treatment in an STP results in subsequent emission via effluent to surface water and sediment, and by land application of sewage sludge to soil and groundwater.

For outdoor uses, emission to the environment is direct; the only affected compartment is soil (treatment of subterranean parts of ant nests).

No emission to air is foreseen: permethrin is not volatile, therefore no significant evaporation of permethrin from treated areas is expected; the ejecta from the aerosol can when using the straw are in the form of a liquid stream - no suspended aerosols are formed and no spray drift ensues.

Note that permethrin environmental metabolites are less toxic than permethrin itself – an environmental risk assessment that is adequate for permethrin will cover risks of these metabolites, with the exception of groundwater. DCVA and PBA are expected to be more mobile in soil which may result in leaching to the groundwater due to outdoor use or after distribution of sewage sludge. Therefore, the risk for the soil compartment and groundwater is assessed quantitatively for the major metabolite DCVA. Considering that PBA is less persistent and less mobile, the risk assessment for DCVA is considered to cover the risks for PBA.

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

No new data are available.

Leaching behaviour (ADS)

No new data are available.

Testing for distribution and dissipation in soil (ADS)

No new data are available.

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

No new data are available.

Testing for distribution and dissipation in air (ADS)

No new data are available.

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

Not relevant for intended uses.

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

Not relevant for intended uses.

2.2.8.2 Exposure assessment

Emission to the environment of household (and professional) insecticides is estimated using the models described in the OECD emission scenario document for insecticides, acaricides and products to control other arthropods for household and professional uses (the 'ESD'), ENV/JM/MONO(2008)14. The only outdoor use supported for HG tegen kruipend ongedierte is the subterranean treatment of ant nests.

The major emission route after indoor application of insecticides concerns the waste phase which is emission of either a diluted liquid waste stream or a solid (dust) stream from cleaning activities. Wet cleaning of treated surfaces will lead to the release of the active substance to waste water (STP), whereas dry cleaning will lead to the release of active substance to solid waste. In the European ESD document on insecticide applications for household and professional uses, the STP is considered as a "receiving compartment" for wet cleaning, whereas the 'waste dump' is the receiving compartment for dry cleaning. The 'waste dump', and with it dry cleaning (sweeping, vacuuming) is not relevant for the environment, while the STP is an intermediate compartment that ultimately emits to the surface water and soil (by application of sewage sludge to land) as "final" environmental compartments.

The application mode of HG tegen kruipend ongedierte is considered a cracks and crevices application. For indoor uses of HG tegen kruipend ongedierte, it is prescribed to skip cleaning of treated areas as much as possible since the product will continue to work up to 6 weeks after application. Nonetheless, some wet cleaning of accessible areas of the cracks and crevices may occur and will result in emission to the STP; as such, indirect exposure of surface water and soil after indoor use is foreseen.
The ESD also includes that a fraction of the applied product is emitted to the applicator, which is removed to the STP after washing of clothing. The default for surface treatments is 0.004 for aerosol application. This default is based on contamination of clothes from spray drift when using aerosol cans for surface treatments. When using HG tegen kruipende

insecten cans, which are equipped with an actuator with straw attached, no spray drift whatsover ensues since no aerosol is produced. The fraction of the applied product emitted to the applicator is therefore set to 0 for all uses.

General information

Assessed PT	PT18
Assessed scenarios	Scenario 1 Indoor, cockroaches, ants and silverfish, cracks and crevices - straw Scenario 2 Outdoor, ant nests - straw
ESD(s) used	Predicted Environmental Concentrations (PECs) for indoor and outdoor applications were calculated in accordance with the scenarios from the Emission Scenario Document (ESD) for Insecticides, acaricides and products to control arthropods (PT18) for household and professional use (OECD, 2008), based on the use patterns of HG tegen kruipende insecten for targeted spot and cracks and crevice treatments in domestic premises.
Approach	Average consumption per individual application
Distribution in the environment	Calculated based on Guidance on BPR Vol IV Part B+C (2017), ESD No. 18 and TAB (v. 2.1, 2019)
Groundwater simulation	Screening steps FOCUS PEARL 4.4.4
Confidential Annexes	No
Life cycle steps assessed	All scenarios: Production: No Formulation: No (RTU products) Use: Yes Service life: No
Remarks	none

Evaluation by the eCA:
Ant nest treatment as indicated in the intended use also involves the scenario for nest treatment on terraces, which should be added to the PAR. This involves TAB agreement ENV154 and ENV 157 and considers 4 treated nests emitting to a receiving area of 8.5 m2. Although the TAB aims at four bait stations and it is assumed that 20% enters the soil after flooding, For open spray applications the amount to the soil is expected to be larger and set at 80%.

Emission estimation

Scenario [1] Indoor control of crawling insects (indoor use only)

For crack and crevice applications the treatment can take place anywhere in the house. In

addition, there is no relationship between the room size and the quantity of product applied. The product sprayed ends up on the treated object and on the floor around it. A default value of 2 m^2 has been set for cracks and crevice treatment (strips/plinths against ants, cockroaches, silverfish); however, applicant is of the opinion that this is an overestimation of the foreseeable use of HG tegen kruipend ongedierte; a representative value of 1 m^2 was proposed (which is equivalent to 10 meters of strip/plinth). Dedicated efficacy tests were run supporting the cracks and crevices use on 1 m^2. As 2 m^2 has been set as default treatment area for cracks and crevice treatments (TAB ENV 142 and ENV 144), use instructions have been set to 2 m^2 and risk assessment has been performed accordingly.

Since the final receiving compartments are the surface water and soil receiving emissions from an STP, as intermediate receiving compartment, simultaneous use in the entire service area of a single STP has to be taken into account. To that end, the ESD assumes a standard STP services a community of 10000 inhabitants, occupying, on average, 4000 houses per STP catchment. Given the residual efficacy of permethrin-containing HG tegen kruipend ongedierte for 6 weeks, the prescribed treatment frequency of max 2 times per year, and the instruction to contact a pest control company if it is suspected that after two applications the product is not effective, an appropriate simultaneity factor of 0.002042 is proposed. This simultaneity factor is based on the numbers for 'one to two times per year' in line with the ESD.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: Indoor spot application (crawling insects: cockroaches, ants and silverfish (cracks and crevices)). RTU product, non-professional user			
Application rate of biocidal product	25	mL/m^2	Set
Concentration of active substance in the product	0.2	% w/w	Set; max concentration
Area of treated surface	2 m^2 (spot-crack)	-	Default
Number of preparations per day, house	0 (RTU)	-	Default
Number of applications per day, house	1	-	Default
Fraction emitted to the applicator during application	0 (straw)	-	Set; When using HG tegen kruipende insecten cans, which are equipped with an actuator with straw attached, no spray drift whatsover ensues since no aerosol is produced.
Washable or disposable coveralls	Washable	-	Default

Fraction emitted to solid waste from applicator	0	-	Default
Fraction emitted to wastewater from applicator	1	-	Default
Number of houses/STP	4000	-	Default
Simultaneity factor	0.2042	%	Set; Based on a maximum use of 1-2 times per year
Cleaning method	Sweeping with a broom, vacuum cleaning, wet cleaning	-	Default
Cleaning efficiency	0.03	-	Default

Calculations for Scenario [*1*] Indoor applications

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	$2.40 \cdot 10^{-5}$	

Scenario [2) Treatment of ant nests outdoors

In the treatment of ant nests outdoors, HG tegen kruipend ongedierte is applied directly into the entrance of the nest, using the straw. This will deposit all of the insecticide applied to the inside surfaces of the nest - i.e. on or in the soil. From such applications, permethrin would be subject to leaching to lower soil layers and/or groundwater (depending on fate properties of the substance), but not to wash off or run-off. Furthermore, given the manner of application, with a straw, and inside nest entrances, no deposition of product on the applicator or his/her clothes is foreseen. Note that the relevant environmental emission scenario is 'outdoor spot application'.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: Outdoor spot application (ant nests). RTU product, non-professional user			
Application rate of biocidal product	12.5	mL	Set; per nest
Concentration of active substance in the product	0.2	% w/w	Set; max concentration
Area of treated surface	0.25	m^2	Default; Outdoor spot application (nest)
Number of preparations per day, house	0 (RTU)	-	Default

Number of applications per day, house	1	-	Default
Fraction emitted to the soil during application	1	-	Set; outdoor spot application scenario for powder was used with Fsoil set to 1 instead of the default 0.9
Volume of exposed soil	0.125	m^3	Default; Outdoor spot application

Calculations for Scenario [2] Outdoor spot application – ant nests

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/campaign]**	**Remarks**
Local emission due to direct application to soil	$2.5 \cdot 10^{-5}$	

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway					
Representative scenario	**STP**	**Surface water**	**Sediment**	**Soil**	**Porewater**
PT18					
Scenario 1 indoor	++	+	+	+	+
Scenario 2 outdoor	-	-	-	++	+

++ compartment directly exposed; + compartment indirectly exposed; - compartment not exposed; Q will be assessed qualitatively

Input parameters (only set values) for calculating the fate and distribution in the environment – permethrin			
Input	Value	Unit	Remarks
Molecular weight	391.3	g/mol	
Melting point	35	°C	
Boiling point	305	°C	
Vapour pressure (at 20 °C)	2.16×10^{-6}	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	Experimental value

Input parameters (only set values) for calculating the fate and distribution in the environment – permethrin			
Input	Value	Unit	Remarks
Henry's Law Constant	0.05	$Pa/m^3/mol$	
Biodegradability	*Not Readily biodegradable*		
Rate constant for STP (at 295.65 K)	0.0121	h^{-1}	Data agreed at WG level
Bioconcentration factor	15108 (wet earthworm) 570 (fish)	L/kg	
DT_{50} for degradation in soil (at 12°C)	106	d	

Input parameters (only set values) for calculating the fate and distribution in the environment – DCVA			
Input	Value	Unit	Remarks
Molecular weight	209.07	g/mol	
Organic carbon/water partition coefficient (Koc)	93.2	L/kg	Experimental value
Henry's Law Constant	0.05	$Pa/m^3/mol$	See parent
Biodegradability	*Not Readily biodegradable*		
DT_{50} for degradation in soil (at 12°C)	175	d	
Formation fraction	0.2589	-	fraction parent degraded Data agreed at WG level

The fate of permethrin in a sewage treatment plant (STP) is calculated with SimpleTreat vs. 4.0 with 3.1 settings and is given in the next table:

Calculated fate and distribution in the STP		
Compartment	Percentage [%]	Remarks
Air	0.034	Same distribution For all scenarios
Water	11.92	
Sludge	62.2	
Degraded in STP	25.9	

Metabolites

As discussed previously, the risk for the soil compartment (including groundwater) is assessed quantitatively for the major metabolite DCVA. Considering that PBA is less persistent and less mobile, the risk assessment for DCVA is considered to cover the risks for PBA. The concentrations in groundwater result from the terrestrial PEC. The latter was

calculated by correcting the concentration active substance for the differences in molar weight (209.07/391.3=0.534) and the observed maximum fraction in soils (11.3%).

Calculated PEC values

Summary table on calculated PEC values - Permethrin					
Scenario	**PEC_{STP}** [mg/L]	**PEC_{SW}** [mg/L]	**PEC_{SED}** [mg/kg_{wwt}]	**PEC_{SOIL}** [mg/kg_{wwt}]	**$PEC_{PoreWater}$** [µg/L]
Scenario 1 Indoor, cracks and crevices - straw	$1.43 \cdot 10^{-6}$	$1.38 \cdot 10^{-7}$	$8.06 \cdot 10^{-5}$	$2.7 \cdot 10^{-5}$	$3.68 \cdot 10^{-5}$
Scenario 2 Outdoor, ant nests - straw	-	-	-	0.118	$2.47 \cdot 10^{-1}$*

*> 0.1 µg/L; PEC_{GW} calculated using FOCUS PEARL 4.4.4 is presented below.

Summary table on calculated PEC values - DCVA					
Scenario	**PEC_{STP}** [mg/L]	**PEC_{SW}** [mg/L]	**PEC_{SED}** [mg/kg_{wwt}]	**PEC_{SOIL}** [mg/kg_{wwt}]	**$PEC_{PoreWater}$** [µg/L]
Scenario 1 Indoor, cracks and crevices - straw	-	-	-	$1.63 \cdot 10^{-6}$	$2.22 \cdot 10^{-6}$
Scenario 2 Outdoor, ant nests - straw	-	-	-	$7.12 \cdot 10^{-3}$	$1.49 \cdot 10^{-2}$

Groundwater FOCUS modelling

FOCUS PEARL 4.4.4 was used to model leaching to groundwater of permethrin for the use against ant nests (scenario 2). The use scenario was translated to an application scheme for use in FOCUS PEARL 4.4.4 modelling as follows:
Ant nests are treated in gardens (of private houses). A typical garden is 140 m² (OECD PT18 ESD). One ant nest treatment applies 25 mg permethrin (12.5 mL product containing 0.2% w/w permethrin). As worst case, it is assumed that a hectare (10,000 m^2) consists of gardens only and in all gardens ant nests are treated, 1 per garden, 2x per year, at a six-week interval. This results in an application scheme of (10,000 m^2/140 m^2)· 25 mg = 1,786 mg/ha = 0.0018 kg/ha permethrin followed after six weeks by a second application of 0.0018 kg/ha permethrin.
Application was set to start on Apr 01 with a second application on May 16 to the soil surface. Grassland was chosen as the crop.

Input parameters for modelling in FOCUS PEARL 4.4.4.

Parameter	**Permethrin**
Molecular mass (g/mol)	391.29
Vapour pressure at test temperature (Pa)	$2.16 \cdot 10^{-6}$
Test temperature vapour pressure (°C)	20
Water solubility at test temperature (mg/L)	0.00495
Test temperature solubility (°C)	20
K_{foc} (L/kg)	26930

K_{om} (L/kg)	15621
Half-life for biodegradation in soil (days, 12°C)	106 (Q10: 2.2)
Formation fraction	n.a.
Freundlich exponent 1/n	1*
DT_{50} water (20°C)	1000**
DT_{50} sediment (20°C)	180.2 (Q10: 2.2)

* Worst-case default value as single Freundlich coefficients are not available but ranges which are all >1.

** Worst-case value from water sediment results. Degradation is assigned to the sediment phase because of high K_{oc}.

PEC_{GW} for permethrin (with FOCUS PEARL 4.4.4) for scenario 2

Scenario	**80th Percentile PECgw at 1 m Soil Depth (µg/L)**
	Permethrin
Chateaudun	<0.001
Hamburg	<0.001
Jokioinen	<0.001
Kremsmuenster	<0.001
Okehampton	<0.001
Piacenza	<0.001
Porto	<0.001
Sevilla	<0.001
Thiva	<0.001

Primary and secondary poisoning

Primary poisoning of birds and mammals

As the proposed uses will not result in direct exposure of birds and mammals, the risk for the primary poisoning is considered acceptable. Outdoor use is scattered enough that direct exposure of birds and mammals is not expected.

Secondary poisoning

According to Guidance a calculation for $PEC_{oral,\ predator_r}$ should be conducted if the active substance shows a potential for bioaccumulation, indicated by a log K_{OW} value >3. Since permethrin has a potential for bioaccumulation (log K_{OW} is 4.67) the risk of secondary poisoning via the food chain was evaluated.

A BCF fish of 570 L/kg and a BCF earthworm of 15108 L/kg_{wwt} was applied for permethrin in the assessment of secondary poisoning through the consumption of fish or earthworms by birds and mammals. The default BMF for substances with a BCF < 2000 L/kg is 1.

The $PEC_{surface\ water}$, $C_{porewater}$ and C_{soil} are dived by two as according to Guidance on BPR Vol IV Part B+C (2017) a scenario where 50 % of the diet comes from a local area (represented

by the PEClocal) and 50 % of the diet comes from a regional area (represented by the PECregional) is the most appropriate for the assessment.

Calculations:

Scenario 1:

$PEC_{oral,\ predator} = PEC_{surface\ water/2} \cdot BCF_{fish} \cdot BMF = 1.38 \cdot 10^{-7}/2 \cdot 570 \cdot 1 = 3.93 \cdot 10^{-5}$ mg/kg$_{wet\ fish}$

$PEC_{oral,\ predator} = ((BCF_{earthworm} \cdot C_{porewater}) + (C_{soil} \cdot F_{gut} \cdot CONV_{soil})) / (1 + (F_{gut} \cdot CONV_{soil})) = ((15108 \cdot 3.68 \cdot 10^{-8}/2) + (2.7 \cdot 10^{-5}/2 \cdot 0.1 \cdot 1.13)) / (1 + (0.1 \cdot 1.13)) = 2.51 \cdot 10^{-4}$ mg/kg$_{wet\ earthworm}$.

Scenario 2:

No emission to surface water, neither direct nor indirect via STP.

$PEC_{oral,\ predator} = ((BCF_{earthworm} \cdot C_{porewater/2}) + (C_{soil/2} \cdot F_{gut} \cdot CONV_{soil})) / (1 + (F_{gut} \cdot CONV_{soil})) = ((15108 \cdot 2.47 \cdot 10^{-4}/2) + (0.118/2 \cdot 0.1 \cdot 1.13)) / (1 + (0.1 \cdot 1.13)) = 1.68$ mg/kg$_{wet\ earthworm}$.

Summary table on calculated PEC values for secondary poisoning		
	Aquatic	**Terrestrial**
	[mg/kg$_{wet\ fish}$]	[mg/kg$_{wet\ earthworm}$]
Scenario 1 Indoor, cracks and crevices – straw	$3.93 \cdot 10^{-5}$	$2.51 \cdot 10^{-4}$
Scenario 2 Outdoor, ant nests - straw	-	1.68

2.2.8.3 Risk characterisation

Atmosphere

Not applicable

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values	
	PEC/PNEC$_{STP}$
Scenario 1 Indoor, cracks and crevices - straw	< 0.001
Scenario 2 Outdoor, ant nests - straw	Not applicable

Conclusion: The risks to the STP compartment are considered acceptable from use of the products in the BPF HG tegen kruipend ongedierte when used in accordance with label instructions.

Aquatic compartment

Summary table on calculated PEC/PNEC values		
	PEC/PNEC$_{water}$	**PEC/PNEC$_{sed}$**
Scenario 1 Indoor, cracks and crevices - straw	0.293	0.372
Scenario 2 Outdoor, ant nests - straw	Not applicable	Not applicable

n.a. = not applicable

Conclusion: Only indirect exposure of the aquatic compartment via the STP has to be considered for the indoor uses. The risks to the aquatic compartment are considered acceptable from use of the products in the BPF HG tegen kruipend ongedierte when used in accordance with label instructions.

Terrestrial compartment

Calculated PEC/PNEC values	
	PEC/PNEC$_{soil}$
Scenario 1 Indoor, cracks and crevices - straw	< 0.001

Scenario 2 Outdoor, ant nests - straw	0.672

Conclusion: Indirect exposure of the soil due to sludge application has to be considered for the indoor use scenario. Direct exposure of the soil has to be considered for the outdoor use scenario. The risks to the soil compartment are considered acceptable from use of the products in the BPF HG tegen kruipend ongedierte when used in accordance with label instructions.

Groundwater

Summary table on calculated risk quotients		
	$PEC_{groundwater}$ (µg/L) - permethrin	**$PEC_{groundwater}$ (µg/L) - DCVA**
Tier 1: Based on $PEC_{porewater}$		
Scenario 1 Indoor, cracks and crevices – straw	$3.68 \cdot 10^{-5}$	$2.22 \cdot 10^{-6}$
Scenario 2 Outdoor, ant nests – straw	**$2.47 \cdot 10^{-1}$**	$1.49 \cdot 10^{-2}$
Tier 2: FOCUS PEARL 4.4.4 modelling		
Scenario 2 Outdoor, ant nests - straw	<0.001	Not applicable

Conclusion: The risks to groundwater are considered acceptable from use of the products in the BPF HG tegen kruipend ongedierte when used in accordance with label instructions.

Primary and secondary poisoning

Primary poisoning
Soil-dwelling organisms might be directly exposed to permethrin when products are used outside. However, as the products in this BPF are applied as aerosol spray, without food attractant, direct poisoning of mammals and birds is not considered a risk (ESD PT 18).
Indirect exposure might occur when sludge from STP is applied to agricultural soil.
Bees might be exposed when products are applied outside. However, the use is limited to the immediate surrounding of the house.
It is proposed to include the following warning sentence on the label:
"Be aware that this biocidal product contains permethrin which is toxic to bees."

Secondary poisoning

Summary table on calculated PEC/PNEC values		
Scenario	**$PEC/PNEC_{birds}$**	**PEC/PNEC $_{mammals}$**
Aquatic		
Scenario 1 Indoor, cracks and crevices – straw	< 0.001	< 0.001

Scenario 2 Outdoor, ant nests - straw	Not applicable	Not applicable
Terrestrial		
Scenario 1 Indoor, cracks and crevices – straw	< 0.001	< 0.001
Scenario 2 Outdoor, ant nests - straw	0.10	0.014

Conclusion: The risks by primary and secondary poisoning of birds and mammals in the aquatic and terrestrial environment are considered acceptable from use of the products in the BPF HG tegen kruipend ongedierte when used in accordance with label instructions.

Mixture toxicity

Mixture toxicity is not relevant. The products in this BPF contain one active substance, permethrin and no substances of concern for the environment. An assessment of mixture toxicity is not relevant.

****

Evaluation by the eCA

After the first evaluation the applicant has witdrawn treatment against flying insects and a number of crawling insects from the proposed use. As these uses are not supported anymore the evaluation is limited to 4 uses for non-professionals:

1.1 Indoor cracks and crevice treatment against crawling insects, ants and silverfish
1.2 Indoor cracks and crevice treatment against silverfish
1.3a Indoor cracks and crevice treatment against ants
1.3b Outdoor nest treatment against ants

For the risk assessment three scenarios are assessed: indoor cracks and crevices treatment (cockroaches, ants and silverfish), outdoor spot application (ant nests) and outdoor treatment of terraces (ant nests).

In all cases the applicant has reduced the maximum number of applications to 1-2 times per year. HGX tegen kruipend ongedierte is used for the control of a combination of target species like cockroaches, ants and silver fish that can occur in the same household and in different areas of the house. Moreover, it is not expected that non-professionals will request for treatment by a professional at reoccurrence of infestation by species such as ants and silverfish. Therefore, the eCA considers considers a 3-11 times as more representative for this product with the use against crawling insects.

All indoor uses are dosed with a so called "RTU Aerosol spray can with straw" at a rate of 25 ml per m^2. Oudoor treatment of a nest is set at 12.5 ml of product.
Note that the "RTU Spray" used is not an RTU aerosol spray as defined by the PT18 ESD as a *"RTU aerosol systeem contains a mixture of gas and the product and sprays with particle sizes in the range of 0.1 to 10 µm of 20 µm and sometimes 50 µm"*. Instead the present system is a can where the product (a liquid mixture with the active substance) is incorporated in a bag that is put under pressure. It resembles a normal trigger spray which

also can be a applied with a straw. The latter has a higher Fce of 0.25 - 0.5 in stead of 0.03 – 0.2. Nevertheless the APCP expert considers this product as an RTU aersol spray and does not require further information on the spray characteristics, because the spray can has a straw. Therefore the calculations below were based on the FCE of 0.03 for cracks and crevice treatment.

The following relevant efficacy studies were submitted:

Target	Description test	Remarks / conclusion
Ants	Outdoor field trial Application rate: 0 (untreated) and 12.5 ml/nest Treated area: the nestopening of the nest	Sufficient efficacious for the claim outdoor nest treatment
separate tests with ants, cockroaches silverfish	Simulated-use test Application rate: 25 ml/m^2 0.24 m^2 is treated among the 6 m^2 test chamber. Test room: 3 x 2 x 2 m chamber (12 m^3) is 6 m^2 surface The "furniture" is a pile of 5 non-porous lacquer wood boards of 1 m x 1 m (usual dimensions of kitchen furniture), assembled together but letting a 3 cm space between each other in order to create the cracks/crevices. On the first 15 cm of these cracks/crevice (entry of the "furniture"), 16 ceramic tiles of 15 cm x 15 cm are set of the material to be claimed but only 2/3 of its surface is treated (first 10 cm are treated and 5 cm are not treated). 2 types of treated surfaces 16 tiles of (15x15 cm, of which is treated 10x15 cm): porous: ceramic tile porous side non-porous: -ceramic tile	The ESD uses for spot treatment 2 m^2 in a house of 130 m^2 floor (1/63). Recalculating 0.24 m^2 treated surface in a 6 m^2 room to the surface in a 130 m2 house results in 5.2 m^2 treated surface indicating more or less barrier treatment. Issue also could be whether still sufficient efficacy would be reached if also untreated attractive furnitures were set in the test room.

Conclusion

On basis of the information in the table above it is concluded that for crawling insects cracks and crevice treatment is appropriate, however, the amount of product used in the test resembles a barrier type of use in stead of a spot treatment. Therefore the eCA considers it appropriate that for the risk assessment barrier cracks and crevice treatment is decisive for the risk assessment with a frequency of 3 to 11 times a year.

1.1 Emission calculations - Indoor use:

For completeness four options are included: barrier and spot – both cracks and crevice treatment, as well as a frequency of 3-11 and 1-2 applications per year.

Input parameters for calculating the local emission				
Input	**Value**		**Unit**	**Remarks**
Scenario: Indoor spot application (crawling insects: cockroaches, ants and silverfish (cracks and crevices)). RTU product, non-professional user				
	Applicant	eCA		
Application rate of biocidal product	25		mL/m²	Set
Concentration of active substance in the product	0.2		% w/w	Set; max concentration
Total area applied with insecticide in a standard house (total area treated)	2 m²	20 m²	-	Default for barrier treatment
Area of treated surface	2 m² (spot/crack)	5.9 m² (barrier/crack)	-	Default for barrier treatment
Number of preparations per day, house	0 (RTU)		-	Default
Number of applications per day, house	1		-	Default
Selection application method		Default surface treatment		See explanation in introductory text
Fraction emitted to air during application step	-	0.02		Default
Fraction emitted to the applicator during application	0 (straw)*	0.02	-	Default
Fraction emitted to floor during application step	-	0.11		Default
Fraction emitted to treated surfaces during application step	-	0.85		Default
Washable or disposable coveralls	Washable		-	Default
Fraction emitted to solid waste from applicator	0		-	Default
Fraction emitted to wastewater from applicator	1		-	Default
Number of houses/STP	4000		-	Default
Simultaneity factor	0.002042**	0.008151	-	Set
Cleaning method	Sweeping with a broom, vacuum cleaning, wet cleaning		-	Default
Cleaning efficiency	0.03		-	Default

* The applicant proposes no emission in case of using a straw. Note this straw is not fixed to the HG tegen kruipende insecten cans, so when attaching the straw to the can may cause exposure of the applicant. No information was provided to conclude that indeed no emission to the applicant occurs during treatment with this type of product. The commonly agreed approach is to use the default emission factor for surface treatment for the risk assessment;
** The applicant lowered the Fsim based on a restriction added to the SPC that the maximum use of the product is 1-2 times per year. Such a restriction is not realistic because the product is used against several target species, which may be a problem at different times in the year and at different places in the house. See also our explanation in the introductory text of this eCA evaluation.

Summary table for emission values			
Compartment	**Area treated**	**Frequence treated**	**Local emission ($Elocal_{compartment}$) [kg/d]**
STP	Barrier cracks and crevice treatment	3 – 11 times application	$9.29 \cdot 10^{-4}$
		1 – 2 times application	$2.33 \cdot 10^{-4}$
	Spot cracks and crevice treatment	3 – 11 times application	$1.59 \cdot 10^{-4}$
		1 – 2 times application*	$3.99 \cdot 10^{-5}$

* the local emission would be $7.42 \cdot 10^{-4}$ kg/d if the Fce=0.25 would be used for normal spray cracks and crevice treatment – resembling the 3-11 times per year barrier cracks and crevice treatment

1.2 Emission calculations - outdoor use:

The emission to soil for one nest treatment per house per day as performed by the applicant is in line with eCA's calculations (and is discussed as default in the ESD for PT18). The eCA agrees with these calculations.

According to TAB agreement 154, however, also a terrace scenario should be applied, because this scenario considers a larger number of nests and will emit to soil and groundwater.
Although still under discussion at present for the use on terraces, emission to surface water is not calculated, but this may become relevant in future risk assessments. Note further that the present outdoor scenario only assumes one application, although the product is applied one to two times per year according to instructions and could be larger as it concerns treatment by non-professionals and it concerns outdoor use where it can be expected that the product is washed away by rain and will be re-applied when ants return. The eCA does not expect that non-professionals will ask for a professional if ants re-appear when the product has already been used twice that year/season. Hence, risk mitigation measures are considered not feasible.

Input parameters for calculating the local emission due to terrace treatment in ant nests			
Input	**Value**	**Unit**	**Remarks**
Scenario: Outdoor application (ant nests) on terrace. RTU product, non-professional user			
Application rate of biocidal product	12.5	mL	Set; per nest
Concentration of active substance in the product	0.2	% w/w	Set; max concentration
Number of nests	4	-	
Area of treated surface	8.5	m^2	Default; Outdoor spot application (nest)
Fraction emitted to the soil during application	0.8	-	Set; outdoor spot application scenario for powder was used with Fsoil set to 1 instead of the default 0.9
Volume of exposed soil	4.25	m^3	Default; Outdoor spot application

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/campaign]**	**Remarks**
Local emission due to direct spot application to soil	$2.5 \cdot 10^{-5}$	
Local emission to soil due to application on a terrace	$1.00 \cdot 10^{-4}$	

2.1 Risk assessment from indoor use with emission surface water via the STP

PEC and PEC/PNEC values for indoor use of Permethrin						
	STP		**fresh water**		**sediment**	
	PEC (mg/L)	**PEC/PNEC**	**PEC (mg/L)**	**PEC/PNEC**	**PEC (mg/kg wwt)**	**PEC/PNEC**
Indoor barrier, cracks and crevices treatment against crawling insects - Non-professional users						
3-11 times application	5.54E-05	0.011	5.33E-06	**11.3**	3.12E-03	**14.4**
1-2 times application	1.39E-05	0.003	1.33E-06	**2.84**	7.82E-04	**3.61**
Indoor spot, cracks and crevices treatment against crawling insects - Non-professional users						
3-11 times application	9.49E-06	0.002	9.12E-07	**1.94**	5.35E-04	**2.46**
1-2 times application	2.38E-06	<0.001	2.29E-07	0.486	1.34E-04	0.617

Spot - cracks and crevices treatment indicates an acceptable risk for aquatic organisms, when the product is used a maximum of two times per year. However, as discussed above, the eCA does not consider that the available data are sufficient for spot cracks and crevices treatment and also that it is not realistic to assume that the product will be used only twice a year.

Barrier cracks and crevice treatment shows an unacceptable risk for aquatic organisms even with a reduction of the treatment frequency. And unacceptable risks are also demonstrated when the product is applied 3-11 times per year, for both spot and barrier scenarios.

Moreover, as also discussed above, it should be noted that a low cleaning efficiency (0.03) was applied based on RTU aerosols for both the barrier and the spot scenario, even though it is not clear if the product is a RTU aerosol or an automated trigger spray. The cleaning efficiency for trigger spray is much higher (0.25).

Hence, the eCA concludes that the risks are unacceptable for freshwater and sediment when considering realistic use of the product.

Procedural decision

On basis of the risk assessment the CA questions whether a safe use can be identified for the intended indoor use against crawling insects. For other products, upon decision on a referreal of the Coordination Group, however, certain products were authorized, by reducing the packaging size, use of designed spray lance for cracks and crevice treatment, the use of the product is restricted to one target species only and in combination with a number of instructions and restrictions on the SPC/label.

If this approach is extrapolated to HGX then the following adaptations to the product must be applied: the package size is reduced to 100 ml, representing 2 times spot treatment of 2 m^2 with a designed spray nozzle/lance for cracks and crevice treatment and a reduction of the number of target species on the SPC/label to one in combination with the following instructions and restrictions on the SPC/label:

"Do not apply more than 50 mL solution/application when treating a private house."

"Only apply on restricted areas in cracks and crevices."

"If you suspect that after two applications the product is not effective, contact a pest control company."

Please note that the aggregated use of these meta's still results in an unacceptable risk, but this cannot be prevented as it concerns separate products.

2.2.1 Risk assessment for soil due to indoor and outdoor use

Although the emissions to soil estimated by the eCA are higher, the PEC calculations by the eCA resulted in slightly lower values for scenario 1 (indoor use) than those of the applicant. This could not be reproduced.

Summary table on calculated PEC and PEC/PNEC values - Permethrin		
	soil	porewater

	PEC (mg/kg wwt)	PEC/PNEC	PEC (µg/L)
Indoor barrier cracks and crevice treatment emission to soil via sludge on land			
3-11 times application	1.78E-04	0.001	2.20E-04
1- 2 times application	4.46E-05	<0.001	5.52E-05
Indoor spot cracks and crevice treatment emission to soil via sludge on land			
3-11 times application	3.05E-05	<0.001	3.77E-05
1- 2 times application	7.65E-06	<0.001	9.45E-06
Outdoor nest treatment			
Spot treatment on soil	1.18E-01	0.672	**0.25**
Spot treatment on terrace	1.38E-02	0.079	0.029

The PEC/PNEC for all intended uses are below the trigger value of 1 and therefore the risks for soil organisms are considered acceptable.

However, for both outdoor scenarios, the porewater levels exceed the groundwater criterion of 0.1 µg/L and refinement is required (please refer to Section 2.2.3 below).

2.2.2 Metabolites

Degradation of the active substance in soils and in the STP results in formation of the metabolites DCVA and PBA. Although the risks for the aquatic and terrestrial compartments have been sufficiently covered by the assessment of permethrin as the parent is expected to be far more toxic compared to its metabolites, the metabolites may leach to groundwater. As also discussed by the applicant, DCVA is expected to be more mobile and persistent than PBA, and therefore only DCVA is included in the groundwater assessment and this assessment also covers the risks for PBA. The concentration in the STP's effluent and sludge was derived from the fraction parent degraded (0.2589) corrected for differences in molar weight and the transformation fraction. As a worst-case for both surface water and soils, the fraction to water and sludge were set to one. Subsequent concentrations in water and sludge were calculated in accordance to the BPR guidance part B.

Summary table on calculated PEC and PEC/PNEC values - DCVA			
	soil		porewater
	PEC (mg/kg wwt)	PEC/PNEC	PEC (µg/L)
Indoor barrier - cracks and crevice treatment emission to soil via sludge on land			
3-11 times application	$2.56 \cdot 10^{-04}$	<0.001	$8.5 \cdot 10^{-2}$
1- 2 times application	$6.41 \cdot 10^{-05}$	<0.001	$2.1 \cdot 10^{-2}$
Indoor spot - cracks and crevice treatment emission to soil via sludge on land			
3-11 times application	$4.38 \cdot 10^{-05}$	<0.001	$1.5 \cdot 10^{-2}$
1- 2 times application	$1.10 \cdot 10^{-05}$	<0.001	$3.7 \cdot 10^{-3}$
Outdoor nest treatment			
Spot treatment on soil	$1.63 \cdot 10^{-02}$	0.004	**9.23**
Spot treatment on terrace	$1.91 \cdot 10^{-03}$	<0.001	**1.09**

For all intended uses the PEC/PNEC values for soil are below the trigger value of 1 and therefore risks for soil organisms are considered acceptable. Porewater levels for indoor uses are also below the trigger value, but for outdoor uses the porewater levels are above

the trigger value. The applicant, however, did not include groundwater calculations for the metabolites, although from the first tier can be derived that the standard for groundwater of DCVA is exceeded. Refinement is included in Section 2.2.3 below.

2.2.3 Groundwater refinement

The highest PECgw for the active substance permethrin in soil is 0.25 µg/L and exceeds the maximum permissible concentration laid down by Directive 98/83/EC (0.1 µg/L). Also in the first tier calculations predicted unacceptable emission of the metabolite DCVA to groundwater. The other metabolite PBA is also included in this assessment, for completeness. Emission was subsequently assessed with PEARL based on the worst-case average emission assuming 16 houses (terraces per hectare – 4 nests - 2 applications per year (in total 32) split in 10 applications as described in TAB ENV 157. Also for the metabolites the applicant's scenario for nest treatment with emission to groundwater was calculated with PEARL.

Scenario	Terrace treatment	Soil nest treatment
Parameters	All locations were selected	All locations were selected
Scenario	Grasslands (=alfalfa)	Grasslands (=alfalfa)
Application rate	0.356 g a.s./ha*	1.786 g a.s./ha**
Application type	No incorporation	No incorporation
Application dates	10th of Januari 15th of Februari 24th of of March 29th of April 5th of June 11th of July 17th of August 22th of September 29th of October 4th of December	1st of April 16th of May
Application depth	0 m	0 m

* Qprod (12.5 ml/nest)*Fai (0.002)*Nnests (4) *Fsoil,appl (0.8) *Nappl per year (2) / Npearl appl. (10)

** Scenario applicant: Ngardens per ha (10000/140) * dosage per garden (25/1000)

General input parameters (only set values) for calculation of environmental exposure				
Input	**Parent**	**Metabolite 1**	**Metabolite 2**	**Remarks**
Substance Name	Permethrin	DCVA	PBA	
Molar mass (g/mol)	391.29	209.07	214.22	value taken from CAR
Saturated vapour pressure (Pa)	0.00000216 (20°C)	0.26 (25°C)	0.000421 (25°C)	value taken from CAR

General input parameters (only set values) for calculation of environmental exposure				
Input	**Parent**	**Metabolite 1**	**Metabolite 2**	**Remarks**
Substance Name	Permethrin	DCVA	PBA	
solubility at test temperature (mg/L)	<0.00495 (20°C)	127.6 (25°C)	16.91 (25°C)	value taken from CAR
Koc (L/kg)	73441	93.2	141.2	value taken from CAR
Kom, pH-independent (L/kg at 20°C)	42599	54.1	81.9	Koc / 1.724
Freundlich sorption exponent	1	1	1	
Fraction tranformed	N/A	1 (from parent)	1 (from parent)	
Transformation half-life in soil (d at 12°C)	106	175	2.5	value taken from CAR

Treatment of terraces - PEC_{gw} for Permethrin and metabolites on land (with FOCUS PEARL 4.4.4)				
Crop	**Scenario**	**80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)**		
		Permethrin	**DCVA**	**PBA**
Grass (=alfalfa)	Châteaudun	<0.001	0.021843	<0.001
	Hamburg	<0.001	0.034303	<0.001
	Jokioinen	<0.001	0.026264	<0.001
	Kremsmünster	<0.001	0.023242	<0.001
	Okehampton	<0.001	0.027980	<0.001
	Piacenza	<0.001	0.024461	<0.001
	Porto	<0.001	0.018236	<0.001
	Sevilla	<0.001	0.009302	<0.001
	Thiva	<0.001	0.013373	<0.001

Treatment of two nests per garden on soil - PEC_{gw} for Permethrin and metabolites on land (with FOCUS PEARL 4.4.4)				
Crop	**Scenario**	**80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)**		
		Permethrin	**DCVA**	**PBA**
Grass (=alfalfa)	Châteaudun	<0.001	0.029907	<0.001
	Hamburg	<0.001	0.047675	<0.001
	Jokioinen	<0.001	0.036398	<0.001
	Kremsmünster	<0.001	0.032236	<0.001
	Okehampton	<0.001	0.038231	<0.001
	Piacenza	<0.001	0.033070	<0.001
	Porto	<0.001	0.023602	<0.001
	Sevilla	<0.001	0.012478	<0.001
	Thiva	<0.001	0.018726	<0.001

Spot treatment on soil (ant nests) is worst case, compared to treatment on terraces, due to the higher peak treatment and repeated twice with a short period. For the representative Dutch scenario (Kremsmünster), as well as for all other scenarios, the concentrations for the parent and both metabolites are below 0.1 µg/L for the worst-case scenario. Conclusively, unacceptable emission to groundwater are not expected.

2.3 Secondary poisoning risk assessment

The applicant carried out a secondary poisoning risk assessment on basis of the guidance in Vol IV part B&C assuming spot cracks and crevice wit a maximum of two applications per year. Note that on basis of this assessment (with PEC/PNEC values of maximum 0.1) also for larger indoor treated areas use like barrier cracks and crevice and 3-11 applications per year the risks for fish and earthworm eating mammals and birds is not exceeded.

According to the PT18 ESD, however, also a different approach for secondary poisoning calculations should be assessed. The secondary poisoning assessment included in Vol IV part B&C (and performed by the applicant) covers fish and earthworm eating birds and mammals. Using the approach in the PT18 ESD, the risks for herbivorous and insectivorous animals can also be assessed. The eCA performed the assessment for the outdoor spot scenario (which has the highest outdoor/soil emission), using the local concentration in soil as calculated to obtain the PECsoil (please refer to calculation sheet below. The indicator species were chosen as worst-case and the two relevant species with the highest ETE/PNEC values are presented in the summary table below.

Summary table on calculated PEC and PEC/PNEC values - Permethrin			
		ETE	ETE/PNEC
		mg/kg bw per day	
Outdoor spot treatment			
Acute exposure	ETE/PNECacute,mammal,worm	1.21	0.20
	ETE/PNECacute,bird,worm	1.50	0.72
Short-term exposure	ETE/PNECshort-term,mammal,worm	1.21	0.20
	ETE/PNECshort-term,bird,worm	1.50	0.72

All ETE/PNEC values are below the trigger value of 1, indicating an acceptable risk for herbivorous and insectivorous birds and mammals.

Calculation table with the input data :

Secondary poisoning

Input

Variable/parameter		*Symbol*	*Value*	*Unit*	*S/D/O/P* [1]	*References / Calculation formulas / Explanations*
Repeated applications by spraying?	Yes					
Multiple application factor		MAF	1	[-]	S	
Application specific factor, acute exposure		$Fappl_{acute}$	1	[-]	S	
Application specific factor, short term exposure		$Fappl_{short-term}$	1	[-]	S	
Effective application rate, acute exposure		$Tappl_{acute}$	1.00E-04	$kg.m^{-2}$	O	**$Tappl_{acute}$** = Q_{prod} * F_{AI} * $Fappl_{acute}$ / $A_{soil,exposed}$
Effective application rate, short-term exposure		$Tappl_{short-term}$	1.00E-04	$kg.m^{-2}$	O	**$Tappl_{short-term}$** = Q_{prod} * F_{AI} *$Fappl_{short-term}$ / $A_{soil,exposed}$
Bioconcentration factor for earthworms		BCFworm	15108	$l.kg_{wwt}^{-1}$	S	
Additional factor to translate Tappl for 1 ha		ADF	1.00E-04	$ha.kg^{-1}$	D	
Density of solid phase		RHO_{solid}	2500	$kg.m^{-3}$	D	
Volume fraction of solids in soil		F_{solid}	0.6	m3.m-3	D	BPR Guidance Vol IV Part B+C

Fraction of gut loading in worm	F_{gut}	0.1	$kg_{dwt}.kg_{wwt}^{-1}$	D	BPR Guidance Vol IV Part B+C
Soil-water partition coefficient	$K_{soil-water}$	808.1000018	$m^3.m^{-3}$	S	
Conversion factor for soil concentration wet - dry weight soil	$CONV_{soil}$	1.13	$kg_{wwt}.kg_{dwt}^{-1}$	O	**CONV** = RHO_{soil} / (F_{solid} * RHO_{solid})
Local concentration in soil	C_{soil}	5.88E-08	$kg.kg_{wwt}^{-1}$	O	**C_{soil}** = $C_{soil,appl}$ / 2
Local concentration in porewater	C_{porew}	1.24E-10	$kg.l^{-1}$	O	**C_{porew}** = C_{soil} * RHO_{soil} / ($K_{soil-water}$ * 1000)
Concentration in earthworm	$C_{earthworm}$	1.69E+00	$mg.kg_{wet\ earthworm}^{-1}$	O	**$C_{earthworm}$** = ($BCF_{earthworm}$ * $C_{porewater}$ + C_{soil} * F_{gut} * $CONV_{soil}$)*10^6 / (1 + F_{gut} * $CONV_{soil}$)
Insectivorous indicator species					
Select insectivorous indicator species	Medium insectivorous bird - Blackbird			P	
Mean body weight of indicator species	bw	113	g	D	
Food intake rate of indicator species (fresh weight)	FIR	87.1 87.1	$g.d^{-1}$	D	
Residue per Unit Dose					
acute exposure (90%)	RUD_{acute}	14 14	$mg.kg^{-1}$	D	
short-term exposure (mean)	$RUD_{short-term}$	5.1 5.1	$mg.kg^{-1}$	D	
Avoidance factor (1 = no avoidance; 0 = complete avoidance)	AV	1	[-]	D	
Fraction of diet obtained in treated area (value between 0 and 1)	PT	1	[-]	D	
Fraction of food type in diet in the diet of species of concern (value between 0 and 1; one food type or more types)	PD	1	[-]	D	

Herbivorous indicator species

Select herbivorous indicator species		Medium herbivorous mammal - Rabbit		P
Mean body weight of indicator species	bw	1500	g	D
Food intake rate of indicator species (fresh weight)	FIR	387.4 387.4	$g.d^{-1}$	D
Residue per Unit Dose				
acute exposure (90%)	RUD_{acute}	87 87	$mg.kg^{-1}$	D
short-term exposure (mean)	$RUD_{short-term}$	40 40	$mg.kg^{-1}$	D
Avoidance factor (1 = no avoidance; 0 = complete avoidance)	AV	1	[-]	D
Fraction of diet obtained in treated area (value between 0 and 1)	PT	1	[-]	D
Fraction of food type in diet in the diet of species of concern (value between 0 and 1; one food type or more types)	PD	1	[-]	D

Mammals eating worms indicator species

Select mammals eating worms indicator species		Small insectivorous mammal - Mole		P
Mean body weight of indicator species	bw	85	g	D
Food intake rate of indicator species (fresh weight)	FIR	61.2 61.2	$g.d^{-1}$	D
Avoidance factor (1 = no avoidance; 0 = complete avoidance)	AV	1	[-]	D
Fraction of diet obtained in treated area (value between 0 and 1)	PT	1	[-]	D
Fraction of food type in diet in the diet of species of concern (value between 0 and 1; one food type or more types)	PD	1	[-]	D

Birds eating worms indicator species

Select birds eating worms indicator species		Omnivorous bird - Black-billed Magpie		P
Mean body weight of indicator species	bw	225	g	D
Food intake rate of indicator species (fresh weight)	FIR	200.9 200.9	$g.d^{-1}$	D
Avoidance factor (1 = no avoidance; 0 = complete avoidance)	AV	1	[-]	D
Fraction of diet obtained in treated area (value between 0 and 1)	PT	1	[-]	D
Fraction of food type in diet in the diet of species of concern (value between 0 and 1; one food type or more types)	PD	1	[-]	D

Output

Estimated daily uptake of active substance via the consumption of contaminated food by predators

Acute exposure				
	$ETE_{acute,insectivorous}$	1.08E-03	$mg.kg^{-1}.d^{-1}$	O	$ETE_{acute,insectivorous} = (FIR/bw) * RUD_{acute} * Tappl_{acute} * AV * PT * PD * ADF * 10^4$
	$ETE_{acute,herbivorous}$	2.25E-03	$mg.kg^{-1}.d^{-1}$	O	$ETE_{acute,herbivorous} = (FIR/bw) * RUD_{acute} * Tappl_{acute} * AV * PT * PD * ADF * 10^4$
	$ETE_{acute,mammal,worm}$	1.21E+00	$mg.kg^{-1}.d^{-1}$	O	$ETE_{acute,mammal,worm} = C_{worm} * (FIR/bw) * AV * PT * PD$
	$ETE_{acute,bird,worm}$	1.50E+00	$mg.kg^{-1}.d^{-1}$	O	$ETE_{acute,bird,worm} = C_{worm} * (FIR/bw) * AV * PT * PD$
Short-term exposure				
	$ETE_{short-term,insectivorous}$	3.93E-04	$mg.kg^{-1}.d^{-1}$	O	$ETE_{short-term,insectivorous} = (FIR/bw) * RUD_{short-term} * Tappl_{short-term} * AV * PT * PD * ADF * 10^4$
	$ETE_{short-term,herbivorous}$	1.03E-03	$mg.kg^{-1}.d^{-1}$	O	$ETE_{short-term,herbivorous} = (FIR/bw) * RUD_{short-term} * Tappl_{short-term} * AV * PT * PD * ADF * 10^4 * MAF$ (in case of repeated applications MAF is taken into account)

	$ETE_{short-term,mammal,worm}$	1.21E+00	$mg.kg^{-1}.d^{-1}$	O	$ETE_{short-term,mammal,worm} = C_{worm} * (FIR/bw) * AV * PT * PD$
	$ETE_{short-term,bird,worm}$	1.50E+00	$mg.kg^{-1}.d^{-1}$	O	$ETE_{short-term,bird,worm} = C_{worm} * (FIR/bw) * AV * PT * PD$

Aggregated exposure (combined for relevant emission sources)

The 2014 assessment reports for permethrin inclusion in Annex I for PTs 8 and 18 state the following:

The need to discuss the aggregated environmental exposure arising when an active substance is approved across multiple product types has been discussed during TMI2012 and TMIII2012. At TMIII 2013 it was proposed that such an assessment would be required for permethrin. However, in the absence of robust guidance that would allow a quantitative assessment to be carried out, it was agreed that a qualitative analysis would suffice. For this, the decision tree finalised by DE at TMIII2012 is used for the discussion.

The current submission includes three products – two under PT18 and one under PT8. In the case of the two PT18 products the only environmental exposure is via emissions to wastewater and subsequent processing at a domestic STP. Clearly in this instance there is potential for usage of the two products to overlap in time and space. At the product authorisation stage the CA should bear in mind that there is a possibility for the a.s to load to the different environmental compartments after discharge from the STP (SW, soil, sludge, sed and GW). The PT8 product also involves discharges to an STP. However in the case of Industrial Preventive Processes the CA has already recommended retention of the wastewaters at the industrial facility and treatment as hazardous waste. Therefore there should be no additional loading of permethrin from this source. The only other possible discharge to STP for PT8 is in the 'Noise Barrier' scenario. This is a niche scenario and thus is unlikely to contribute significant quantities, relative to PT18. Nonetheless CAs should bear this in mind at the product authorisation stage.

The other scenarios in PT8 mostly involve leaching of the a.s. from wood to the soil directly beneath them. Transport through the soil is not expected so it is unlikely that loadings of permethrin from the various scenarios would aggregate to any significant extent. However it is possible to envisage a development containing a high density of houses, fences and other treated wooden products where there may be some possibility for leaching to the one soil body. Again, this should be borne in mind by the CA at product authorisation stage.

To summarise there are two possible situations where aggregated exposure may be expected:

- *Overlap in time and space in usage of the two PT18 products (and to a lesser extent the PT8 product) where discharges to a municipal STP result in a loading to the different environmental compartments (SW, soil, sludge, sed and GW).*
- *Developments containing a high density of treated wooden products where leaching to the same soil body may occur.*

As indicated above, overlap in environmental exposure between PT08 and PT18 uses can be considered unlikely. Additionally, in the Netherlands, permethrin-treated wood is not a common, outside building material. In fact, all PT08 authorizations for permethrin-containing products are for uses for wood under cover. As such no environmental exposure from PT08 uses, and consequently no aggregated exposure from PT08 and PT18 overlap is foreseen.

Overlap in space and time from use of different PT18 products is, in fact, already taken care of in the default ESD scenario. The only relevant 'area' where different uses, or use of different products, would result in exposure of the same compartment is the use of insecticides for which the route via STP to surface water is relevant. Due to the assumptions built into the standard exposure scenario (which is based on a French overview of 'insecticide use'; thus automatically including all products, and indoor use types, even for

different active substances) the emission estimates already represent an aggregated exposure. No further assessment would therefore be required.

The above argumentation was not acknowledged in the PT18 Assessment Report and although we are of the opinion that the simultaneity factor takes the overlap in time and space already into account for PT18 products, aggregated exposure was assessed for the uses in this BPF.

HG tegen kruipend ongedierte has three indoor uses (against crawling insects, against silverfish, against ants) with very similar use instructions and by applying the same dose rate which has been shown to be efficacious against crawling insects including ants and silverfish. Treatment of plinths/strips with product against ants or silverfish will not only work for 6 weeks against the specified target organism, but also against other crawling insects, and vice versa. The consumer will have no need to treat the same space at the same time for another type of crawling insect as all crawling insects are killed. Aggregated exposure of the three indoor uses is considered not relevant.

The outdoor use can overlap in time with the indoor use. Outdoor use against ant nests results in emission to the soil compartment only, and emission is limited to soil around buildings (gardens). Indoor use against crawling insects indirectly emits to the soil compartment by sludge application to agricultural soil and grassland. Emissions to soil of outdoor and indoor uses of HG tegen kruipend ongedierte therefore do not overlap in space and no aggregated exposure is considered relevant for soil and groundwater.

Overall conclusion on the risk assessment for the environment of the product
The intended uses for the products in the BPF 'HG tegen kruipend ongedierte' when used in accordance with the label instructions will not result in risks for the environment.

****

Evaluation by the eCA

On basis of the information on efficacy submitted to the eCA a barrier cracks & crevice treatment is considered appropriate.

The resulting risk assessment performed shows that acceptable risks for the aquatic compartment are expected from indoor use of "HG tegen kruipend ongedierte" used indoors use against crawling insects when applied 1-2 times. However, the eCA questions whether 2 application times per year is appropriate for meta 1 as the products in meta 1 are against 3 different target species, which may result in more frequent use (see also reference to recent CG decisions below).

When applied 3-11 times, which is considered more realistic for a product against multiple target organisms an unacceptable risks for the aquatic compartment is concluded.

After recent CG discussions certain products were authorized, by reducing the packaging size, use of designed spray lance for cracks and crevice treatment, the use of the product is restricted to one target species only and in combination with a number of instructions and restrictions on the SPC/label.

When this approach is extrapolated to HGX the following adaptations need to be applied to the products:

- The package size is reduced to 100 ml, representing 2 times spot treatment of 2 m^2;
- The packaging is provided only with a designed spray nozzle/lance for cracks and crevice treatment;

- The following instructions and restrictions on the SPC/label:

"Do not apply more than 50 mL solution/application when treating a private house."

"Only apply on restricted areas in cracks and crevices."

"If you suspect that after two applications the product is not effective, contact a pest control company."

Outdoor use in ant nests (use # 1.3) does not indicate unacceptable risks to the environment, under the risk mitigation measurement:

"Do not apply this product in areas with a drain."

Remaining authorised uses from the environmental perspective are:
Use # 1.1 – Cockroaches - indoor (spot - cracks and crevices)
Use # 1.2 – Silverfish - indoor (spot - cracks and crevices)
Use # 1.3 - Ants- indoor (spot - cracks and crevices) and Outdoor (terraces) - Nest treatment

Use of these total of products still results in an unacceptable risk, but aggregated use is not part of the authorisation framework.

****

2.2.9 Measures to protect man, animals and the environment

The biocidal product family (BPF) named "HG tegen kruipend ongedierte" consists of MetaSPC 1 - Spray can : HG tegen kruipend ongedierte aerosol

Based on the assessment presented in this report the following measures apply

MetaSPC 1 - Spray can : HG tegen kruipend ongedierte aerosol

Measures following physical/chemical hazards:
Pressurized container: may burst if heated
Pressurized container: Do not pierce or burn, even after use.
Protect from sunlight. Do not expose to temperatures exceeding 50°C / 122° F.
Keep away from heat/sparks/open flames/hot surfaces. – No smoking.

Measures to protect man:
If medical advice is needed, have product container or label at hand.
Keep out of reach of children.

Measures to protect the environment:
Very toxic to aquatic life with long lasting effects.
Avoid release to the environment.
Collect spillage.
Dispose of contents/container to hazardous or special waste collection point.

RMM following risk assessment:
Do not apply on (pet) animals and plants.

The product should be applied where children and pets do not come in contact with the product.
Unprotected persons and animals should be kept away during application.
Keep cats away from treated surfaces. Due to their particular sensitivity to permethrin, the product can cause severe adverse reactions in cats.

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.

If you suspect that after two applications the product is not effective, contact a pest control company.

Do not apply this product in areas with a drain.

2.2.10 Assessment of a combination of biocidal products

The biocidal products in BPF 'HG tegen kruipend ongedierte' are not intended to be authorised for the use with other biocidal products.

2.2.11 Comparative assessment

Does not apply since permethrin does not meet the criteria for a comparative assessment.

3 ANNEXES[3]

3.1 List of studies for the biocidal product (family)

Section No / Reference No	Author	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) Published or Unpublished
1 (confidential)			LoA Permethrin
1 (confidential)			Art 95 declaration
2 (confidential)	Anonymous	2018	Composition and classification spreadsheet HG HG International BV Damsluisweg 70, 1303 AB, Almere, The Netherlands 11-10-2018 GLP not applicable Not published
3.1 tot 3.19	[redacted]	2018 a	Physical and chemical properties of HGX tegen vliegend en kruipend ongedierte * HG International BV Damsluisweg 70, 1303 AB, Almere, The Netherlands 11-10-2018 GLP not applicable Not published
3.1 to 3.19	[redacted]	2021a	Physical and chemical properties of HGX tegen vliegend en kruipend ongedierte HG International BV Damsluisweg 70, 1303 AB, Almere, The Netherlands 22-03-2021 GLP not applicable Not published
3.1	[redacted]	2018 b	HGX tegen vliegend en kruipend ongedierte determination of the appearance. HG International BV Damsluisweg 70, 1303 AB, Almere, The Netherlands HG Report 01, 11-10-2018 GLP not applicable Not published

[3] When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included.

Section No / Reference No	Author	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) Published or Unpublished
3.2	[redacted]	2018 c	HGX tegen vliegend en kruipend ongedierte determination of pH HG International BV Damsluisweg 70, 1303 AB, Almere, The Netherlands HG Report 02, 11-10-2018 GLP not applicable Not published
3.3	[redacted]	2018 d	HGX tegen vliegend en kruipend ongedierte determination of relative density HG International BV Damsluisweg 70, 1303 AB, Almere, The Netherlands HG Report 04, 11-10-2018 GLP not applicable Not published
3.4.1.1	[redacted]	2018 e	HGX tegen vliegend en kruipend ongedierte determination of accelerated storage HG International BV Damsluisweg 70, 1303 AB, Almere, The Netherlands HG Report 08, 11-10-2018 GLP not applicable Not published
3.4.1.1	[redacted]	2019 b	HGX tegen vliegend en kruipend ongedierte determination of accelerated storage in commercial packaging HG International BV Damsluisweg 70, 1303 AB, Almere, The Netherlands HG Report 13, 01-04-2019 GLP not applicable Not published
3.4.1.2	[redacted]	2018 f	HGX tegen vliegend en kruipend ongedierte determination of long term storage HG International BV Damsluisweg 70, 1303 AB, Almere, The Netherlands HG Report 10, 20-11-2018 GLP not applicable Not published
3.4.1.2	[redacted]	2019c	HGX tegen vliegend en kruipend ongedierte determination of long term storage UPDATE 2019 HG International BV Damsluisweg 70, 1303 AB, Almere, The Netherlands HG Report 10, 03-04-2019 GLP not applicable

Section No / Reference No	Author	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) Published or Unpublished
			Not published
3.4.1.2	[redacted]	2018 g	HGX tegen vliegend en kruipend ongedierte determination of low temperature stability HG International BV Damsluisweg 70, 1303 AB, Almere, The Netherlands HG Report 09, 11-10-2018 GLP not applicable Not published
3.4.1.2	[redacted]	2019a	HGX tegen vliegend en kruipend ongedierte determination of low temperature stability in commercial packaging HG International BV Damsluisweg 70, 1303 AB, Almere, The Netherlands HG Report 12, 01-04-2019 GLP not applicable Not published
3.4.1.2	[redacted]	2021b	HG tegen kruipend ongedierte – aerosol product appearance and function HG International BV Damsluisweg 70, 1303 AB, Almere, The Netherlands HG Report 16-03-2021 GLP not applicable Not published
3.4.1.2	[redacted]	2021c	HG tegen kruipend ongedierte long term storage test HG International BV Damsluisweg 70, 1303 AB, Almere, The Netherlands HG Report 19-03-2021 GLP not applicable Not published
3.5.12	[redacted]	2018 h	HGX tegen vliegend en kruipend ongedierte spraying pattern HG International BV Damsluisweg 70, 1303 AB, Almere, The Netherlands HG Report 07, 18-10-2018 GLP not applicable Not published
3.5.12	[redacted]	2018	Testergebnisse tropfengrossenverteilung MalvernPanalytical GmbH Herrenberg, Deutschland 10-12-2018 GLP not applicable Not published

Section No / Reference No	Author	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) Published or Unpublished
3.8	[redacted]	2018 i	HGX tegen vliegend en kruipend ongedierte determination of the surface tension HG International BV Damsluisweg 70, 1303 AB, Almere, The Netherlands HG Report 03, 11-10-2018 GLP not applicable Not published
3.9	[redacted]	2018 j	HGX tegen vliegend en kruipend ongedierte determination of viscosity HG International BV Damsluisweg 70, 1303 AB, Almere, The Netherlands HG Report 05, 11-10-2018 GLP not applicable Not published
	[redacted]	2021d	HG tegen kruipend ongedierte determination of the dynamic viscosity HG International BV Damsluisweg 70, 1303 AB, Almere, The Netherlands HG Report 04-03-2021 GLP not applicable Not published
4.1 to 4.17	[redacted]	2018 a	Physical and chemical properties of HGX tegen vliegend en kruipend ongedierte HG International BV Damsluisweg 70, 1303 AB, Almere, The Netherlands 11-10-2018 GLP not applicable Not published
4.1 to 4.17	[redacted]	2021a	Physical and chemical properties of HGX tegen vliegend en kruipend ongedierte HG International BV Damsluisweg 70, 1303 AB, Almere, The Netherlands xx-03-2021 GLP not applicable Not published
4. 6 (IUCLID)	[redacted]	2018 k	HGX tegen vliegend en kruipend ongedierte determination of flashpoint HG International BV Damsluisweg 70, 1303 AB, Almere, The Netherlands HG Report 06, 11-10-2018 GLP not applicable Not published

Section No / Reference No	Author	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) Published or Unpublished
4.16	[redacted]	2021	Corrosion testing of the product 'HG against crawling pests', on steel and aluminium panels according to UN Transport of Dangerous Goods Manual 2009, Section 37 Class 8. COT, BV, Haarlem, The Netherlands LAB21-0100-REP GLP not applicable Not published
4.17 (IUCLID)	[redacted]	2018	Determination of the auto ignition temperature of HGX tegen kruipend en vliegend ongedierte according to EU A.15 LAUS GmbH Auf der Schafweide 20, 67489 Kirrwieler, Germany Study nr 18102214N962, 26-11-2018 GLP not applicable Not published
5	[redacted]	2018 L	HGX tegen vliegend en kruipend ongedierte HPLC method validation HG International BV Damsluisweg 70, 1303 AB, Almere, The Netherlands HG Report 11, 28-11-2018 GLP not applicable Not published
5	Anonymous	2018	Appendix 1- results HG International BV Damsluisweg 70, 1303 AB, Almere, The Netherlands HG Report 11, 18-10-2018 GLP not applicable Not published
5	Anonymous	2018	Appendix 2 – calculation HG International BV Damsluisweg 70, 1303 AB, Almere, The Netherlands HG Report 11, 18-10-2018 GLP not applicable Not published
5	Anonymous	2018	Appendix 3 – CoA Permethrin HG International BV Damsluisweg 70, 1303 AB, Almere, The Netherlands HG Report 11, 18-10-2018 GLP not applicable Not published
6.1	[redacted]	2018	HGX tegen vliegend en kruipend ongedierte aerosol. Intended uses and efficacy.

Section No / Reference No	Author	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) Published or Unpublished
			GLP not applicable Not published
6.1	[redacted]	2018	HGX tegen vliegend en kruipend ongedierte. Intended uses and efficacy. GLP not applicable Not published
6.7	[redacted]	2018a	Laboratory trial of the efficacy of a insecticidal product against various flying and crawling target organisms. HGX Insecticide Spray Trigger Spray RTU – 0.2% permethrin w/w Laboratoire T.E.C. 1, rue Jules Vedrines, ZAC Maignon, 64600 Anglet, France November 2018 - 2389a-spray-LAB/0918 GLP not applicable Not published
6.7	[redacted]	2018b	Simulated-use trial of the efficacy of a insecticidal product against various pests. HGX Insecticide Spray Trigger Spray RTU – 0.2% permethrin w/w Laboratoire T.E.C. 1, rue Jules Vedrines, ZAC Maignon, 64600 Anglet, France November 2018 - 2389b-spray-SIMUSE/0918 GLP not applicable Not published
6.7	[redacted]	2018c	Laboratory trial of the efficacy of a insecticidal product against various flying and crawling target organisms. HGX Insecticide Spray Aerosol – 0.2% permethrin w/w Laboratoire T.E.C. 1, rue Jules Vedrines, ZAC Maignon, 64600 Anglet, France November 2018 - 2389c aeosol-LAB/0918 GLP not applicable Not published
6.7	[redacted]	2018d	Simulated-use trial of the efficacy of a insecticidal product against various pests. HGX Insecticide Spray Aerosol – 0.2% permethrin w/w Laboratoire T.E.C. 1, rue Jules Vedrines, ZAC Maignon, 64600 Anglet, France November 2018 - 2389d aeosol-SIMUSE/0918 GLP not applicable

Section No / Reference No	Author	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) Published or Unpublished
			Not published
6.7		2018e	Field trial of the efficacy of a insecticidal product against ants. HGX Insecticide Spray Trigger Spray RTU – 0.2% permethrin w/w Laboratoire T.E.C. 1, rue Jules Vedrines, ZAC Maignon, 64600 Anglet, France November 2018 - 2389e-spray-LN/0918 GLP not applicable Not published
6.7		2018f	Field trial of the efficacy of a insecticidal product against ants. HGX Insecticide Spray Aerosol – 0.2% permethrin w/w Laboratoire T.E.C. 1, rue Jules Vedrines, ZAC Maignon, 64600 Anglet, France November 2018 - 2389f-aeosol-LN/0918 GLP not applicable Not published
6.7		2021	Simulated-use trial of the efficacy of an insecticidal product. Cracks and crevices treatment crawling insects. HG against crawling insects - permethrin 0.2% aerosol Laboratoire T.E.C. 1, rue Jules Vedrines, ZAC Maignon, 64600 Anglet, France March 2021, Report 2628/1120 GLP not applicable Not published
8			Consexpo output is included in Annex PAR
8/9			EU assessment report permethrin see ECHA website
8/9	Anonymous	2018	Composition and classification spreadsheet HG HG International BV Damsluisweg 70, 1303 AB, Almere, The Netherlands 11-10-2018 GLP not applicable Not published
10	Anonymous	2021	EUSES output_scenario 1_HG tegen kruipende insecten_GLP not applicable Not published
10	Anonymous	2021	EUSES output_scenario 2_HG tegen kruipende insecten_ GLP not applicable Not published
10	Anonymous	2021	FOCUS PEARL output_HG tegen kruipend ongedierte GLP not applicable

Section No / Reference No	Author	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) Published or Unpublished
			Not published
13	Anonymous	2018	SDS HGX tegen vliegend en kruipend ongedierte aerosol HG International BV Damsluisweg 70, 1303 AB, Almere, The Netherlands 11-10-2018 GLP not applicable Not published
13	Anonymous	2021	SDS HG tegen kruipend ongedierte HG International BV Damsluisweg 70, 1303 AB, Almere, The Netherlands 11-10-2018 GLP not applicable Not published

*please note that during the evaluation, part of the originally intended uses are no longer supported, as a result, the name of the products, metaSPC and product family has changed. The product itself has not changed. HGX tegen vliegend en kruipend ongedierte (aerosol) is the same product as HG tegen kruipend ongedierte (aerosol). All tetst results are still valid.

3.2 Output tables from exposure assessment tools

The details from ConsExpo calculated for the human RA are presented below:

Spray can - Cracks and crevices – one minute application

Substance			
Name	permethrin		
CASNumber	52645-53-1		
Molecular weight		391	g/mol
KOW		4.67	10Log
Product			
Name		HG BPF	
Weight fraction substance		0.2	%
Population			
Name		ConsExpo fact sheet adult	
Body weight		60	kg
Scenario 2021 applicant spray can cracks 1 minute			
Frequency		2	per year
Description			
Inhalation			
Exposure model		Exposure to spray - Spraying	
Spray duration		1	minute
Exposure duration		240	minute
Product in pure form		No	
Molecular weight matrix			
The product is used in dilution		No	
Weight fraction substance		0.2	%
Room volume		20	m³
Room height		2.5	m
Ventilation rate		0.6	per hour
Inhalation rate		1.25	m³/hr
Spraying towards person		No	
Mass generation rate		0.55	g/s
Airborne fraction		0.2	
Density non volatile		1.8	g/cm³
Inhalation cut off diameter		15	µm
Aerosol diameter distribution		LogNormal	
Median diameter		3.6	µm
Arithmetic coefficient of variation		0.57	
Maximum diameter		50	µm
Include oral non-respirable material exposure		No	
Absorption model		Fixed fraction	
Absorption fraction		100	%
Dermal			
Exposure model		Direct contact - Constant rate	
Exposed area		1.95E+03	cm²

Weight fraction substance	0.2	%
Contact rate	100	mg/min
Release duration	1	minute
Absorption model	Fixed fraction	
Absorption fraction	50	%

Oral
Exposure model n.a.
Absorption model n.a.

Results for scenario 2021 applicant spray can cracks 1 minute

Inhalation		
Mean event concentration	0.112	mg/m³
Peak concentration (TWA 15 min)	0.517	mg/m³
Mean concentration on day of exposure	0.0187	mg/m³
Year average concentration	0.000205	mg/m³
External event dose	0.00935	mg/kg bw
External dose on day of exposure	0.00935	mg/kg bw
Internal event dose	0.00935	mg/kg bw
Internal dose on day of exposure	0.00935	mg/kg bw/day
Internal year average dose	0.000102	mg/kg bw/day
Dermal		
Dermal load	0.000103	mg/cm²
External event dose	0.00333	mg/kg bw
External dose on day of exposure	0.00333	mg/kg bw
Internal event dose	0.00167	mg/kg bw
Internal dose on day of exposure	0.00167	mg/kg bw/day
Internal year average dose	1.83E-05	mg/kg bw/day
Integrated		
Internal event dose	0.011	mg/kg bw
Internal dose on day of exposure	0.011	mg/kg bw/day
Internal year average dose	0.000121	mg/kg bw/day

Post-application child

Substance		
Name	permethrin	
CASNumber	52645-53-1	
Molecular weight	391	g/mol
KOW	4.67	10Log
Product		
Name	HG kruipend ongedierte	
Weight fraction substance	0.2	%
Population		
Name	child post	
Body weight	8	kg

Scenario post application (child) verfijnd		
Frequency	2	per year
Description		

Inhalation		
Exposure model	n.a.	
Absorption model	n.a.	

Dermal		
Exposure model	Direct contact - Rubbing off	
Exposed area	1.17E+03	cm²
Weight fraction substance	0.2	%
Transfer coefficient	0.6	m²/hr
Dislodgeable amount	3.83	g/m²
Contact time	60	minute
Contacted surface	2	m²
Release duration	1	min
Absorption model	Fixed fraction	
Absorption fraction	50	%

Oral		
Exposure model	Direct product contact - Constant rate	
Weight fraction substance	0.2	%
Ingestion rat	3.8	mg/min
Exposure duration	60	minute
Absorption model	Fixed fraction	
Absorption fraction	100	%

Results for scenario post application (child) verfijnd

Dermal		
Dermal load	0.0092	mg/cm²
External event dose	0.57	mg/kg bw
External dose on day of exposure	0.57	mg/kg bw
Internal event dose	0.29	mg/kg bw
Internal dose on day of exposure	0.29	mg/kg bw/day
Internal year average dose	0.00157	mg/kg bw/day

Oral		
External event dose	0.057	mg/kg bw
External dose on day of exposure	0.057	mg/kg bw
Internal event dose	0.057	mg/kg bw
Internal dose on day of exposure	0.057	mg/kg bw/day
Internal year average dose	0.000312	mg/kg bw/day
Integrated		
Internal event dose	0.34	mg/kg bw
Internal dose on day of exposure	0.34	mg/kg bw/day
Internal year average dose	0.00189	mg/kg bw/day

3.3 New information on the active substance

Not applicable

3.4 Residue behaviour

Not applicable

3.5 Summaries of the efficacy studies (B.5.10.1-xx)[4]

Reference to IUCLID and 2.2.5.5 PAR

[4] If an IUCLID file is not available, please indicate here the summaries of the efficacy studies.

3.6 Confidential annex

Please refer to separate confidential document.