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

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)

PISTOLA INSECTICIDA PER04

Product type 18

Permethrin as included in the Union list of approved active substances

Case Number in R4BP: BC-KU023212-34

Evaluating Competent Authority: Spain

Date: October 2023

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1 CONCLUSION

The biocidal product PISTOLA INSECTICIDA PER04 is a ready to use water-based formulation to be used for the control of arthropods (e.g. insects, arachnids and crustaceans), by means other than repulsion or attraction as PT 18.

Physical, chemical and technical properties

The biocidal product contains 0.4 %w/w permethrin and given the nature of the formulation it is not considered explosive, oxidizing, corrosive, highly flammable or auto-flammable. Therefore, there not be hazards associated with the physico-chemical properties of the product under normal conditions of use.

There are not substances of concern in the biocidal product, hence there are some substances different to the active substance that do not contribute to the product hazard classification with regard to physical chemical properties according to hazardous (Regulation (EC) No 1272/2008).

A validated analytical method is available for determining the concentration of permethrin in the biocidal product. Validated analytical methods are also available for the determination of permethrin in soil, water and air matrices. Other analytical methods are not required.

Efficacy:

ES CA considers that the tests provided in the dossier demonstrate the efficacy of the biocidal product by spraying for the following uses:

- against crawling insects, cockroaches, ants and silverfishes, as spot to surface in hiding places (including crack and crevices) for general public and professionals (indoors). Application rate for cockroaches and ants: 15 mL/m^2. Application rate for silverfishes: 25.5 mL/m^2;
- against crawling insects, cockroaches and silverfishes, as spot to surface in hiding places (including crack and crevices) for trained professionals (indoors). Application rate for cockroaches and ants: 15 mL/m^2. Application rate for silverfishes: 25.5 mL/m^2.
- against ants as nest application and in surrounding areas for the general public, professionals and trained professionals. Application rate: 3 mL per nest (in 0.2 m^2, e.g. 45cm*45cm), 15 mL/m^2 ; and
- against cat fleas, house dust mites and ticks on non-washable textile surfaces. Application rate: 15 mL/m^2.

Human health:

The biocidal product has not been tested in any in vivo studies but it has been tested in vitro for eye corrosion. It was considered that the acute oral, dermal, inhalation, skin corrosion and irritation, eye irritation and the sensitisation studies on the active ingredient were adequate for the classification and labelling of the product and for the human health risk assessment

Based on the existing knowledge there is no indication of concern regarding the ED properties of the substances used in the biocidal product if one or several components are identified as having ED properties in the future, the conditions for granting the biocidal product authorisation will be revised.

Finally, evaluating the exposure and characterizing the risk to human health of the biocidal products according to the pattern of use requested by the applicant, the conclusions for each scenario are:

Summary table risk assessment for human health			
Scenario	**Scenario**	**Conclusion**	**Exposed group**
1.	Indoor application by trigger spray.	A **safe** situation has been identified for spraying application in indoor areas when the corresponding PPEs and instruction for use are used.	Professional / Trained professional users
2.	Outdoor application by trigger spray.	A **safe** situation has been identified for spraying application in outdoor areas when the corresponding PPEs and instruction for use are used.	Professional / Trained professional users
3.	Indoor application by trigger spray.	A **safe** situation has been identified for spraying application in indoor areas when the corresponding instruction for use is used.	Non-professional users
4.	Outdoor application by trigger spray.	A **safe** situation has been identified for spraying application in outdoor areas when the corresponding instruction for use is used.	Non-professional users
5.	Indoor application by trigger spray on non-washable textile surfaces.	A **safe** situation has been identified for spraying application in indoor areas when the corresponding instruction for use is used.	Non-professional users
Combined scenarios 3 + 4 + 5	Indoor / outdor applications	A **safe** situation has been identified for spraying applications in indoor / outdoor areas when the corresponding instruction for use is used.	Non-professional users
6.	Inhalation of volatilized residues	A **safe** situation has been identified for inhalation of volatilized residues.	General public
7.	Adults/Toddler playing on treated surfaces	A **safe** situation has been identified for adult / toddler playing and/or crawling on treated surfaces when the corresponding instruction for use and RMMs are used.	General public (chronic)
8.	Laundering	A **safe** situation has been identified for adults laundering contaminated work clothing when the corresponding instruction for use and RMMs are used.	General public (chronic)
Combined scenarios 1 + 2 + 8	Indoor / outdor applications + laundering	A **safe** situation has been identified for spraying applications in indoor / outdoor areas and laundering contaminated work clothing when the corresponding PPEs, instruction for use and RMMs are used.	General public (adult-chronic)
Combined scenarios 3 + 4 + 5 + 7	Indoor / outdoor applications + Adults playing / crawling on treated surfaces	A **safe** situation has been identified for spraying applications in indoor / outdoor areas and adult playing and/or crawling on treated surfaces when the corresponding instruction for use and RMMs are used.	General public (adult-chronic)

All scenarios resulted in acceptable risk. In addition, risk assessment for consumers via residues in food and animal health is not foreseen when RMM are set on the product label.

Environment:
From environmental perspective, an acceptable risk should be foreseen for all scenarios at the assessed environmental compartments when the use instructions given in the product's label and the proposed risk mitigations measures are followed for each use.

Overall conclusion

According to the assessment performed for the biocidal product, the following uses are proposed for authorization, considering the appropriate risk mitigation measures indicated in the table below:

Uses	Target organisms	User categories	Authorised application rates	Use conditions:	
				Specific risk mitigation measures	**General risk mitigation measures**
Use # 1 – Indoor – spot to surface in hiding places including crack and crevices– crawling insects – cockroaches, ants and silverfishes – General public / Professionals	Crawling insects Cockroaches: *Blattella germanica* (adults and nymphs) *Blatta orientalis* (adults and nymphs) Ants: *Lasius niger* (adults) Silverfishes: *Lepisma saccharina* (adults)	General public / Professional	For cockroaches and ants: 15 mL/m² (equivalent to 10 sprayings) For silverfishes: 25.5 mL/m^2 (equivalent to 17 sprayings) In case of re-invasion, re-apply the product if necessary every 4 weeks (maximum 12 applications per year). If the infestation persists, contact a (trained) professional.	The product has to be applied only on restricted areas on surfaces not regularly cleaned, for example behind or under the fridge, under the oven or the water heater, in all cracks and crevices that can be a harbourage for crawling insects. <u>Professional:</u> Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information). New gloves for each work shift. Wear a protective coverall (at least type X, EN XXXXX) which is impermeable for the biocidal product (coverall material to be specified by the authorisation holder within the product information). Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with combination filter gas/P2 is required (filter type (code letter, colour) to be specified	Do not spray directly on people, animals or bedding. Do not use/apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock/pets. Keep cats away from treated surfaces. Due to their particular sensitivity to pyrethroids, the product can cause severe adverse reactions in cats. Contains Permethrin, may be dangerous/toxic to pets (e.g. cats, bees, fish and other aquatic organisms). Do not apply in rooms where fish tanks and/or terrariums are present. Keep uninvolved persons, children and pets away from

Uses	Target organisms	User categories	Authorised application rates	Use conditions:	
				Specific risk mitigation measures	**General risk mitigation measures**
				by the authorisation holder within the product information). (Trained) Professionals are not allowed to wash contaminated clothes at home. <u>General public:</u> Due to the fact that the product is intended for use by consumers (non-professionals), it is necessary to make clear that there might be a risk of building up resistance and that this can be reduced. Since consumers have no knowledge of resistance issues the label claim should contain information to prevent it. The following phrase is proposed: "To avoid resistance occurrence, keep the label instructions and avoid repeated use of products containing permethrin. Alternate with products containing different active substances. When the infestation persists contact a professional."	treated surfaces/areas until dried.
Use # 2 – Indoor – spot to surface in hiding places including crack and crevices – crawling insects –	Crawling insects Cockroaches: *Blattella germanica* (adults and nymphs) *Blatta orientalis* (adults and nymphs)	Trained Professional	For cockroaches: 15 mL/m² (equivalent to 10 sprayings with the trigger spray)	The product has to be applied only on restricted areas on surfaces not regularly cleaned, for example behind or under the fridge, under the oven or the water heater, in all cracks and crevices that can be a harbourage for crawling insects.	

Uses	Target organisms	User categories	Authorised application rates	Use conditions:	
				Specific risk mitigation measures	General risk mitigation measures
cockroaches and silverfishes – Trained professionals	Silverfishes: *Lepisma saccharina* (adults)		For silverfishes: 25.5 mL/m^2 (equivalent to 17 sprayings with the trigger spray) In case of re-invasion, re-apply the product if necessary every 4 weeks (maximum 12 applications per year).	Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information). New gloves for each work shift. Wear a protective coverall (at least type X, EN XXXXX) which is impermeable for the biocidal product (coverall material to be specified by the authorisation holder within the product information). Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with combination filter gas/P2 is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information). (Trained) Professionals are not allowed to wash contaminated clothes at home.	
Use # 3 – Outdoor – Directly application in ant nests – Trained	Black ant (*Lasius niger)* - adults, larvae, nymphs, queen	Trained professionals / Professionals	3 mL per nest (in 0.2 m^2, e.g. 45cm*45cm), equivalent to 2 sprayings)	Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product	

Uses	Target organisms	User categories	Authorised application rates	Use conditions:	
				Specific risk mitigation measures	General risk mitigation measures
professionals / Professionals			with the trigger spray. Application rate: 15 mL/m^2 Repeat the treatment 1-2 times per year.	information). New gloves for each work shift. Wear a protective coverall (at least type X, EN XXXXX) which is impermeable for the biocidal product (coverall material to be specified by the authorisation holder within the product information). Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with combination filter gas/P2 is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information). (Trained) Professionals are not allowed to wash contaminated clothes at home. Apply only in areas that are not liable to submersion or becoming wet, i.e. protected from rain, floods and cleaning water. Do not use where release to drains (sewer) and/or surface water cannot be prevented.	
Use # 4 – Outdoor – Directly application in	Black ant (*Lasius niger)* - adults, larvae, nymphs, queen	General public (non-professional users)	3 mL per nest (in 0.2 m^2, e.g. 45cm*45cm),	Apply only in areas that are not liable to submersion or becoming wet, i.e. protected from rain, floods and cleaning water.	

Uses	Target organisms	User categories	Authorised application rates	Use conditions:	
				Specific risk mitigation measures	General risk mitigation measures
ant nests – General public (non-professional users)			equivalent to 2 sprayings) with the trigger spray. Application rate: 15 mL/m^2	Do not use where release to drains (sewer) and/or surface waters cannot be prevented. Due to the fact that the product is intended for use by consumers (non-professionals), it is necessary to make clear that there might be a risk of building up resistance and that this can be reduced. Since consumers have no knowledge of resistance issues the label claim should contain information to prevent it. The following phrase is proposed: "To avoid resistance occurrence, keep the label instructions and avoid repeated use of products containing permethrin. Alternate with products containing different active substances. When the infestation persists contact a (trained) professional".	
Use # 5 – Indoor – Non-washable textile surfaces– General public (non-professional users)	*Dermatophagoides pteronyssinus* – adults and nymphs *Rhipicephalus sanguineus* – adults and nymphs *Ixodes ricinus*– adults and nymphs *Ctenocephalides felis* – Cat fleas - adults	General public (non-professional users)	15 mL/m² (equivalent to 10 sprayings) This use is intended to be applied once per year or in those cases where infestation exists. Do not	Due to the fact that the product is intended for use by consumers (non-professionals), it is necessary to make clear that there might be a risk of building up resistance and that this can be reduced. Since consumers have no knowledge of resistance issues the label claim should contain information to prevent it. The following phrase is proposed: "To avoid resistance occurrence, keep the label	

Uses	Target organisms	User categories	Authorised application rates	Use conditions:	
				Specific risk mitigation measures	General risk mitigation measures
			apply more than two times per year. If the infestation persists contact a (trained) professional.	instructions and avoid repeated use of products containing permethrin. Alternate with products containing different active substances. When the infestation persists contact a (trained) professional."	

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier	**Country (if relevant)**
PISTOLA INSECTICIDA PER04	Spain

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Comercial Química Massó S.A.
	Address	Viladomat 321 5ª 08029 Barcelona Spain
Authorisation number	ES-APP(NA)-2023-18-00908	
Date of the authorisation	XX/11/2023	
Expiry date of the authorisation	XX/11/2033	

2.1.1.3 Manufacturer(s) of the products

Name of manufacturer	Comercial Química Massó S.A.
Address of manufacturer	Viladomat 321 5ª 08029 Barcelona Spain
Location of manufacturing sites	Avda Cadí 12-14 P.I. Sant Pere Molanta 08799 OLERDOLA (Barcelona) Spain

2.1.1.4 Manufacturer(s) of the active substance

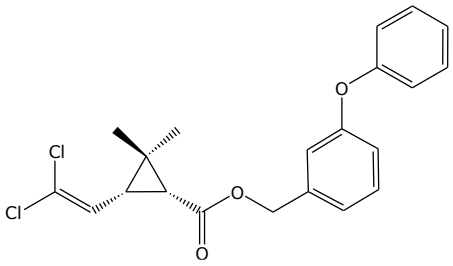
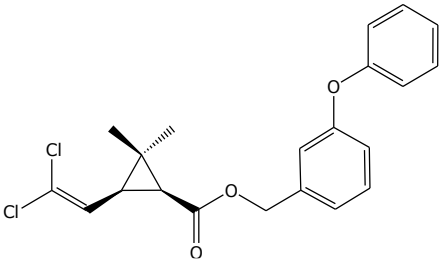
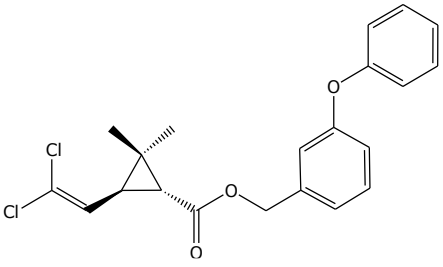
Active substance	Permethrin
Name of manufacturer	TAGROS CHEMICALS INDIA LIMITED
Address of manufacturer	Jhaver Center", IV Floor, Rajha Annamalai Building , No. 72, Marshalls Road, Egmore, Chennai - 600 008, India
Location of manufacturing sites	A4/1&2, SIPCOT Industrial Complex, Kudikadu, Cuddalore Tamil Nadu, India

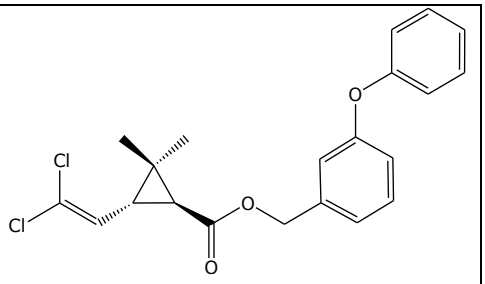
2.1.2 Product composition and formulation

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

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

Main constituent	
ISO name	Permethrin
IUPAC or EC name	(3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane-1-carboxylate
EC number	258-067-9
CAS number	52645-53-1
Index number in Annex VI of CLP	613-058-00-2
Minimum purity / content	Specification ≥ 93.0% w/w sum of all permethrin isomers.
Structural formula	1Rcis isomer  1Scis isomer  1Rtrans isomer  1Strans isomer

2.1.2.2 Candidate(s) for substitution

Permethrin does not meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012, and is therefore not considered as a candidate for substitution.

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

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
Permethrin	(3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane-1-carboxylate	Active substance	52645-53-1	258-067-9	0.4
Propan-2-ol	2-Propanol	Solvent	67-63-0	200-661-7	0.24
Other components	For further details on product composition please refer to the Confidential PAR.				up to 100

	AS content
Formulation recipe: Content of the AS used for the formulation of the BP (%)	0.4
AS content in the BP to be indicated in the SPC (%)	**0.4**
Minimum purity in the source of the AS (%)	93
"Minimum pure" AS content (%)	**0.372**

2.1.2.4 Information on technical equivalence

The source of permethrin active substance supplied by Tagros Chemicals India Limited is the known source from the BPD/BPR process for the active substance permethrin. Therefore, this source is not a technical equivalence.

2.1.2.5 Information on the substance(s) of concern

Based on the BPR Art. 3.1(f) definition of 'substance of concern' which includes the condition «*and is present or is produced in a biocidal product in sufficient concentration to present risks of such an effect*» no 'substances of concern' are present in the biocidal product.

Regarding to the environment, besides the active substance permethrin, this product contains another substance of concern Propan-2-ol, this substance is an active substance for other product types (PT1, PT2 and PT4) and it is in a concentration higher than 0.1% in the biocidal product. Therefore, although it is not considered as toxic for the environment, applying the specifications of Art. 3 (1f) of Regulation (EU) No 528/2012, this substance must be considered a Substance of Concern (SoC) and included into the environmental risk assessment.

Information on the complete composition is provided in the Confidential PAR.

2.1.2.6 Type of formulation

AL - Any other liquid.

2.1.3 Hazard and precautionary statements

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

Classification	
Hazard category	Aquatic Acute 1 Aquatic Chronic 1
Hazard statement	H400: Very toxic to aquatic life H410: Very toxic to aquatic life with long lasting effects
Labelling	
Signal words	Warning
Hazard pictogram	 GHS09
Hazard statements	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. P103: Read label before use. P273: Avoid release to the environment. P391: Collect spillage. P501: • Trained professional and Professionals users: Dispose of contents/container as hazardous waste to a registered establishment or undertaking, in accordance with current regulations. • Non-professional users: Dispose of content and / or its container as hazardous waste according to the regulations in force.
Note	EUH208: Contains permethrin. May produce an allergic reaction.

2.1.4 Authorised use(s)

2.1.4.1 Use description

Table 1. Use # 1 – Indoor – spot to surface in hiding places including crack and crevices– crawling insects – cockroaches, ants and silverfishes – General public / Professionals

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	The product is a ready-for-use formulation to be applied by trigger sprayer into spot and/or crack and crevices treatments against crawling insects in empty rooms at domestic facilities as kitchens and food store rooms. It is applied in hiding places (e.g. voids, grooves, crack and crevices) where crawling insects are looking for food, paying special attention to grooves and cracks and areas behind or under machinery, kitchen equipment or pipes.
Target organism (including development stage)	Crawling insects Cockroaches: *Blattella germanica* (adults and nymphs) *Blatta orientalis* (adults and nymphs) Ants: *Lasius niger* (adults) Silverfishes: *Lepisma saccharina* (adults)
Field of use	Indoor – spot to surface in hiding places including crack and crevices on restricted areas not regularly cleaning
Application method(s)	Spraying. The product is applied by spraying downwards on corners (spot treatment) and in hiding places including crack and crevices wherein the insects use to pass or hide using trigger or handheld sprayers.
Application rate(s) and frequency	For cockroaches and ants: 15 mL/m² (equivalent to 10 sprayings) For silverfishes: 25.5 mL/m^2 (equivalent to 17 sprayings) In case of re-invasion, re-apply the product if necessary every 4 weeks (maximum 12 applications per year). If the infestation persists, contact a (trained) professional.
Category(ies) of users	General public / Professional
Pack sizes and packaging material	Plastic bottle (250 mL 500 mL, 1L) in boxes Plastic bottle with trigger spray (500 mL, 750 mL, 1L)

2.1.4.1.1 Use-specific instructions for use

Refer to general direction of use (section 2.1.5)

2.1.4.1.2 Use-specific risk mitigation measures

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

Professional:

Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information). New gloves for each work shift.

Wear a protective coverall (at least type X, EN XXXXX) which is impermeable for the biocidal product (coverall material to be specified by the authorisation holder within the product information).

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with combination filter gas/P2 is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information).

(Trained) Professionals are not allowed to wash contaminated clothes at home.

General public:

Due to the fact that the product is intended for use by consumers (non-professionals), it is necessary to make clear that there might be a risk of building up resistance and that this can be reduced. Since consumers have no knowledge of resistance issues the label claim should contain information to prevent it. The following phrase is proposed: "To avoid resistance occurrence, keep the label instructions and avoid repeated use of products containing permethrin. Alternate with products containing different active substances. When the infestation persists contact a (trained) professional."

Please refer to general direction of use for further information.

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

Refer to general direction of use (section 2.1.5)

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

(Trained) Professional users:

Empty containers, unused product, washing water, containers and other waste generated during application are considered hazardous waste. Deposit packaging waste at the established collection points or deliver it to a registered hazardous waste operator as agreed with the extended producer responsibility system. Deliver the other wastes to a registered establishment or undertaking for hazardous waste, in accordance with current regulations.

Code the waste according to Decision 2014/955 / EU.

Do not release to soil, ground, surface water or any kind of sewer

Non professional users:

Empty containers, unused product and other waste generated during the treatment are considered hazardous waste. Dispose of in accordance with current regulations. Do not release into soil, ground, surface water or any kind of sewer.

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

Refer to general direction of use (section 2.1.5)

2.1.4.2 Use description

Table 2. Use # 2 – Indoor – spot to surface in hiding places including crack and crevices – crawling insects – cockroaches and silverfishes – Trained professionals

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	The product is a ready-for-use formulation to be applied by spraying into spot and/or crack and crevices treatments against crawling insects in empty rooms at industrial and domestic facilities as kitchens and store rooms. It is applied in hiding places (e.g. voids, grooves, crack and crevices) of garages, lofts, attics, garrets, kitchens… where crawling insects are looking for food, paying special attention to grooves and cracks and areas behind or under machinery, kitchen equipment or pipes.
Target organism (including development stage)	Crawling insects Cockroaches: *Blattella germanica* (adults and nymphs) *Blatta orientalis* (adults and nymphs) Silverfishes: *Lepisma saccharina* (adults)
Field of use	Indoor – spot to surface in hiding places including crack and crevices on restricted areas not regularly cleaning
Application method(s)	Spraying. The product is applied by spraying downwards on corners (spot treatment) and in hiding places including crack and crevices wherein the insects use to pass or hide using hand held or backpack sprayers (low pressure 1-3 bars).
Application rate(s) and frequency	For cockroaches: 15 mL/m² (equivalent to 10 sprayings with the trigger spray) For silverfishes: 25.5 mL/m^2 (equivalent to 17 sprayings with the trigger spray) In case of re-invasion, re-apply the product if necessary every 4 weeks (maximum 12 applications per year).
Category(ies) of users	Trained professionals
Pack sizes and packaging material	Plastic bottle (250 mL, 500 mL, 1L) in boxes Jerry can (5L, 10 L, 20 L, 25 L) Plastic bottle with trigger spray (500 mL, 750 mL, 1L)

2.1.4.2.1 Use-specific instructions for use

Refer to general direction of use (section 2.1.5)

2.1.4.2.2 Use-specific risk mitigation measures

The product has to be applied only on restricted areas on surfaces not regularly cleaned, for example behind or under the fridge, under the oven or the water heater, in all cracks and crevices that can be a harbourage for crawling insects. Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information). New gloves for each work shift. Wear a protective coverall (at least type X, EN XXXXX) which is impermeable for the biocidal product (coverall material to be specified by the authorisation holder within the product information). Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with combination filter gas/P2 is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information). (Trained) Professionals are not allowed to wash contaminated clothes at home. Please refer to general direction of use for further information.

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

Refer to general direction of use (section 2.1.5)

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

Empty containers, unused product, washing water, containers and other waste generated during application are considered hazardous waste. Deposit packaging waste at the established collection points or deliver it to a registered hazardous waste operator as agreed with the extended producer responsibility system. Deliver the other wastes to a registered establishment or undertaking for hazardous waste, in accordance with current regulations. Code the waste according Decision 2014/955/EU. Do not release to soil, ground, surface water or any kind of sewer.

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

Refer to general direction of use (section 2.1.5)

2.1.4.3 Use description

Table 3. Use # 3 – Outdoor – Directly application in ant nests – Trained professionals / Professionals

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	The product is sprayed directly into the ants' nests.
Target organism (including development stage)	Black ant (*Lasius niger)* - adults, larvae, nymphs, queen
Field of use	Outdoor The product is applied directly to the ant nests, around houses on paved ways, balconies, and terraces where ant nests are located.
Application method(s)	Spraying
Application rate(s) and frequency	3 mL per nest (in 0.2 m^2, e.g. 45cm*45cm), equivalent to 2 sprayings) with the trigger spray. Information only for trained-professionals: Application rate: 15 mL/m^2 Repeat the treatment 1-2 times per year.
Category(ies) of users	Trained professionals / Professionals
Pack sizes and packaging material	Trained professionals: Plastic bottle (250 mL, 500 mL, 1L) in boxes Jerry can (5L, 10 L, 20 L, 25 L) Plastic bottle with trigger spray (500 mL, 750 mL, 1L) Professionals: Plastic bottle (250 mL, 500 mL, 1L) in boxes Plastic bottle with trigger spray (500 mL, 750 mL, 1L)

2.1.4.3.1 Use-specific instructions for use

To achieve full effect, identify the ant nest's location carefully and apply the product there. For use only in areas that are inaccessible to infants, children, pets and non-target animals. Secure the treated area so that no one can access the nests during product application and action. After product's application, cover the treated area with a plastic tarp or small bucket to avoid that the product could be carried away by rainwater or air. Please refer to general direction of use for further information.

2.1.4.3.2 Use-specific risk mitigation measures

Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information). New gloves for each work shift. Wear a protective coverall (at least type X, EN XXXXX) which is impermeable for the biocidal product (coverall material to be specified by the authorisation holder within the product information). Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with combination filter gas/P2 is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information). (Trained) Professionals are not allowed to wash contaminated clothes at home. Apply only in areas that are not liable to submersion or becoming wet, i.e. protected from rain, floods and cleaning water. Do not use where release to drains (sewer) and/or surface water cannot be prevented. Please refer to general direction of use for further information.

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

Refer to general direction of use (section 2.1.5)

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

(Trained) Professional users: Empty containers, unused product, washing water, containers and other waste generated during application are considered hazardous waste. Deposit packaging waste at the established collection points or deliver it to a registered hazardous waste operator as agreed with the extended producer responsibility system. Deliver the other wastes to a registered establishment or undertaking for hazardous waste, in accordance with current regulations. Code the waste according Decision 2014/955/EU. Do not release to soil, ground, surface water or any kind of sewer.

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

Refer to general direction of use (section 2.1.5)

2.1.4.4 Use description

Table 4. Use # 4 – Outdoor – Directly application in ant nests – General public (non-professional users)

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	The product is sprayed directly into the ants' nests.
Target organism (including development stage)	Black ant (*Lasius niger)* - adults, larvae, nymphs, queen
Field of use	Outdoor The product is applied directly to the ant nests, around houses on paved ways, balconies, and terraces where ant nests are located.
Application method(s)	Spraying
Application rate(s) and frequency	3 mL per nest (in 0.2 m^2, e.g. 45cm*45cm), equivalent to 2 sprayings) with the trigger spray.
Category(ies) of users	General public (non-professional users)
Pack sizes and packaging material	Plastic bottle with trigger spray (500 mL, 750 mL, 1L)

2.1.4.4.1 Use-specific instructions for use

To achieve full effect, identify the ant nest's location carefully and apply the product there.

For use only in areas that are inaccessible to infants, children, pets and non-target animals.

Secure the area so that no one can access the nests during product application and action.

After product's application, cover the treated area with a plastic tarp or small bucket to avoid that the product could be carried away by rainwater or air.

Please refer to general direction of use for further information.

2.1.4.4.2 Use-specific risk mitigation measures

Apply only in areas that are not liable to submersion or becoming wet, i.e. protected from rain, floods and cleaning water.

Do not use where release to drains (sewer) and/or surface waters cannot be prevented.

Due to the fact that the product is intended for use by consumers (non-professionals), it is necessary to make clear that there might be a risk of building up resistance and that this can be reduced. Since consumers have no knowledge of resistance issues the label claim should contain information to prevent it. The following phrase is proposed: "To avoid resistance occurrence, keep the label instructions and avoid repeated use of products containing permethrin. Alternate with products containing different active substances. When the infestation persists contact a (trained) professional".

Please refer to general direction of use for further information.

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

Refer to general direction of use (section 2.1.5)

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

Empty containers, unused product and other waste generated during the treatment are considered hazardous waste. Dispose of in accordance with current regulations Do not release to soil, ground, surface water or any kind of sewer.

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

Refer to general direction of use (section 2.1.5)

2.1.4.5 Use description

Table 5. Use # 5 – Indoor – Non-washable textile surfaces–General public (non-professional users)

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	The product is applied at domestic use (houses, flats, apartments) over textile surfaces that must be cleaned by dry treatments once the product formulation is dried. It is intended to be applied in textile materials as mattresses, blankets, bedspreads, bedsteads, pillows, carpets, moquette…
Target organism (including development stage)	*Dermatophagoides pteronyssinus* – adults and nymphs *Rhipicephalus sanguineus* – adults and nymphs *Ixodes ricinus*– adults and nymphs *Ctenocephalides felis* – Cat fleas - adults
Field of use	Indoors – non-washable textile surfaces (surface treatment)
Application method(s)	Spraying with a hand held trigger spray. The product is sprayed over the mattresses, carpet, moquette,… directly from the ready-to-use trigger sprayer.
Application rate(s) and frequency	15 mL/m² (equivalent to 10 sprayings) This use is intended to be applied once per year or in those cases where infestation exists. Do not apply more than two times per year. If the infestation persists contact a (trained) professional.
Category(ies) of users	General public (non-professional users)
Pack sizes and packaging material	Plastic bottle with trigger spray (500 mL, 750 mL, 1L)

2.1.4.5.1 Use-specific instructions for use

This use involves the following steps of application:
1) First step consists in spraying the product on the surfaces to be treated (mattresses, blankets, bedspreads, bedsteads, pillows, carpets …).
2) The excess of the product on non-treated surfaces contaminated during the application must be remove with a damp paper and dispose as solid waste.
3) For cleaning, do not use wet cleaning procedures. Use only dry-cleaning procedures such as vacuum, damp paper, broom... After cleaning, dispose the collected residues or the damp papers used as solid wastes.

2.1.4.5.2 Use-specific risk mitigation measures

Due to the fact that the product is intended for use by consumers (non-professionals), it is necessary to make clear that there might be a risk of building up resistance and that this can be reduced. Since consumers have no knowledge of resistance issues the label claim should contain information to prevent it. The following phrase is proposed: "To avoid resistance occurrence, keep the label instructions and avoid repeated use of products containing permethrin. Alternate with products containing different active substances. When the infestation persists contact a (trained) professional."

Please refer to general direction of use for further information.

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

Refer to general direction of use (section 2.1.5)

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

Empty containers, unused product and other waste generated during the treatment are considered hazardous waste. Dispose of in accordance with current regulations.
Do not release into soil, ground, surface water or any kind of sewer.

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

Refer to general direction of use (section 2.1.5)

2.1.5 General directions for use

2.1.5.1 Instructions for use

Comply with the instructions for use.

The biocidal product contains permethrin (synthetic pyrethroid). DO NOT USE if under medical advice NOT to work with such compounds.

Further specific information for each use can be found in respective section of the use.

2.1.5.2 Risk mitigation measures

Do not spray directly on people, animals or bedding.

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

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

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

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

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

Further specific information for each use can be found in respective section of the use.

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

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

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

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

IF ON SKIN: 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 MEDICAL ADVICE IS NEEDED, HAVE THE PRODUCT CONTAINER OR LABEL AT HAND AND CONTACT THE POISON CONTROL CENTER.

IF PETS/ANIMALS EXPOSURE, get veterinary advice/attention.

Emergency measures to protect the environment:

- Avoid to contaminate soil/subsoil.

- Prevent spills into surface water or the drainage system.

- Retain contaminated washing water and discard.

- If the product gets into water or soil, it should be removed mechanically. Transfer to a suitably labelled container and dispose of as hazardous waste according to local legislation.

- Suitable material for containment: absorbing material, organic, sand.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Please, see specific instructions for safe disposal of the product and its packaging provided above.

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

Shelf life: 2 years.

Store in the original container in dry well-ventilated place.

Store the original container tightly closed.

Keep away from sun radiation and all others heat sources.

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

Keep/store away from food, drink and animal feedstuffs.

2.1.6 Other information

This product contains a bittering agent that makes it repulsive to people or pets.

Only for Spain:

According to national legislation, in Spain there are until three user categories:

- Trained professional users (TP): pest control operators, having received specific training in biocidal product uses according to the national legislation in force.
- Professional users (P or NTP): professionals that use the biocidal products in the context of his profession, that is not pest control operator, and that are unlikely to have received any specific training in biocidal product use according to the national legislation in force. It can be expected that they have some knowledge and skills handling chemicals (if they must use it in their job) and they are able to use correctly some kind of PPE if necessary.
- Non-professional users (NP): users who are not professionals and that apply the biocidal product is in his private life.

At the same time, there are also some restrictions of packaging in relation to those user categories and product types. In this case, for professional and non-professional users the maximum size that can be authorized is 1 kg / 1 L.

In that context, the exposure assessment will be the same for professionals and trained professional users and the difference between the two will depend on the expert judgment following "limiting criteria" below:

1. The hazardousness of the product under evaluation.
2. The use being requested.
3. The frequency of use.
4. Complexity of control measures

2.1.7 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
Bottle	250, 500, 1000 mL	plastic	Cap or trigger spray	Trained Professional and Professional users	Yes
Jerry can	5, 10, 20, 25 L	plastic	Cap	Trained Professional	Yes
Bottle	500, 750, 1000 mL	plastic	Trigger spray	Trained Professional, Professional and Non-professional users	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

No new data on the active substance itself or on the substances of concern has been submitted in function of this product application. All new information relates to the biocidal product described within this application.
The reference list (including updates) for the studies submitted in support of the BPD dossier has been included in Annex 3.1 whilst the reference list for the studies considered confidential has been included in the confidential PAR.

2.1.8.2 Access to documentation

The applicant "Comercial Química Massó S.A." has submitted a letter of access for the active substance included in biocidal product submitted; Limaru NV formerly by Tagros Chemicals India Limited as owner of data dossiers for Permethrin active substance.

2.2 Assessment of the biocidal product

2.2.1 Intended uses as applied for by the applicant

Table 6. Use # 1 – Indoor voids/cavities treatment – crawling insects - Professional

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	The product is a ready-for-use formulation to be applied by spraying into spot and/or crack and crevices treatments against crawling insects in empty rooms at industrial and

	domestic facilities as kitchens and store rooms. It is applied in hiding places (e.g. voids, grooves, crack and crevices) of garages, lofts, attics, garrets, kitchens… where crawling insects are looking for food, paying special attention to grooves and cracks and areas behind or under machinery, kitchen equipment or pipes.
Target organism (including development stage)	*Blattella germanica* – Cockroaches (adult + nymphs) *Blatta orientalis* - Cockroaches (adult + nymphs) *Lasius niger* - Ants (adult + larvae + nymphs + queen) *Lepisma saccharina* – Silverfishes (adult) *Dermatophagoides pteronyssinus* – Mites (adult + nymphs) *Acarus siro* (flour mite) – adults *Ixodes ricinus* – Ticks (adult + nymphs) *Rhipicephalus sanguineus* – Ticks (adult + nymphs) *Ctenocephalides felis* – Cat fleas (adults + larvae)
Field of use	Indoor – voids/cavities treatment
Application method(s)	Spraying. The product is applied directly on voids and cavities particularly the corners (spot treatment) or cracks and crevices wherein the insects use to pass or hide using professional spraying equipment.
Application rate(s) and frequency	15 mL/m² In case of re-invasion, re-apply the product if necessary every 4 weeks (maximum 12 applications per year).
Category(ies) of users	Professional (trained and non-trained professional)
Pack sizes and packaging material	Plastic bottle (from 250 mL to 25 L) Jerry can (from 250 mL to 25 L) Plastic bottle with trigger spray (≤ 1000 mL)

Table 7. Use # 2 – Indoor – voids/cavities treatment – Crawling insects – General public

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	The product is a ready-for-use formulation to be applied by trigger sprayer into spot and/or crack and crevices treatments against crawling insects in empty rooms at domestic facilities as kitchens and food store rooms. It is applied in hiding places (e.g. voids, grooves, crack and crevices) where crawling insects are looking for food, paying special attention to grooves and cracks and areas behind or under machinery, kitchen equipment or pipes.
Target organism (including development stage)	*Blattella germanica* – Cockroaches (adult + nymphs) *Blatta orientalis* - Cockroaches (adult + nymphs) *Lasius niger* - Ants (adult + larvae + nymphs + queen) *Lepisma saccharina* – Silverfishes (adult) *Dermatophagoides pteronyssinus* – Mites (adult + nymphs) *Acarus siro* (flour mite) – adults *Ixodes ricinus* – Ticks (adult + nymphs) *Rhipicephalus sanguineus* – Ticks (adult + nymphs) *Ctenocephalides felis* – Cat fleas (adults + larvae)
Field of use	Indoor – voids/cavities treatment

Application method(s)	Spraying. The product is applied by spraying using a trigger spray on voids and cavities and particularly the corners (spot treatment) or cracks and crevices wherein the insects use to pass or hide using a trigger sprayer.
Application rate(s) and frequency	15 mL/m² (equivalent to 10 pulverizations) In case of re-invasion, re-apply the product if necessary every 4 weeks (maximum 12 applications per year). If the infestation persists, contact a professional.
Category(ies) of users	General public (non-Professional)
Pack sizes and packaging material	Plastic bottle with trigger spray (≤ 1000 mL)

Table 8. Use # 3 – Indoor – Non-washable textile surfaces – General public

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	The product is applied at domestic use (houses, flats, apartments) over textile surfaces that must be cleaned by dry treatments once the product formulation is dried. It is intended to be applied in textile materials as mattresses, blankets, bedspreads, bedsteads, pillows, carpets, moquette…
Target organism (including development stage)	*Dermatophagoides pteronyssinus* – Mites (adult + nymphs) *Ixodes ricinus* – Ticks (adult + nymphs) *Rhipicephalus sanguineus* – Ticks (adult + nymphs) *Ctenocephalides felis* – Cat fleas (adults + larvae)
Field of use	Indoor – surface treatment
Application method(s)	Spraying The product is sprayed over the mattresses, carpet, moquette,… directly from the ready-to-use trigger sprayer. Once the efficacy time is over (set by the efficacy trials which are ongoing), the treated surface is vacuumed with the vacuum cleaner in order to release killed insects and product's residue.
Application rate(s) and frequency	15 mL/m² (equivalent to 10 pulverizations). This use is intended to be applied once per year or in those cases where infestation exists. Do not apply more than two times per year. If the infestation persists contact a professional.
Category(ies) of users	General public (non-Professional)
Pack sizes and packaging material	Plastic bottle with trigger spray (≤ 1000 mL)

Table 9. Use # 4 – Outdoor – Directly application in ant nests – Professional

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	The product is sprayed directly into the ants' nest.

Target organism (including development stage)	*Lasius niger* - Ants (adult + larvae + nymphs + queen)
Field of use	Outdoor Around houses on paved ways, balconies and terraces where ant nests are located.
Application method(s)	Spraying
Application rate(s) and frequency	3.75 mL of average amount for a nest* Residual efficiency is proved during 4 weeks. If the infestation persist, apply a second time after 4 weeks.
Category(ies) of users	Professional (Trained and non-trained professional)
Pack sizes and packaging material	Plastic bottle (from 250 mL to 25 L) Jerry can (from 250 mL to 25 L) Plastic bottle with trigger spray (≤ 1000 mL)

* an average area of 0.25 m^2 is deemed for a nest (0.5 m x 0.5 m)

Table 10. Use # 5 – Outdoor – Directly application in ant nests – General public

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	The product is sprayed directly into the ants' nest.
Target organism (including development stage)	*Lasius niger* - Ants (adult + larvae + nymphs + queen)
Field of use	Outdoor (Ant's nest)
Application method(s)	Spraying
Application rate(s) and frequency	3.75 mL/nest (approx. 2-3 pulverizations/nest*) Residual efficiency is proved during 4 weeks. If the infestation persist, apply a second time after 4 weeks and if the infestation persist, contact with Pest Control Operator (PCO).
Category(ies) of users	General public (non-Professional)
Pack sizes and packaging material	Plastic bottle with trigger spray (≤ 1000 mL)

* an average area of 0.25 m^2 is deemed for a nest (0.5 m x 0.5 m)

Table 6. Use # 6 – Outdoor – Around paved and rain protected areas of buildings – Ants - Professional

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	The product is intended to be applied around buildings on small surfaces as spots and crack and crevice paved surfaces where ants stay or wander around. These intended locations to be treated must be located on places protected from the rain, floods and cleaning water.
Target organism (including development stage)	*Lasius niger* – Ants (adult)

Field of use	Outdoor On spots and crack and crevices around houses on paved ways, balconies and terraces not connected to STP and protected from rain, flood and water courses.
Application method(s)	Spraying
Application rate(s) and frequency	15 mL/m² Residual efficiency is proved during 4 weeks. If the infestation persist, apply a second time after 4 weeks. Up to 2 applications per year.
Category(ies) of users	Professional (trained and non-trained)
Pack sizes and packaging material	Plastic bottle with trigger spray (≤ 1000 mL)

Table 7. Use # 7 – Outdoor –Around paved and rain protected buildings – Ants - General public

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	The product is intended to be applied by spraying around buildings on small surfaces as spots and crack and crevice paved surfaces where ants stay or wander around. These intended locations to be treated must be located on places protected from the rain, floods and cleaning water.
Target organism (including development stage)	*Lasius niger* – Ants (adult)
Field of use	Outdoor On spots and crack and crevices around houses of paved ways, balconies and terraces not connected to STP and protected from rain, flood and water courses.
Application method(s)	Spraying
Application rate(s) and frequency	15 mL/m² (equivalent to 10 pulverizations) Residual efficiency is proved during 4 weeks. If the infestation persist, apply a second time after 4 weeks. Up to 2 applications per year. If infestation persists contact a professional.
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	Plastic bottle with trigger spray (≤ 1000 mL)

Table 8. Use # 8 – Indoor – Spot surface application against flies and mosquitoes – General public

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	The product is a ready-for-use formulation to be applied by spot spraying against flies and mosquitoes for use in empty premises at homes.

Target organism (including development stage)	*Musca domestica* – Flies (adult) *Culex pipiens* – Mosquito (adult, female) *Aedes aegypti* – Mosquito (adult, female) *Aedes albopictus* – Tiger mosquito (adult, female)
Field of use	Indoor
Application method(s)	Spraying. The product is applied by using a trigger spray directly on surface areas and particularly the windows corners or frames (spot treatment) or cracks and crevices wherein the flies and mosquitoes use to lay.
Application rate(s) and frequency	15 mL/m² (equivalent to 10 pulverizations) It is intended to be applied once the infestation appears. Maximum 12 applications per year. If infestation persist contact a Pest Control Operator.
Category(ies) of users	General public (non-Professional)
Pack sizes and packaging material	Plastic bottle with trigger spray (≤ 1000 mL)

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	EPA OPPTS 830.6302	Permethrin (0.4%)	Initially, after 14 days at 54ºC and after 2 years at 20ºC: Opalescent Liquid	CH-621/2015
Colour at 20 °C and 101.3 kPa	EPA OPPTS 830.6303	Permethrin (0.4%)	Initially, after 14 days at 54ºC and after 2 years at 20ºC: White	CH-621/2015
Odour at 20 °C and 101.3 kPa	EPA OPPTS 830.6304	Permethrin (0.4%)	Initially, after 14 days at 54ºC and after 2 years at 20ºC: Characteristic odour	CH-621/2015
Acidity / alkalinity	CIPAC MT 75.3 OECD 122	Permethrin (0.4%)	Initially: 6.4 After 14 days at 54ºC: 6.7 After 2 years at 20ºC: 4.6	CH-621/2015
Relative density / bulk density	CIPAC MT 186	Permethrin (0.4%)	1.0008 g/mL at 20°C	CH-621/2015
Storage stability test – **accelerated storage**	CIPAC MT 46.3	Permethrin (0.4%)	After 14 days at 54°C, no changes were observed.	CH-624/2015
Active substance content			Initially: Sum: 0.37±0.01 % w/w Cis: 0.10±0.01 % w/w Trans: 0.27±0.01 % w/w After 14 days at 54ºC: Sum: 0.38±0.01 % w/w Diference: 2.70 % w/w Cis: 0.10±0.01 % w/w Diference: 0.00 % w/w Trans: 0.28±0.01 % w/w Diference: 3.70 % w/w	
Homogeneity of application			Constant test item loss after each spray	

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
Appearance and stability of the package			No changes were observed.	
Storage stability test – **long term storage at ambient temperature**	EPA OPPTS 830.6313	Permethrin (0.4%)	After two years at ambient temperature, no changes were observed. Thus a shelf life of two years is proposed.	CH-625/2015
Active substance content			Initially: Sum: 0.37±0.01 % w/w Cis: 0.10±0.01 % w/w Trans: 0.27±0.01 % w/w After 2 years at 20ºC: Sum: 0.38±0.01 % w/w Diference: 2.70 % w/w Cis: 0.10±0.01 % w/w Diference: 0.00 % w/w Trans: 0.28±0.01 % w/w Diference: 3.70 % w/w	
Homogeneity of application			Constant test item loss after each spray	
Appearance and stability of the package			No changes were observed.	
Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3	Permethrin (0.4%)	After 7 days at 0 ± 2°C, no changes were observed.	CH-621/2015
Effects on content of the active substance and technical characteristics of the biocidal product – **light**	Justification for non-submission of data	-	The product application is not affected by light.	-

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	CIPAC MT 46.3	Permethrin (0.4%)	No changes were observed.	CH-624/2015
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	CIPAC MT 46.3	Permethrin (0.4%)	No effects and reactivity on container material was observed after 14 days of storage at 54°C: the container didn't present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena.	CH-624/2015
Wettability		-	Justification for non-submission of data	-
Suspensibility, spontaneity and dispersion stability		-	Justification for non-submission of data	-
Wet sieve analysis and dry sieve test		-	Justification for non-submission of data	-
Emulsifiability, re-emulsifiability and emulsion stability		-	Justification for non-submission of data	-
Disintegration time		-	Justification for non-submission of data	-
Particle size distribution, content of dust/fines, attrition, friability		-	Justification for non-submission of data	-
Persistent foaming		-	Justification for non-submission of data	-
Flowability/Pourability/Dustability		-	Justification for non-submission of data	-
Burning rate — smoke generators		-	Justification for non-submission of data	-
Burning completeness — smoke generators		-	Justification for non-submission of data	-
Composition of smoke — smoke generators		-	Justification for non-submission of data	-
Spraying pattern — trigger spray/aerosols	--	Permethrin (0.4%)	Initially, after 14 days at 54ºC and after 2 years at 20 ºC: Mean diameter = 28.5 cm Discharge rate = 1.5 g/hub	CH-624/2015 CH-625/2015 D.0106.13

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
Physical compatibility		-	Justification for non-submission of data	-
Chemical compatibility		-	Justification for non-submission of data	-
Degree of dissolution and dilution stability		-	Justification for non-submission of data	-
Surface tension	OECD 115 EU 440/2008 No A.5	Permethrin (0.4%)	37.5 mN/m at 20°C	CH-621/2015
Viscosity	CIPAC MT 22.1 OECD 114	Permethrin (0.4%)	Kinematic viscosity: 1.264 cSt at 20°C; 0.913 at cSt at 40° Dynamic viscosity: 1.265 cP at 20°C; 0.913 at cP at 40°	CH-621/2015

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

NOTE:
The applicant has noted that the studied batches have the same composition as the marketed formulation.

Appearance
The preparation is a opalescent white liquid with characteristic odour.

Acidity / alkalinity
The pH is determined in the pure product at 100% concentration. Since the pH value ranged from 4 to 10, the acidity or alkalinity test was not performed.

Relative density / bulk density
From the experimental data obtained according to the guideline A.3 in Council Regulation (EC) No 440/2008 part A, CIPAC method MT 3.2 and OECD Test No 109, it can be concluded that the density of the Permetrina RTU 0,4% formulation sample is 1.0008 g/mL at 20°C; the specific gravity is 1.0026 at 20°C, and the relative density (D204) is 1.0008.

Accelerated storage
The Permetrina RTU 0,4% formulation sample is stable in its commercial packaging under the tested accelerated storage conditions.

Long term storage at ambient temperature
The Permetrina RTU 0,4% formulation sample is stable in its commercial packaging under the tested two years storage conditions.

Low temperature stability test for liquids
The Permetrina RTU 0,4% formulation sample, after 7 days at 0 ± 2°C, did not show separation of solid or liquid material, nor changes in its physical state.

Effects of light
The formulation is contained in a closed bottle and no expousure with light is expected during storage and uses, thus the test is not performed.
The product application is not affected by light. According with the experience of the registrant, effects of light in the product stability are not expected.

Effects of temperature and humidity
The product is not affected by temperature and humidity if stored at room temperature.

Technical characteristics of the biocidal
The studies do not need to be conducted because the formulation is a ready-to-use water-based formulation and the product is not diluted before the application.

Spraying pattern
Four plastic bottle with trigger spray filled with the test item were weighted using the technical balance; then each bottle was sprayed 20 times and re-weighting after each

spray. The trigger status was inspected visually and possible blockage of the nozzle are detected.

Physical and chemical compatibility with other products
The formulation is not expected to be used with other product, thus the test is not required.

Surface Tension
The surface tension is lower than 60 mN/m under the conditions of the plate method, therefore the biocidal product should be regarded as a surface-active material.

Viscosity
Viscosity was determined by two different U-Tube viscosimeters at 20ºC and 40ºC.

Conclusions
The preparation is an opalescent white liquid with characteristic odour, containing 0.4 % w/w of permetrin. Its density is 1.0008 g/mL. It has a pH of 6.4.
The viscosity measurement at 20ºC determined a mean value of 1.26 mPa s whereas the other measurement at 40ºC provided mean results of 0.91 mP s. Moreover, the product is surface active.
After 14 days of storage at 54°C, the active ingredient content and the physical-chemical properties of the test item are comparable to the relevant values obtained in the initial characterisation. No change in the sample appearance, colour or odour, was found in the formulation stored in plastic bottle with trigger for 14 days of storage at 54°C and no variation was found in colour or in either the internal or external configuration, or loss of sample or evident corrosion phenomena.
Moreover, no significant changes in pH value, trigger spray head performance and spray diameter were found in the test item stored in plastic bottle with trigger for 14 days of storage at 54°C
After 7 days at 0 ± 2°C, the sample did not show changes, so the phrase "protect from frost" is not necessary in the label.
After two years of storage at ambient temperature, the test item did not show any significant difference in terms of active ingredient content, aspect and emulsion characteristic, respect the initial conditions. The variation on the pH is acceptable to this kind of product once it is ensured the active ingredient content and the compatibility with the packaging is not affected. Thus the test item can be considered stable and a shelf life of two years is proposed.

There is no effect at high and low temperature on the stability of the formulation, since neither the active ingredient content nor the technical properties were changed.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
Explosives	CHETAH software (Chemical Thermodynamic And Hazard evaluation)	Permethrin (0.4%)	The test item has no explosive properties according to the CHETAH method.	CH-622/2015
Flammable gases		-	Not applicable	-
Flammable aerosols		-	Not applicable	-
Oxidising gases			Not applicable	-
Gases under pressure			Not applicable	-
Flammable liquids	EU Method A.9	Permethrin (0.4%)	Not flammable	CH-622/2015
Flammable solids			Not applicable	-
Self-reactive substances and mixtures		-	Justification for non-submission of data	-
Pyrophoric liquids		-	Justification for non-submission of data	-
Pyrophoric solids			Not applicable	-
Self-heating substances and mixtures		-	Justification for non-submission of data	-
Substances and mixtures which in contact with water emit flammable gases			Not applicable	-
Oxidising liquids	CHETAH software (Chemical Thermodynamic And Hazard evaluation)	Permethrin (0.4%)	The test item has no oxidizing properties according to the CHETAH method.	CH-622/2015
Oxidising solids			Not applicable	-
Organic peroxides		-	Justification for non-submission of data	-
Corrosive to metals	UN Manual of Tests and Criteria - Test C.1 UN-MTC, Part III, Section 37, Paragraph 37.4 method	Pistola insetticida Permetrina 0,4% - Pertrin RTU	No corrosive to metals	R-FD-22-008577

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
Auto-ignition temperatures of products (liquids and gases)	EC 440/2008 No A.15	Permethrin (0.4%)	No auto-ignition until 600°C	CH-621/2015
Relative self-ignition temperature for solids		-	Not applicable	-
Dust explosion hazard		-	Not applicable	-

Conclusion on the physical hazards and respective characteristics of the product

Note:
The applicant has noted that the studied batches have the same composition as the marketed formulation.

Explosives
None of their components has been classified as explosive. Therefore explosivity is not expected.

Flammability
No typical flammability phenomena was observed upto 130°C. The pilot flame was extinguished at this temperature. Thus the preparation is not classifeid as Flammable.

Self-reactive substances and mixtures
The study does not need to be conducted because there are no chemicals groups present in the molecule which are associated with explosive or self-reactive properties and hence, the classification procedure does not need to be applied.

Pyrophoric liquids
The test does not need to be conducted because the formulation does not contain any pyrophoric substance.

Self-heating substances and mixtures
The study does not need to be conducted because none of the components is classified as explosive or associated with self-reactive properties and hence, the classification procedure does not need to be applied.

Oxidising properties
None of the solution components has oxidising properties. Therefore oxidising properties are not expected. Not relevant conclusions for this endpoint.

Organic peroxides
The study does not need to be conducted because none of the components does not fall under the definition of organic peroxides according to GHS and the relevant UN Manual tests and criteria.

Corrosive to metals
It is not possible to waive an endpoint on physical hazards by the structure of the BP components, when one of the components (permethrin comprises chlorine) comprises a chemical group which indicates that the BP may corrode metals. Therefore, the test needs to be applied.
Corrosion has not present on either fully immersed or partially immersed samples or in samples exposed to vapour. Furthermore, the data, photos in the report clearly show that the biocidal product is not corrosive.

Auto-ignition temperature (liquids and gases)
The auto-ignition temperature of the sample is 600°C at 1010 mbar (ignition delay time: 12 seconds), according to the A.9 method.

Conclusions
The biocidal product has not been classified as flammable, corrosive, explosive and oxidising.
Therefore, it does not need to be classified regarding physical and chemical hazards as it is not flammable and not corrosive to metals, not oxidising or explosive and does not self-ignite.

2.2.4 Methods for detection and identification

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
permethrin	HPLC-UV	75 %, 100 % and 125 % of the nominal concentration of active ingredieng / 6	128.3 to 299.4 µg/mL r^2 = 0.99	Yes	Sum of isomer: 95.71 – 100.00	Sum of isomer: 98.1	0.63	--	CH-623/2015
Permethrin Cis isomer	HPLC-UV			Yes			0.64	--	
Permethrin Trans isomer	HPLC-UV			Yes			0.76	--	
All four permethrin stereoisomers in an EW formulation	Chiral HPLC-DAD	CIPAC Validated	CIPAC Validated	CIPAC/4946*	CIPAC Validated	CIPAC Validated	CIPAC Validated	CIPAC Validated	AR/CAR (IE CA, 2014, 2017 addendum).
All four permethrin stereoisomers in an EC formulation	Chiral HPLC-DAD	1S-cis Permethrin (S,S) 0.69 %w - 4.63%w 1R-cis Permethrin (R,R) 0.69 %w -4.59 %w 1S-trans Permethrin (S,R) 1.93 %w - 12.9 %w	R^2 = 1.000 for all 1S-cis Permethrin (S,S): 0.013-0.34 mg/mL (n = 6 points) 1R-cis Permethrin (R,R): 0.013-0.33 mg/mL (n = 6 points)	No significant interference	n = 2 at each level – 3 levels 1S-cis Permethrin (S,S) 97.3 – 98.7% 1R-cis Permethrin (R,R) 98.2 – 99.5%	n = 2 at each level – 3 levels 1S-cis Permethrin (S,S) Recovery level (0.69 %w): 97.3 % Recovery level (2.31%w): 98.7 % Recovery level (4.63%w): 98.3 %	Six samples (single injection) from 1 batch – 1S-cis Permethrin (S,S): 0.46 %. 1R-cis Permethrin (R,R): 0.41 % 1S-trans Permethrin	Not applicable	AR/CAR (IE CA, 2014, 2017 addendum).

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
		1R-trans Permethrin (R,S) 1.91 %w - 12.8 %w	1S-trans Permethrin (S,R): 0.035-0.93 mg/mL (n = 6 points) 1R-trans Permethrin (R,S): 0.035-0.93 mg/mL (n = 6 points)		1S-trans Permethrin (S,R) 97.5 – 99.5% 1R-trans Permethrin (R,S) 96.6 – 99.1%	1R-cis Permethrin (R,R) (n = 2) Recovery level (0.69 %w): 98.6 % Recovery level (2.30 %w): 99.5 % Recovery level (4.59 %w):98.2% 1S-trans Permethrin (S,R) (n = 2) Recovery level (1.93 %w): 97.5 % Recovery level (6.43 %w): 99.5 % Recovery level (12.9 %w): 98.1 % 1R-trans Permethrin (R,S) (n = 2)	(S,R): 0.34 % 1R-trans Permethrin (R,S): 0.62 %		

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
						Recovery level (1.91 %w): 96.6 % Recovery level (6.38 %w): 99.1 % Recovery level (12.8 %w): 98.0 %			
All four permethrin stereoisomers in an WP formulation	Chiral HPLC-DAD	1S-cis Permethrin (S,S) 0.99 %w – 6.57%w 1R-cis Permethrin (R,R) 0.98 %w -6.52 %w 1S-trans Permethrin (S,R) 2.74 %w - 18.3 %w	As for EC formulation above	No significant interference	n = 2 at each level – 3 levels 1S-cis Permethrin (S,S) 98.8 – 101.2% 1R-cis Permethrin (R,R) 98.0 – 101.4% 1S-trans Permethrin (S,R) 99.3 – 100.9%	n = 2 at each level – 3 levels 1S-cis Permethrin (S,S) Recovery level (0.99% w/w): 98.8 % Recovery level (3.29%): 100.7 % Recovery level (6.57%): 101.2 % 1R-cis Permethrin (R,R)	Six samples (single injection) from 1 batch – 1S-cis Permethrin (S,S): 1.08%. 1R-cis Permethrin (R,R): 1.11 % 1S-trans Permethrin (S,R): 0.96 %	Not applicable	AR/CAR (IE CA, 2014, 2017 addendum).

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
		1R-trans Permethrin (R,S) 2.72 %w - 18.3 %w			1R-trans Permethrin (R,S) 99.4 – 101.0%	Recovery level (0.98% w/w): 98.0 % Recovery level (3.26%): 100.8 % Recovery level (6.52%): 101.4 % 1S-trans Permethrin (S,R) Recovery level (2.74%): 99.3 % Recovery level (9.13%): 100.9 % Recovery level (18.3% w/w): 100.8 % 1R-trans Permethrin (R,S) Recovery level (2.72% w/w): 99.4 % Recovery level (9.05% w/w): 101.0 % Recovery level	1R-trans Permethrin (R,S): 0.93 %		

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
						(18.1 % w/w): 100.9 %			
All four permethrin stereoisomers in wood preservatives with common co-formulants	Chiral HPLC-DAD	No data provided	No data provided	No significant interference for TC or basic product formulation, however significant interference when formulations became more complex (higher number of actives and or higher number of common co-formulants found in wood preservatives.	No data provided	No data provided	No data provided	Not applicable	AR/CAR (IE CA, 2014, 2017 addendum).
Impurities in Permethrin	GC-FID, HPLC-UV, and GC-MS								AR/CAR (IE CA, 2014, 2017 addendum).
* The method has been peer-validated by CIPAC for EW formulations and is available under the pre-publication scheme (CIPAC/4946).									

Analytical methods for monitoring									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		

Analytical methods for soil									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Permethrin in silt and sandy loam	HPLC/MS/MS	5 µg/kg (= LOQ level), and 50 µg/kg	1 µg/L to 100 µg/L (2 to 200 µg/kg) r > 0.9992	No signals / peaks interfering with the detection of the analyte were observed in extracts of untreated blank control specimens.	70-110		<20	5.0 µg/kg	AR/CAR (IE CA, 2014, 2017 addendum).

Analytical methods for air									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Permethrin	HPLC/MS/MS	LOQ and 10-fold LOQ n = 5	5.0 ng/mL to 500 ng/mL r = 0.997	The chromatograms of the control specimens showed no signals (<1 µg/m^3) at the retention time of permethrin.	87-92	89.63	≤6 %	5 µg/m^3	AR/CAR (IE CA, 2014, 2017 addendum).

	GC-MS/MS	0.0001 and 0.001 mg/m^3	0.05-10 mg/L. y = 152187.4x + 1081.4 r = 1.0	The method is specific for the determination of Permethrin in air since no interferences were observed in the chromatograms of solvent, control samples and fortification levels.	72-74	73	1.85-3.35	0.0001 mg/m^3	

Analytical methods for water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Permethrin in drinking and surface water	HPLC/MS/MS	0.05 µg/L and 0.5 µg/L n = 10	0.04 µg/L -10 µg/L r > 0.9995	The control chromatograms generally have no peaks above the chromatographic background and the spiked sample chromatograms contain only the analyte peak of interest.	70-110		1.7-2.2	0.05 µg/L	AR/CAR (IE CA, 2014, 2017 addendum).

Analytical methods for animal and human body fluids and tisues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		

Analytical methods for monitoring of active substances and residues in food and feeding stuff									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		

Conclusion on the methods for detection and identification of the product

Note:
The applicant has noted that the studied batches have the same composition as the marketed formulation.

Analytical methods for the analysis of the product as such including the active substance, impurities and residues
A suitable combination method (achiral and chiral) was peer-validated by CIPAC.
The validation study reports (EC, EW and WP) indicated that the chiral CIPAC method of analysis was considered acceptable for EC, EW and WP formulations. However the study indicated that considerable interference can occur with some complex wood preservative formulations, and that the CIPAC chiral method may not be suitable under these more complex conditions.
The method submitted by the applicant for analising the active substance in the biocidal product could be considered acceptable.

Analytical methods for soil
An acceptable validated method for residues of Permethrin in soil was presented.

Analytical methods for air
Acceptable validated methods were provided for residues of Permethrin in air.

Analytical methods for water
Acceptable validated methods were provided for residues of permethrin in water.

Analytical methods for animal and human body fluids and tisues
Not relevant as the active substances are neither toxic nor highly toxic.

Analytical methods for monitoring of active substances and residues in food and feeding stuff
Food and feeding stuff will not be exposed to permethrin based on the proposed usage.

Conclusion
The methods are indicated in the Assessment Report for the inclusion in annex I (PT18).
The applicant has also submitted the letter of access granted by Lanxess Deutschland GmbH for information on analytical methods for the Permethrin active substance.
Finally, the analytical method submitted for the analyses of the active substance in the formulation could be deemed sufficiently specific and precise.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

Main group 03: Pest control
Product type 18: Insecticides, acaricides and products to control other arthropods.
The biocidal product PISTOLA INSECTICIDA PER04 is intended to be used against cockroaches, silverfishes and ants in private/commercial buildings and hospitals and against cat fleas, mites and ticks on non-washable textile surfaces indoors, as well against ant nests outdoors.

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

The organisms to be controlled are:

-crawling insects, cockroaches (*Blatella germanica* and *Blatta orientalis*, adults and nymphs), ants and silverfishes as spot application in hiding surfaces (including crack and crevices) indoors.

- ants (*Lasius niger*, adults, larvae, nymphs, queen) as nest application outdoors, around houses on paved ways, balconies and terraces where ant nests are located.

-cat fleas (*Ctenocephalides felis*), house dust mite (*Dermatophagoides pteronyssinus*) and mites (*Rhipicephalus sanguineus* and *Ixodes ricinus*) on non-washable textile surfaces indoors.

The biocidal product is applied in empty rooms at industrial and domestic facilities as kitchens and store rooms, outdoors against ant nests and over textile surfaces indoors.

2.2.5.3 Effects on target organisms, including unacceptable suffering

PISTOLA INSECTICIDA PER04 produces mortality and knockdown of all organisms. These effects were seen when the organisms were exposed to the biocidal product. It is not possible to assess unacceptable suffering.

2.2.5.4 Mode of action, including time delay

PISTOLA INSECTICIDA PER04 is formulated with the active substance permethrin (synthetic pyrethroid).

According to the CAR, permethrin is a synthetic pyrethroid that acts as a contact insecticide that causes convulsions, paralysis and ultimately death in target organisms. Pyrethroids act on the insect nervous system by slowing action potential decay and thereby initiating repetitive discharges in motor and sensory axons. Electrophysiological studies have suggested that these phenomena result from modification of the gating kinetics of neuronal, voltage-sensitive sodium channels. Single channel studies have been conducted which have shown that pyrethroids slow the kinetics of opening and closing of sodium channels.

Pyrethroids show high potency and selectivity for insects over mammals. The negative temperature dependence of pyrethroid action is partly responsible for the low mammalian toxicity of these compounds. Permethrin belongs to the type 1 pyrethroids which produce a poisoning syndrome characterised by progressive fine whole body tremor, exaggerated start response, uncoordinated muscle twitching and hyperexcitability. The effects are generated largely by effects in the central nervous system. Permethrin also induces hepatic microsomal enzymes.

2.2.5.5 Efficacy data

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Insecticide	Indoors	PERMETRINA RTU 0.4%	*Periplaneta americana,* adults	Laboratory test: Residual efficacy According to TNsG 18-19	Non- porous (ceramic side) and porous surfaces (marble) were treated with the product . Temperature: 25±1°C Relative humidity: 60±5%. Knockdown (2, 5, 7, 10, 15, 20, 25, 30, 35, 40, 50 and 60 minutes) and mortality (24 hours) were assessed after treatment and tile drying (T0), one week after the treatment (T1), two weeks after the treatment (T2) and three weeks after treatment (T3). 5 replicates (10 insects per both treated and control group). Application rates: 25 mL/m^2 (Non-porous surface) 31.25 mL/m^2 (porous surface)	<u>Non-porous surfaces:</u> T0: 100% knockdown (20 minutes) T1: 92% knockdown (20 minutes) and 100% knockdown (30 minutes) T2: 94% knockdown (25 minutes) and 100% knockdown (35 minutes) T3: 94% knockdown (30 minutes) and 100% knockdown (35 minutes) Mortality (T0, T1, T2 and T3, after 24 hours): 100% Controls: 0% knockdown, 0% mortality <u>Porous surfaces:</u> T0: 100% knockdown (40 minutes) T1: 100% knockdown (60 minutes) T2: 64% knockdown (60 minutes): Mortality (T0 and T1 after 24 hours): 100% Mortality (T2 after 24 hours): 84% Controls: 0% knockdown, 0% mortality **The efficacy is demonstrated against *Periplaneta americana* (adults) in laboratory conditions until 3 weeks**	Test report: CHEPER071015 – 08 See confidential annex

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
						on non-porous surfaces at the application rate of 25 mL/m² and until 1 week on porous surfaces at the application rate of 31.25 ml/m².	
Insecticide	Indoors	PERMETRINA RTU 0.4%	*Blatta orientalis,* adults	Laboratory test: Residual efficacy According to TNsG 18-19	Non- porous surfaces (ceramic tiles- side up) were treated with the product Temperature: 25±1°C Relative humidity: 60±5%. Knockdown (2, 5, 7, 10, 15, 20, 25, 30, 35, 40, 50 and 60 minutes) and mortality (24 hours) were assessed after treatment and tile drying (T0), one week after the treatment (T1), two weeks after the treatment (T2) and three weeks after treatment (T3). 5 replicates (10 insects per both treated and control group). Application rate: 20 mL/m²	<u>Non-porous surfaces:</u> T0: 96% knockdown (60 minutes) T1: 98% knockdown (50 minutes) T2: 90% knockdown (40 minutes) and 98% knockdown (60 minutes) T3: 96% knockdown (60 minutes) Mortality (T0, T1, T2, after 24 hours): 100% Mortality (T3, after 24 hours): 98% Controls: 0% knockdown, 0% mortality **The efficacy is demonstrated against *Blatta orientalis* (adults) until 3 weeks on non-porous surfaces in laboratory conditions at the application rate of 20 mL/m².**	Test report: CHEPER071015 – 01 See confidential annex
Insecticide	Indoors	PERMETRINA RTU 0.4%	*Blattella germanica,* adults	Laboratory test:	Non- porous (ceramic side) and porous surfaces (marble) were	<u>Non-porous surfaces:</u>	Test report: CHEPER071015 – 02

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
				Residual efficacy According to TNsG 18-19	treated with the product. Temperature: 25±1°C Relative humidity: 60±5%. Knockdown (2, 5, 7, 10, 15, 20, 25, 30, 35, 40, 50 and 60 minutes) and mortality (24 hours) were assessed after treatment and tile drying (T0), one week after the treatment (T1), two weeks after the treatment (T2) and three weeks after treatment (T3). 5 replicates (10 insects per both treated and control group). Application rates: 20 mL/m^2 (Non-porous surface) 25 mL/m^2 (porous surface)	T0: 90% knockdown (7 minutes) and 100% knockdown (15 minutes) T1: 100% knockdown (10 minutes) T2: 90% knockdown (10 minutes) and 100% knockdown (15 minutes) T3: 92% knockdown (10 minutes) and 100% knockdown (15 minutes) Mortality (T0, T1, T2 and T3, after 24 hours): 100% Controls: 0% knockdown, 0% mortality <u>Porous surfaces:</u> T0: 98% knockdown (15 minutes) and 100% knockdown (20 minutes) T1: 100% knockdown (15 minutes) T2: 92% knockdown (40 minutes) and 96% knockdown (60 minutes) Mortality (T0 and T1, after 24 hours): 100% Mortality (T2, after 24 hours): 72% Controls: 0% knockdown, 0% mortality **The efficacy is demonstrated against *Blattella germanica* (adults) until 3 weeks**	See confidential PAR.

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
						on porous and until 1 week on non-porous surfaces in laboratory conditions at the application rates of 20 mL/m² (Non-porous surface) and 25 mL/m² (porous surface).	
Insecticide	Indoors	PERMETRINA RTU 0.4%	*Lasius niger,* adults	Laboratory test: Residual efficacy According to TNsG 18-19	Non- porous (ceramic side) and porous surfaces (marble) were treated with the product. Temperature: 25±1°C Relative humidity: 60±5%. Knockdown (2, 5, 7, 10, 15 and 30 minutes) and mortality (24 hours) were assessed after treatment and tile drying (T0), one week after the treatment (T1), two weeks after the treatment (T2) and three weeks after treatment (T3). 5 replicates (20 insects per both treated and control group). Application rates: 14 mL/m² (Non-porous surface)	<u>Non-porous surfaces:</u> T0 and T1: 100% knockdown (7 minutes) T2: 92% knockdown (7 minutes) and 100% knockdown (10 minutes) T3: 94% knockdown (10 minutes) and 100% knockdown (15 minutes) Mortality (T0, T1, T2 and T3, after 24 hours): 100% Controls: 0% knockdown, 0% mortality <u>Porous surfaces:</u> T0: 98% knockdown (20 minutes) and 100% knockdown (25 minutes) T1: 94% knockdown (20 minutes) and 100% knockdown (30 minutes) T2: 94% knockdown (30 minutes) T3: 93% knockdown (25 minutes) and 100% knockdown (30 minutes) Mortality (T0, T1, T2 and T3, after 24 hours): 100%	Test report: CHEPER071015 – 10 See confidential PAR

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
					16 mL/m^2 (porous surface)	Controls: 0% knockdown, 0% mortality **The efficacy is demonstrated against *Lasius niger* (adults) until 3 weeks on porous and non-porous surfaces in laboratory conditions at the application rates of 14 mL/m^2 (Non-porous surface) and 16 mL/m^2 (porous surface).**	
Insecticide	Indoors	PERMETRINA RTU 0.4%	*Ctenocephalides felis,* adults	Laboratory test: Residual efficacy According to TNsG 18-19	Non- porous (ceramic side) and porous surfaces (marble) were treated with the product. Temperature:25±1°C Relative humidity: 60±5%. Knockdown (2, 5, 10, 15, 20, 25, 30, 40, 50 and 60 minutes) and mortality (24 hours) were assessed after treatment and tile drying (T0) and one week after the treatment (T1). 5 replicates (10 insects per both treated and control group).	<u>Non-porous surfaces:</u> T0: 100% knockdown (10 minutes) T1: 100% knockdown (15 minutes) Mortality (after 24 hours): 100% (T0) and 98% (T1) Controls: 0% knockdown, ≤2% mortality <u>Porous surfaces:</u> T0: 98% knockdown (60 minutes) T1: 94% knockdown (50 minutes) Mortality (after 24 hours): 92% (T0) and 100% (T1) Controls: 0% knockdown, ≤6% mortality **The efficacy is demonstrated against**	Test report: CHEPER071015 - 04 See confidential PAR

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
					Application rates: 18 mL/m^2 (Non-porous surface) 20 mL/m^2 (porous surface)	***Ctenocephalides felis* (adults) until 1 week on non-porous surfaces in laboratory conditions at the application rate of 18 mL/m^2.**	
Insecticide	Indoors	PERMETRINA RTU 0.4%	*Lepisma saccharina,* adults	Laboratory test: Residual efficacy According to TNsG 18-19	Non- porous surfaces (ceramic side) were treated with the product. Temperature: 25±1°C Relative humidity: 60±5%. Knockdown (2, 5, 7, 10, 15, 20, 25 and 30 minutes) and mortality (24 hours) were assessed after treatment and tile drying (T0), one week after the treatment (T1), two weeks after the treatment (T2) and three weeks after treatment (T3). 5 replicates (10 insects per both treated and control group). Application rate: 18 mL/m^2	<u>Non-porous surfaces:</u> T0: 100% knockdown (10 minutes) T1: 100% knockdown (15 minutes) T2: 90% knockdown (15 minutes) and 100% knockdown (20 minutes) T3: 100% knockdown (20 minutes) Mortality (T0, T1, T2 and T3, after 24 hours): 100% Controls: 0% knockdown, 0% mortality **The efficacy is demonstrated against *Lepisma saccharina* (adults) until 3 weeks on non-porous surfaces in laboratory conditions at the application rate of 18 mL/m^2**	Test report: CHEPER071015 – 05a See confidential PAR
Insecticide	Indoors	PERMETRINA RTU 0.4%	*Lepisma saccharina,* adults	Laboratory test:	Porous surfaces (marble) were treated with the product.	<u>Porous surfaces:</u>	Test report: CHEPER071015 – 05c

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
				Residual efficacy According to TNsG 18-19	Temperature:25±1°C Relative humidity: 60±5%. Knockdown (2, 5, 7, 10, 15, 20, 25, 30, 40, 50 and 60 minutes) and mortality (24 hours) were assessed after treatment and tile drying (T0) and one week after the treatment (T1). 5 replicates (10 insects per both treated and control group). Application rate: 25 mL/m^2	T0: 92% knockdown (20 minutes) and 100% knockdown (25 minutes) T1: 100% knockdown (25 minutes) Mortality (after 24 hours): 100% (T0) and 90% (T1) Controls: 0% knockdown, 0% mortality **The efficacy is demonstrated against *Lepisma saccharina* (adults) until 1 week on porous surfaces in laboratory conditions at the application rate of 25 mL/m^2**	See confidential PAR
Insecticide	Indoors Flies	PERMETRINA RTU 0.4%	*Musca domestica,* adults	Laboratory test: Residual efficacy According to TNsG 18-19	Non- porous (ceramic side) and porous surfaces (marble) were treated with the product. Temperature: 25±1°C Relative humidity: 60±5%. Knockdown (2, 5, 10, 15, 20, 25, 30, 40, 50 and 60 minutes) and mortality (24 hours) were assessed after treatment and tile drying (T0), one week	<u>Non-porous surfaces:</u> T0: 92% knockdown (20 minutes) and 100% knockdown (25 minutes) T1: 94% knockdown (20 minutes) and 100% knockdown (25 minutes) T2: 88% knockdown (20 minutes) and 100% knockdown (50 minutes) T3: 84% knockdown (20 minutes) and 100% knockdown (25 minutes) Mortality (T0, T1, T2 and T3, after 24 hours): 100%	Test report: CHEPER071015 - 03 See confidential PAR

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
					after the treatment (T1), two weeks after the treatment (T2) and three weeks after treatment (T3). 5 replicates (10 insects per both treated and control group). Application rates: 14 mL/m^2 (Non-porous surface) 16 mL/m^2 (porous surface)	Controls: 0% knockdown, 0% mortality <u>Porous surfaces:</u> T0: 84% knockdown (35 minutes) and 96% knockdown (60 minutes) T1: 82% knockdown (50 minutes) and 90% knockdown (60 minutes) T2: 84% knockdown (40 minutes) and 96% knockdown (60 minutes) T3: 86% knockdown (40 minutes) and 96% knockdown (60 minutes) Mortality (T0, T1 after 24 hours): >90% and 90% (T2, T3) Controls: 0% knockdown, 0% mortality **The efficacy is demonstrated against *Musca domestica* (adults) until 3 weeks on porous surfaces and until 1 week on non-porous surfaces in laboratory conditions at the application rates of 14 mL/m^2 (non-porous surface) and 16 mL/m^2 (porous surface).**	

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Insecticide	Indoor Mosquitoes	PERMETRINA RTU 0.4%	*Culex pipiens,* adults	Laboratory test: Residual efficacy According to TNsG 18-19	Non- porous (ceramic side) and porous surfaces (marble) were treated with the product. Temperature: 25±1°C Relative humidity: 60±5%. Knockdown (2, 5, 7, 10, 15, 20 (only porous surfaces), 25 (only porous surfaces) and 30 minutes) and mortality (24 hours) were assessed after treatment and tile drying (T0), one week after the treatment (T1), two weeks after the treatment (T2) and three weeks after treatment (T3). 5 replicates (20 females per both treated and control group). Application rates: 18 mL/m^2 (Non-porous surface) 20 mL/m^2 (porous surface)	<u>Non-porous surfaces:</u> T0: 100% knockdown (7 minutes) T1: 87% knockdown (7 minutes) and 100% knockdown (10 minutes) T2: 82% knockdown (7 minutes) and 100% knockdown (10 minutes) T3: 88% knockdown (7 minutes) and 100% knockdown (10 minutes) Mortality (T0, T1, T2 and T3, after 24 hours): 100% Controls: 0% knockdown, 0% mortality <u>Porous surfaces:</u> T0: 92% knockdown (15 minutes) and 100% knockdown (20 minutes) T1: 84% knockdown (15 minutes) and 100% knockdown (20 minutes) T2: 100% knockdown (20 minutes) T3: 98% knockdown (20 minutes) and 100% knockdown (25 minutes) Mortality (T0, T1, T2 and T3, after 24 hours): 100% Controls: 0% knockdown, 0% mortality **The efficacy is demonstrated against**	Test report: CHEPER071015 - 09 See confidential PAR

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
						***Culex pipiens* (adults) until 3 weeks on porous and non-porous surfaces in laboratory conditions at the application rates of 18 mL/m² (non-porous surface) and 20 mL/m² (porous surface).**	
Insecticide	Indoor Mosquitoes	PERMETRINA RTU 0.4%	*Aedes albopictus,* adults	*Laboratory test: Residual efficacy According to TNsG 18-19*	Non- porous (ceramic side) and porous surfaces (marble) were treated with the product. Temperature: 25±1°C Relative humidity: 60±5%. Knockdown (2, 5, 7, 10, 15, 20 (only porous surfaces), 25 (only porous surfaces) and 30 minutes) and mortality (24 hours) were assessed after treatment and tile drying (T0), one week after the treatment (T1), two weeks after the treatment (T2) and three weeks after treatment (T3). 5 replicates (20 females per both treated and control group).	<u>Non-porous surfaces:</u> T0: 100% knockdown (7 minutes) T1: 100% knockdown (10 minutes) T2: 83% knockdown (7 minutes) and 100% knockdown (10 minutes) T3: 87% knockdown (7 minutes) and 100% knockdown (15 minutes) Mortality (T0, T1, T2 and T3, after 24 hours): 100% Controls: 0% knockdown, 0% mortality <u>Porous surfaces:</u> T0: 83% knockdown (15 minutes) and 100% knockdown (25 minutes) T1: 97% knockdown (20 minutes) and 100% knockdown (25 minutes) T2: 100% knockdown (20 minutes)	Test report: CHEPER071015 - 07 See confidential PAR

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
					Application rates: 18 mL/m^2 (Non-porous surface) 20 mL/m^2 (porous surface)	T3: 90% knockdown (20 minutes) and 98% knockdown (30 minutes) Mortality (T0, T1, T2 and T3, after 24 hours): 100% Controls: 0% knockdown, 0% mortality **The efficacy is demonstrated against *Aedes albopictus* (adults) until 3 weeks on porous and non-porous surfaces in laboratory conditions at the application rates of 18 mL/m^2 (non-porous surface) and 20 mL/m^2 (porous surface).**	
Insecticide	Indoors	PERMETRINA RTU 0.4%	*Dermatophagoides pteronyssinus,* adults	Laboratory test: No-choice test According to TNsG 18-19	Non-porous surfaces (ceramic tile) were treated with the product. Temperature: 25±1°C Relative humidity: 60±5%. Mortality (24 hours) was assessed after the application. 5 replicates (20 insects per both treated and control group).	<u>Non-porous surfaces:</u> 91% mortality Controls: 0% mortality **The efficacy is demonstrated against *Dermatophagoides pteronyssinus* (adults) on non-porous surfaces in laboratory conditions at the application rate of 20 mL/m^2.**	Test report: CHEPER071015 - 11 See confidential PAR

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
					Application rate: 20 mL/m^2		
Insecticide	Indoors	PERMETRINA RTU 0.4%	*Dermatophagoides pteronyssinus,* adults	Laboratory test: No-choice test According to TNsG 18-19	Porous surfaces (parquet tile) were treated with the product. Temperature: 25±1°C Relative humidity: 60±5%. Mortality (24 hours) was assessed after the application. 5 replicates (around 30 insects (26-35) per both treated and control group). Application rate: 31.5 mL/m^2	<u>Porous surfaces:</u> 98.14% mortality Controls: ≥18.76% mortality **The efficacy is NOT demonstrated against *Dermatophagoides pteronyssinus* (adults) on porous surfaces in laboratory conditions at the application rate of 31.5 mL/m^2 due to the high mortality in the control groups.**	Test report: CHEPER07 1015 – 11B See confidential PAR
Insecticide	Indoors	PERMETRINA RTU 0.4%	*Ixodes ricinus,* adults	Laboratory test: No-choice test According to TNsG 18-19	Non- porous (ceramic side) and porous surfaces (marble) were treated with the product. Temperature: 25±1°C Relative humidity: 60±5%. Knockdown (2, 5, 7, 10, 15, 20, 25 and 30 minutes) and mortality (24 hours) were assessed after	<u>Non-porous surfaces:</u> T0: 90% knockdown (7 minutes) and 100% knockdown (10 minutes) T1: 94% knockdown (10 minutes) and 100% knockdown (20 minutes) T2 and T3: 90% knockdown (10 minutes) and 100% knockdown (15 minutes) Mortality (T0, T1, T2 and T3, after 24 hours): 100% Controls: 0% knockdown, 0% mortality	Test report: CHEPER071015 - 06 See confidential PAR

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
					treatment and tile drying (T0), one week after the treatment (T1), two weeks after the treatment (T2) and three weeks after treatment (T3). 5 replications (10 insects per both treated and control group). Application rates: 20 mL/m^2 (Non-porous surface) 25 mL/m^2 (porous surface)	<u>Porous surfaces:</u> T0: 100% knockdown (15 minutes) T1: 90% knockdown (10 minutes) and 100% knockdown (15 minutes) T2 and T3: 100% knockdown (15 minutes) Mortality (T0, T1, T2 and T3, after 24 hours): 100% Controls: 0% knockdown, 0% mortality **The efficacy is demonstrated against *Ixodes ricinus* (adults) until 3 weeks on porous and non-porous surfaces in laboratory conditions at the application rates of 20 mL/m^2 (non-porous surface) and 25 mL/m^2 (porous surface).**	
Insecticide	Indoors	PERTRIN RTU – 0.4% permethrin w/w	*Musca domestica,* adults (MDa) *Aedes aegypti,* female adults (AAa) *Aedes albopictus,* female adults (AAa')*)*	Guidance on the Biocidal Products Regulation - Volume II Efficacy – Assessment and Evaluation (Parts B&C)	Two trials were conducted: on non-porous (ceramic tiles) and on porous surfaces (blocks of concrete). Test chamber: 15 m^3 (6 m^2 floor, the treated area was 3m^2) kept at a temperature	100% knockdown on non-porous and porous surfaces Non-porous surfaces (min) / Porous surfaces (min) MDa 10 10 AAa 10 10 AAa' 10 10	Test report: 2296–RTU-SIM/0118-04 See confidential PAR

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
			Culex pipiens, female adults (CPa) *Blattella germanica,* adults and nymphs (BGa and BGn) *Blatta orientalis,* adults and nymphs (BOa and BOn) *Lasius niger,* adults (LNa) *Lepisma saccharina,* adults (LSa) *Ctenocephalides felis,* adults and larvae (CFa and CFl) *Ixodes Ricinus,* adults and nymphs (IRa and IRn) *Ripicephalus sanguineus,* adults and nymphs (RSa and RSn) *Dermatophagoides pteronyssinus,* adults+nymphs (DPan)	– Version 1.0 - February 2017	26°C+1°C, a relative humidity of 70%+5%, smooth ventilation (< 10 m3/h) and light: 700 lux 12 hours + 12 hours darkness. The product was used to treat only spots crack&crevices (non barriers and non surfaces) located within the 3m² area where cardboards and polystyrene blocks were piled simulating furniture and crack and crevices, to mimic the reality of use. For ticks, a mouse was a bite target. Knockdown (10, 20, 30, 40 and 60 minutes) and mortality (24 hours) were assessed. 5 replicates of 25 insects for surface and for specie. Application rate: 15 mL/m² (the product was applied using a trigger spray).	CPa 10 10 BGa 30 30 BGn 30 30 BOa 30 30 BOn 30 30 LNa 10 10 LSa 30 40 CFa 30 40 CFl[1] 10 10 IRa 30 10 IRn 10 10 RSa 20 30 RSn 30 30 DPan 30 30 ASan 30 30 [1]The inhibition of the development of larvae into adult fleas was not demonstrated. Controls: <1 % knockdown (4hours) 100 % mortality in both surfaces. Controls: ≤4 % mortality For ticks, blood-feeding ticks were observed in the control groups, but not in the treated groups. **The test demonstrated the efficacy of all organisms tested (except for flea larvae) in simulated use**	

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
			Acarus siro, adults+nymphs (ASan)			**conditions on porous and non-porous surfaces at the application rate of 15 mL/m².**	
Insecticide	Indoors	PERTRIN RTU - 0.4% permethrin w/w	*Blattella germanica,* adults *Blatta orientalis,* adults	-Guidance on the Biocidal Products Regulation. Volume II Efficacy – Assessment and Evaluation (Parts B&C). Version 1.0. February 2017 - CEB French standard n° 249	Apartments: 60-80 m² (treated area (kitchen): 12-15 m²) 5 replicates (for treated areas and controls). Pre-assessment monitoring: 5 sticky traps (placed during 24 hours)/site Two pre-counts at Day 14 and Day 7: the mean of these values gave the pre-treatment infestation level. Product application: The product was applied as a cracks and crevices and spot treatment: under the fridge, under the kitchen sink, under the oven and the water-heater, on all cracks and crevices that can be an harbourage for cockroaches). Application rate: 15 mL/m² (The product was applied using a professional sprayer	Blattella germanica-Population reduction: D1: 74.5% D7: 91.2% D14: 92.2% D28: 97.4% Control groups≤4.6 % Blatta orientalis-Population reduction: D1: 92.3% D7: 95.3% D14: 98.5% D28: 98.1% Control groups ≤2.4% **The field test demonstrates the efficacy of the product against cockroaches at the application rate of 15 mL/m²**	Test report: 2296-RTU-FIELDCO/0118 See confidential PAR

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
					with an anti-drop nozzle, pressurized) Assessments were carried out 1, 7, 14 and 28 days after treatment.		
Insecticide	Ant nests	PERTRIN RTU - 0.4% permethrin w/w	*Lasius niger*	- Guidance on the Biocidal Products Regulation. Volume II Efficacy – Assessment and Evaluation (Parts B&C). Version 3.0. April 2018 - ECHA - C.E.B. method No. 196 (1997) - C.E.B. method MG1 - EPPO guidelines	Frequency of crossing in surface was measured before and after the treatment, then to open the nest after 4 weeks. Temperature: average 22.6 ºC Rain: 67 mm Hours of sun: 248 The observation was done in a square of 1 m^2 around the main nest entry. Application rate: 15 ml/m^2. Nests and surrounding areas from 0.252 m^2 (3.78 ml) to 0.188 m^2 (2.83 ml) were treated. (The product was applied using a professional pressurized sprayer with an anti-drop nozzle (1 bar)) 5 nests were monitored (as for the untreated controls).	<u>Population reduction</u> Test product: 93.8% (day 1 after the treatment) and 100% (days 14, 21 and 28 after the treatment) After 4 weeks the nest was open, 100% mortality. Control groups≤2.5 % For control groups > 500 ants were found alive. **The field test demonstrates the efficacy of the product as nest ants application (and surrounding areas) at the application rate of 15 mL/m^2.**	Test report: 2296-RTU-FIELDANT/0118-03 See confidential PAR

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
					6 assessments were done: -1, and +1, 7, 14, 21, 28 days after treatment.		
Insecticide	Indoors	PERTRIN RTU - 0.4% permethrin w/w	*Ctenocephalides felis,* male adults, female adults and larvae *Ixodes Ricinus,* male adults, female adults and nymphs *Ripicephalus sanguineus,* male adults, female adults and nymphs *Dermatophagoides pteronyssinus,* male adults, female adults and nymphs	Guidance on the Biocidal Products Regulation - Volume II Efficacy – Assessment and Evaluation (Parts B&C) – Version 3.0 – April 2018 - ECHA	Two trials were conducted: on carpet and on wood. Test chamber: 15 m3 (6 m² floor, the treated area was 3m²) kept at a temperature 26°C+1°C, a relative humidity of 70%+5%, smooth ventilation (< 10 m3/h) and light: 700 lux 12 hours + 12 hours darkness. Cardboards and polystyrene blocks and a water and food source were set on the floor of the test chamber. For ticks, the bite target was a mouse. Knockdown (30 minutes, 1 and 4 hours) and mortality (24 hours) were assessed. 5 replicates of 25 male insects, female insects	100% knockdown (30 minutes) on both surfaces Controls: ≤5% (4 hours) Mortality (24 hours): 100 % (on both surfaces). Controls: ≤2% For ticks, blood-fed ticks were observed in the control groups, but not in the treated groups. <u>Fleas (larvae):</u> The inhibition of the development of larvae into adult fleas was not demonstrated. **The test demonstrated the efficacy of all organisms tested (except for flea larvae) in sumulated use conditions on carpet**	Test report: 2296–RTU-SIM-HDMFT/0118-01 See confidential PAR

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
					and nymphs/larvae for surface and for specie. Application rate: 15 ml/m^2 (the product was applied using a trigger spray).	**and wood at the application rate of 15 mL/m^2.**	
Insecticide	-	PISTOLA INSECTICIDA PER04	-	The aim of this study is to determine the trigger spray performance (amount of product discharge per stroke) of the test item.	Four plastic bottles with trigger spray filled with the test item were weighed using the technical balance. Then, each bottle was weighed ten times (after each discharge).	The mean value of product discharged in discharge is 1.5 mL. The number of rotations to reach the application rate of 15 mL/m^2 are 10.	See confidential PAR

Conclusion on the efficacy of the product

It should be noted that there are three categories of users in Spain: general public, professionals and trained professionals. Therefore, the norms and criteria in the guidance for consumers are considered for the general public and professional users, and the norms and criteria for professionals indicated in the guidance are considered for trained professional users.

According to the evaluation of the results of the above studies, the eCA concludes that:

Efficacy against cockroaches (*Periplaneta Americana, Blattella germanica, Blatta orientalis)*

The applicant withdrew the claim for *Periplaneta americana*. Therefore, this claim has not been assessed.

The applicant has submitted laboratory, simulated-use and field tests against *Blattella germanica* and *Blatta orientalis*:

- The product has shown KD > 90% in 15 minutes for adult *Blattella germanica* on porous and non-porous surfaces (ceramic tiles, side down and side up) and in 60 minutes for adult *Blatta orientalis* on non-porous surfaces. The residual efficacy for both species on non-porous surfaces was demonstrated until 3 weeks and for *Blattella germanica* on porous surfaces until 1 week. It should be note that these test were carried out at a higher application rate (20-25 mL/m^2) than claimed by the applicant (15 mL/m^2).
- The simulated-use test 2296–RTU-SIM/0118-04 resulted in 100% knockdown (in 30 minutes) and 100% mortality after 24 h at an application rate of 15 mL/m^2 (on ceramic tiles and blocks of concrete) for both adult and nymph cockroaches after the product application as spot in crack and crevices.
- In the field test 2296-RTU-FIELDCO/0118, the product was applied as spot application and crack and crevices treatment in apartments of 60-80 m^2 (treated area (kitchen): 12-15 m^2) at an application rate of 15 mL/m^2. After 4 weeks, the population reduction exceeds ≥90% relative to pre-treatment levels.

The requirements of the guidance are met for the use as spot including crack and crevices for the general public and professional users as well as for trained professional users (laboratory and simulated-use tests reached 100% mortality and field tests a population reduction ≥90% within 4 weeks).

It should be noted that laboratory tests were carried out at a higher application rate (20-25 mL/m^2) than claimed by the applicant (15 mL/m^2). However, the simulated-uses test and the field test were conducted with 15 mL/m^2. Therefore, we consider that the data package is complete.

Therefore,the eCA concludes that the product PISTOLA INSECTICIDA PER04 is effective against cockroaches (*Blattella germanica* and *Blatta orientalis,* adults and nymphs*)* by spraying as spot to surface in hiding places (including crack and crevices) for the general public, professionals and trained professional users (indoors).

Efficacy against Black ants (*Lasius niger*)

The applicant has provided laboratory, simulated-use and field tests.

- The laboratory test showed KD > 90% in 7 minutes on non-porous surfaces and 20 minutes on porous surfaces (ceramic tiles, side down and side up), mortality of 100% in 24 hours and residual efficacy until 3 weeks on both surfaces.
- In the simulated-use test, 2296–RTU-SIM/0118-04, 100% knockdown in 10 minutes and 100% mortality after 24 h were achieved on ceramic tiles and blocks of concrete with an application rate of 15 mL/m^2 against adult black ants. This test demonstrated the efficacy of the product as spot in crack and crevices indoors.
- The field trial 2296-RTU-FIELDANT/0118-03 investigated the efficacy of the product applied by spraying on ant nests. This test was conducted in summer although the guidance recommends performing the test preferably during the early springs. As no population decline was observed in control groups, ES CA concluded that the population decrease in the treated groups was not due to natural causes, it was due to the effects of the insecticide. The study demonstrated the efficacy of the product against black ants (ant nests application) at the application rate of 15 mL/m^2 (3 mL maximum per nest (in 0.2 m^2, e.g. 45cm*45cm)).

According to the guidance, products intended for use as general surface treatment for the general public and professional users require results in laboratory tests and simulated-use tests (≥90% knockdown and mortality ≥90% in 24 hours). These criteria are met. Furthermore, the requirements for the use of the product as nest ants application was demonstrated (laboratory test reached 100% mortality and field tests a population reduction of 100% within 4 weeks) for the general public, professionals and trained professional users.

The requirements of the guidance are not met for the use outdoors (around and rain protected areas of buildings) since neither simulated-use test nor field test were carried out in outdoor conditions.

It should be noted that laboratory tests on porous surfaces were carried out at a higher application rate (16 mL/m^2) than claimed by the applicant (15 mL/m^2). However, we consider the difference between the dose claimed and the dose tested to be negligible. Furthermore, the simulated-uses test and the field test were conducted with 15 mL/m^2. Therefore, we consider that the data package is complete.

The eCA concludes that the product PISTOLA INSECTICIDA PER04 is effective against *Lasius niger* by spraying as spot in crack and crevices for the general public and professional users (adult ants, indoors) and as nest application including surrounding areas (against adults, larvae, nymphs and queen fleas) for the general public and professionals and trained professional users.

Efficacy against silverfishes (*Lepisma saccharina*)

Considering that there are no specific requirements for silverfishes in the guidance and comparing with those required for other insects, ES CA considers that laboratory and simulated tests are necessary to demonstrate the efficacy of a product against silverfishes (surface application).

The laboratory tests have shown KD of 100% in 10 minutes on non-porous surfaces and > 90% in 20 minutes on porous surfaces. Mortality of 100% in 24 hours was reached on both surfaces. The product showed residual efficacy up to 3 weeks on non-porous surfaces and up to 1 week on porous surfaces. The application rate was 18-25 mL/m^2.

In the simulated-use test (2296–RTU-SIM/0118-04) was obtained 100% mortality and 100% KD in 30 minutes on non-porous and in 40 minutes on porous surfaces and 100% mortality after 24 h (on both surfaces) was achieved at an application rate of 15 mL/m^2.

It should be noted that the application rate is established in 25 mL/m^2 taking into account both laboratory and simulated-use tests.

The eCA concludes that the product PISTOLA INSECTICIDA PER04 is effective against adult silverfishes (*Lepisma saccharina)* by spraying as spot in crack and crevices treatment indoors for the general public, professionals and trained professional users.

Efficacy against houseflies (*Musca domestica*)

The applicant has submitted a laboratory test and a simulated-use tests:

- The laboratory test has demonstrated KD ≥80 % in 20 minutes on non-porous surfaces and in 35 minutes on porous surfaces. The mortality in both cases was >90%. The product showed residual efficacy up to 3 weeks on non-porous surfaces and up to 1 week on porous surfaces.
- In the simulated-use test, 2296–RTU-SIM/0118-04, 100% knockdown in 10 minutes and 100% mortality after 24h were achieved on ceramic tiles and blocks of concrete with an application rate of 15 mL/m^2. However, this test was carried out applying the product as spot in crack and crevices in hiding places. **Due to this use for houseflies is not relevant, this use was not considered valid.**

Efficacy against mosquitoes (*Culex pipiens, Aedes albopictus* and *Aedes aegypti)*

Two laboratory tests were submitted against mosquitoes (for *Culex pipiens* and for *Aedes albopictus*) where were observed KD > 90% in 7 minutes on non-porous surfaces and in 15 minutes on porous surfaces. Mortality of 100% was reached on both surfaces. The product showed residual efficacy up to 3 weeks on both surfaces.

In the simulated-use test against *Culex pipiens, Aedes albopictus* and *Aedes aegypti*, 2296–RTU-SIM/0118-04, 100% knockdown in 10 minutes and 100% mortality after 24h were achieved on ceramic tiles and blocks of concrete with an application rate of 15 mL/m^2. However, this test was carried out applying the product as spot in crack and crevices in hiding places. **Due to this use for mosquitoes is not relevant, this use was not considered valid.**

Efficacy against cat fleas *(Ctenocephalides felis)*

Laboratory and simulated-use tests were provided by the applicant:

- The laboratory test has shown 100% KD in 10 minutes on non-porous surfaces and 98% in 60 minutes on porous surfaces and 100% mortality (24 hours) on non-porous surfaces and 92% on porous surfaces (100% KD is not reached and then, the efficacy in laboratory conditions is only demonstrated on non-porous surfaces). The residual efficacy on non-porous surfaces was observed until 1 week.
- Two simulated-use tests (test reports 2296–RTU-SIM/0118-04 and 2296–RTU-SIM-HDMFT/0118-01) were provided by the applicant to demonstrate the efficacy against cat fleas at an application rate of 15 mL/m^2. The test report 2296–RTU-SIM/0118-04 demonstrated the efficacy of the product against adult fleas on ceramic tiles and blocks of concrete as spot in crack and crevices (100% KD in 30 minutes on non-porous surfaces and 40 minutes on porous surfaces and 100% mortality in 24 hours for both surfaces). However, taking into account the flea

lifecycle, ES CA does not consider that ceramic tiles and blocks of concrete are representative surfaces. In the second simulated-use test submitted (test report 2296–RTU-SIM-HDMFT/0118-01), the product was tested on representative surfaces: carpet and wood. This test showed 100% KD in 30 minutes and 100% mortality for adult fleas on both surfaces. The inhibition of the development of larvae into adult fleas was not demonstrated in any of the trials.

The results obtained in the tests (simulated-use test for both surface and laboratory tests on non-porous surfaces) are in line with the requirements of the guidance for an adulticidal product against fleas (100% knockdown within 24 hours and ≥90% mortality within 48 hours). However, the ovicidal/larvicidal effect was not demonstrated because no inhibition of the development of eggs/larvae into adult fleas was shown. The only representative surface considered for fleas was carpet, therefore the only use to be authorised is on non-washable textile surfaces and only for the general public (the applicant has only claimed this user).

It should be noted that laboratory tests on non-porous surfaces were carried out at a higher application rate (20 mL/m^2) than claimed by the applicant (15 mL/m^2). However, since two simulated-use tests were provided, we consider that the data package is complete.

The eCA concludes that the product PISTOLA INSECTICIDA PER04 is effective against adult cat fleas (*Ctenocephalides felis)* by spraying on non-washable textile surfaces for general public (only category of user required by the applicant).

Efficacy against mites (*Dermatophagoides pteronyssinus* and *Acarus siro*)

Laboratory and simulated-use tests were provided by the applicant:

- The laboratory test demonstrates the efficacy of the product against *Dermatophagoides pteronyssinus* at 20 mL/m^2 on ceramic tiles (non-porous surfaces) (91% mortality). By contrast, the efficacy is not demonstrated in laboratory conditions on porous surfaces due to the high mortality in control groups.
- Two simulated-use tests (test reports 2296–RTU-SIM/0118-04 and 2296–RTU-SIM-HDMFT/0118-01) were submitted at an application rate of 15 mL/m^2. The test report 2296–RTU-SIM/0118-04 was carried out on ceramic and concrete surfaces against *Dermatophagoides pteronyssinus* and *Acarus siro* as spot in crack and crevices. The test report 2296–DUST-SIM-HDMFT /0118R was carried out on wood and carpet against *Dermatophagoides pteronyssinus.* The results in both tests were 100% KD in 30 minutes and 100% mortality in 24 hours in adults and nymphs.

  The efficacy against *Acarus siro* has not been demonstrated. There is no laboratory test. Furthermore, the simulated-use test was carried out on ceramic and concrete surfaces (not representative surfaces).

  The laboratory test against *Dermatophagoides pteronyssinus* was carried out at an application rate of 20 mL/m^2. This application rate is higher than the actual conditions of use of the biocidal product. Nevertheless, ES CA considers that as the efficacy was demonstrated in two semi-field tests, the laboratory test is not required. Due to mites survive well in surfaces as mattresses, carpets, or bedding, these types of surfaces were considered for the use of the biocidal product against

Dermatophagoides pteronyssinus taking into account the surfaces were mites survive well.

The results for laboratory test and simulated-use test for *Dermatophagoides pteronyssinus* met the requirements of the guidance for the use on non-washable textile surfaces: laboratory tests ≥90% mortality in 24 hours and simulated-use tests ≥90% mortality in 1 week. This use is only requested for the general public.

The eCA concludes that the product PISTOLA INSECTICIDA PER04 is effective against house dust mites (*Dermatophagoides pteronyssinus,* adults and nymphs) by spraying on non-washable textile surfaces for the general public.

Efficacy against ticks (*Rhipicephalus sanguineus and Ixodes ricinus*)

The applicant provides a laboratory trial for *Ixodes ricinus* and two simulated-use tests with both ticks (*Rhipicephalus sanguineus* and *Ixodes ricinus*).

- The laboratory test has demonstrated the efficacy of the product against *Ixodus ricinus* on ceramic tiles and marble (100% knockdown in 10 minutes on porous surfaces and 15 minutes on non-porous surfaces. 100% mortality in 24 hours). The residual efficacy was demonstrated until 3 weeks.
- Two simulated-use tests (test reports 2296–RTU-SIM/0118-04 and 2296–RTU-SIM-HDMFT/0118-01) were submitted at an application rate of 15 mL/m^2: one of them on ceramic and concrete surfaces as spot in crack and crevices (not representative surfaces taking into account the tick lifecycle) and the other one on wood and carpet. The two tests demonstrated the efficacy against *Rhipicephalus sanguineus* and *Ixodes ricinus* (100% KD within 30 minutes and 100% mortality in 24 hours in adults and nymphs).

  The laboratory test against *Ixodes ricinus* was carried out at an application rate of 20 mL/m^2 for non-porous surfaces and 25 mL/m^2 for porous surfaces. This application rate is higher than the actual conditions of use of the biocidal product. Furthermore, the applicant did not provide a laboratory test for *Rhipicephalus sanguineus*. Nevertheless, ES CA considers that laboratory tests can be waived as the efficacy has been demonstrated in two semi-field test for both ticks (≥95% mortality before ticks start feeding) with similar conditions to the intended use of the biocidal product.

The eCA concludes that the product PISTOLA INSECTICIDA PER04 is effective against ticks (*Rhipicephalus sanguineus and Ixodes ricinus,* adults and nymphs) by spraying on non-washable textile surfaces for the general public (only category of user required by the applicant).

Application rate

The applicant has provided a test to determinate the number of sprayings to apply 15 mL/m^2 of biocidal product. The number of sprayings required are 10 (1.5 mL/in each spraying). Therefore, for 3 mL the number of aprayings are 2, and for an application rate of 25 mL as the number of sparyings are 16.6, the application rate should be adjusted to 25.5 mL (17 sprayings)

In conclusion, the following claimed uses are compliant with the requirements of the TNsG on product evaluation for PT18/19 (2012):

- Use against crawling insects, cockroaches (*B. germanica* and *B. orientalis,* adults and nymphs*),* ants (*L. niger,* adults) and silverfishes (*L. saccharina,* adults) as spot to surface in hiding places (including crack and crevices) for the general public and professionals (indoor). Application rate for cockroaches and ants: 15 mL/m^2. Application rate for silverfishes: 25.5 mL/m^2.
- Use against crawling insects, cockroaches (*B. germanica* and *B. orientalis,* adults and nymphs*)* and silverfishes as spot to surface in hiding places (including crack and crevices) for trained professionals (indoor). Application rate for cockroaches: 15 mL/m^2. Appliction rate for silverfishes: 25.5 mL/m^2.
- Use against *Lasius niger* (adults, larvae, nymphs and queens) as nest application and surrounding areas for the general public, professionals and trained professionals. Application rate: 3 mL per nest (in 0.2 m^2, e.g. 45cm*45cm), 15 mL/m^2.
- Use against adult cat fleas (*Ctenocephalides felis),* house dust mite (*Dermatophagoides pteronyssinus*) and ticks (*Rhipicephalus sanguineus* and *Ixodes ricinus*) by spraying on non-washable textile surfaces for the general public. Application rate: 15 mL/m^2.

2.2.5.6 Occurrence of resistance and resistance management

According to the CAR, resistance to permethrin has been documented in wide varieties of insects: pear psylla, german cockroach, spotted tentiform leafminer, diamondback moth, house fly, Stable fly, headlice or tobacco budworm. The level of resistance is less than tenfold in some of the species but high levels of resistance have been observed in cockroaches (45-fold), lice (up to 385 fold), and budworm (1400 fold).
In general, pyrethroid resistance has been attributed to reduced neural sensitivity, enhanced metabolism, and reduced penetration ratio in many insects. A substantial degree of resistance remaining after synergism suggests the presence of other resistance mechanisms. Cross-resistance to pyrethroids and the susceptibility to carbaryl suggested that a common site of pyrethroid action exists. Application of permethrin synergists such as Piperonyl butoxide (PBO) or Triphenyl phosphate (TPP) to permethrin resistant head lice suggests that monooxygenases (cytochrome P-450s) and the esterase enzyme systems were responsible for some pyrethroid resistance. A lack of synergism of D-phenothrin resistance by Piperonyl butoxide suggests that a non-oxidative mechanism, such as nerve insensitivity is also present in resistant lice.
The authorisation holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management.

The principles of strategies for managing the development of resistance are as follow: "To avoid resistance occurrence, keep the label instructions and avoid repeated use of products containing permethrin. Alternate with products containing different active substances. When the infestation persists contact a professional."

2.2.5.7 Known limitations

None.

2.2.5.8 Evaluation of the label claims

In conclusion, the following claimed uses are compliant with the requirements of the TNsG on product evaluation for PT18/19 (2012):

- Use against crawling insects, cockroaches (*B. germanica* and *B. orientalis,* adults and nymphs*),* ants (*L. niger,* adults) and silverfishes (*L. saccharina,* adults) as spot to surface in hiding places (including crack and crevices) for the general public and professionals (indoor). Application rate for cockroaches and ants: 15 mL/m^2. Application rate for silverfishes: 25.5 mL/m^2.

- Use against crawling insects, cockroaches (*B. germanica* and *B. orientalis,* adults and nymphs*)* and silverfishes as spot to surface in hiding places (including crack and crevices) for trained professionals (indoor). Application rate for cockroaches: 15 mL/m^2. Appliction rate for silverfishes: 25.5 mL/m^2.
- Use against *Lasius niger* (adults, larvae, nymphs and queens) as nest application and surrounding areas for the general public, professionals and trained professionals. Application rate: 3 mL per nest (in 0.2 m^2, e.g. 45cm*45cm), 15 mL/m^2.
- Use against adult cat fleas (*Ctenocephalides felis),* house dust mite (*Dermatophagoides pteronyssinus*) and ticks (*Rhipicephalus sanguineus* and *Ixodes ricinus*) by spraying on non-washable textile surfaces for the general public. Application rate: 15 mL/m^2.

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

PISTOLA INSECTICIDA PER04 is not intended to be use with other biocidal products.

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

The biocidal product, PISTOLA INSECTICIDA PER04 , has not been tested in any in vivo studies but it has been tested in vitro for eye corrosion. It was considered that the acute oral, dermal, inhalation, skin corrosion and irritation, eye irritation and the sensitisation studies on the active ingredient were adequate for the classification and labelling of the product and for the human health risk assessment.

The results of the in vitro test for eye corrosion (Andres, I., 2016) performed with the biocidal product PERMETHRIN 0.4 RTU, identical to PISTOLA INSECTICIDA PER04 and in conformity with OECD Guideline 437 on bovine corneas (BCOP) demonstrated that the product is non-corrosive for the eye and therefore, it does not require any classification for eye irritation or serious eye damage.

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	No skin corrosion and irritation.
Justification for the value/conclusion	Based on the classification of Permethrin and the coformulants, and their respective content in the final formulation
Classification of the product according to CLP Regulation	Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, no classification is required

Data waiving	
Information requirement	Skin Irritation
Justification	Skin irritation toxicity studies for PISTOLA INSECTICIDA PER04 have not been performed. There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) Nº 1272/2008 (CLP Regulation), and synergistic effects between any of the components are not expected. Thus the study does not need to be conducted. Therefore, INSECTICIDA DUST PER ZNZ can be considered as no irritant to skin and do not meet the criteria for classification as irritant or corrosive. It is therefore proposed that the preparation PISTOLA INSECTICIDA PER04 is not a skin irritant and is not classified.

Eye irritation

Summary table of in vitro studies on serious eye damage and eye irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Dose levels, Duration of exposure**	**Results**	**Remarks**	**Reference**
OECD Guideline no. 437 EU method B.47, GLP	fresh bovine corneas / *Bos primigenius* Taurus / 9 corneas (3 for each treatment group); exposure time: 10 min at 32 ± 1 °C.	PERMETHRIN 0.4 RTU	cornea opacity score mean IVIS: -0.17 (Test item) 0.21 (Neg CTRL) 60.84 (Pos CTRL) Reversability: not specified	Max score: -0.27 (Test item) 0.44 (Neg CTRL) 80.06 (Pos CTRL)	Study No.: 15102905 G850

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	No ocular irritant.
Justification for the value/conclusion	The test item PERMETHRIN 0.4 RTU showed no effects on the cornea of the bovine eye. The calculated IVIS (in vitro irritancy score) is -0.17 at time point 10 min. According to OECD Guideline no. 437 (Jul. 2013), a substance with an IVIS ≤ 3 requires no classification for eye irritation or serious eye damage.
Classification of the product according to CLP Regulation	Not classified

Data waiving	
Information requirement	Eye Irritation
Justification	Eye irritation study for PISTOLA INSECTICIDA PER04 have been performed. The test item PERMETHRIN 0.4% RTU showed no effects on the cornea of the bovine eye.

	PERMETHRIN 0.4% RTU is the same product than PISTOLA INSECTICIDA PER04 therefore can be considered as no irritant to eye.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	Based on the classification of Permethrin and the coformulants, and their respective content in the final formulation
Classification of the product according to CLP and DSD	Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, no classification is required for respiratory tract irritation.

Data waiving	
Information requirement	Respiratory Tract Irritation
Justification for the conclusion	No study on the respiratory tract irritation of the formulation PISTOLA INSECTICIDA PER04 has been performed. No data on respiratory tract irritation is submitted. Furthermore, this data is not required under Biocides Regulation. However, there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) Nº 1272/2008 (CLP Regulation). No classification is required for respiratory tract irritation.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	No skin sensitizer
Justification for the value/conclusion	Based on the classification of Permethrin and the coformulants, and their respective content in the final formulation
Classification of the product according to CLP and DSD	The preparation PISTOLA INSECTICIDA PER04 is not classified as skin sensitiser. According to the CLP regulation, no H phrase is applicable (being permethrin content in the biocidal product lower than 1%) and EUH208 special precautionary phrase should be added on the label.

Data waiving	
Information requirement	Skin sensitisation
Justification	Skin sensitisation studies for have not been performed. There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) Nº 1272/2008 (CLP Regulation), and synergistic effects between any of the components are not expected. Thus the study does not need to be conducted. No classification is required for skin sensitization. According to the CLP regulation, no H phrase is applicable (being permethrin content in the biocidal product lower than 1%) and EUH208 special precautionary phrase should be added on the label.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not respiratory sensitiser
Justification for the value/conclusion	Based on the classification of Permethrin and the coformulants, and their respective content in the final formulation.
Classification of the product according to CLP and DSD	The preparation PISTOLA INSECTICIDA PER04 is not classified as respiratory sensitiser.

Data waiving	
Information requirement	Respiratory sensitization
Justification	No data on the respiratory sensitisation of the product PISTOLA INSECTICIDA PER04 has been submitted According CLP the preparation PISTOLA INSECTICIDA PER04 is not classified as respiratory sensitiser.

Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	LD_{50}>2000mg/kg bw
Justification for the selected value	Permethrin is classified H302 , regarding the content of a.s no toxicity effects at the maximum dose rate of 2000 mg/Kg bw
Classification of the product according to CLP and DSD	Based on the available data on active substance, The acute toxicity estimate (ATE) of the mixture is >2000 mg/Kg bw. Also, according to CLP Regulation, the formulation PISTOLA INSECTICIDA PER04 is not classified as harmful by the oral route

Data waiving	
Information requirement	Acute oral toxicity
Justification	Acute oral toxicity studies for product PISTOLA INSECTICIDA PER04 have not been performed. According to CLP Regulation,the product is not classified for Acute oral toxicity.

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Not harmful by the inhalation route
Justification for the selected value	Based on the classification of a.s and coformulants
Classification of the product according to CLP and DSD	According to the classification rules laid down in the CLP regulation, no classification is required for inhalation acute toxicity

Data waiving	
Information requirement	Acute inhalation toxicity
Justification	Acute inhalation toxicity studies for PISTOLA INSECTICIDA PER04 have not been performed. According to CLP Regulation,the product PISTOLA INSECTICIDA PER04 is not classified for Acute inhalation toxicity.

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	No study is available.
Justification for the selected value	The acute dermal toxicity studies on the active ingredient are adequate for the classification and labelling of the product and for the human health risk assessment. In fact, neither the active substance, nor the coformulants are classified for acute dermal toxicity.
Classification of the product according to CLP Regulation	Not classified under CLP Regulation.

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Permethrin
Value(s)	50 %
Justification for the selected value(s)	No study has been performed on PISTOLA INSECTICIDA PER04, thus the default value of 50 % according to Guidance on Dermal Absorption (EFSA Journal 2017; 15(6):4873) was considered in the current risk assessment.

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

Based on the BPR Art. 3.1(f) definition of 'substance of concern' which includes the condition «*and is present or is produced in a biocidal product in sufficient concentration to present risks of such an effect*» no 'substances of concern' are present in the biocidal product.

Available toxicological data relating to a mixture

No data.

Other

Endocrine disruption

Assessment of the ED properties of the active substance:

The biocidal product contains Permethrin. According to the CAR for Permethrin there is no indication for endocrine disrupting properties of the active substance. However, a comprehensive ED-assessment for the active substance and its metabolites according to

Regulation (EU) 2017/2100 and the "Revised Guidance Document 150 on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption" will need to be performed at the renewal stage.

Assessment of the ED properties of non-active substances (co-formulants):

Since 7 June 2018, date when the Regulation (EU) 2017/2100 came into force, endocrine disruption assessment of co-formulants is mandatory according to the article 19. According to the document "*Practical approach for the assessment of ED properties of a biocidal product by rMS/eCA*" agreed at CG-41, the following sources were considered to check the potential endocrine disrupting properties of the co-formulants contained in the biocidal product, see confidential Annex.

Overall conclusion on the biocidal product regarding ED properties:

Based on the existing knowledge there is no indication of concern regarding the ED properties of the substances used in the biocidal product PISTOLA INSECTICIDA PER04 If one or several components are identified as having ED properties in the future, the conditions for granting the biocidal product authorisation will be revised.

2.2.6.2 Exposure assessment

General Remarks

The assessment of occupational exposure towards *PISTOLA INSECTICIDA PER04* as insecticide against crawling insects is based on information provided by the Applicant. In the absence of human exposure data, the exposure estimation to *PISTOLA INSECTICIDA PER04* is based on the selected models and default values from the Biocides Human Health Exposure Methodology (BHHEM 2015) along with HEEG recommendations and the Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation (Parts B+C) Version 4.0 December 2017.

The proposed tiered approach for human exposure assessment is applied as follows. In several cases it is considered not to be appropriate to calculate a "reasonable worst case" exposure (Tier 1) according to the Guidelines. The dermal absorption of permethrin in humans is well established as outlined above. Assuming no protection by the human skin (as proposed for Tier 1 estimates) is considered not to be reasonable. For all of the following calculations the established dermal absorption figure for humans is applied. Despite the fact that protective measures could be supposed to be carefully observed in a professional environment, a Tier 1 is proposed as a worst case. Then, personal protective equipment will be assumed to be worn as second scenario (Tier 2).

Unless otherwise specified, a default penetration value of 10% for gloves and clothing was assumed, which is in accordance with HEEG Opinion on "Default protection factors for protective clothing and gloves" (when potential hand exposure data are available, a factor of 10 -90 % reduction of exposure by gloves manufactured from appropriate material- can be used as a reasonable and conservative default value to convert the potential to actual hand exposure when using appropriate gloves: MOTA v6, 4.2.9.9 HEEG Opinion 9). On the other hand, if data on exposure inside protective gloves is available, these will be used for exposure assessment (MOTA v6, 4.2.9.2 HEEG Opinion 2).

If no appropriate models are available in the BHHEM, surrogate models are chosen and a justification is provided.

Where exposure is calculated based on empirical data (Biocides Human Health Exposure Methodology (BHHEM 2015) along with HEEG recommendations), these data are applied in agreement with the recommendations given by the guidelines as follows: In case of continuous (chronic) exposure scenarios the typical exposure is calculated based on the

75%-ile of the data. The 95%-ile is considered to represent the typical case when recommended by applicable guidelines. Where 95%-iles are not given, the maximum values are used instead.

PISTOLA INSECTICIDA PER04 (PERMETHRIN 0.4% RTU) is a ready-to-use water-based formulation containing 0.4% w/w permethrin, for indoor and outdoor use by (trained) professionals and general public for the control of crawling insects, cat fleas, house dust mites and ticks.

Human exposure towards the active substance from its use in the biocidal product can take place via different "routes of exposure", i.e. via inhalation, dermal contact and/or ingestion (see below).

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							
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.	Yes	Yes	n.a.	Yes	Yes	No
Dermal	n.a.	Yes	Yes	n.a.	Yes	Yes	No
Oral	n.a.	No	No	n.a.	No	Yes	No
n.a.: not applicable							

Exposure resulting from the production of the active substance is not considered as the manufacturing processes are not performed in the EU. Exposure resulting from the formulation and packaging processes which take place in Italy is also not considered since adequate protective clothing and equipment are used to prevent exposure of the workforce.

In the exposure assessment presented below, the following stages have been considered.

PRIMARY EXPOSURE

- Loading of biocidal product into a hand-held spraying equipment. The Biocidal product is a RTU product therefore the exposure is considered to be negligible. (Professional & Consumer Use)
- Professional and non-professional use of biocidal product by spraying (Professional & Consumer Use).

SECONDARY EXPOSURE

- Inhalation exposure: inhalation of volatilized residues of active substance. The active substance in water-based formulations is a substance with an extremely low vapour pressure, and are therefore not very volatile. The inhalation exposure due to evaporation is therefore considered to be negligible. (Professional & Consumer Indirect Exposure)
- Indirect exposure: exposure of consumers to materials or articles containing residues of biocide: dermal exposure in treated areas, skin contact with working clothes. (Professional & Consumer Indirect Exposure)

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario**	**Primary or secondary exposure / Description of scenario**	**Exposed group**
1.	Application	**Primary exposure.** Indoor application by spraying.	Trained Professional / Professional
2.	Application	**Primary exposure.** Outdoor application of product in ant's nest entries.	Professional / Trained professional
3.	Application	**Primary exposure.** Indoor application by spraying.	Non-professional
4.	Application	**Primary exposure.** Outdoor application of product in ant's nest entries.	Non-professional
5.	Application	**Primary exposure.** Indoor application by spraying on non-washable textile surfaces.	Non-professional
6.	Post-application	**Secondary exposure:** Inhalation of volatilized residues	General public
7.	Post-application	**Secundary exposure.** Adults/toddlers playing/crawling on treated surfaces and hand to mouth contact after insecticide treatments.	General public
8.	Post-application	**Secondary exposure.** Persons laundering contaminated work clothing	General public

Industrial exposure

Industrial users are involved in manufacturing, handling and/or packaging of actives or products in industry and in producing end-products containing biocidal products. Industrial users have received suitable information, instruction and training in their use. Thus no industrial exposure is foreseen anf it is not considered since adequate protective clothing and equipment are used to prevent exposure of the workforce.

Professional/Trained Professional exposure

Scenario [1] – Indoor application

Description of Scenario [1]
Exposure estimates for workers were calculated according to the Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure Methods and models to assess exposure to biocidal products in different product types. Spraying Model 1, TNsG 2002 user guidance for professionals was considered appropriate for the intended use of B.P. by hand-held spraying equipment. The model reflects mixing and loading liquids in compression sprayers or dusting applicators, and applying at 1 to 3 bar pressure as a coarse or medium spray, indoors and outdoors, overhead and downwards. The Tier 1 assessment assumes that no personal protective equipment is worn by workers. Hence clothing penetration is set to 100% for dermal exposure. The Tier 2 assessment assumes that workers wear additionally protective clothing such as a coverall and/or respiratory protective equipment (RPE). Accordingly Tier 2a

calculation considers workers wearing a coated coverall, gloves and respiratory protection and Tier 2b workers wearing impermeable coverall, gloves (inside new gloves) and respiratory protection. Protection factor for clothing was adopted from the HEEG opinion 9 on default protection factors for protective clothing and gloves (cotated coverall – 10 % penetration, impermeable coverall – 5 % penetration, protective gloves [new gloves for each work shift] – reduce exposure aprox. factor of 0.52). A respiratory protection factor of 10 (10% penetration) by a mask is assumed.

The model is partially based on measured data on occupational exposure to Permethrin during its use as a public hygiene insecticide published in a HSE, UK study by Llewllyn et al (1996). According to this data, typically, less than two hours a day is spent using pesticides, thus, a task duration of 2 hours was used to refine the worst case risk assessment.

In general, a body weight of 60 kg was assumed and an inhalation rate of 0.0208 m^3/min for light activity (Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure Default human factor values for use in exposure assessments for biocidal products). Dermal penetration of Permethrin was set to 50% according to the EFSA guidance.

	Parameters	Value / Units	Justification / Source
Tier 1	Weight fraction of active substance	0.4 %	Section 2.1.2
	Body weight	60 kg	Recommendation no. 14, 2017
	Expected duration of actual exposure	120 minutes	Recommendation no. 6, 2020
	Dermal exposure		
	Potential dermal exposure	92 mg/min	Recommendation no. 6, 2020
	Hand exposure without gloves	181 mg/min	Recommendation no. 6, 2020
	Dermal Absorption	50%	Guidance on Dermal Absorption (EFSA, 2017)
	Inhalation exposure		
	Potential Inhalation exposure	104 mg/m^3	Recommendation no. 6, 2020
	Inhalation rate	1.25 m^3/h	Recommendation no. 14, 2017
	Inhalation absorption	100%	Default value.
Tier 2a	Hand exposure with gloves*	10.7 mg/min	Recommendation no. 6, 2020
	Coated coverall	10%	HEEG Opinion 9 (2010)
	RPE	APF = 10	TNsG
Tier 2b	Hand exposure with gloves**	10.7 mg/min	Recommendation no. 6, 2020
	Impermeable coverall	5%	HEEG Opinion 9 (2010)
	RPE	APF = 10	TNsG

* assuming only protective gloves (5% penetration)
** assuming protective gloves (5% penetration) and new gloves for each work shift (exposure is reduced a factor of 0.52 approx.).

Calculations for Scenario [1]

Systemic effects

Summary table: systemic exposure from professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg a.s./kg/day)**	**Estimated dermal uptake (mg a.s./kg/day)**	**Estimated total uptake (mg a.s./kg/day)**
Scenario 1	1 / none	1.73E-02	1.09E-00	1.11E-00
Scenario 1	2a / PPEs	1.73E-03	7.96E-02	8.13E-02
Scenario 1	2b / PPEs	1.73E-03	4.07E-02	4.24E-02

Further information and considerations on scenario [1]
None.

Scenario [2] – Outdoor application

Description of Scenario [2]
The biocidal product is applied directly to the ant nests, around houses on paved ways, balconies, and terraces where ant nests are located for the outdoor use. Exposure for the (trained) professional user is only during application since, being a ready to use formulation, no mixing and loading is foreseen. Assuming that the work is peripatetic, with lone working most common. Typically, less than two hours a day is spent using pesticides, with some applications being seasonal. Therefore, this scenario is deemed to be covered by scenario 1.

Combined scenarios
Not applicable.

Non-professional exposure

Scenario [3] – Indoor application by trigger spray.

Description of Scenario [3]
The biocidal product is a ready to use water-based formulation containing 0.4% w/w permethrin for crack and crevice / targeted spot treatment against crawling insects, intended for use by the general public (non-professional users). The default scenario in RIVM ConsExpo Web, version 1.1.0: Pest Control Products /Sprays /Crack & Crevice /Application (trigger spray) is used to estimate the exposure to the consumer, so the corresponding calculations can be considered to be the reasonable worst case. The inhalation exposure 'spray' model and the dermal exposure model 'constant rate' from ConsExpo Web are used to describe the scenario. The oral exposure is handled in the inhalation exposure model. ConsExpo assumes that the non-respirable fraction is taken in orally. Hence exposure via dermal, oral and inhalation route is expected. Parameters for the inhalation model are taken from RIVM report 320005002/2006 Pest Control Products Fact Sheet. The model assumes that: 1. the product is used 9 times a year maximum. 2. the trigger spray is applied during 4 minutes with a mass generation rate of 0.38 g/s. Also, the scenario considers that this product is applied in a 20 m^3 room (with 8 m^2 floor surface). Hence the total amount applied according to this model would be 0.38 g/s x 10 min / 8 m^2 = 11.4 g/m^2 To our case:

1. the product is used 12 times a year.
2. The mass generation rate would be: 25.5 mL/m^2 x 1.0008 g/mL x 8 m^2 / 4 min = 0.85 g/s

for Tier 1.

	Parameters	Value / Units	Justification / Source
Tier 1	Weight fraction of a.s.	0.4%	Section 2.1.2.
	Application rate	25.5 g/m^2	Section 2.2.5 (worst case)
	Frequency of use	12 days/year	Section 2.2.8
	Body weight	60 kg	Recommendation 14, 2017
	Dermal exposure		
	Exposed body surface area	8300 cm^2	Recommendation no. 14, 2017 (half of total adult body surface area)
	Contact rate	46 mg/min	RIVM report 320005002/2006 Pest Control Products Fact Sheet
	Release duration	4 min	RIVM report 320005002/2006 Pest Control Products Fact Sheet
	Dermal absorption	50%	Guidance on Dermal Absorption (EFSA, 2017)
	Inhalation exposure		
	Spray duration	4 min	RIVM report 320005002/2006 Pest Control Products Fact Sheet
	Exposure duration	240 min	RIVM report 320005002/2006 Pest Control Products Fact Sheet
	Room volume	20 m^3	RIVM report 320005002/2006 Pest Control Products Fact Sheet
	Room height	2.5 m	RIVM report 320005002/2006 Pest Control Products Fact Sheet
	Ventilation Rate	0.6 / h	RIVM report 320005002/2006 Pest Control Products Fact Sheet
	Inhalation rate	1.25 m^3/h	Recommendation 14, 2017
	Mass generation rate	0.85 g/s	Calculated value.
	Airborne fraction	0.008	RIVM report 320005002/2006 Pest Control Products Fact Sheet
	Density non-volatile	1.8 g/cc	RIVM report 320005002/2006 Pest Control Products Fact Sheet
	Inhalation cut off diameter	15 µm	RIVM report 320005002/2006 Pest Control Products Fact Sheet
	Aerosol diameter distribution	logNormal	RIVM report 320005002/2006 Pest Control Products Fact Sheet
	Median diameter	7.7 µm	RIVM report 320005002/2006 Pest Control Products Fact Sheet
	Arithmetic coefficient of variation	1.9	RIVM report 320005002/2006 Pest Control Products Fact Sheet
	Maximum diameter	50 µm	RIVM report 320005002/2006 Pest Control Products Fact Sheet
	Inhalation absorption	100%	Default value.
	Oral exposure		
	No parameters	Parameters are set in inhalation exposure route	RIVM report 320005002/2006 Pest Control Products Fact Sheet
	Oral absorption	100%	Default value

Calculations for Scenario [3]

Summary table: systemic exposure from non-professional uses as [mg/kg bw/d]					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [3]	Tier 1/ no PPE	2.86E-03	6.13E-03	4.25E-05	9.03E-03

Further information and considerations on scenario [3]
None.

Scenario [4] – Outdoor application by trigger spray

Description of Scenario [4]
The biocidal product is applied directly to the ant nests, around houses on paved ways, balconies, and terraces where ant nests are located for the outdoor use. In absence of appropriate product-specific data, the default scenario in RIVM ConsExpo Web, version 1.1.0: Pest Control Products /Sprays /Crack & Crevices /Application (trigger spray) is used to estimate the exposure to the consumer, so the corresponding calculations can be considered to be the reasonable worst case and hence to cover exposure from directly to the ant nests spraying.

Calculations for Scenario [4]

Summary table: systemic exposure from non-professional uses as [mg/kg bw/d]					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [4]	Tier 1/ no PPE	2.86E-03	6.13E-03	4.25E-05	9.03E-03

Further information and considerations on scenario [4]
None.

Scenario [5] – Indoor application by trigger spray on non-washable textile surfaces

Description of Scenario [5]
The biocidal product is applied at domestic use (houses, flats, apartments) over textile surfaces that must be cleaned by dry treatments as mattresses, blankets, bedspreads, bedsteads, pillows, carpets, moquette… In absence of appropriate product-specific data, the default scenario in RIVM ConsExpo Web, version 1.1.0: Pest Control Products /Sprays /Crack & Crevices /Application (trigger spray) is used to estimate the exposure to the consumer, so the corresponding calculations can be considered to be the reasonable worst case and hence to cover exposure from over textile surfaces spraying.

Calculations for Scenario [5]

Summary table: systemic exposure from non-professional uses as [mg/kg bw/d]					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [5]	Tier 1/ no PPE	2.86E-03	6.13E-03	4.25E-05	9.03E-03

Further information and considerations on scenario [5]
None.

Combined scenarios

There is the possibility that the scenarios 3, 4 and 5 will be developed by the same user in the same day so the exposure of combined scenario should be estimated for these scenarios:

Summary table: combined systemic exposure from professional uses to permethrin					
Scenarios combined	**Tier/PPE**	**Estimated inhalation uptake [mg/kg bw/d]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated oral uptake [mg/kg bw/d]**	**Estimated total uptake [mg/kg bw/d]**
Scenarios [3, 4, 5]	1/no PPE	8.58E-03	1.84E-02	1.28E-04	2.71E-02

Exposure of the general public

Secondary exposure to the active substances as a result of biocidal product use can occur.

Scenario [6] - Inhalation of volatilized residues

Description of Scenario [6]			
Professional and general public may be exposed to volatilised residues from permethrin residues will vaporise and could be available for inhalation by people present in the room. However, based on the document, HEEG opinion 13 on Assessment of Inhalation Exposure of volatilised biocide active substance, it might not be necessary to calculate the exposure to volatilised residues: - For permethrin: 0.328 x (391.29 x 2.16E-06 / 0.05) = 5.53E-03 ≤ 1 **The result of this equation is lower than 1 for permethrin. The exposure to volatilised residues indoor can be considered negligible for non-professionals and general public for the biocidal product according to the assessment of effects on human health conclusions.** Chronic inhalation exposure to volatilised residues indoors should be assessed for adult considering the scenario "assessment of Inhalation Exposure of Volatilised Biocide Active Substance" from the Opinion n°13 of HEEG with calculation of the Saturated Vapour Concentration (SVC) for 24 hours (worst-case) following this formula: $SVC = (Mw \times Vp) / (R \times T)$ (mg/m^3) The exposure would be calculated with the following formula: Exposure = SVC x inhalation rate / body weight (mg/kg bw/d)			
	Parameters1	**Value / Units**	**Justification / Source**
Tier 1	Weight fraction	0.4%	Section 2.1.2.

	Body weight	60 kg (adults) 23.9 kg (children) 10 kg (toddlers) 8 kg (infants)	Recommendation no. 14, 2017.
	Inhalation rate	16 m^3/24h (adults) 12 m^3/24h (children) 8 m^3/24h (toddlers) 5.4 m^3/24h (infants)	Recommendation no. 14, 2017.
	Vapour pressure (Vp)	2.16E-06 Pa	AR/CAR (IE CA, 2014, 2017 addendum).
	Molecular weight (Mw)	391.29 g/mol	AR/CAR (IE CA, 2014, 2017 addendum).
	Gas constant (R)	8.31451 $J.mol^{-1}.K^{-1}$	HEEG opinion no. 13 (2011)
	Temperature (T)	293 K	HEEG opinion no. 13 (2011)

Calculations for Scenario [6]

No calculations are needed.

Further information and considerations on scenario [6]
None.

Scenario [7] – Adults/toddlers re-entry period / Adults/toddlers playing/crawling on treated surfaces

Description of Scenario [7]
The exposure after application is described for crawling children who are present in the room after a crack and crevice / targeted spot treatment has been carried out. Crack & Crevice application represents the worst case scenario and therefore no further assessment will be performed for targeted spot use. It is assumed that a toddler (worst case) crawls over the treated surface for 1 hour a day and the model is also used to estimate the possible adult exposure after application playing with a toddler on the treated surface. Exposure is modelled using the dermal exposure model 'rubbing off' and the oral exposure model 'constant rate' from RIVM ConsExpo Web, version 1.1.0 described in Pest control Fact Sheet RIVM report 320005002/2006 (General surface application – Post Application). Total amount sprayed is 25.5 g/m^2 as indicated by the maximum application rate. The scenario assumes that 25% of the floor area is taken to be the treated surface; for the room mentioned above (surface 8 m^2), this is equivalent to 2 m^2. The model also assumes that 85% of the amount sprayed ends up on the floor surface and 30% of this amount is dislodgeable (default values for exposure during general surface application with a trigger spray, RIVM Report 320005002/2006). Hence, if the amount of formulation per surface unit is 25.5 g/m^2, assuming that 85% of the amount sprayed ends up and 30% thereof will be dislodgeable, a dislodgeable amount of • 25.5 g/m^2 x 0.85 x 0.3 = 6.5 g/m^2 is calculated. In addition, dermal exposure of adults/toddlers can take place on any uncovered skin, that is, on the head, the arms and hands, and on the legs and feet. The ConsExpo model gives a transfer coefficient of 0.6 m²/h but a transfer factor of 0.20 m²/h for toddlers and

0.78 m^2/h for adults according to the Recommendation for indoor transfer coefficients no. 12 (2016) is considered The ingestion rate is calculated based on the assumption that 10 % of dermal load (ConsExpo) will be ingested by hand-to-mouth transfer:

- 6.5 g/m^2 x 0.20 m^2/h x 0.1 / 60 min = 2.17E-03 g/min for toddlers.
- 6.5 g/m^2 x 0.78 m^2/h x 0.1 / 60 min = 8.45E-03 g/min for adults.

These data are included in Tier 1, for Tier 2 the dislodgeable residue can be refined taking into account the US EPA Residential SOPs (2012), where, after the revision of complete datasets for some chemicals, it is concluded in table 7-9 that the dislodgeable residue for permethrin in hard surfaces is 3% (75th percentile). Therefore:

- the dislodgeable amount would be: 15 g/m^2 x 0.85 x 0.03 = 0.65 g/m^2

and

- the ingestion rate would be: 0.65 g/m^2x 0.2 m^2/h x 0.1 / 60 min = 2.17E-04 g/min for toddlers.
- the ingestion rate would be: 0.65 g/m^2x 0.78 m^2/h x 0.1 / 60 min = 8.45E-04 g/min for adults.

For exposure assessment purposes chronic exposure is considered (i.e., exposure is not averaged over a year).

Tier 1	**Parameters**	**Value / Units**	**Justification / Source**
	Weight fraction of permethrin	0.4%	Section 2.1.2
	Application rate	25.5 g/m^2	Section 2.2.5 (worst case)
	Frequency of use	126 days/year	RIVM report 320005002/2006 Pest Control Products Fact Sheet
	Transfer coefficient adults	0.78 m^2/h (adults) 0.20 m^2/h (toddlers)	Recommendation no. 12, 2016.
	Body weight	60 kg (adults) 10 kg (toddlers)	Recommendation no. 14, 2017.
	Dermal exposure		
	Exposed body area toddlers	2410 cm^2	Recommendation no. 14, 2017
	Exposed body area adults	9520 cm^2	Recommendation no. 14, 2017
	Contact time	60 min	RIVM report 320005002/2006 Pest Control Products Fact Sheet
	Contact surface	2 m^2	RIVM report 320005002/2006 Pest Control Products Fact Sheet
	Dermal absorption	50%	Guidance on Dermal Absorption (EFSA, 2017)
	Dislodgeable residue	30%	RIVM report 320005002/2006 Pest Control Products Fact Sheet
	Dislodgeable amount	6.5 g/m^2	Calculated value.
	Oral exposure		
	Exposure duration	60 min	RIVM report 320005002/2006 Pest Control Products Fact Sheet

	Transfer hand to mouth	10%	RIVM report 320005002/2006 Pest Control Products Fact Sheet
	Oral absorption	100%	Default value
	Ingestion rate	8.45E-03 g/min (adults) 2.17E-03 g/min (toddlers)	Calculated value.
Tier 2	Dislodgeable residue	3%	Standard Operating Procedures for Residential Pesticide Exposure Assessment - October 2012
	Dislodgeable amount	0.65 g/m^2	Calculated value.
	Ingestion rate	8.45E-04 g/min (adults) 2.17E-04 g/min (toddlers)	Calculated value.

Calculations for Scenario [7]

Summary table: indirect exposure of general public [mg/kg bw/d]					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [7] (toddlers)	Tier 1/ none	-	2.60E-01	5.21E-02	3.12E-01
Scenario [7] (adults)	Tier 1/ none	-	1.69E-01	3.38E-02	2.03E-01
Scenario [7] (toddlers)	Tier 2/ none	-	2.60E-02	5.21E-03	3.12E-02
Scenario [7] (adults)	Tier 2/ none	-	1.69E-02	3.38E-03	2.03E-02

Further information and considerations on scenario [7]
None.

Scenario [8] – Laundering work clothes

Description of Scenario [8]
Exposure to product can occur when washing contaminated work clothes. Persons at risk are adults professionals. The exposure is considered acute intermediary, as it does not occur on a daily basis but may be longer-term. In general, this approach assumes that the washing is carried out in a domestic automatic washing machine, therefore, the exposure will be dermally through the hands, from handling the contaminated clothes before and during the introduction of the clothes in the washing machine. Laundering is considered to be after a five-day work week, hence the total amount of product on work clothes is assumed to be five times the daily contamination associated with the application method used and it is assumed that the clothing to be washed is a coverall worn by a (trained) professional. The contamination of clothes is based on the professional spraying from which the tier that shows safe use is tier 2b where PPEs are worn.

Description of Scenario [8]			
It is assumed that applicator wear regular clothes which, according to HEEG opinion 9, have a Default Protection Factor of 50%.			
	Parameters	**Value**	**Justification / Source**
Tier 1	Weight fraction of active substance	0.4%	Section 2.1.2.
	Body weight	60 kg	Recommendation no. 14, 2017
	Dermal exposure		
	Indicative value from model	5244 mg/d	Indoor Application by spraying for (trained) professionals
	Surface medium-sized coverall	22700 cm^2	Estimated parameter usually accepted
	Regular clothes penetration	50 %	HEEG Opinion 9 (2010)
	Dermal Absorption	50%	Guidance on Dermal Absorption (EFSA, 2017)
	Skin surface area in contact	820 cm^2	For an adult, the total area of both hands (front and back) is 820 cm^2 (Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure Default human factor values for use in exposure assessments for biocidal products (revision of HEEG opinion 17 agreed at the Human Health Working Group III on 12 June 2017))
	Transfer coefficient	30 %	BHHEM, 2015 - Cotton, knitwear, plastic, wood Dried fluid - wet hand

Calculations for Scenario [8]

Summary table: systemic exposure from general public					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake [mg/kg bw/d]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated oral uptake [mg/kg bw/d]**	**Estimated total uptake [mg/kg bw/d]**
Scenario [8]	1/no PPE	--	9.47E-03	--	9.47E-03

Further information and considerations on scenario [8]
Not applicable.

Combined scenarios

Summary table: combined systemic exposure from non-professional uses				
Scenarios combined	**Estimated inhalation uptake [mg/kg bw/d]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated oral uptake [mg/kg bw/d]**	**Estimated total uptake [mg/kg bw/d]**
Scenarios [1, 8]	1.73E-03	5.01E-02	--	5.19E-02
Scenarios [3, 4, 5, 7]	8.58E-03	3.53E-02	3.51E-03	4.74E-02

Monitoring data

No monitoring data available.

Dietary exposure

No dietary exposure is foreseen since the product is not intended for the use on food, drinking water or livestock. Moreover dietary exposure is considered as not relevant, as the biocidal product is sprayed only in a band around the perimeter of the room in a directed manner and should not be applied in areas where food for human consumption is exposed at the time of treatment. Thus dietary exposure has not been assessed.

Information of non-biocidal use of the active substance

Summary table of other (non-biocidal) uses			
	Sector of use	**Intended use**	**Reference value(s)**
1. Permethrin	Plant protection products	IN - Insecticide	Not approved (1) MRL (2)
2. Permethrin	Veterinary use	Antiparasitic agents/Agents againstectoparasites	MRL (3)

(1) Commission Decision of 27 December 2000 concerning the non-inclusion of permethrin in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance.
(2) COMMISSION REGULATION (EU) 2017/623 of 30 March 2017 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acequinocyl, amitraz, coumaphos, diflufenican, flumequine, metribuzin, permethrin, pyraclostrobin and streptomycin in or on certain products
(3) COMMISSION REGULATION (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin. For milk further provisions in Commission Directive 98/82/EC are to be observed.

Residue definitions

Pharmacologically active substances and their classification regarding maximum residue limits (MRL) (COMMISSION REGULATION (EU) No 37/2010 of 22 December 2009):

Pharmacologically active Substance	**Marker residue**	**Animal Species**	**MRL**	**Target Tissues**
Permethrin	Permethrin (sum of isomers)	Bovine	50 µg/kg 500 µg/kg 50 µg/kg 50 µg/kg 50 µg/kg	Muscle Fat Liver Kidney Milk

Estimating Livestock Exposure to Active Substances used in Biocidal Products

Based on intended uses, human exposure through residues in livestock is expected to be very limited and feeding and metabolism studies in livestock to permit evaluation of residues in food of animal origin are not required

Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)

No transfer of active substance into foods as results of professional and/or industrial application of PISTOLA INS PER04 is expected since the product is not applied by spraying such that food or feeding stuffs could be contaminated. Therefore, there is no requirement to assess potential residues on foodstuffs.

Estimating transfer of biocidal active substances into foods as a result of non-professional use

No transfer of active substance into foods as results of non-professional use of PISTOLA INS PER04 is expected since the product is not applied in such a way that food or feeding stuffs could be contaminated. Therefore, there is no requirement to assess potential residues on foodstuffs.

According to Guidance on the BPR: Volume III Parts B+C Version 4.0 December 2017, 5. Guidance on Estimating Dietary Risk from Transfer of Biocidal Active Substances into Foods – Non-professional Uses, the following risk mitigation measures are added to PAR required:

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

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

Exposure during the production and formulation of the biocidal product should be addressed under other EU legislation (e.g. REACH).
Disposal should be done as described according to label instructions.

Aggregated exposure

No guidance neither methodology are available to assess human aggregated exposure. Moreover exposure calculations have been conducted taking into account worst case assumptions. Thus an adequate margin of safety can be anticipated even for aggregated exposure and no further data are provided.

Summary of exposure assessment

Scenarios and values to be used in risk assessment to permethrin			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake [mg/kg bw/d]**
1. Indoor application	Professionals / Trained professionals	Tier 1 / no PPE	1.11E+00
		Tier 2a / protective gloves (inside used gloves), coated coverall and RPE (APF = 10)	8.13E-02
		Tier 2b / protective gloves (inside new gloves), impermeable	4.24E-02

Scenarios and values to be used in risk assessment to permethrin			
		coverall and RPE (APF = 10)	
2. Outdoor application	Professionals / Trained professionals	Tier 1 / no PPE	Cover by scenario 1
		Tier 2a / protective gloves (inside used gloves), coated coverall and RPE (APF = 10)	Cover by scenario 1
		Tier 2b / protective gloves (inside new gloves), impermeable coverall and RPE (APF = 10)	Cover by scenario 1
3. Indoor application	Non-professionals	Tier 1 / no PPE	9.03E-03
4. Outdoor application	Non-professionals	Tier 1 / no PPE	9.03E-03
5. Indoor application	Non-professionals	Tier 1 / no PPE	9.03E-03
3 + 4 + 5.	Non-professionals	Tier 1 / no PPE	2.71E-02
6. Inhalation of volatilized residues	Non-professionals	Tier 1 / no PPE	Negligible.
7. Adults/toddlers playing/crawling on treated surfaces	General public (adults)	Tier 1 / no PPE	2.03E-01
	General public (adults)	Tier 2 / no PPE	2.03E-02
	General public (toddlers)	Tier 1 / no PPE	3.12E-01
	General public (toddlers)	Tier 2 / no PPE	3.12E-02
8. Laundering working clothes	General public	Tier 1 / no PPE	9.47E-03
1 + 8.	Non-professionals	Tier 1 / no PPE	5.19E-02
3 + 4 + 5 + 7.	General public	Tier 1 / no PPE	4.74E-02

2.2.6.3 Risk characterisation for human health

Reference values for Permethrin to be used in Risk Characterisation

Reference	Study	NOAEL	AF	Correction for oral absorption	Value
AEL short term	2 year oral study rat	59.46 mg/kg bw/day	100	-	0.5 mg/kg bw/day
AEL medium term	12-month study dog	5 mg/kg bw/day	100	-	0.05 mg/kg bw/day
AEL long term	12-month study dog	5 mg/kg bw/day	100	-	0.05 mg/kg bw/day

Maximum residue limits or equivalent

MRLs or other relevant reference values	Reference	Relevant commodities	Value
MRL	EU Reg. 396/2005 (PPP)	All commodities	Cf: Reg. (EU) 2017/623
	EU Reg. 470/2009 (VMP)	Food of animal origin (bovine)	Cf: Reg (EU) 37/2010

PPP: plant protection product
VMP: veterinary medicinal product

Specific reference value for groundwater
Not applicable.

Risk for industrial users

As previously stated, no relevant exposure is foreseen considering that industrial users are adequately trained in the safe handling of the active substance and the product, and adequate protective measures are in place in industrial facilities. Thus no risk is envisaged for industrial users.

Risk for professional/trained professional and non professional users

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)
1. Indoor application	Tier 1 / no PPE	5	0.05	1.11E-00	222	**No**
	Tier 2a / PPEs*	5	0.05	8.13E-02	163	**No**
	Tier 2b / PPEs**	5	0.05	4.24E-02	84.8	Yes
2. Outdoor application	Tier 1 / no PPE	Cover by scenario 1				
	Tier 2a / PPEs*					
	Tier 2b / PPEs**					

* protective gloves (inside used gloves, coated coverall and RPE (APF = 10) ** protective gloves (inside new gloves, impermeable coverall and RPE (APF = 10)

No unacceptable risk has been identified for different tasks considered when workers wear protective gloves (inside new gloves, impermeable coverall and RPE (APF = 10).

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

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

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

Residues of permethrin on treated surfaces are predicted to be low due to the presence of adequately ventilated areas. Hence, the final concentration of permethrin is assumed to be lower than 4000 ppm.

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

Combined scenarios
Not applicable.

Conclusion
Based on the results obtained in the risk assessment, the exposure of workers results in level of exposure lower than the relevant reference values for systemic exposure and local inhalation and dermal exposure. Therefore, no unacceptable risk can be identified taking into account the instruction for use and PPEs proposed.

Risk for non-professional users

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)
3. Indoor application	Tier 1 / no PPE	5	0.05	9.03E-03	18.1	Yes
4. Outdoor application	Tier 1 / no PPE	5	0.05	9.03E-03	18.1	Yes
5. Indoor application	Tier 1 / no PPE	5	0.05	9.03E-03	18.1	Yes

No unacceptable risk has been identified for different tasks considered.

Combined scenarios

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

3 + 4 + 5.	Tier 1 / no PPE	5	0.05	2.71E-02	54.2	Yes

No unacceptable risk has been identified for different combined tasks considered.

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

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

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

Residues of permethrin on treated surfaces are predicted to be low due to the presence of adequately ventilated areas. Hence, the final concentration of permethrin is assumed to be lower than 4000 ppm.

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

Conclusion
Based on the results obtained in the risk assessment, the exposure of general public results in level of exposure lower than the relevant reference values for systemic exposure and local inhalation and dermal exposure. Therefore, no unacceptable risk can be identified taking into account the instruction for use proposed.

Risk for the general public

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)
7. Adults/toddlers playing/crawling on treated surfaces	Tier 1 (adults)	5	0.05	2.03E-01	406	**No**
	Tier 2 (adults)	5	0.05	2.03E-02	40.6	Yes
	Tier 1 (toddlers)	5	0.05	3.12E-01	624	**No**
	Tier 2 (toddlers)	5	0.05	3.12E-02	62.4	Yes
8. Laundering working clothes	Tier 1	5	0.05	9.47E-03	18.9	Yes

No unacceptable risk has been identified for different tasks considered.

Combined scenarios

Scenarios combined	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
1 + 8	Tier 2b (1) Tier 1 (8)	5	0.05	5.19E-02	104	**No**
3 + 4 + 5 + 7	Tier 1 (3, 4, 5) Tier 2 (7) (adults)	5	0.05	3.38E-02	67.7	Yes

No unacceptable risk has been identified for different combined tasks considered with the exception of the combined tasks for workers where the workers cannot wash the contaminated clothes at home to avoid the overexposure to active substance.

Local effects
Indirect dermal exposure to BP is possible through contact treated surfaces.

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

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

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

Residues of permethrin on treated surfaces are predicted to be low due to the presence of adequately ventilated areas. Hence, the final concentration of permethrin is assumed to be lower than 4000 ppm.

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

Conclusion

The risk derived from the use of biocidal product by general public as secondary exposure appears to be acceptable when the exposure of the user to permethrin is compared to its chronic AEL. Moreover the biocidal product contains denatonium benzoate which is a substance added to the formulation specifically to give it a bitter taste and prevent it from being ingested by the child.

To avoid contact to treated surfaces by children and contaminated clothes by workers, the following RMMs were therefore assigned:

- *Keep out of reach of children and non-target animals/pets.*
- *(Trained) Professionals are not allowed to wash contaminated clothes at home.*

Therefore, no unacceptable risk can be identified taking into account the RMMs and the instruction for use proposed.

Risk for consumers via residues in food

The biocidal product is not intended for the use on food neither directly nor in areas where food is stored. Moreover no transfer of active substance into foods as results of professional,

non-professional and/or industrial application is expected since the product is not applied by spraying or dusting such that food or feeding stuffs could be contaminated. Therefore, there is no requirement to assess risk to consumers via residues in food.

In addition, to prevent any potential risk by its use, the following RMMs are included:
- *Do not (use/apply) directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock/pets.*
- Keep out of reach of children and non-target animals/pets.

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

The biocidal product does not contain any further active substance or substance of concern so a combined exposure is not expected.

2.2.7 Risk assessment for animal health

The bittering agent is supposed to repel children from orally ingesting dangerous amounts of the biocidal product. It is not acceptable to conclude that it is working the same way on all pet species, limiting the oral uptake. However, due to the lack of appropriate guidance, exposure is assumed to be similar to these of toddlers and children and no specific measure is needed (except for cats). Especially cats may even increase their licking behaviour in case they detect unpleasant residues on their fur. Also, cats are known to have a preference to hide in hard to reach places.

Cats are known to be more sensible to pyrethroids than others animals due to a slower metabolisation of these substances. Intoxication are very common and may be dangerous. In order to protect cats, the following Risk Mitigation Measure must be added on the label:

- *Keep cats away from treated surfaces. Due to their particular sensitivity to pyrethroids, the product can cause severe adverse reactions in cats.*
- *Contains Permethrin, may be dangerous/toxic to pets (e.g. cats, bees, fish and other aquatic organisms).*

In addition, to prevent any exposure of animals the following RMMs are included:
- *Do not spray directly on people, animals or bedding.*
- *Keep out of reach of children and non-target animals/pets.*
- *Do not use/apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock/pets.*
- *Remove or cover terrariums, aquariums and animal cages before application. Turn off aquarium air-filter while spraying.*
- *Keep uninvolved persons, children and pets away from treated surfaces/areas until dried.*

2.2.8 Risk assessment for the environment

ESCA: The applicant has not provided any new study with the biocidal product. The environmental risk assessment for PISTOLA INS PER04 has been done using the Competent Authority Report on the active substance permethrin. The whole assessment submitted by the applicant has been included and reviewed by the ES CA. The comments of the ES CA are included in grey boxes.

According to the applicant the product is a ready to use spray containing one active substance, permethrin (0.4% w/w). This product is intended to control crawling and flying insects indoor and outdoor by non-professional, professionals and trained professionals. Since the efficacy of this product against flying insects and against ants around buildings have not been supported by efficacy studies, these uses have not been reviewed.

Based on the efficacy studies the product is effective indoor for killing crawling insects as a spot treatment to a surface including crack and crevices, and also is effective against cat fleas, house dust mite and ticks by spraying non washable textiles surfaces. This product has shown also to be effective outdoor directly on ant nest.

Besides the active substance permethrin, this product contains another substance of concern Propan-2-ol, this substance is an active substance for other product types (PT1, PT2 and PT4) and it is in a concentration higher than 0.1% in the biocidal product. Therefore, although it is not considered as toxic for the environment, applying the specifications of Art. 3 (1f) of Regulation (EU) No 528/2012, this substance must be considered a Substance of Concern (SoC) and included into the environmental risk assessment.

2.2.8.1 Effects assessment on the environment

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 environmental fate and behaviour studies were conducted with the product, as it was considered that the studies on the active ingredient were adequate for the purpose. Summary of the fate and distribution in the environmental of the active substance, as reported in the Assessment Report of permethrin (April 2014), is reported in Environmental Risk Assessment document attached in the section 13 of IUCLID data set.

No aquatic, terrestrial or secondary poisoning toxicity studies were conducted with the product PERMETHRIN 0.4% RTU, as it was considered that the acute and chronic studies on the active ingredient were adequate for the classification and labelling of the product and for the environmental risk assessment. Therefore, it is concluded that the product should be classified with respect to aquatic toxicity as Acute Tox 1 (H400) and Chronic Tox 1 (H410).

Summary on PNEC used for the risk assessment							
Substance	**Surface water [$PNEC_{aquatic}$ (mg/L)]**	**Sediment [$PNEC_{sediment}$ (mg/kg wwt)]**	**STP microorganism [$PNEC_{STP}$ (mg/L)]**	**Soil [$PNEC_{soil}$ (mg/kg wwt)]**	**Birds [$PNEC_{oral,\ birds}$ (mg/kg diet)]**	**Mammals [$PNEC_{oral,\ mammals}$ (mg/kg diet)]**	**Reference**
Permethrin	4.7E-07	2.17E-04	0.00495	0.175	16.7	120	AR, 2014
DCVA	0.015	0.012	-	4.6	-	-	AR, 2014
PBA	>0.010	0.009	-	1.44	-	-	AR, 2014
PB alcohol	No data available						AR, 2014

ESCA: The biocidal product contains a SoC, Propan-2-ol, which has been included by ES CA in the environmental risk assessment, the sumary on PNEC used for the risk assessment are in the following table:

Summary on PNEC used for the risk assessment							
Substance	**Surface water [$PNEC_{aquatic}$ (mg/L)]**	**Sediment [$PNEC_{sediment}$ (mg/kg wwt)]**	**STP microorganism [$PNEC_{STP}$ (mg/L)]**	**Soil [$PNEC_{soil}$ (mg/kg wwt)]**	**Birds [$PNEC_{oral,\ birds}$ (mg/kg diet)]**	**Mammals [$PNEC_{oral,\ mammals}$ (mg/kg diet)]**	**Reference**
Propan-2-ol (*as SoC)*	2.82	2.41	10	0.496*	-	-	AR, 2015

* by equilibrium partitioning method.

Following propan-2-ol's AR (2015), propan-2-ol has a low BCF and it is not expected to accumulate in the environment. Therefore, the risk of secondary poisoning is assumed to be negligible via ingestion of contaminated food by birds or mammals.

Further Ecotoxicological studies

Data waiving	
Information requirement	Further ecotoxicological studies
Justification	Ecotoxicological studies on the formulation are generally not required for biocidal products as long as sufficient information can be extrapolated from the active substance. Moreover an inhibition of microbial activity (CH-619/2015, Dini R., 2016) and an acute toxicity on earthworm (CH-620/2015, Dini R., 2016) tests have been performed on the Permethrin 0.5% Dust. However, results of these tests, does not modified the endpoint used for the risk assessment. The ecotoxicological testing of the active substance permethrin were adequately covered in the AR (2014), and there are no other components in the PERMETHRIN 0.4% RTU formulation which are of ecotoxicological relevance (confidential information, see Section B2.2), therefore no additional studies were performed and reference is made to the CAR, document IIA, section 4.2.

ESCA: ES CA agrees with the applicant

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

Data waiving	
Information requirement	No data required
Justification	No further data necessary

ESCA: ES CA agrees with the applicant

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

Data waiving	
Information requirement	No data required
Justification	No further data necessary

ESCA: ES CA agrees with the applicant

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

Data waiving	
Information requirement	No data required
Justification	No further data necessary

ESCA: ES CA agrees with the applicant

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

No data is available.

ESCA: ES CA agrees with the applicant

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

For the biocidal product PERMETHRIN 0.4% RTU used as insecticide and acaricide, the following life cycle stages are identified:

1. Manufacturing of permethrin
2. Formulation of PERMETHRIN 0.4% RTU
3. Intended Use of PERMETHRIN 0.4% RTU
    a) Mixing and Loading of PERMETHRIN 0.4% RTU (only for professional users)
    b) Application of PERMETHRIN 0.4% RTU (both hand-held equipment and trigger-sprayer).

Due to the intended uses, the following table summarizes the foreseen entries (primarily exposed) into the environment and the likely environmental compartments that may be secondarily exposed:

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
Indoors application	n.r.*	n.r.*	n.r.	n.r.	n.r.*	+	++	+	(+)
Outdoors applications	n.r.**	n.r.**	n.r.	n.r.	n.r.**	+	++	+	(+)

++ Primarily exposed, + secondarily exposed, (+) potentially exposed, n.r. not relevant.

* As it is claimed in the product's label, the product can only be used on surfaces and textiles that are not going to be cleaned and in those cases where a cleaning treatment hast to be carried out, they must be done using dry cleaning methods. Hence, neither exposure by STP nor surface water exposure are expected by its application and post-application.

**Outdoor applications must be developed on paved surfaces as terraces which must be protected from the rain (roof-covered areas) and not be connected to STP (i.e. not on bare soil and protected from rain fall, flooding or cleaning wash). Therefore, following ENV 158 from Technical Agreements for Biocides (TAB- ENV v.2.1), no environmental risk assessment needs to be provided for the aquatic and terrestrial compartment.

Ant-nest application must be done directly into the nest on summer seasons, taken into account the weather forecast and avoiding raining days. The treated nest must be covered by a plastic tarp in order to avoid that the product could be dragged by the air or water and also to avoid any potential risk for animals by primary or secondary poisoning. After 2 days of application, the plastic tarp can be removed and the nest must be buried.

1 - Information regarding the environmental exposure during the manufacturing process of the biocidal product/active substance

According to the "EU Evaluation Manual for the Authorisation of Biocidal Products; final version 1.0" emissions from active substance production and product formulation are considered less significant compared to emissions from the application phase, in service and waste phase of the product and these phases are not part of Regulation (EU) No 528/2012.

2 - Information regarding the environmental exposure during the formulation of the biocidal product

According to the "EU Evaluation Manual for the Authorisation of Biocidal Products; final version 1.0" emissions from product formulation are considered less significant compared to emissions from the application phase, in service and waste phase of the product and these phases are not part of Regulation (EU) No 528/2012.

The formulation step is not covered by the ESD for PT 18; nevertheless it was no risk is identified for freshwater, air and agricultural soil compartments, provided that solid and liquid spills and cleaning waters are collected and dispose of as dangerous waste and all operations are conducted under aspiration and the collected emissions are treated before any release to air.

3 - Information regarding expected environmental exposure during application of the formulated product

PERMETHRIN 0.4% RTU may be used by users (professionals and non-professionals) for indoor and outdoor applications and it is a ready to use liquid formulation containing 0.4% w/w Permethrin which is not diluted prior to use.

The recommended usage concentration of the liquid is 15 mL for square meter, equivalent to 60 mg/m^2 of permethrin (assuming density of 1 g/mL), for use against insects.

In the ESD for PT18 it is generally assumed that insecticides used indoors will not directly reach the environmental compartments, but it is concluded that after the application of the insecticide, the cleaning step will lead the releases to waste water through wet cleaning

methods. However, PERMETHRIN 0.4% RTU is specifically intended to be applied in areas that are not cleaned and in those cases where they are cleaned, dry cleaning methods are used. Then solid residues must be vacuumed and managed as solid hazardous wastes. Hence, soil is the main environmental compartment of concern deemed in the current assessment.

On this basis, the environmental exposure assessment has been performed for permethrin active substance and its metabolites.

Since no clear recommendations are available for metabolites at the time of writing, the chosen approach was to estimate the concentrations of relevant metabolites as a percentage of the concentrations of the parent compound permethrin. There are only minor differences between molecular weights of permethrin and its metabolites. Hence, correction based on the molecular weights was considered negligible.

ES CA:

ES CA considers in the following table, according to the intended uses, the foreseen entries (primarily exposed) into the environment and the likely environmental compartments that may be secondarily exposed:

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
Indoor application	+	+	n.r.	n.r.	++	++	+	+	(+)
Outdoor application	+	+	n.r.	n.r.	-	+	++	+	(+)

++ Primarily exposed, + secondarily exposed, (+) potentially exposed.

Although the applicant proposes some instruction of use which avoid the emissions to the environment, we consider that the table above shows the most realistic emissions to the environment for the intended uses of the biocidal product.

As it is stated by the applicant, the recommended usage concentration of the liquid is 15 mL for square meter, equivalent to 60 mg/m^2 of permethrin (assuming density of 1 g/mL), for use against insects but, according to the efficacy tests, there are different application rates depending on the target organism and the use proposed, for the application rate see section 2.2.8.2.

To estimate PEC in the environmental compartments for the metabolites DCVA and PBA, their own Koc value has been considered. Following the releases to STP, concentrations in effluent were estimated considering the ratio of the molecular weight of the metabolite compared to the molecular weight of permethrin (0.534 for DCVA and 0.547 for PBA). PECs surface water was further estimated considering the metabolite formation fraction (max. % occurrence) in the aquatic compartment.

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

Data waiving	
Information requirement	No data required
Justification	No further data necessary

ES CA: ES CA agrees with the applicant.

Leaching behaviour (ADS)

Data waiving	
Information requirement	No data required
Justification	No further data necessary

ES CA: ES CA agrees with the applicant.

Testing for distribution and dissipation in soil (ADS)

Data waiving	
Information requirement	No testing for distribution and dissipation in soil has been conducted on PERMETHRIN 0.4% RTU.
Justification	The environmental fate and behaviour of the active substance permethrin has been adequately covered in the AR for the active substance (2014), so reference is made to the said report, document IIA, section 4.1. Therefore, and in view of the low environmental exposure expected following the use of the formulation, testing for distribution and dissipation in the environment is not required.

ES CA: ES CA agrees with the applicant.

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

Data waiving	
Information requirement	No testing for dissipation and distribution in water and sediment has been conducted on PERMETHRIN 0.4% RTU.
Justification	The environmental fate and behaviour of the active substance permethrin has been adequately covered in the AR for the active substance (2014), so reference is made to the said report, document IIA, section 4.1. Therefore, and in view that no aquatic environmental exposure must be expected according to formulation uses, testing for distribution and dissipation in the environment is not required.

ES CA: ES CA agrees with the applicant.

Testing for distribution and dissipation in air (ADS)

Data waiving	
Information requirement	No testing for dissipation and distribution in air has been conducted in PERMETHRIN 0.4% RTU
Justification	The environmental fate and behaviour of the active substance permethrin has been adequately covered in the AR for the active

	substance (2014), so reference is made to the said report, document IIA, section 4.1. Therefore, and in view of the low environmental exposure expected following the use of the formulation, testing for distribution and dissipation in the environment is not required.

ES CA: ES CA agrees with the applicant.

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)

No data required.

ES CA: ES CA agrees with the applicant.

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

ES CA: ES CA agrees with the applicant.

2.2.8.2 Exposure assessment

Formulation and use of the insecticide and acaricide PERMETHRIN 0.4% RTU may lead to harmful emission to the environment. Therefore, an environmental exposure assessment has been done in accordance with the Emission Scenario Document for insecticides, acaricides and products to control arthropods (PT18) for household and professional use (OECD, 2008) as well as the technical agreements reached for the evaluation of biocidal products "Technical Agreements for Biocides" v.2.1) and the EUSES 2.2.0 and is based on information relating to the intended uses of PERMETHRIN 0.4% RTU.

The environmental exposure assessment has been performed for the active substance permethrin and their metabolites and was conducted for the local scale only, as required for biocidal products.

General information

Assessed PT	PT18
Assessed scenarios	Scenario 1: Indoor – voids/cavities treatment a) Professional b) Non-professional Scenario 2: Indoor – Spot surface application to flying insects by non-professional users Scenario 3: Indoor – Non-washable textile surfaces Scenario 4: Outdoor – Ant nests Scenario 5: Outdoor – Around buildings in voids/cavities paved areas protected from rain and wash.

ESD(s) used	• Emission Scenario Document for insecticides, acaricides and products to control arthropods (PT18) for household and professional use (OECD, 2008); • Technical Agreements for Biocides (TAB) – ENV v.2.1; • EUSES 2.2.0
Approach	All scenarios by Average consumption
Distribution in the environment	Calculated based on TGD 2003
Groundwater simulation	Yes
Confidential Annexes	Yes
Life cycle steps assessed	For all scenarios: Production: No Formulation No Use: Yes Service life: No
Remarks	According to label mentions: - Indoor use (scenarios 1, 2 and 3) must be done only in voids/cavities, window frames, spots on walls , or textile surfaces as mattresses, rugs and carpets to be cleaned by dry cleaning methods. This assumption has been deemed in the exposure assessment, so the potential emission derived from cleaning have been considered. - Outdoor use into ant's nests (Scenario 4) is done by spraying directly into the ant nest and then, the nest must be covered by plastic tarp in order to avoid any loss of liquid from the nest by air or rainfall. - Outdoor use into voids/cavities on paved surfaces (as terraces) around buildings (Scenario 5) is developed on locations non connected to STP and protected from rainfall and flooding. By this way any potential emission to wastewater or surface water sources is avoided and only potential exposure by secondary poisoning is considered of concern for the environment (ENV 158 -TAB v.2.1).

Following endpoints ENV158 and ENV159 from TAB-ENV 2019, no environmental risk assessment needs to be provided for the aquatic and terrestrial compartment when the product is intended to be applied outdoor by professional user on paved surfaces (not on bare soil) and in roof-covered areas, which cannot be affected by flooding and protected from rain fall or cleaning wash. This is one of the main intended outdoor applications of PERMETHRIN 0.4% RTU against ants so the emission from professional applications outdoors (Scenarios 4 and 5) should be considered at safe. In addition, the product is also intended to be applied as spot application on paved surfaces around domestic premises for general public use. Hence, the terrace scenario is deemed by taken into account the urban area as worst case.

ESCA considers that the most suitable scenarios to evaluate the environmental risk due to the intended uses of this biocidal product are indicated in the table below:

ESCA agrees with the applicant: following endpoints ENV158 and ENV159 from TAB-ENV 2019, no environmental risk assessment needs to be provided for the aquatic and terrestrial compartment when the product is intended to be applied outdoor by professional user on paved surfaces (not on bare soil) and in roof-covered areas, which cannot be affected by flooding and protected from rain fall or cleaning wash (following label instructions and RMM). This is one of the main intended outdoor applications of PISTOLA INS PER04 against ants so the emission from professional applications outdoors (Scenario 4) should be considered at safe. However, scenario 4 for professional use has been evaluated to calculate the risk to secondary poisoning.

Assessed PT	PT18
Assessed scenarios	Scenario 1: Indoor – spot to a surface- crawling insects -professional Scenario 2: Indoor – barrier treatment- crawling insect-non-professional users Scenario 3: Indoor – Non-washable textile surfaces Scenario 4: Outdoor – Ant nests
ESD(s) used	• Emission Scenario Document for insecticides, acaricides and products to control arthropods (PT18) • Technical Agreements for Biocides (TAB) – ENV v.2.1;
Approach	All scenarios by Average consumption
Distribution in the environment	Calculated based on Guidance on Biocidal product regulation, 2017
Groundwater simulation	Yes
Confidential Annexes	Yes
Life cycle steps assessed	For all scenarios: Production: No Formulation No Use: Yes Service life: No
Remarks	According to efficacy tests uses 1 and 2 correspond to a spot to a surface, therefore to evaluate the environmental risk assessment, ES CA considers that for a professional user the scenario "spot to a surface" covers the risk to the environment (SCENARIO 1), however, for a non-professional user the most convenient scenario to assess the risk to the environment is a "barrier scenario" (SCENARIO 2). From the environmental section, the use to control flying insects and the outdoor use around buildings have not been evaluated since this use has not been supported by efficacy test. SCENARIOS 3 and 4 are the same as those proposed by the applicant.

Assessed scenarios: Intended uses and application rates for PERMETHRIN 0.4% RTU

Scenarios	Uses #[1]	Indoor / Outdoor	User	Type of application	EUSES scenario	EUSES treatment	Target pest	Application rate (a.i.)
1	#1	Indoor	Professional	Spraying in voids/cavities (cracks and crevices)	18.2.1	Spot, crack and crevices	Crawling insects [2]	60 mg/m^2
	#2	Indoor	Professional and General public	Spraying – crack and crevice (including foams) – spot, surface		Spot, crack and crevice (including foams)		
2	#8	Indoor	General public	Spraying– crack and crevice (including foams) – spot, surface	18.2.1	Spot treatment to a crack and crevice (including foams)	Flying insects[3]	60 mg/m^2
3	#3	Indoor	General public	Spraying on non-washable textile surfaces by wet cleaning methods	18.2.1	crack and crevice (including foams) in carpets and/ or furniture surface	Dust mites, bed bugs	60 mg/m^2
4	#4 and #5	Outdoor	Professional and general public[4]	Nest spraying directly into the nest	18.3.3	Outdoor, nest spraying	Ants	15 mg per nest[5]
5	#6 and #7	Outdoor	Professional and general public	Spraying in voids/cavities of paved surfaces and roof-covered areas	18.3.2	Outdoor crawling insects in foundations and soil around the building	Ants	60 mg/m^2

[1] As indicated in the section 2.1.4 Authorized uses
[2] Cockroaches deemed as worst case
[3] Flies deemed as representative case
[4] General public is deemed in Section 2.1.4 but no considered in the assessment because is not considered an option in EUSES 2.2.0.
[5] This amount is estimated following the assumption of OECD ESD No.18 where an area of 0.25 m^2 (0.5m x 0.5m) is considered for a nest and taken into account the application rate of the product 15 g/m^2 a total amount of 3.75g$_{product}$ should be applied for a nest, equivalent to 15 mg$_{a.s}$.

According to the efficacy tests, the uses and the application rates demonstrated by the applicant for this biocidal product are detailed in the table below:

Assessed scenarios: Intended uses and application rates for PERMETHRIN 0.4% RTU

Scenarios	Uses #[1]	Indoor / Outdoor	User	Type of application	Target pest	Application rate[2]
1	#1	Indoor	Professional	Spot to a surface in hiding places including crack and crevices	Cockroaches and ants	15 mL/m^2
					Silver fish	25,5 mL/m^2
2	#2	Indoor	General public	Spot to a surface in hiding places including crack and crevices	Cockroaches and ants	15 mL/m^2
					Silver fish	25,5 mL/m^2
3	#3	Indoor	General public	Non-washable textiles	Dust mites, bed bugs	15 mL/m^2
4	#4 and #5	Outdoor	Professional and general public	Nest spraying directly into the nest	Ants	3 mL/nest

[1] As indicated in the section 2.1.4 Authorized uses.
[2] As a fist tier ES CA has evaluated the lowest dose, 15 mL/m2.

Emission estimation

In the following, Predicted Environmental Concentrations (PECs) for the active substance permethrin and its metabolites for the relevant compartments are calculated.

All PECs were calculated with EUSES 2.2.0 and for complete calculations see Annex 3.2.

The input parameters for the EUSES calculation are shown in the tables below. All parameters are based on the Assessment Report for the Inclusion of active substance permethrin in Annex I or IA to Directive 98/8/EC (Product Type 18) (AR, 2014).

Scenario 1 - *Indoor – Spraying into voids/cavities (spots, crack and crevice)*

No mixing and loading is deemed for non-trained professional users and general public as the product is a ready-to-use by trigger sprayer. However, for trained professional users, mixing and loading is considered for 3 preparations per day in a large building. As it is mandatory in the product label, dry cleaning methods are deemed in the assessment and as worst case washable coveralls are deemed. The following table shows further inputs considering in the assessment.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenarios 1: Indoor – Spraying into voids/cavities (spots, crack and crevice)			
Application rate of biocidal product	15	mL/m²	Density of 1 g/ml is deemed
Concentration of active substance in the product	0.4	% w/w	
Area treated, house	2	m^2	
Area treated, larger building	9.3[1]	m^2	According to ENV142 of TAB-ENV v.2.1
Number of applications per day, house	1	d^{-1}	
Number of applications per day, large building	1	d^{-1}	
Quantity of commercial product used per preparation[2]	139.5	G	Only considered in mixing/loading for professional users
Fraction emitted to applicator during mixing and loading (only for professional users)	1.2E-03	-	default
Fraction emitted to floor during mixing and loading (only for professional users)	4E-04	-	default
Frequency of application in standard houses and large buildings	12	Monthly	
Simultaneity factor for indoor uses of insecticide in standard houses and large buildings	0.01386	-	
Fraction emitted to air during application	0.02	-	default
Fraction emitted to floor during application	0.11	-	default
Fraction emitted to applicator during application	0.02	-	default
Fraction emitted to treated surfaces	0.85	-	default

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenarios 1: Indoor – Spraying into voids/cavities (spots, crack and crevice)			
Cleaning efficiency for users as spray formulation to be used in crack and crevice	0.25	-	According to ENV149 of TAB-ENV v.2.1.
Number of houses per STP	4000	-	default
Number of buildings per STP	300	-	Not relevant for non-professional user
Number of emission days	300	$d.yr^{-1}$	default
Tier 2 (without emissions from cleaning treatment of treated surfaces)			
Cleaning efficiency for users as spray formulation to be used in crack and crevice	0	-	By the applicant (considering no cleaning actions after product's use)

[1] This value is considered by using the same relation between the treated and total surface for the commercial building as for the domestic house. Because the application in voids/cavities can be deemed as spot application, 9.3 m^2 has been deemed as the most realistic value.

[2] As 9.3 m^2 is the highest surface to be treated in large buildings by professional users, then 139.5 ml of product is applied per treated area. As the volume of the product's commercial packaging is above this value, only one application and one preparation is considered enough.

Calculations for Scenario 1

The following table summarizes the ways of emission to the environment obtained from EUSES 2.2.0:

Local emission	**Type of area treated**		
	Professional user		**Non-professional user**
	Standard houses	**Large buildings**	**Standard houses**
Tier 1			
Emissions during Mixing/loading (only should be considered for professional users)			
Local emission to air [$kg.d^{-1}$]	0	0	-
Local emission to applicator [$kg.d^{-1}$]	6.7E-07	6.7E-07	-
Local emission to floor [$kg.d^{-1}$]	2.23E-07	2.23E-07	-
Emissions during product's application			
Local emission to air [$kg.d^{-1}$]	2.4E-06	1.12E-05	2.4E-06
Local emission to applicator [$kg.d^{-1}$]	2.4E-06	1.12E-05	2.4E-06
Local emission to floor [$kg.d^{-1}$]	1.32E-05	6.14E-05	1.32E-05
Local emission to treated surfaces [$kg.d^{-1}$]	1.02E-04	4.74E-04	1.02E-04
Emissions during cleaning residues of mixing/loading (only for professional users)			
Local emission to wastewater from washing applicator's coveralls	6.7E-07	6.7E-07	-

Local emission	Type of area treated		
	Professional user		Non-professional user
	Standard houses	**Large buildings**	**Standard houses**
Local emission to wastewater from wet cleaning the floor	2.23E-07	2.23E-07	-
Emissions during cleaning residues from product's application			
Local emission to wastewater from washing applicator's coveralls	2.4E-06	1.12E-05	2.4E-06
Emission to solid waste from disposing of the coveralls	0	0	0
Local emission to wastewater from wet cleaning the floor	3.3E-06	1.53E-05	3.3E-06
Local emission to wastewater from wet cleaning the treated	0	0	0
Emission to solid waste from dry cleaning the treated surfaces*	2.55E-05	1.19E-04	2.55E-05
Tier 2 (without emissions from cleaning treatment of treated surfaces)			
Emissions during Mixing/loading (only considered for professional users)			
Local emission to air [$kg.d^{-1}$]	0	0	-
Local emission to applicator [$kg.d^{-1}$]	6.7E-07	6.7E-07	-
Local emission to floor [$kg.d^{-1}$]	2.23E-07	2.23E-07	-
Emissions during product's application			
Local emission to air [$kg.d^{-1}$]	2.4E-06	1.12E-05	2.4E-06
Local emission to applicator [$kg.d^{-1}$]	2.4E-06	1.12E-05	2.4E-06
Local emission to floor [$kg.d^{-1}$]	1.32E-05	6.14E-05	1.32E-05
Local emission to treated surfaces [$kg.d^{-1}$]	1.02E-04	4.74E-04	1.02E-04
Emissions during cleaning residues of mixing/loading (only for professional users)			
Local emission to wastewater from washing applicator's coveralls	6.7E-07	6.7E-07	-
Local emission to wastewater from wet cleaning the floor	2.23E-07	2.23E-07	-
Emissions during cleaning residues from product's application			
Local emission to wastewater from washing applicator's coveralls	2.4E-06	1.12E-05	2.4E-06
Emission to solid waste from disposing of the coveralls	0	0	0
Local emission to wastewater from wet cleaning the floor	0	0	0
Local emission to wastewater from wet cleaning the treated	0	0	0

Local emission	Type of area treated		
	Professional user		Non-professional user
	Standard houses	**Large buildings**	**Standard houses**
Emission to solid waste from dry cleaning the treated surfaces*	0	0	0

*Obtained by ESD PT18 Excel spreadsheet

The following table summarizes the total local emissions derived from this scenario:

Resulting total local emission to relevant environmental compartments			
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**		**Remarks**
	Non-professional users (standard houses)	**Professional users (standard houses and large buildings)**	
Tier 1			
Local emission to air (E_{air})	1.33E-04	1.79E-04	None
Local emission to wastewater (E_{water})	3.16E-04	4.80E-04	None
Local emission to solid waste (E_{waste})*	1.41E-03	1.91E-03	None
Tier 2			
Local emission to air (E_{air})	1.33E-04	1.79E-04	None
Local emission to wastewater (E_{water})	1.33E-04	2.33E-04	None
Local emission to solid waste (E_{waste})*	0	0	None

ESCA: ESCA does not agree with the scenario proposed by the applicant (crack and crevices) to evaluate the risk of this use (use 1, crawling insect by professional) since, according to the efficacy test, this use is a "spot to a surface" including crack and crevices in hiding places so, ES CA considers that the "spot to a surface" scenario with a FCE of 50% covers the emissions to the environment for this use. Calculation has been performed with the lowest dose 15 mL/m^2:

Scenario 1: Spot to a surfaces-professional user – crawling insects

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenarios 1: Indoor – Spot to a surface-professional user (cockroaches)			
Application rate of biocidal product	15	mL/m²	Density of 1 g/ml is deemed.

Concentration of active substance in the product	0.4	% w/w	
Concentration of the SoC	0.24	% w/w	
Area treated, house	2	m^2	
Area treated, larger building	9.3	m^2	
Number of applications per day, house	1	d^{-1}	
Number of applications per day, large building	1	d^{-1}	
Quantity of commercial product used per preparation[2]	139.5	G	Applicant data
Container type/volume	1	L	with unspecific design
Fraction emitted to floor during mixing and loading (for professional users)	0.0001	-	
Fraction emitted to applicator during mixing and loading (for professional users)	0.0012	-	
Frequency of application in standard houses and large buildings	12	Monthly	
Simultaneity factor for indoor uses of insecticide in standard houses and large buildings	0.01386	-	
Fraction emitted to air during application	0.02	-	Default
Fraction emitted to floor during application	0.128	-	Default, compressed sprayer 1-3 bars
Fraction emitted to applicator during application	0.002	-	Default, compressed sprayer 1-3 bars
Fraction emitted to treated surfaces	0.85	-	Default
Cleaning efficiency	0.50	-	According to ENV149 of TAB-ENV v.2.1.
Number of houses per STP	4000	-	Default
Number of buildings per STP	300	-	Default

The following table summarizes the total local emission derived from this scenario:

Permethrin:

Resulting total local emission to relevant environmental compartments (permethrin)			
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**		**Remarks**
	Professional users (standard houses)	**Professional users (large buildings)**	
Local emission to wastewater (E_{water})	3.27 E-03	1.14 E-03	None

	Local emission ($Elocal_{compartment}$) [kg/d] (large buildings + standard houses)	
Local emission to wastewater (E_{water})	4.41 E-03	

Propan-2-ol:

Resulting total local emission to relevant environmental compartments (propan-2-ol)			
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**		**Remarks**
	Professional users (standard houses)	**Professional users (large buildings)**	
Local emission to wastewater (E_{water})	1.96 E-03	6.85 E-04	None
	Local emission ($Elocal_{compartment}$) [kg/d] (large buildings + standard houses)		
Local emission to wastewater (E_{water})	2.65 E-03		

Scenario 2 - ***Indoor – Spraying against flying insects as spot surface treatment by non-professional users***

As in the case of scenario before, no mixing and loading is deemed for general public as the product is a ready-to-use by trigger sprayer. As it is mandatory in the product label, dry cleaning methods are deemed in the assessment and as worst case washable coveralls are deemed. The following table shows further inputs considering in the assessment.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenarios 2: Indoor – Spraying against flying insects as spot surface treatment			
Application rate of biocidal product	15	mL/m²	Density of 1 g/ml is deemed
Concentration of active substance in the product	0.4	% w/w	
Area treated, house	2	m^2	Default
Wet cleaning zone in a standard house (leading to releases to the STP)	2	m^2	Default
Number of applications per day, house	1	d^{-1}	
Frequency of application in standard houses and large buildings	12	Monthly	
Simultaneity factor for indoor uses of insecticide in standard houses and large buildings	0.01386	-	
Fraction emitted to air during application	0.02	-	Default
Fraction emitted to floor during application	0.11	-	Default

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenarios 2: Indoor – Spraying against flying insects as spot surface treatment			
Fraction emitted to applicator during application	0.02	-	Default
Fraction emitted to treated surfaces	0.85	-	Default
Cleaning efficiency for general public as RTU spray formulation to be used in crack and crevice	0.25	-	According to ENV149 of TAB-ENV v.2.1.
Number of houses per STP	4000	-	Default
Number of buildings per STP	300	-	Not relevant for non-professional user
Number of emission days for Non-professional	365	$d.yr^{-1}$	Default
Tier 2 (without emissions from cleaning treatment of treated surfaces)			
Cleaning efficiency for users as spray formulation to be used in crack and crevice	0	-	By the applicant (considering no cleaning actions after product's use)

Calculations for Scenario 2

The following table summarizes the ways of emission to the environment obtained from EUSES 2.2.0:

Local emission [$kg.d^{-1}$]	**Type of area treated**	
	Non-professional user / Standard houses	
	Tier 1	**Tier 2**
Emissions during product's application		
Local emission to air [$E_{application,air}$]	2.4E-06	2.4E-06
Local emission to applicator [$E_{application,applicator}$]	2.4E-06	2.4E-06
Local emission to floor [$E_{application,floor}$]	1.32E-05	1.32E-05
Local emission to treated surfaces [$E_{application,treated}$]	1.02E-04	1.02E-04
Emissions during cleaning residues from product's application		
Local emission to wastewater from washing applicator's coveralls [$E_{ww,applic,applicator}$]	2.4E-06	2.4E-06
Local emission to solid waste from disposing of the coveralls [$E_{waste,applic,applicator}$]	0	0
Local emission to wastewater from wet cleaning the floor* [$E_{ww,applic,cleaning\_floor}$]	3.30E-06	0
Local emission to wastewater from wet cleaning the treated surfaces [$E_{ww,applic,cleaning\_treated}$]	0	0
Local emission to solid waste from dry cleaning the treated surfaces [$E_{waste,applic,cleaning\_treated}$]	2.55E-05	0

The following table summarizes the total local emission derived from this scenario

Resulting total local emission to relevant environmental compartments			
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**		**Remarks**
	Non-professional users (standard houses)		
	Tier 1	**Tier 2**	
Local emission to air (E_{air})	1.33E-04	1.33E-04	None
Local emission to wastewater (E_{water})	3.16E-04	1.33E-04	None
Local emission to solid waste (E_{waste})*	1.41E-03	0	None

* ECHA's Excel spreadsheets for ESD PT18

Local emissions above are the same that local emission from Scenario 1 for non-professional (n-P), so identical PECs will be obtained from both scenarios.

ESCA:

The scenario 2 proposed by the applicant is a scenario to evaluate the risk of controlling flying insects but this use has not been supported by efficacy test, so this scenario has not been reviewed. For scenario 2, ESCA has evaluated the use of this product by non-professionals against crawling insects. Although the efficacy test indicates a treatment as spot to a surface, ES CA considers that the scenario that best represents the emissions due to this use is the barrier scenario.

Scenario 2: Barrier treatment-non-professional user – crawling insects

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenarios 1: Indoor – Spot to a surface-professional user (cockroaches)			
Application rate of biocidal product	15	mL/m²	Density of 1 g/ml is deemed
Concentration of active substance in the product	0.4	% w/w	
Concentration of the SoC	0.24	% w/w	
Area treated, house	5.9	m^2	
Number of applications per day, house	1	d^{-1}	
Frequency of application in standard houses and large buildings	12	Monthly	
Simultaneity factor for indoor uses of insecticide in standard houses and large buildings	0.01386	-	Applicant data
Fraction emitted to air during application	0.02	-	Default, hand held trigger spray
Fraction emitted to floor during application	0.124	-	Default, hand held trigger spray (table 3.3.1 ESD PT18)

Fraction emitted to applicator during application	0.006	-	Default, hand hell trigger spray (table 3.3.3 ESD PT18)
Fraction emitted to treated surfaces	0.85	-	Default, hand held trigger spray
Cleaning efficiency for professional users and general public as spray formulation to be used in crack and crevice	0.50	-	According to ENV149 of TAB-ENV v.2.1.
Number of houses per STP	4000	-	Default

The following table summarizes the total local emission derived from this scenario:

Permethrin:

Resulting total local emission to relevant environmental compartments (permethrin)		
	Local emission ($Elocal_{compartment}$) [kg/d]	
Local emission to wastewater (E_{water})	9.68 E-03	

Propan-2-ol:

Resulting total local emission to relevant environmental compartments (propan-2-ol)		
	Local emission ($Elocal_{compartment}$) [kg/d]	
Local emission to wastewater (E_{water})	5.81 E-03	

Scenario 3 - *Indoor – Spraying over non washable textile surfaces by wet cleaning methods*

No mixing and loading is deemed as the product is a ready-to-use. Moreover dry cleaning methods and washable coveralls (as worst case) are deemed in the assessment. The additional EUSES 2.2.0 scenario 18.2.1 "indoor, spray application" with the treatment of "carpets and/or furniture surface" and the formulation/use: "RTU aerosol – crack and crevice (including foams) has been used as the most suitable for this assessment.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 3: Indoor – Spraying over non washable textile surfaces by wet cleaning methods			
Application rate of biocidal product	15	mL/m²	Density of 1 g/ml is deemed
Concentration of active substance in the product	0.4	% w/w	
Area treated in a standard house	22	m^2	

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 3: Indoor – Spraying over non washable textile surfaces by wet cleaning methods			
Wet cleaning zone in a standard house (leading to releases to the STP)*	5.9	m^2	
Number of applications per day, house	1	-	default
Simultaneity factor	0.002042	-	1- 2 times per year
Fraction emitted to air	0.02	-	default
Fraction emitted to floor	0.11	-	default
Fraction emitted to applicator	0.02	-	default
Fraction emitted to treated surfaces	0.85	-	default
Cleaning efficiency	0.2*	-	default
Number of houses per STP	4000	-	default
Number of emission days	365	$d.yr^{-1}$	default

* Following the endpoint TAB ENV 147, a default cleaning efficiency of 20% has been taken into account as a worst case.

It is important to bear in mind, that although the product is intended to be applied on textile surfaces that are not intended to be washed or cleaning by wet methods, there is considered a default surface for wet cleaning. This is not accordance with the intended use of the product and the potential emission to wastewater must be deemed as not in accordance with the right use of the product. A Tier 2 is developed to estimate the emission without considering any cleaning treatment.

Calculations for Scenario 3

Emissions from application and cleaning are deemed of concern for the environment. The following table summarizes the application emissions obtained from EUSES 2.2.0:

Local emissions from Private use		
Sub-task from scenario	**Value**	
	Tier 1	**Tier 2**
Application emissions		
Local emission to air [$kg.d^{-1}$]	2.64E-05	2.64E-05
Local emission to applicator [$kg.d^{-1}$]	2.64E-05	2.64E-05
Local emission to floor [$kg.d^{-1}$]	1.45E-04	1.45E-04
Local emission to treated surfaces [$kg.d^{-1}$]	1.12E-03	1.12E-03
Cleaning emissions from application		
Local emission to wastewater from washing applicator's coveralls [$kg.d^{-1}$]	2.64E-05	2.64E-05
Local emission to wastewater from wet cleaning the floor [$kg.d^{-1}$]	7.79E-06	0
Local emission to wastewater from wet cleaning the treated surfaces [$kg.d^{-1}$]	0	0

The following table summarizes the total local emission derived from this scenario:

Resulting local emission to relevant environmental compartments			
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**		**Remarks**
	Tier 1	**Tier 2**	
STP	2.79E-04	2.16E-04	None
Air	2.16E-04	2.16E-04	None

ES CA: Scenario 3, *Indoor – Spraying over non washable textile surfaces*

ESCA agrees with the scenario perfomed by the applicant, ESCA has recalculate the values taking into account the specific parameters of a hand trigger spray.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 3: Indoor – Spraying over non washable textile surfaces by wet cleaning methods			
Fraction emitted to air	0.02	-	Default
Fraction emitted to floor	0.124	-	Default, hand hell trigger spray (table 3.3.3 ESD PT18)
Fraction emitted to applicator	0.006	-	Default, hand hell trigger spray (table 3.3.1 ESD PT18)
Fraction emitted to treated surfaces	0.85	-	Default

Permethrin:

Tier 1 - *Spraying over non washable textile surfaces*

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	1.21E-04	None

ES CA has evaluated a second tier considering the following instruction of use "*The excess of the product on non-treated surfaces contaminated during the application must be remove with a damp paper and dispose as solid waste.*"

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	1.73E-05	None

Propan-2-ol:

Tier 1 *Spraying over non washable textile surfaces*

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	7.28E-05	None

ES CA has evaluated a second tier considering the following instruction of use "*The excess of the product on non-treated surfaces contaminated during the application must be remove with a damp paper and dispose as solid waste.*"

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	1.04E-05	None

Scenario 4 - *Outdoor – Spot application into ant's nest*

Following ESD PT18 No.18, it is expected that direct application into the nest should be considered as spot application on soil. In this case, the possible receiving compartments are the soil and to a lesser extent, the air. Release to the air is considered negligible. It is not current practice to collect unconsumed product.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 4: Outdoor – Spot application into ant's nest			
Quantity of commercial product applied	3.75	G	See note below
Concentration of active substance in the product	0.004	-	
Fraction emitted to soil during application	0.3	-	
Number of nests treated per day	1	-	
Area exposed to insecticide (50 cm diameter circular surface)	0.19635	m^2	default

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 4: Outdoor – Spot application into ant's nest			
Depth of exposed soil	0.5	M	default
Volume of exposed soil	0.098	m^3	default
Bulk density of soil	1700	Kgwwt. m^{-3}	default
Density of solid phase	2500	Kgwwt. m^{-3}	default
Volume fraction of solids in soil	0.6	$m^3.m^{-3}$	default
Soil-water partition coefficient	84.43	$m^3.m^{-3}$	
Conversion factor for soil concentration wet-dry weight soil	1.133	Kgwwt.$kgdwt^{-1}$	
Application specific factor, acute exposure for secondary poisoning	1	-	
Application specific factor, short-term exposure for secondary poisoning	1	-	
Effective application rate, for acute and short-term exposure	7.64E-05	Kg.m^{-2}	
Bioconcentration factor for earthworms	562.1	l.$kgwwt^{-1}$	
Fraction of gut loading in worm	0.1	Kgdwt.$kgdwt^{-1}$	

Note: Following OEC ESD No.18 (page 133) a default area of a cube of 0.5 m x 0.5 m (0.25 m^2) has been considered in the estimation of product's quantity to be applied on ant's nests. Taking into account the application rate of the product 15 g/m^2, a total amount of 3.75 g is considered to be applied for a nest area of 0.25 m^2.

Calculations for Scenario 4

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/campaign]**	**Remarks**
Soil	4.5E-06	None

Other outputs obtained from EUSES 2.2.0 are:

Local concentration in soil (PECsoil)	2.7E-08	Kg.$kgwwt^{-1}$
Local concentration in porewater (PECgw)	5.43E-10	Kg.l^{-1}
Concentration in earthworm	0.277	mg.kgwt $earthworm^{-1}$

ES CA: This scenario has been calculated for both professionals and non-professionals. Although, emissions to the terrestrial and aquatic compartment are not expected when the product is applied by professionals, this scenario has been calculated to determine the risk for secondary poisoning.

There have been calculated the emissions for both, paved and unpaved surfaces. Direct emissions on unpaved surfaces is the same for both professional and non-professional users. For paved surfaces, the following scenarios have been calculated: terraces scenario for non-professionals and terraces scenario around buildings for professionals.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 4: Outdoor – Spot application into ant's nest			
Quantity of commercial product applied	3	G	According to efficacy tests (density 1 g/ml)
Concentration of active substance in the product	0.004	-	
Concentration of the SoC	0.0024	-	
Fraction emitted to soil during application	0.99	-	
Number of nests treated per day (direct application)	1	-	
Number of nests treated per day (private houses)	4	-	
Number of nests treated per day (large buildings)	67		
Area exposed to insecticide (terrace)	8.5	m^2	Default
Area exposed to insecticide (nest)	0.2	m^2	According to the efficacy test, 3 ml per nest (in 0,2 m^2)
Depth of exposed soil	0.5	M	Default
Bulk density of soil	1700	Kgwwt. m^{-3}	Default
Density of solid phase	2500	Kgwwt. m^{-3}	Default

Direct application:

PECs	**Permethrin**	**SoC**	**Units**
Local concentration in soil (PECsoil)	6.99E-08	3.35E-08	Kg.kgwwt^{-1}
Local concentration in porewater (PECgw)	1.38E-1	1.91E+02	µ.l^{-1}

Terrace scenario (private houses):

PECs	Permethrin	SoC	Units
Local concentration in soil (PEC_{soil})	6.58E-09	3.95E-09	$Kg.kgwwt^{-1}$
Local concentration in porewater (PEC_{gw})	1.38E-2	2.24E+01	$\mu.l^{-1}$

Large building (terraces around large building):

As it is stated by the applicant, following endpoints ENV158 and ENV159 from TAB-ENV 2019, no environmental risk assessment needs to be provided for the aquatic and terrestrial compartment when the product is intended to be applied outdoor by professional user on paved surfaces (not on bare soil) and in roof-covered areas, which cannot be affected by flooding and protected from rain fall or cleaning wash. This is one of the main intended outdoor applications of PISTOLA INS PER04 against ants so the emission from professional applications outdoors (Scenarios 4) should be considered at safe". ES CA agrees with the applicant about that this is a safe use but, emissions for scenario 4 have been calculated in order to assess the potential risk for secondary poisoning.

Resulting local emission to relevant environmental compartments (permethrin)		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	4.85E-07	None

Resulting local emission to relevant environmental compartments (propan-2-ol)		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	2.91E-07	None

Scenario 5 - Outdoor – Spraying into voids/cavities of paved surfaces and roof-covered areas.

ES CA: this scenario has not been reviewed since this use has not been supported by efficacy studies.

The product is intended to be used only on specific paved surfaces (crack and crevice, cavities…), in roof-covered areas and not on bare soil. Hence, the treated area cannot be affected by flooding, and is protected from rain fall or cleaning wash so emissions are

unlikely to occur and according to TAB-ENV v.2.1 no environmental risk assessment needs to be provided for the aquatic and terrestrial compartment. However, it is considered necessary to assess the environmental risk for general public application.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 5: Outdoor – Spraying into voids/cavities of paved surfaces and roof-covered areas. Urban areas treated by general public.			
Application rate of biocidal product	15	mL/m²	Density of 1 g/ml is deemed
Concentration of active substance in the product	0.004	-	
Number of standard houses connected to the same STP	2500	-	Default
Number of emission days	365	$d.yr^{-1}$	
Frequency of application in standard houses and large buildings	1-2	Times a year	
Simultaneity factor for outdoor use of insecticide in standard houses	2.042E-03	-	
Fraction emitted to soil during application on foundation	0.3	-	
Fraction emitted to soil due to wash-off by rainfall	0	-	This value has been changed from the default value (0.5) due that the treated area must be protected from rainfall
Fraction emitted to soil during application on the soil around the house/building: - emitted to treated area - emitted to untreated area	 0.99 4.2E-03	 - -	
Values deemed for <u>standard houses:</u>		-	
Area of foundation treated per day	25	$m^2.d^{-1}$	default
Area of soil treated per day	26	$m^2.d^{-1}$	default
Area of untreated zone	28	$m^2.d^{-1}$	Default

<u>Note</u>: Mixing and loading task is considered no covered for general public as the formulation is marketed as RTU for this type of user.

<u>Calculations for Scenario 5</u>

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
	Non-professional use /Standard houses	
Wastewater	0.01	None

Other outputs obtained from EUSES 2.2.0 are:

- Derived from application emissions:

Local emissions	**Non-Professional users**
	Standard houses
	Permethrin
Local emission due to application on foundations [$Kg.d^{-1}$]	4.5E-04
Local emission due to application on soil, treated area [$Kg.d^{-1}$]	1.54E-03
Local emission due to application on soil, untreated area [$Kg.d^{-1}$]	7.06E-06
Local emission due to wash-off (from foundations) [$Kg.d^{-1}$]	0

Note: As it was mentioned before fraction emitted to soil due to wash-off by rainfall is considered 0 according to intended use of the formulation. Hence, the local concentration in soil is due to the application.

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway									
Scenario	**Fresh-water**	**Freshwater sediment**	**Sea-water**	**Seawater sediment**	**STP**	**Air**	**Soil**	**Ground-water**	**Secondary poisoning**
Scenario 1	No*	No*	No	No	No*	No	Yes	Yes	No
Scenario 2	No*	No*	No	No	No*	No	Yes	Yes	No
Scenario 3	No*	No*	No	No	No*	No	Yes	Yes	No
Scenario 4	No	No	No	No	No	No	Yes	Yes	Yes
Scenario 5	No*	No*	No	No	No*	No	Yes	Yes	Yes

* Although due to product's application these compartments should not be deemed of concern, the use of default emission models consider its potential emission so they have been considered in the current assessment as worst and unreal cases.

ES CA does not agree with the fate and distribution in exposed environmental compartments, in the table below ES CA indicates the relevant receiving compartments based on the exposure pathway.

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway									
Scenario	**Fresh-water**	**Freshwater sediment**	**Sea-water**	**Seawater sediment**	**STP**	**Air**	**Soil**	**Ground-water**	**Secondary poisoning**
Scenario 1	Yes	Yes	No	No	Yes	No	Yes	Yes	No
Scenario 2	Yes	Yes	No	No	Yes	No	Yes	Yes	No
Scenario 3	Yes	Yes	No	No	Yes	No	Yes	Yes	No
Scenario 4	No	No	No	No	No	No	Yes	Yes	Yes

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	Value	Unit	Remarks
Molecular weight	391.29		
Melting point	35	°C	
Boiling point	305	°C	
Vapour pressure (at XC)	2.155E-6	Pa	
Water solubility (at X°C)	0.18	mg/l	From TAGROS (0.00495 mg/L is set for another a.s. supplier)
Log Octanol/water partition coefficient	4.67	Log 10	
Organic carbon/water partition coefficient (Koc)	26930	l/kg	arithmetic mean, n=10
Henry's Law Constant (at X C)*[if measured data available]*	4.6E-3	Pa/m3/mol	
Biodegradability	*Not Ready biodegradable*		
DT_{50} for degradation in soil	106	d (at 12ºC)	geometric mean, n=5
DT_{50} for degradation in air	0.701	d	geometric mean, n=5

Input parameters (only set values) for calculating the fate and distribution in the environment				
Input	DCVA	PBA	Unit	Remarks
Molecular weight	267.11*	214.22*	g/mol	
Percentage metabolite in soil	11.3	15	%	
Percentage metabolite in water	62.6	28.8	%	
Percentage metabolite in sediment	21.7	16.4	%	

* Obtained from EPIwin software

In order to estimate potential environmental exposure to the major metabolites, the percentage of each metabolite established in the AR (see table below) has been assumed. These PECs represents an extreme worse-case estimate for surface water's, sediment's or soil's exposure.

PECs have been calculated only for DCVA and PBA, as no data are available for PB alcohol metabolite.

Seawater and sea sediment are not considered relevant in the assessment.

ES CA:

Active substance: Permethrin

Input parameters used in the environmental exposure assessments according to the CAR (April, 2014)		
Input	Value	Unit
Permethrin		
BCF fish	20700	$L.kg^{-1}$
BCF eartworm	23.8	$L.kg^{-1}$
BMF fish	2	-
Metabolites		
DCVA		
Molecular weight	209.07	$g.mol^{-1}$
Degradation in soil (DT_{50}) (at 12°C)	175	days
Koc	93.2	$L.kg^{-1}$
PBA		
Molecular weight	214.22	$g.mol^{-1}$
Degradation in soil (DT_{50}) (at 12°C)	2.5	days
Koc	141.2	$L.kg^{-1}$

Calculated fate and distribution of Permethrin in the STP (EUSES model 2.1)	
Compartment	Percentage [%]
Air	0
Water	26.19
Sludge	73.81
Degraded in STP	0

Calculation method of metabolites emissions

To estimate PEC in the environmental compartments for the metabolites DCVA and PBA, their own Koc value has been considered. Following the releases to STP, concentrations in effluent were estimated considering the ratio of the molecular weight of the metabolite compared to the molecular weight of permethrin (0.534 for DCVA and 0.547 for PBA). PECs surface water was further estimated considering the metabolite formation fraction (max. % occurrence) in the aquatic compartment.

ES CA agrees with the input parameter for propan-2-ol adding the following:

Input parameters (only set values) for calculating the fate and distribution in the environment of propan-2-ol as SoC			
Input	**Value**	**Unit**	**Remarks**
DT_{50} for degradation in soil	30	d (at 12ºC)	

Calculated PEC values

- **Permethrin**

Summary table on calculated PEC values							
Scenarios		**PEC_{STP}**	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**
		[mg/L]	[mg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[mg/l]	[mg/m^3]
Scenario 1 – (P)	Tier 1	2.40E-04	6.04E-06	3.54E-03	6.39E-04	8.71E-07	4.10E-08
	Tier 2	1.16E-04	2.93E-06	1.72E-03	3.11E-04	4.23E-07	4.10E-08
Scenarios 1 and 2 – (n-P)	Tier 1	1.58E-04	3.98E-06	2.33E-03	4.22E-04	5.74E-07	3.70E-08
	Tier 2	6.65E-05	1.68E-06	9.82E-04	1.78E-04	2.43E-07	3.70E-08
Scenario 3 (n-P)	Tier 1	3.66E-05	3.51E-06	2.06E-03	3.73E-04	5.08E-07	5.99E-08
	Tier 2	2.82E-05	2.71E-06	1.59E-03	2.88E-04	3.93E-07	5.99E-08
Scenario 4		-	-	-	2.69E-02	5.42E-04	-
Scenario 5 (crack/crevice outdoor cover to weather by non-professional)		1.34E-03	1.29E-04	0.075	0.014	1.85E-05	3.99E-11

(P) Professional; (n-P) non-Professional

ES CA:

Permethrin:

Summary table on calculated PEC values							
Scenarios		**PEC_{STP}**	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**
		[mg/L]	[mg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[mg/l]	[mg/m^3]
Scenario 1 (indoor professionals)		5,77E-04	5,55E-05	3,25E-02	6,06E-03	8,25E-03	-
Scenario 2 (indoor non-professionals)		1,27E-03	1,22E-04	7,14E-02	1,33E-02	1,81E-02	-
Scenario 3 (non-washable textile)		2,27E-06	2,18E-07	1,28E-04	2,38E-05	3,24E-05	-
Scenario 4 (Nest)	Direct application				6.99E-02	1.38E-01	
	House (terraces)				6,58E-03	1,38E-02	

	Large buildings (terraces)	6,35E-08	6,11E-09	3,58E-06	6,67E-07	9,07E-07	-

- **Metabolites**

Summary table on calculated PEC values for Permethrin's metabolites									
		DCAV				PBA			
		PEC_{water}	**PEC_{sed}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{GW}**
		[mg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[mg/l]	[mg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[mg/l]
Scenario 1 - (P)	Tier 1	3.78E-06	7.68E-04	7.22E-05	9.84E-08	1.74E-06	5.81E-04	9.59E-05	1.31E-07
	Tier 2	1.83E-06	3.73E-04	3.51E-05	4.78E-08	8.44E-07	2.82E-04	4.67E-05	6.35E-08
Scenario 2 (Non-professional)	Tier 1	2.49E-06	5.06E-04	4.77E-05	6.49E-08	1.15E-06	3.82E-04	6.33E-05	8.61E-08
	Tier 2	1.05E-06	2.13E-04	2.01E-05	2.75E-08	4.84E-07	1.61E-04	2.67E-05	3.65E-08
Scenario 3 (n-P)	Tier 1	2.20E-06	4.47E-04	4.21E-05	5.74E-08	1.01E-06	3.38E-04	5.60E-05	7.62E-08
	Tier 2	1.70E-06	3.45E-04	3.25E-05	4.44E-08	7.80E-07	2.61E-04	4.32E-05	5.90E-08
Scenario 4 (direct emission due to a campaign)		-	-	3.04E-03	6.12E-05	-	-	4.04E-03	8.13E-05
Scenario 5 (crack/crevice outdoor cover to weather by non-professional)		8.08E-05	1.63E-02	1.58E-03	2.09E-06	3.72E-05	1.23E-02	2.10E-03	2.78E-06

(P) Professional; (n-P) non-Professional

ES CA:

Permethrin metabolites:

	Summary table on calculated PEC values for Permethrin's metabolites								
		DCVA				PBA			
		PEC_{water}	**PEC_{sed}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{GW}**
		[mg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/l]	[mg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[mg/l]
Scenario 1 (indoor professionals)		1,86E-05	3,77E-03	3,66E-04	1,34E-01	8,76E-06	2,92E-03		
Scenario 2 (indoor non-professionals)		4,07E-05	8,27E-03	8,02E-04	2,94E-01	1,92E-05	6,42E-03		
Scenario 3 (non-washable textile)		7,29E-08	1,48E-05	1,44E-06	5,28E-04	3,44E-08	1,15E-05		
Scenario 4 (Nest)	Direct application			3,37E-03	1,91	9,64E-10	3,22E-07		
	House (terraces)			3,97E-04	2,25E-01	2,79E-05	9,31E-03		

	Large buildings (terraces)	2,04E-09	4,15E-07	4,02E-08	1,48E-05	4,43E-05	1,48E-02		

ES CA:

Propan-2-ol:

Summary table on calculated PEC values

Scenarios		PEC_{STP}	PEC_{water}	PEC_{sed}	PEC_{soil}	PEC_{GW}	PEC_{air}
		[mg/L]	[mg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[mg/l]	[mg/m^3]
Scenario 1 (indoor professionals)		3.46E-04	3.46E-05	2.96E-05	2.15E-03	2.95	-
Scenario 2 (indoor non-professionals)		7.60E-04	7.60E-05	6.49E-05	4.71E-03	6.47	-
Scenario 3 (non-washable textile)		1,36E-06	1,36E-07	1,16E-07	8,43E-06	1,16E-02	-
Scenario 4 (Nest)	Direct application				3,35E-02	1,91E+02	
	House (terraces)				3,95E-03	2,24E+01	
	Large buildings (terraces)	3,81E-08	3,81E-09	3,26E-09	2,36E-07	3,24E-04	-

Primary and secondary poisoning

Primary poisoning

According to the ESD for PT 18 primary poisoning is only a matter of concern if insecticides are applied together with food attractants. As this is not the intended use of the product, the assessment in not required.

ES CA agrees with the applicant

Secondary poisoning

The log octanol/water partition coefficient of permethrin (4.67) is above the trigged value of 3 suggesting that the substance may have significant potential for bioconcentration in both aquatic and terrestrial biota. However, as it was mentioned before, aquatic compartment must never be reached by PERMETHRIN 0.4% RTU residues when the label's claim are followed.

Scenarios 1 and 2 (where the cleaning of mixing/loading by professional users is deemed to be developed by wet cleaning methods) and Scenario 3 (use in non-washable textile)

disclose a potential emission to wastewater due to the use of reference scenarios. These scenarios considers by default an emission to wastewater by wet cleaning treatment, which is not the intended use of the product. Therefore, in order to develop a realistic assessment, only secondary poisoning due to soil compartment contamination should be developed for primary and secondary poisoning. On the other hand, the risk derived from outdoor scenarios 4 and 5 are estimated for each potential specie considered in the ESD PT18 by ECHA's Excel spreadsheet for ESD PT18. Secondary exposure by Scenario 5 should be deemed irrelevant as the product is used in urban areas not connected to STP where the emission of product's residues should be out of animal's reach.

ESCA agrees with the applicant but secondary poisoning has been recalculated with the new PEC values calculated.

- ***Scenarios 1, 2, 3 and 5***

Summary table on secondary poisoning for permethrin			
Scenario		**Concentration**	**PEC $_{oral\ predator}$**
Scenario: Application, aquatic compartment		**PECsw (mg/L)**	**(mg/kg wet fish)**
Scenario 1 – (P)	Tier 1	6.04E-06	9.23E-03
	Tier 2	2.93E-06	4.48E-03
Scenarios 1 and 2 – (n-P)	Tier 1	3.98E-06	7.40E-03
	Tier 2	1.68E-06	3.12E-03
Scenario 3 (n-P)	Tier 1	3.51E-06	6.54E-03
	Tier 2	2.71E-06	5.05E-03
Scenario 5		1.29E-04	2.39E-01
Scenario: Application, terrestrial compartment		**PECsoil – 180 day (mg/kg wwt)**	**(mg/kg wet earthworm)**
Scenario 1 – (P)	Tier 1	4.14E-04	2.41E-04
	Tier 2	2.01E-04	1.17E-04
Scenarios 1 and 2 – (n-P)	Tier 1	2.73E-04	1.59E-04
	Tier 2	1.15E-04	6.71E-05
Scenario 3 (n-P)	Tier 1	2.42E-04	1.41E-04
	Tier 2	1.87E-04	1.09E-04
Scenario 5		8.81E-03	5.12E-03

(P) Professional; (n-P) non-Professional

- ***Scenario 4:***

The following table summarizes the estimated theoretical exposure (ETE) for secondary poisoning for each indicator species obtained from EUES 2.2.0:

Representative specie	ETE ($mg.kg^{-1}.d^{-1}$)							
	Insectivorous		Herbivorous		Mammals eating worms		Birds eating worms	
	Acute exposure	Short-term exposure	Acute exposure	Short-term exposure	Acute exposure	Short-term exposure	Acute exposure	Short-term exposure
Small insectivorous mammal 1 (pipistrelle) – 7.6 g *	7.32E-04	2.67E-04	-	-	-	-	-	-
Small insectivorous mammal 2 (mole) – 85 g	-	-	-	-	0.199	0.199	-	-
Medium insectivorous mammal – 1100 g – hedgehog *	1.67E-04	6.1E-05	-	-	0.094	0.094	-	-
Large insectivorous mammal – 10100 g (badger) *	8.7E-05	3.17E-05	-	-	0.049	0.049	-	-
Medium herbivorous mammal – 1500 g (rabbit) *	-	-	1.72E-03	7.89E-04	-	-	-	-
Small Insectivorous bird (Tree sparrow, robin) – 22 g	3.25E-03	1.81E-03	-	-	-	-	-	-
Medium Insectivorous bird – 113 g (blackbird) *	8.24E-04	3E-04	-	-	-	-	-	-
Omnivorous bird – 225 g (Black-billed magpie) *	4.39E-04	1.6E-04	-	-	-	-	0.247	0.247

*Indicator species considered as relevant for lawn/garden.

ES CA:

Scenarios 1 and Scenario 4 (direct emission) have been chosen as worst cases to calculate the secondary poisoning for calculate the food of fish-eating predators and the concentration of the a.s. in earthworms, respectively.

For secondary poisoning, the concentration in surface water is used as input for calculating the concentration of Permethrin and DCVA in food (fish) of fish-eating predators (PECoral, predator,aquatic) according to equation (95) of the Guidance on BPR IV/B+C (2017). An estimated BCF fish of 20700 L/kgwwt fish and a BMF of 2 (Kow =4.67) are used for calculations.

For the calculation of the concentration of a.s. in earthworms ($C_{earthworm}$ = $PEC_{oral,\ predator}$ according equation 99 of the Guidance on BPR IV/B+C, 2017), equation 103c of the guidance is used considering PECsoil averaged over a period of 180 days. Therefore, a BCF earthworm of 23.8 $L/kg_{wwt,\ earthworm}$ and the concentrations in pore water have been used as input parameter to calculate the following $PEC_{oral,\ predator}$ for the terrestrial and aquatic compartment.

Summary table on secondary poisoning		
	Permethrin	**DCVA**
Aquatic food chain	**PEC $_{oral,predator,aquatic}$ (mg/kg)**	
Scenario 1		
	5,04E+00	1,69E+00
Terrestrial food chain	**PEC $_{oral.predator.terrestrial}$ (mg/kg)**	
Scenario 4 (direct emissions)		
	8,21E-03	1,79E-03

2.2.8.3 Risk characterisation

Risk characterisation for environment was conducted by comparing predicted environmental concentrations (PEC) and the concentrations below which effects on organism will not occur (PNEC) according to the guidance in Technical Guidance Document on Risk Assessment (TGD, 2003, Part II). If the predicted environmental concentration is greater than the predicted no-effect concentration, i.e. the PEC/PNEC ratio is greater than one, the substance is "of concern" and further action has to be taken.

Even if the aquatic metabolites DCVA and PBA are far less toxic to aquatic organism than the parent active ingredient, the risk characterization in water, sediment and soil has been performed for the sake of completeness.

No assessment on PB alcohol can be performed as no data on PNEC value are available.

Atmosphere

Conclusion:

The formulation type of the product (AL), its application mode, the low vapour pressure (Pure) and Henry's Law constant of the active substance permethrin (K = 4.6E-03 $Pa.m^3.mol^{-1}$) indicate that there will be negligible loss of permethrin to the atmosphere.

ESCA agrees with the conclusion of the applicant.

Sewage treatment plant (STP)

The risk characterization for microorganisms in STPs compartment is carried out by comparing the PEC_{STP} with the $PNEC_{microorganisms}$. The PEC/PNEC ratio has been calculated and the results are shown in the table below.

Summary table on calculated PEC/PNEC values		
Scenarios		**$PEC/PNEC_{STP}$**
Scenario 1 – (P)	Tier 1	0.05
	Tier 2	0.02
Scenarios 1 and 2 – (n-P)	Tier 1	0.03
	Tier 2	0.01
Scenario 3 (n-P)	Tier 1	0.01
	Tier 2	0.01
Scenario 4		-
Scenario 5		0.27

(P) Professional; (n-P) non-Professional.

Conclusion: According to the obtained PEC/PNEC ratios, the use of PERMETHRIN 0.4% RTU is safe for the microorganisms involved in biodegradation processes in the STP, since the ratio between the predicted environmental concentration and the predicted no-effect concentration is lower than 1.

ES CA: Values recalculated by ES CA,

Permethrin and propan-2-ol:

Summary table		
Scenarios	**$PEC/PNEC_{STP}$**	
	Permethrin	**SoC (Propan-2-ol)**
Scenario 1 (indoor professionals)	1,17E-01	3,46E-05
Scenario 2 (indoor non-professionals)	2,56E-01	7,60E-05
Scenario 3 (non-washable textile)	4,59E-04	1,36E-07

Scenario 4 (Nest)	Direct application		
	House (terraces)		
	Large buildings (terraces)	1,28E-05	3,81E-09

Conclusions:

Same conclusions than those indicated by the applicant: According to the obtained PEC/PNEC ratios for the assessed scenarios, the use of PISTOLA INS PER04 is safe for the microorganisms involved in biodegradation processes in the STP, since the ratio between PEC/PNEC is lower than 1.

Aquatic compartment

The risk characterization for aquatic compartment is carried out by comparing the PEC_{sw} with the $PNEC_{sw}$.

The risk characterization for sediment compartment is carried out by comparing the PEC_{sed} with the $PNEC_{sed}$.

Seawater and sea sediment compartments have not been deemed relevant in the current assessment. The PEC/PNEC ratio has been calculated and the results are shown in the table below

Summary table on calculated PEC/PNEC values					
Scenarios		**PEC/PNEC$_{water}$**	**PEC/PNEC$_{sed}$**	**PEC/PNEC$_{seawater}$**	**PEC/PNEC$_{seased}$**
Scenario 1 (P)	Tier 1	**12.85**	**16.31**	Not relevant	Not relevant
	Tier 2	**6.23**	**7.93**	Not relevant	Not relevant
Scenarios 1 and 2 –(n-P)	Tier 1	**8.47**	**10.74**	Not relevant	Not relevant
	Tier 2	**3.57**	**4.53**	Not relevant	Not relevant
Scenario 3 (n-P)	Tier 1	**7.47**	**9.49**	Not relevant	Not relevant
	Tier 2	**5.77**	**7.33**	Not relevant	Not relevant
Scenario 4		-	**-**	Not relevant	Not relevant
Scenario 5		**274.47**	**345.62**	Not relevant	Not relevant

Values on bold are above the trigger value and that would be deemed of concern in the case the label instructions are not followed. (P) Professional; (n-P) non-Professional.

Conclusion for aquatic compartment:

According to the intended use of PERMETHRIN 0.4% RTU and proposed Risk Mitigation measures, no potential emission from any scenario to aquatic compartment should be foreseen. However, the assessment of scenarios 1, 2 and 3 considers a potential emission from application and cleaning areas of treated premises by default (Tier 1). Under this default-assumption, taking into account permethrin's outputs, all scenarios 1, 2, 3 and 5

would be unacceptable risk for aquatic compartment. On the other hand, when no cleaning treatment is deemed after product's application (Tier 2), unacceptable risk is still expected due mainly to application treatment where emission is considered to wastewater.

The following risk mitigation measure is proposed in order to avoid any emission to wastewater during application:

- *Do not apply in areas connected or suspected to be connected to STP*

ES CA:

Permethrin and propan-2-ol:

Summary table					
Scenarios		**Permethrin**		**Propan-2-ol**	
		PEC/PNEC$_{water}$	**PEC/PNEC$_{sed}$**	**PEC/PNEC$_{water}$**	**PEC/PNEC$_{sed}$**
Scenario 1 (indoor professionals)		**1,18E+02**	**1,50E+02**	3,46E-05	1,24E-05
Scenario 2 (indoor non-professionals)		**2,59E+02**	**3,29E+02**	7,60E-05	2,72E-05
Scenario 3 (non-washable textile)		4,64E-01	5,89E-01	1,36E-07	4,86E-08
Scenario 4 (Nest)	Direct application				
	House (terraces)				
	Large buildings (terraces)	1,30E-02	1,65E-02	1,36E-09	

Permethrin metabolites:

Summary table					
Scenarios		**DCVA**		**PBA**	
		PEC/PNEC$_{water}$	**PEC/PNEC$_{sed}$**	**PEC/PNEC$_{water}$**	**PEC/PNEC$_{sed}$**
Scenario 1 (indoor professionals)		1,24E-03	3,14E-01	8,76E-04	3,25E-01
Scenario 2 (indoor non-professionals)		2,71E-03	6,89E-01	1,92E-03	7,13E-01
Scenario 3 (non-washable textile)		4,86E-06	1,23E-03	3,44E-06	1,28E-03
Scenario 4 (Nest)	Direct application				
	House (terraces)				
	Large buildings (terraces)	1,36E-07	3,46E-05	9,64E-08	9,31E-03

Conclusion for aquatic compartment:

The assessment of scenarios 1 and 2 (indoor use, professional and non-professional) showed an unacceptable risk for surface water and sediment compartments. However, this risk can be reduced to acceptable levels or prevented by imposing the following RMM: *The product has to be applied only on restricted areas on surfaces not regularly cleaned, for example behind or under the fridge, under the oven or the water heater, in all cracks and crevices that can be a harbourage for crawling insects*. Therefore, these uses are acceptable.

Following the label instruction for Use 3 (non-washable textile surfaces non-professionals user): "*The excess of the product on non-treated surfaces contaminated during the application must be remove with a damp paper and dispose as solid waste*" no risk for the aquatic compartment is expected.

For scenario 4, the risk is acceptable.

Terrestrial compartment

The risk characterization for terrestrial compartment was carried out by comparing the PEC_{soil} with the $PNEC_{soil}$.

The PEC/PNEC ratio has been calculated and the results are shown in the table below.

Summary table on calculated PEC/PNEC values		
Scenarios		**$PEC/PNEC_{soil}$**
Scenario 1 – (P)	Tier 1	3.65E-03
	Tier 2	1.78E-03
Scenarios 1 and 2 – (n-P)	Tier 1	2.41E-03
	Tier 2	1.02E-03
Scenario 3 (n-P)	Tier 1	2.13E-03
	Tier 2	1.65E-03
Scenario 4		1.54E-01
Scenario 5		8.00E-02

(P) Professional; (n-P) non-Professional.

Conclusion: According to the obtained PEC/PNEC ratio, the use of PERMETHRIN 0.4% RTU is safe for the soil compartment at the majority of scenarios, since the $PEC_{soil}/PNEC_{soil}$ ratio is lower than 1.

ES CA:

Summary table		
Scenarios	**$PEC/PNEC_{SOIL}$**	
	Permethrin	**SoC (Propan-2-ol)**

Scenario 1 (indoor professionals)		3,46E-02	4,29E-03
Scenario 2 (indoor non-professionals)		7,59E-02	9,41E-03
Scenario 3 (non-washable textile)		1,36E-04	1,69E-05
Scenario 4 (Nest)	Direct application	3,99E-01	6,71E-02
	House (terraces)	3,76E-02	7,89E-03
	Large buildings (terraces)	3,81E-06	4,72E-07

Summary table			
Scenarios		**PEC/PNEC$_{SOIL}$**	
		DCVA	**PBA**
Scenario 1 (indoor professionals)		3,66E-04	
Scenario 2 (indoor non-professionals)		8,02E-04	
Scenario 3 (non-washable textile)		1,44E-06	
Scenario 4 (Nest)	Direct application	3,37E-03	
	House (terraces)	3,97E-04	
	Large buildings (terraces)	4,02E-08	

Conclusion: ESCA agrees with the conclusion on the applicant. The use of PISTOLA INS PER04 is safe for the soil compartment at all scenarios, since the $PEC_{soil}/PNEC_{soil}$ ratio is lower than 1.

Groundwater

Summary table on calculated PEC/PNEC values		
Scenarios		**PEC$_{ground\ water}$ / Trigger value**
Scenario 1 – (P)	Tier 1	8.71E-07
	Tier 2	4.23E-07
Scenarios 1 and 2 – (n-P)	Tier 1	5.74E-07
	Tier 2	2.43E-07
Scenario 3 (n-P)	Tier 1	5.08E-07
	Tier 2	3.93E-07
Scenario 4		**5.42E-04**
Scenario 5		1.85E-05

Values on bold are above the trigger value (1E-04 mg/l) and deemed of concern. (P) Professional; (n-P) non-Professional.

Conclusion: According to the obtained PEC_{gw}, the use of PERMETHRIN 0.4% RTU is safe for the groundwater compartment at scenarios 1, 2, 3 and 5, since the PEC_{gw} is lower than the trigger value for drinking water of 0.1 µ/L.

Scenario 4 discloses values slightly above the trigger value, but this values must be deemed as an overestimation because the application is only local concentration and the treated soil as for example of the treated nest must not be used for arable land.

PEC_{gw} was refined by using FOCUS PEARL 4.4.4. and considering TAB ENV 157 with the following assumptions:

- Number of houses treated per hectare: 16 houses without considering Fsim (since already taken into account by the number of applications within a period of time). 3.75 ml of product is applied per nest, so 60 g/ha (3.75 ml/house x 16house/ha) is considered emitted over the year per one application.

- Dates of application: those included in the ESD for PT 8 – Supplement to Appendix 4 (paragraph 594 c, p.178); The application scheme considers that 10 applications takes place over the year (10.01, 15.02, 24.03, 29.04, 05.06, 11.07, 17.08, 22.09, 29.10 and 04.12).

- Crops to be used: grass/alfalfa.

Only private houses in rural areas should be looked at

Taking into account the concentration of each substance and potential metabolite, the following application rates have been considered in the Tier 2 groundwater exposure assessment:

App_rate_Permethrin: 2.4E-04 kg $_{application}$ /ha

The appl_rate before and the following chemical parameters are used for FOCUS PEARL simulations:

Parameter	Value			Unit	Origin
	Permethrin	DCVA*	PBA*		
Molar mass	391.29	267.11	214.22	[g.mol^{-1}]	S
Solubility in water (at test temperature)	0.18	0.18(1)	0.18(1)	[mg.L^{-1}]	S
Molar enthalpy of dissolution	27	27	27	[kJ.mol^{-1}]	D
Vapour pressure (at test temperature)	2.15E-06	2.15E-06(1)	2.15E-06(1)	[Pa]	S
Molar enthalpy of vaporisation	95	95	95	[kJ.mol^{-1}]	D
Diffusion coefficient in water	4.3E-05	4.3E-05	4.3E-05	[m^2.d^{-1}]	D
Gas diffusion coefficient	0.43	0.43	0.43	[m^2.d^{-1}]	D
Reference temperature to degradation, vaporization and dissolution	20	20	20	[ºC]	D
Exponent for the effect of liquid (degradation moisture relationship)	0.7	0.7	0.7	[-]	D
Sorption to soil organic carbon (Koc or Kom) (Kom = Koc / 1.724)	73,441	93.2	141.2	[dm^3.kg^{-1}]	S
Exponent of the Freundlich-Isotherm (1/n)	0.9	0.9	0.9	[-]	D/S
DT_{50} (20°C)	106	175(2)	2(2)	[d]	S
Arrhenius activation energy	65.4	65.4	65.4	[kJ.mol^{-1}]	D
Plant uptake factor	0	0	0	[-]	D

* 11.3% and 15% are the percentage of DCAV and PBA metabolites considered from parent permethrin concentration for soil compartment and used in FOCUS.

(1) values considered from the parent compound as worst-case.

(2) values considered as worse cases according to permethrin's CAR.

Outputs below show the predicted 80th concentrations for Permethrin in groundwater:

FOCUS Scenarios			
Location	Concentration closest to the 80th percentile [µg.L^{-1}]		
	Permethrin	DCVA	PBA
Châteaudun	<0.000001	0.000008	<0.000001
Hamburg	<0.000001	0.000045	<0.000001
Jokioinen	<0.000001	0.000001	<0.000001
Kremsmünster	<0.000001	0.000017	<0.000001
Okehampton	<0.000001	0.000039	<0.000001
Piacenza	<0.000001	0.000037	<0.000001
Porto	<0.000001	0.000013	<0.000001
Sevilla	<0.000001	<0.000001	<0.000001
Thiva	<0.000001	0.000002	<0.000001

* Values on bold are above the trigger value

From the results it can be seen that the average concentration of Permethrin and its metabolites is closest to the 80th percentile is 0.00 $\mu g \cdot L^{-1}$ and thus the predicted concentrations in groundwater are significantly below the threshold criteria of 0.1 $\mu g \cdot L^{-1}$ for all crops and locations.

ESCA:

Summary table on calculated PEC values			
Scenarios		**PEC_{GW} (µg/L)**	
		Permethrin	**SoC**
Scenario 1 (indoor professionals)		8,25E-03	**2,95E+00**
Scenario 2 (indoor non-professionals)		1,81E-02	**6,47E+00**
Scenario 3 (non-washable textile)		3,24E-05	**1,16E-02**
Scenario 4 (Nest)	Direct application	**1,18E-01**	**1,91E+02**
	House (terraces)	1,38E-02	**2,24E+01**
	Large buildings (terraces)	9,07E-07	**3,24E-04**

Permethrin: Predicted environmental concentration in pore water for Scenario 4 (direct application) is > 0.1 µg/L. According to Council Directive 98/83/EC relating to the quality of water intended for human consumption, the maximum admissible concentration for pesticides in drinking water is 0.1 µg/L. The calculated pore water concentration for Permethrin does not comply with this criterion. Therefore, an exposure refinement should be conducted using FOCUS PEARL 4.4.4.

IPA: Regards Propan-2-ol, the concentration is greater than the drinking water threshold trigger value of 0.1 µg/ L for all of scenarios assessed. Following discussions at WG-VII-2018 it was agreed that the following argument forms an acceptable weight of evidence approach to support FOCUS PEARL not offering an appropriate tier 2 refinement for these proposed uses of propan-2-ol.

The FOCUS PEARL model was developed for the determination of groundwater concentrations related to the application of plant protection products (PPP) on agricultural land. Accordingly, the model assumptions for the nine locations rely on e.g. soil properties that are representative for agriculturally used areas in Europe. The unlimited applicability of the model for the very diverse field of biocidal applications is thus questionable. For biocidal applications where the release of active substances to the environment is related to the application of sewage sludge or manure/slurry to agricultural land, the applicability of FOCUS PEARL might be given. In the present case, where the products is used in urban areas where a direct exposure to the urban environment is assumed, the model assumptions of FOCUS PEARL may not be accurate and the results of such a refinement should be evaluated with caution. The same applies, when FOCUS PEARL is used for the groundwater assessment of volatile compounds, for which the model is might not be suitable, since it might overestimate the leaching rate to the groundwater for such compounds. Consequently, the results of the refined groundwater assessment with FOCUS PEARL must also be considered as an unrealistic worst-case.

This discussion is supported by the conclusion at the 21st BPC meeting that if not all nine scenarios show a safe use and the applicability of the models for the substance evaluated can be questioned, a qualitative approach could be applied using expert judgement in a weight of evidence approach.

An acceptable risk of propan-2-ol to groundwater is therefore expected

Permethrin metabolites:

the two major metabolites (DCVA and PBA) are expected to be more mobile in soil with mean K_{oc} for DCVA of 93.2 L/kg (n = 5) and for PBA of 141.2 L/kg, which may result in leaching to the groundwater. Therefore, the risk for the groundwater is quantitatively assessed for the major metabolite DCVA (worst case DT_{50} soil [12°C]: 175 d) covering for the significantly more rapidly degrading PBA (DT_{50} soil [12°C]: 2.5 d). The risk for the soil compartment is presented for completeness.

The maximum observed DCVA in soil compared to the parent was 0.113 and the formation fraction to be used in the groundwater modelling is 1. The environmental behaviour of DCVA was described with a worst-case sorption coefficient K_{oc} of 93.2 $L.kg^{-1}$. The degradation in soil was described with a worst-case half-life of 175 days at 12°C.

Summary table on calculated PEC values			
Scenarios		**PEC_{GW} (µg/L)**	
		DCVA	**PBA**
Scenario 1 (indoor professionals)		**1,34E-01**	
Scenario 2 (indoor non-professionals)		**2,94E-01**	
Scenario 3 (non-washable textile)		5,28E-04	
Scenario 4 (Nest)	Direct application	**1,91E+00**	
	House (terraces)	2,25E-01	
	Large buildings (terraces)	1,48E-05	

Predicted environmental concentrations for DCVA in pore water for Scenarios 1, 2 and 4 (direct application) are > 0.1 µg/L. According to Council Directive 98/83/EC relating to the quality of water intended for human consumption, the maximum admissible concentration for pesticides in drinking water is 0.1 µg/L. The calculated pore water concentration does not comply with this criterion. Therefore, a more realistic exposure assessment is conducted using FOCUS PEARL 4.4.4. The application scheme and the calculation of the application rates for grassland are presented below.

A refinement is done by FOCUS PEARL 4.4. The following parameters were used in the estimation of the application rate to be used in FOCUS program for the estimation of PEC_{GW}:

Parameter	**substance**	**Value**	**Unit**	**Origin**
Molar mass	Permethrin	391.29	[g.mol-1]	S
	DCVA	209.07		
Solubility in water (at 20 ºC)	Permethrin	0.18	[mg.L-1]	S
	DCVA	127.6		
Molar enthalpy of dissolution		27	[kJ.mol-1]	D
Vapour pressure (at 20 ºC)	Permethrin	2.155E-06	[Pa]	S
	DCVA	2.60E-01		
Molar enthalpy of vaporisation		95	[kJ.mol-1]	D

Diffusion coefficient in water		4.3E-05	[m2.d-1]	D
Gas diffusion coefficient		0.43	[m2.d-1]	D
Reference temperature to degradation, vaporization and dissolution		20	[ºC]	D
Exponent for the effect of liquid (degradation moisture relationship)		0.7	[-]	D
Sorption to soil organic carbon (Koc)	Permethrin	73441	[$dm^3.kg^{-1}$]	S
	DCVA	93.2		
Exponent of the Freundlich-Isotherm (1/n)		0.9	[-]	D/S
DT50 $_{soil}$(12°C)	Permethrin	106	[d]	S
	DCVA	175		
Plant uptake factor		0	[-]	D

According to TAB ENV 157, only grassland (alfalfa) was considered. Outputs below show the predicted 80th concentrations for each substance in groundwater:

FOCUS Scenarios for Permethrin and DCVA (grassland)		
Ground land Scenarios	**Concentration closest to the 80th percentile [µg·L^{-1}]**	
	Permethrin	**DVCA**
Châteaudun	<0.01	<0.01
Hamburg	<0.01	<0.01
Jokioinen	<0.01	<0.01
Kremsmünster	<0.01	<0.01
Okehampton	<0.01	<0.01
Piacenza	<0.01	<0.01
Porto	<0.01	<0.01
Sevilla	<0.01	<0.01
Thiva	<0.01	<0.01

Conclusion:

Taking into account the outputs above, no risk for groundwater compartment is expected.

Primary and secondary poisoning

Primary poisoning

Not relevant

Secondary poisoning

The exposure due to secondary poisoning via the terrestrial and aquatic food chain has been evaluated according to the TGD Part II (2003).

The risk to the fish-eating birds and mammals is calculated as the ratio between the concentration in their food and the predicted no-effect concentration for oral intake ($PNEC_{oral,\ fish\ food\ chain}$). The concentration of permethrin in fish has been calculated only for Scenarios 1, 2, 3 and 5 from the potential PEC in surface water and the estimated bioconcentration factor for fish.

The risk to the predators for Scenarios 1, 2, 3 and 5 is calculated as the ratio between the concentration in their food and the predicted no-effect concentration for oral intake ($PNEC_{oral,\ terrestrial\ food\ chain}$). The concentration of permethrin in earthworm has been calculated from the PEC in soil averaged over 180 days and the estimated bioconcentration factor for earthworm.

The PEC/PNEC ratio has been calculated and the results are shown in tables below:

Summary table on secondary poisoning for permethrin					
Scenario		**Concentration**	**PEC oral predator**	**PEC/PNEC birds**	**PEC/PNEC mammals**
Scenario: Application, aquatic compartment		**PECsw (mg/L)**	**(mg/kg wet fish)**		
Scenario 1 – (P)	Tier 1	6.04E-06	9.23E-03	5.53E-04	7.69E-05
	Tier 2	2.93E-06	4.48E-03	2.68E-04	3.73E-05
Scenarios 1 and 2 – (n-P)	Tier 1	3.98E-06	7.40E-03	4.43E-04	6.17E-05
	Tier 2	1.68E-06	3.12E-03	1.87E-04	2.60E-05
Scenario 3 (n-P)	Tier 1	3.51E-06	6.54E-03	3.92E-04	5.45E-05
	Tier 2	2.71E-06	5.05E-03	3.02E-04	4.21E-05
Scenario 5		1.29E-04	2.39E-01	1.43E-02	1.99E-03
Scenario: Application, terrestrial compartment		**PECsoil – 180 day (mg/kg wwt)**	**(mg/kg wet earthworm)**		
Scenario 1 – (P)	Tier 1	4.14E-04	2.41E-04	1.44E-05	2.01E-06
	Tier 2	2.01E-04	1.17E-04	7.01E-06	9.75E-07
Scenarios 1 and 2 – (n-P)	Tier 1	2.73E-04	1.59E-04	9.52E-06	1.33E-06
	Tier 2	1.15E-04	6.71E-05	4.02E-06	5.59E-07
Scenario 3 (n-P)	Tier 1	2.42E-04	1.41E-04	8.44E-06	1.18E-06
	Tier 2	1.87E-04	1.09E-04	6.53E-06	9.08E-07
Scenario 5		8.81E-03	5.12E-03	3.07E-04	4.27E-05

(P) Professional; (n-P) non-Professional.

The risk assessment for specific species by secondary poisoning considered in scenario 4 is estimated by splitting the ETE with the correspondent PNEC (i.e. bird or mammal value). These quotients are showed in the following table:

ETE/PNEC for terrestrial species of secondary poisoning at Scenario 4:

Representative specie	ETE / PNEC							
	Insectivorous		Herbivorous		Mammals eating worms		Birds eating worms	
	Acute exposure	Short-term exposure	Acute exposure	Short-term exposure	Acute exposure	Short-term exposure	Acute exposure	Short-term exposure
Small insectivorous mammal 1 (pipistrelle) – 7.6 g *	6.10E-06	2.23E-06	-	-	-	-	-	-
Small insectivorous mammal 2 (mole) – 85 g	-	-	-	-	1.66E-03	1.66E-03	-	-
Medium insectivorous mammal – 1100 g – hedgehog *	1.39E-06	5.08E-07	-	-	7.83E-04	7.83E-04	-	-
Large insectivorous mammal – 10100 g (badger) *	7.25E-07	2.64E-07	-	-	4.08E-04	4.08E-04	-	-
Medium herbivorous mammal – 1500 g (rabbit) *	-	-	1.43E-05	6.58E-06	-	-	-	-
Small Insectivorous bird (Tree sparrow, robin) – 22 g	1.95E-04	1.08E-04	-	-	-	-	-	-
Medium Insectivorous bird – 113 g (blackbird) *	4.93E-05	1.80E-05	-	-	-	-	-	-
Omnivorous bird – 225 g (Black-billed magpie) *	2.63E-05	9.58E-06	-	-	-	-	1.48E-02	1.48E-02

*Indicator species considered as relevant for lawn/garden.

Conclusion: As it can be observed, the PEC/PNEC ratio is lower than 1 for all the use/scenario, indicating acceptable risk of secondary poisoning trough the terrestrial food-chain via earthworm and aquatic food chain via unlikely fish.

ESCA agrees with the conclusion of the applicant. With the new calculations, taking into account only the worst case an acceptable risk is showed.

Summary table on secondary poisoning		
	Permethrin	**DCVA**
Aquatic food chain	**PEC/PNEC**	
Scenario 1		
	3,02E-01	1,01E-01
Terrestrial food chain	**PEC/PNEC**	
Scenario 4 (direct emissions)		
	4,91E-04	1,07E-04

Risk characterization for metabolites

The risk characterization for surface water, sediment and soil compartments were carried out by comparing the PECs with the PNEC of metabolites.

The PEC/PNEC ratio has been calculated and the results are shown in the table below.

Summary table on calculated RCR for Permethrin's metabolites									
		DCAV				PBA			
		PEC_{water}/ $PNEC_{water}$	PEC_{sed}/ $PNEC_{sed}$	PEC_{soil}/ $PNEC_{soil}$	PEC_{GW} /trigger value	PEC_{water}/ $PNEC_{water}$	PEC_{sed}/ $PNEC_{sed}$	PEC_{soil}/ $PNEC_{soil}$	PEC_{GW} /trigger value
Scenario 1 - (P)	Tier 1	2.52E-04	6.40E-02	1.57E-05	9.84E-04	1.74E-04	6.45E-02	6.66E-05	1.31E-03
	Tier 2	1.22E-04	3.11E-02	7.64E-06	4.78E-04	8.44E-05	3.13E-02	3.24E-05	6.35E-04
Scenario 2 (Non-professional)	Tier 1	1.66E-04	4.21E-02	1.04E-05	6.49E-04	1.15E-04	4.25E-02	4.40E-05	8.61E-04
	Tier 2	7.01E-05	1.78E-02	4.37E-06	2.75E-04	4.84E-05	1.79E-02	1.85E-05	3.65E-04
Scenario 3 (n-P)	Tier 1	1.46E-04	3.73E-02	9.16E-06	5.74E-04	1.01E-04	3.75E-02	3.89E-05	7.62E-04
	Tier 2	1.13E-04	2.88E-02	7.07E-06	4.44E-04	7.80E-05	2.90E-02	3.00E-05	5.90E-04
Scenario 4		-	-	6.61E-04	6.12E-01	-	-	2.80E-03	8.13E-01
Scenario 5		5.38E-03	**1.36**	3.44E-04	2.09E-02	3.72E-03	**1.37**	1.46E-03	2.78E-02

(P) Professional; (n-P) non-Professional.

The potential risk of secondary poisoning derived from metabolites is deemed covered by the parent compound because its concentration and toxicity is higher than any metabolite.

Conclusion: According to the obtained PEC/PNEC ratio, the use of PERMETHRIN 0.4% RTU is safe for the majority of scenarios, since the PEC/PNEC ratio is lower than 1. Only scenario 5 shows unacceptable values (slightly above 1) for sediment compartment. This compartment has already been of concern for the parent substance.

ESCA: please see section for every compartment, both parent and metabolites has been recalculated by the ES CA.

Overall conclusion

Overall conclusion on the risk assessment for the environment of the product
An acceptable risk should be foreseen for all scenarios at the assessed environmental compartments, when the use instructions given in the product's label and the proposed risk mitigations measures are followed for each scenario. Indoor scenarios 1, 2 (spraying into voids/cavities and spot surfaces against crawling and flying insects respectively) and scenario 3 (spraying over non washable textile surfaces),

when consider a default emission to STP, shows an unacceptable risk for aquatic compartment. However, as it was mentioned before the emission to STP should not be considered because the product cannot be applied on washable surfaces nor surfaces connected (or suspected to be connected) to waste water.

When the product is applied outdoors, into ant nests (Scenario 4) no directly emission to aquatic compartment is foreseen and only soil and groundwater compartments are deemed of concern. Both compartments are deemed at safe so acceptable risk is expected for scenario 4.

Outdoor application in voids/crevices of paved terraces not connected to STP and protected to rainfall and wash (Scenario 5), shows an unacceptable risk for the aquatic compartment. However, for all outdoor intended uses, the use of a trap over the adjacent soil of walls, ceilings,… (where the product could be applied) is proposed as efficient risk mitigation measure in order to reduce the fraction emitted to environment during product's application.

The main statement is that the product must be applied on surfaces not connected to wastewater, treated surfaces must not be washed nor cleaned by wet method and in the case of outdoor, treated areas must be protected from rain fall and flooding. Under these assumptions a safe use of the product for the environment must be obtained.

ES CA:

Overall conclusion on the risk assessment for the environment of the product is summarized in the table below:

Summary table for the risk assessment of this product.

	Use	PEC/PNECstp	PEC/PNECwater	PEC/PNECsed	PEC/PNECsoil	PECGW
Scenario 1: indoor, spot to a surface, professional	1	Acceptable	Unacceptable	Unacceptable	Acceptable	Acceptable
Scenario 2: indoor use, spot treatment to a surface, non-professionals	2	Acceptable	Unacceptable	Unacceptable	Acceptable	Acceptable
Scenario 3: indoor use, non-washable textiles, non-	3	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable

professionals (TIER II)						
Scenario 4: Outdoor – Ant nests	4	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable
	5	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable

The assessment of scenarios 1 and 2 (indoor use, professional and non-professional) showed an unacceptable risk for surface water and sediment compartments. However, this risk can be reduced to acceptable levels or prevented by imposing the following RMM: The product has to be applied only on restricted areas on surfaces not regularly cleaned, for example behind or under the fridge, under the oven or the water heater, in all cracks and crevices that can be a harbourage for crawling insects. Therefore, these uses are acceptable.

Following the label instruction for Use 3 (non-washable textile surfaces non-professionals user) and the RMM (calculated in tier II) "The exceed of the product on not treated surfaces contaminated during the application must be remove with a damp paper and dispose as solid waste" no risk for the aquatic compartment is expected.

An acceptable risk should be foreseen for all scenarios at the assessed environmental compartments when the use instructions given in the product's label and the proposed risk mitigations measures are followed for each scenario, the same conclusion can be extrapolated to the higher dose for controlling silverfish.

Uses 4 and 5 are safe, since the PEC/PNEC ratios for all environmental compartments are lower than 1.

Mixture toxicity

Not relevant, the product is not intended to be used with any other formulation type and no further substances of concern apart of the active substance is deemed in the formulation.

ESCA position:

Permethrin is the only substance classified for the aquatic environment, and it also has a factor M = 1000. Propan-2-ol has no significant effects. The PEC/PNECs values of Propan-2-ol (for all the environmental compartments, direct application and via STP), are much lower than those of permethrin, in most of the cases several orders of magnitude.

In addition to this, it does not present synergistic effects with permethrin since it does not affect the effectiveness of the product. The exposure analysis is performed only because it is a substance that has biocidal properties and has been approved for various uses in accordance with the BPR. It meets the criteria to be considered as a substance of concern.

However, based on the results of the evaluation, the overall toxicity of the product is due to the permethrin.

ESCA considers that mixture toxicity is not needed

Aggregated exposure (combined for relevant emission sources)

Not applicable as the product is only intended to be used as PT18.

2.2.9 Measures to protect man, animals and the environment

Please refer to summary of the product assessment (SPC) and to the relevant sections of the assessment report.

2.2.10 Assessment of a combination of biocidal products

Not relevant as the biocidal products are not intended to be authorised for the use with other biocidal products.

2.2.11 Comparative assessment

Not relevant.

3 ANNEXES

3.1 List of studies for the biocidal product

Please, see confidential PAR.

3.2 Output tables from exposure assessment tools

Human Risk Assessment

Exposure Assesment PISTOLA

Environmental Risk Assessment

Outputs from EUSES 2.2.0 are attached in the excel datasheet below:

FINAL_ERA-PERMETH RIN 0.4% RTU_202107

3.3 New information on the active substance

Not available

3.4 Residue behaviour

Not available

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

See summary table of efficacy tests. section 2.2.5.5.

3.6 Confidential annex

Please, see confidential PAR.

3.7 Other

No other information required.