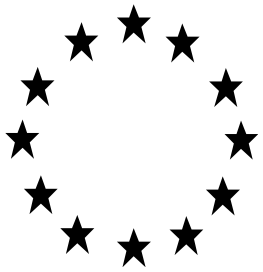
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



MASSOCIDE T05

Product type 18

Permethrin as included in the Union list of approved active substances

Case Number in R4BP: BC-AR023681-37

Evaluating Competent Authority: Spain

Date: April 2023

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OVERVIEW OF APPLICATIONS

Application type	Ref MS	Case number/Asset number in the ref MS	Decision date	Assessment carried out (i.e. first authorisation / amendment /renewal)
NA-APP	ES	BC-AR023681-37	March 2016	Initial assessment
NA-APP	ES	ES-0028855-0000	December 2022	First authorisation
NA-ADC	ES	BC-WN043783-13 ES-0028855-0000	April 2023	Amended only Spain

2 CONCLUSION

The biocidal product MASSOCIDE T05 is a dust preparation 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 properties

The biocidal product MASSOCIDE T05 contains 0.5 %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 MASSOCIDE T05 at an application rate of 10 g/m^2 by dusting for the following uses:

- against crawling insects,cockroaches, as spot to surface in hiding places (including crack and crevices) (indoors);
- against cockroaches, ants, silverfishes and ticks as a surface treatment indoors;
- against ants as nest application and in surrounding areas; and
- against cat fleas, house dust mites and ticks on non-washable textile surfaces.

Human health:

MASSOCIDE T05 contains the active substance permethrin (0.5%) and no substances of concern have been identified. For the classification and labelling of the biocidal product the concentration of active substance and co-formulants in the product has been taken into account. The applicant provides an eye irritation study that has been performed using a formulation different from MASSOCIDE T05. The CA considers that there is sufficient information to read-across from the studies submitted.

According to the CAR document and BPC opinion, permethrin is not considered to have endocrine disrupting properties. After reviewing the potential ED properties of co-formulants, none of them has been identified as having potential endocrine disrupting properties.

After evaluating the exposure and characterizing the risk to human health of the product MASSOCIDE T05 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.	Mixing and loading	A **safe** situation has been identified for loading of products into a handheld duster, bulb duster or a powder container when PPEs and RMMs are used.	Professional / Trained Professional users
2.	Indoor application	A **safe** situation has been identified for spreading the powder evenly on the surfaces and making sure to treat corners, crevices and cracks when RMMs are used.	Professional / Trained Professional users
3.	Outdoor application	A **safe** situation has been identified for spreading directly the powder to the ant nests, around houses on paved ways, balconies, and terraces where ant nests are located when RMMs are used.	Professional / Trained Professional users
Combined scenarios 1 + 2	M&L + Indoor application	A **safe** situation has been identified for M&L and dusting application when RMMs are used.	Professional / Trained Professional users
Combined scenarios 1 + 2 + 3	M&L + Indoor application + Outdoor application	A **safe** situation has been identified for M&L and dusting applications when RMMs are used.	Professional / Trained Professional users
4.	Mixing and loading	A **safe** situation has been identified for loading of products into a handheld duster, bulb duster or a powder container when RMMs are used.	Non-professional users
5.	Indoor application	A **safe** situation has been identified for spreading the powder evenly on the surfaces and making sure to treat corners, crevices and cracks and over textiles when RMMs are used.	Non-professional users
6.	Outdoor application	A **safe** situation has been identified for spreading directly the powder to the ant nests, around houses on paved ways, balconies, and terraces where ant nests are located when RMMs are used.	Non-professional users
Combined scenarios 4 + 5	M&L + Indoor application	A **safe** situation has been identified for M&L and dusting application when RMMs are used.	Non-professional users
Combined scenarios 4 + 5 + 6	M&L + Indoor application + Outdoor application	A **safe** situation has been identified for M&L and dusting applications when RMMs are used.	Non-professional users
7.	Toddler playing on treated surfaces	A **safe** situation has been identified for toddler crawling over a floor after treatment when RMMs are used.	General public (toddler-chronic)
8.	Laundering	A **safe** situation has been identified for general public washing contaminated work clothes when RMMs are used.	General public
Combined scenarios 1 + 2 + 3 + 8	M&L + Indoor application + Outdoor application + Laundering	A **safe** situation has been identified for M&L, dusting applications and laundering contaminated work clothes when RMMs are used.	General public

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

Environmental risk assessment

- The risk assessment for **sewage treatment plants** indicates a safe use for the b.p.
- The risk assessment for **surface water and sediment** indicates safe use for the b.p.
- The risk assessments for **soil**, **groundwater** and **secondary poisoning** indicate safe use for the b.p.

Based on this risk assessment and on available data, the authorized uses of MASSOCIDE T05 are considered safe to the environment when the product is applied according to label instrucctions and following the proposed RMMs.

Overall conclusion

According to the assessment performed for the biocidal product MASSOCIDE T05, 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: risk mitigations measures
Use # 1 – Indoor – spot to surface in hiding places – crawling insects - cockroaches - Professionals / Trained Professionals		Professionals / Trained Professionals	10 g/m² (equivalent to 20 rotations/m^2 with the dust dispenser) If invasion persists, re-apply the product if necessary every 5 weeks.	Cover the soil with a plastic sheet before mixing and loading the biocidal product prior to application. Do not apply to areas susceptible to routine wet cleaning. Remove (clean) product and dead insects when the presence of live insects is stopped. Do not spread onto people and 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 animals. Keep out of reach of children and non-target animals/pets. Keep cats away from treated surfaces. Due to their particular sensitivity to pyrethroids, the product can cause severe adverse reactions in cats.
Use # 2 – Indoor – spot to surface in hiding places – crawling insects - cockroaches - General public (non-professional users)		General public (non-professional users)	10 g/m² (equivalent to 20 rotations/m^2 with the dust dispenser) If invasion persists, re-apply the product if necessary every 4 weeks.	

Uses	Target organisms	User categories	Authorised application rates	Use conditions: risk mitigations measures
				Use Personal Protection Equipment (PPE) for (trained) professionals users Use clean personal protective equipment in good condition. Store personal protective equipment in a clean place, away from the work area. During use, do not eat, drink or smoke. Remove and wash contaminated clothing before reuse. Provide adequate ventilation, especially in closed areas.
				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 # 3 – Outdoor – Directly application in ant nests – Professionals / Trained Professionals	Black ant (*Lasius niger)* - adults, larvae, nymphs, queen	Professionals / Trained Professionals	Apply 2.5 g maximum per nest, equivalent to 5 rotations per nest when the duster dispenser is used (10 g/m²) Repeat the treatment 1-2 times per year.	Cover the soil with a plastic sheet before mixing and loading the biocidal product prior to application.
Use # 4 – Outdoor – Directly application in ant nests – General public	Black ant (*Lasius niger)* - adults, larvae, nymphs, queen	General public (non-professional users)	The application rate is 2.5 g maximum per nest, equivalent to	Do not spread onto people and 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 animals. Keep out of reach of children and non-target animals/pets. Keep cats away from treated surfaces. Due

Uses	Target organisms	User categories	Authorised application rates	Use conditions: risk mitigations measures
(non-professional users)			5 rotations per nest (10 g/m²) Repeat the treatment 1-2 times per year.	to their particular sensitivity to pyrethroids, the product can cause severe adverse reactions in cats. **Use Personal Protection Equipment (PPE) for (trained) professionals users** Use clean personal protective equipment in good condition. Store personal protective equipment in a clean place, away from the work area. During use, do not eat, drink or smoke. Remove and wash contaminated clothing before reuse. Provide adequate ventilation, especially in closed areas.
				To avoid resistance occurrence, keep the label instructions. For resistance management avoid repeated use of products containing permethrin and alternate with products containing active substance with different mode of action and different group. 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 *Ixodes ricinus* – adults and nymphs *Rhipicephalus sanguineus* – adults and	General public (non-professional users)	10 g/m² (equivalent to 20 rotations/m^2 with the dust dispenser) This use is intended to be applied once	Do not spread onto people and 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 animals.

Uses	Target organisms	User categories	Authorised application rates	Use conditions: risk mitigations measures
	nymphs *Ctenocephalides felis* – Cat fleas - adults		per year.	Keep out of reach of children and non-target animals/pets. Keep cats away from treated surfaces. Due to their particular sensitivity to pyrethroids, the product can cause severe adverse reactions in cats. During use, do not eat, drink or smoke. Remove and wash contaminated clothing before reuse. Provide adequate ventilation, especially in closed areas. To avoid resistance occurrence, keep the label instructions. For resistance management avoid repeated use of products containing permethrin and alternate with products containing active substance with different mode of action and different group. When the infestation persists contact a (trained) professional

3 ASSESSMENT REPORT

3.1 Summary of the product assessment

3.1.1 Administrative information

3.1.1.1 Identifier of the product / product family

Identifier	Country (if relevant)
MASSOCIDE T05	Spain

3.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	COMERCIAL QUÍMICA MASSÓ S.A.
	Address	VILADOMAT 321 5ª 08029 Barcellona Spain
Authorisation number	ES/APP(NA)-2022-18-00850	
Date of the authorisation	21/12/2022	
Expiry date of the authorisation	21/12/2032	

3.1.1.3 Manufacturer(s) of the products of the family

Name of manufacturer	COMERCIAL QUÍMICA MASSÓ S.A.
Address of manufacturer	VILADOMAT 321 5ª 08029 Barcellona Spain
Location of manufacturing sites	Avda CADÍ 12-14 P.I. SANT PERE MOLANTA, 08799 OLÈRDOLA (BARCELONA) SPAIN

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

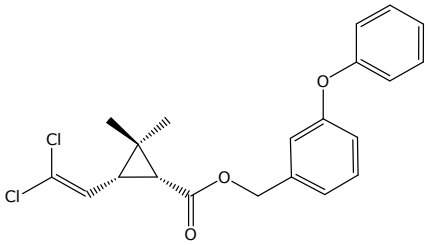
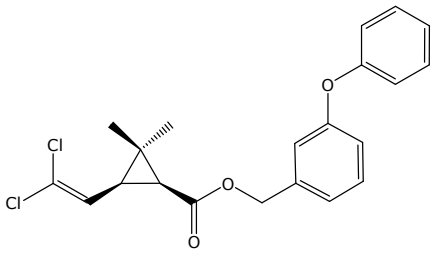
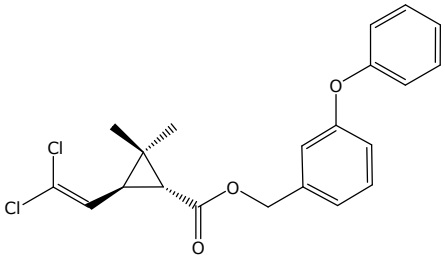
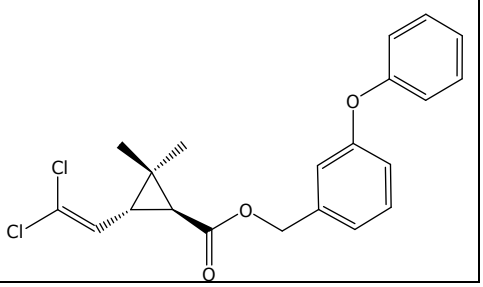
Active substance 1	Permethrin
Name of manufacturer	LIMARU NV (Acting for Tagros Chemicals India Private Limited)
Address of manufacturer	Ziepstraat,5 3680 Neetoeteren Belgium
Location of manufacturing sites	Tagros Chemicals India Limited, "Jhaver Centre", IV floor, Annamalai Building No. 72 Marshalls Road, Egmore, Chennai - 600 008, India Plant Location: A4/1&2, SIPCOT) Industrial Complex, Kudikadu Cuddalore, Tamil Nadu India

3.1.2 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 ☒

3.1.2.1 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 

3.1.2.2 Candidate(s) for substitution

There is no indication that Permethrin would fulfil the exclusion criteria specified in article 5(1), nor the substitution criteria specified in Article 10 (1) of Regulation (EU) No 528/2012.

3.1.2.3 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	0.5
For further details on product composition please refer to the Confidential PAR.					

	AS content
Formulation recipe: Content of the AS used for the formulation of the BP (%)	0.5%
AS content in the BP to be indicated in the SPC (%)	0.5%
Minimum purity in the source of the AS (%)	93%
"Minimum pure" AS content (%)	0.465%

3.1.2.4 Information on technical equivalence

The source of permethrin in MASSOCIDE T05 biocidal formulation is Tagros Chemicals India Limited, which supported permethrin inclusion into Annex I of BPD. Thus, technical equivalence is not to be addressed.

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

3.1.2.6 Type of formulation

DP – Dustable Powder

3.1.3 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 statements	H410: Very toxic to aquatic life with long lasting effects
Precautionary statements	P273 Avoid release to the environment. P391 Collect spillage. P501 Dispose of contents/container…
Note	EUH208 Contains permethrin. May produce an allergic reaction.

3.1.4 Authorised use(s)

3.1.4.1 Use description

Table 1. Use # 1 – Indoor – spot to surface in hiding places – crawling insects - cockroaches - Professionals / 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 applied by spot treatment against crawling insects in empty rooms at industrial and domestic facilities as kitchens and store rooms. It is applied in hiding places and areas as 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)
Field of use	Indoor – spot to surface in hiding places
Application method(s)	Dusting. The product is applied by dusting downwards on corners (spot treatment) and in hiding places including crack and crevices wherein the insects use to hide using the handheld duster, bulb duster or powder container.
Application rate(s) and frequency	10 g/m² (equivalent to 20 rotations/m^2 with the dust dispenser) If invasion persists, re-apply the product if necessary every 5 weeks.
Category(ies) of users	Professional / Trained Professionals users
Pack sizes and packaging material	<u>Professionals:</u> Tube/bottle, plastic (dust dispenser): 250 g, 350 g, 500 g <u>Trained Professionals:</u> Tube/bottle, plastic (dust dispenser): 250 g, 350 g, 500 g Bag, aluminium+plastic. 250 g, 500 g, 1 kg, 5 kg

	Bag (plastic) inside case (cardboard): 500 g, 1 kg, 5 kg Bag (plastic): 5 kg, 20 kg

3.1.4.1.1 Use-specific instructions for use

Do not apply to areas susceptible to routine wet cleaning.
Apply as spot in hiding places including crack and crevices where they are looking for food, paying special attention to grooves and cracks and areas behind or under machinery, kitchen equipment or pipes.
Remove (clean) product and dead insects, when the presence of live insects is stopped.
Do not use of wet cleaning procedures. Use only dry-cleaning procedures (vacuum or broom) or use damp paper. After cleaning, dispose the collected residues or the damp papers used as hazardous wastes in accordance with current regulation.

3.1.4.1.2 Use-specific risk mitigation measures

Do not apply to areas susceptible to routine wet cleaning.
Remove (clean) product and dead insects when the presence of live insects is stopped.
Cover the soil with a plastic sheet before mixing and loading the biocidal product prior to application.

3.1.4.1.3 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).

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

Trained Professional:
Empty containers, unused product, washing water, containers and other waste generated during the treatment are considered hazardous waste. Deliver those wastes to a registered establishment or undertaking, 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.

Professional:
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.

3.1.4.1.5 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).

3.1.4.2 Use description

Table 2. Use # 2 – Indoor – spot to surface in hiding places – crawling insects - cockroaches - 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 a ready-to-use product to be dusted over at domestic facilities as kitchens and store rooms. It is applied in hiding places and areas as 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)
Field of use	Indoor – spot to surface in hiding places
Application method(s)	Dusting. The product is applied by dusting downwards on corners (spot treatment) and in hiding places (including crack and crevices) wherein the insects use to hide using the powder container.
Application rate(s) and frequency	10 g/m² (equivalent to 20 rotations/m^2 with the dust dispenser) If invasion persists, re-apply the product if necessary every 4 weeks.
Category(ies) of users	General public (non- professional users)
Pack sizes and packaging material	Tube/bottle plastic: Tube/bottle, plastic (dust dispenser): 250 g, 350 g, 500 g

3.1.4.2.1 Use-specific instructions for use

Do not apply to areas susceptible to routine wet cleaning. Apply as spot in hiding places including crack and crevices where they are looking for food, paying special attention to grooves and cracks and areas behind or under machinery, kitchen equipment or pipes. Remove (clean) product and dead insects, when the presence of live insects is stopped. **Do not use of wet cleaning procedures. Use only dry-cleaning procedures (vacuum or broom) or use damp paper. After cleaning, dispose the collected residues or the damp papers used as hazardous wastes in accordance with current regulation.**

3.1.4.2.2 Use-specific risk mitigation measures

Do not apply to areas susceptible to routine wet cleaning. Remove (clean) product and dead insects when the presence of live insects is stopped. Because 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. To this aim 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."

3.1.4.2.3 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).

3.1.4.2.4 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.

3.1.4.2.5 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).

3.1.4.3 Use description

Table 3. Use # 3 – Outdoor – Directly application in ant nests – Professionals / 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 dusted directly into the ant 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)	Dusting
Application rate(s) and frequency	Apply 2.5 g maximum per nest (in 0.25 m^2, , e.g. 50cm*50cm), equivalent to 5 rotations per nest when the duster dispenser is used (application rate: 10 g/m^2) Repeat the treatment 1-2 times per year.
Category(ies) of users	Professional / Trained Professionals users

Pack sizes and packaging material	Professional: Tube/bottle, plastic (dust dispenser): 250 g, 350 g, 500 g Trained Professionals: Tube/bottle, plastic (dust dispensder): 250 g, 350 g, 500 g Bag, aluminium+plastic. 250 g, 500 g, 1 kg, 5 kg Bag (plastic) inside case (cardboard): 500 g, 1 kg, 5 kg Bag (plastic): 5 kg, 20 kg

3.1.4.3.1 Use-specific instructions for use

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

3.1.4.3.2 Use-specific risk mitigation measures

Cover the soil with a plastic sheet before mixing and loading the biocidal product prior to application.

3.1.4.3.3 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)

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

Professional: 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. Trained Professional: Empty containers, unused product, washing water, containers and other waste generated during the treatment are considered hazardous waste. Deliver those wastes to a registered establishment or undertaking, 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.

3.1.4.3.5 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)

3.1.4.4 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 dusted directly into the ant 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)	Dusting
Application rate(s) and frequency	The application rate is 2.5 g maximum per nest (in 0.25 m^2, e.g. 50cm*50cm), equivalent to 5 rotations per nest (application rate: 10 g/m^2) Repeat the treatment 1-2 times per year.
Category(ies) of users	General public (non- professional users)
Pack sizes and packaging material	Tube/bottle , plastic. (dust dispenser): 250 g, 350 g, 500 g

3.1.4.4.1 Use-specific instructions for use

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

3.1.4.4.2 Use-specific risk mitigation measures

Because 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. To this aim 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.

3.1.4.4.3 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)

3.1.4.4.4 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 into soil, ground, surface water or any kind of sewer.

3.1.4.4.5 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)

3.1.4.5 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 as mattresses, blankets, bedspreads, bedsteads, pillows, carpets, moquette…
Target organism (including development stage)	*Dermatophagoides pteronyssinus* – adults and nymphs *Ixodes ricinus* – adults and nymphs *Rhipicephalus sanguineus* – adults and nymphs *Ctenocephalides felis* – Cat fleas - adults
Field of use	Indoors – non-washable textile surfaces (surface treatment)
Application method(s)	Dusting The product is a ready-to-use product to be dusted over the mattresses, carpet, moquette,… directly from the ready-to-use powder container. Once the efficacy time is over keep the product up to 24 h maximum and after that, the treated surface must be vacuumed with the vacuum cleaner in order to release killed insects and product's residue.
Application rate(s) and frequency	10 g/m² (equivalent to 20 rotations/m^2 with the dust dispenser) This use is intended to be applied once per year.
Category(ies) of users	General public (non- professional users)
Pack sizes and packaging material	Tube/bottle , plastic. (dust dispenser): 250 g, 350 g, 500 g

3.1.4.5.1 Use-specific instructions for use

Apply to infested rugs paying special attention to edges and wall-to-wall rugs. Do not use of wet cleaning procedures. Use only dry-cleaning procedures (vacuum or broom) or use damp paper. After cleaning, dispose the collected residues or the damp papers used as hazardous wastes in accordance with current regulation.

3.1.4.5.2 Use-specific risk mitigation measures

Because 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. To this aim 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."

3.1.4.5.3 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)

3.1.4.5.4 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.

3.1.4.5.5 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)

3.1.5 General directions for use

3.1.5.1 Instructions for use

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

The product should be applied at 10 g/m².

For non-professionals equivalent to spread the surface during 20 rotations /m^2 (spot to surface in hiding places and non-washable textile surfaces) or 5 rotations (ant nest) when using dust dispenser For other application devices, fill the required quantity using the dossage spoon.

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

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

3.1.5.2 Risk mitigation measures

Do not spread onto people and 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 animals.

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

Use Personal Protection Equipment (PPE) for (trained) professional users

Use clean personal protective equipment in good condition.

Store personal protective equipment in a clean place, away from the work area.

During use, do not eat, drink or smoke. Remove and wash contaminated clothing before reuse. Provide adequate ventilation, especially in closed areas.

Hand protection: wear protective chemical resistant gloves (glove material to be specified by the authorization holder within the product information)

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

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.

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

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

Emergency measures to protect the environment:

- Avoid to contaminate soil/ groundwater .
- Prevent spills into surface water or the drainage system.
- 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 current legislation.

3.1.5.4 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.

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

Shelf life: 3 years.
Store in the original container in dry, well-ventilated place.
Store original container tightly closed. Keep away from sun radiation and all other heat sources.
Keep out of reach of children and non-target animals/pets.
Store away from food, drink and animal feedstuffs.

3.1.6 Other information

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.

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

3.1.7 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)
Tube / Bottle	250 g, 350 g, 500 g	plastic	Dust dispender	Professional / Trained professional / Non-professional	Yes
Bag inside case	500 g, 1 kg, 5 kg	plastic + cardboard	-	Trained professional	Yes
Bag	250 g, 500 g, 1 kg, 5 kg	aluminium and plastic	-	Trained professional	Yes
Bag	5 kg, 20 kg	plastic	-	Trained professional	Yes

3.1.8 Documentation

3.1.8.1 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.

3.1.8.2 Access to documentation

The applicant Comercial Química Massó S.A. has submitted a letter of access by Limaru NV (Belgium) (Acting for Tagros Chemicals India Private Limited), supplier of active substance Permethrin included in Article 95 list, for all data of active substance permethrin in support for the registration of the product MASSOCIDE T05 containing permethrin.

The applicant Comercial Química Massó S.A. submit a letter of access by Copyr and Zelnova for some efficacy, physical chemical and (eco)toxicity data on the formulation Permethrin 0.5% Dust in support for the registration of the product MASSOCIDE T05 containing permethrin.

3.2 Assessment of the biocidal product

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

Table 1. 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 applied by spot treatment against crawling insects in empty rooms at industrial and domestic facilities as kitchens and store rooms. It is applied in hiding places and areas as 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) *Ixodes ricinus* – Ticks (adult + nymphs) *Rhipicephalus sanguineus* – Ticks (adult + nymphs) *Acarus siro* (flour mite) – adults *Ctenocephalides felis* – Cat fleas (adults + larvae)
Field of use	Indoor – voids/cavities treatment
Application method(s)	Dusting. The product is applied by dusting downwards on voids/cavities and particularly the corners (spot treatment) wherein the insects use to hide using handheld duster, bulb duster or powder container
Application rate(s) and frequency	App. Rate: 10 g/m² (RTU product, dilution is not applicable) Be aware for re-invasion and re-apply the product if necessary, every 5 weeks.
Category(ies) of users	Professional (trained and non-trained professional)
Pack sizes and packaging material	Tube/bottle , plastic. >= 50 g - <= 5kg Bag, aluminium+plastic. >= 50 g - <= 25 Kg Bag (plastic) inside case (cardboard). >= 50 g - <= 25 Kg

Table 2. 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 applied by spot treatment against crawling insects in empty rooms at industrial and domestic facilities as kitchens and store rooms. It is applied in hiding places and areas as 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) *Ixodes ricinus* – Ticks (adult + nymphs) *Rhipicephalus sanguineus* – Ticks (adult + nymphs) *Acarus siro* - Flour mite (adults) *Ctenocephalides felis* – Cat fleas (adults + larvae)
Field of use	Indoor – voids/cavities treatment
Application method(s)	Dusting. The product is applied by dusting downwards on voids/cavities and particularly the corners (spot treatment) wherein the insects use to hide using handheld duster, bulb duster or powder container
Application rate(s) and frequency	App. Rate: 10 g/m² (RTU product, dilution is not applicable) This application rate is equivalent to 20 rotations/m² when using dust dispenser. Be aware for re-invasion and re-apply the product if necessary every 4 weeks.
Category(ies) of users	General public (non-Professional)
Pack sizes and packaging material	Bag, plastic. <= 500 g Bag, aluminium+plastic. <= 500 g Tube/bottle, plastic. <= 500 g (dust dispenser)

Table 3. 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 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)	Dusting The product is a RTU product to be dusted over the mattresses, carpet, moquette,… directly from the ready-to-use powder container. Once the efficacy time is over keep the product up to 24 h maximum and after that, the treated surface must be vacuumed with the vacuum cleaner in order to release killed insects and product's residue.
Application rate(s) and frequency	App. Rate: 10 g/m² (RTU product, dilution is not applicable) This application rate is equivalent to 20 rotations/m². This use is intended to be applied once per year or in those cases where infestation exists. It is no usually to apply more than two times per year.
Category(ies) of users	General public (non-Professional)

Pack sizes and packaging material	Bag, plastic. <= 500 g Bag, aluminium+plastic. <= 500 g Tube/ bottle, plastic. <= 500 g

Table 4. 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 dusted 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)	Dusting
Application rate(s) and frequency	App. Rate: 10 g/m² (RTU product, dilution is not applicable) Apply 2.5 g maximum per nest. Repeat the treatment 1-2 times per year.
Category(ies) of users	Professional (Trained and non-trained professional)
Pack sizes and packaging material	Tube/bottles , plastic. >= 50 g - <= 5 Kg Bag, aluminium+plastic. >= 50 g - <= 25 Kg Bag (plastic) inside case (cardboard). >= 50 g - <= 25 Kg

Table 5. 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 dusted 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)	Dusting
Application rate(s) and frequency	App. Rate: 10 g/m² (RTU product, dilution is not applicable) The application rate is 2.5 g maximum per nest, equivalent to 5 rotation per nest. Repeat the treatment 1-2 times per year.
Category(ies) of users	General public (non-Professional)
Pack sizes and packaging material	Bag, plastic. <= 500 g Bag, aluminium+plastic. <= 500 g Tube/ bottle, plastic. <= 500 g

Table 6. Use # 6 – Outdoor – Around paved and rain protected areas of buildings – 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 intended to be applied around buildings on small surfaces as spots and crack and crevice paved surfaces where insects stay or wander around. These intended locations to be treated must be located on places protected to the rain, floods and cleaning water.
Target organism (including development stage)	*Blattella germanica* – Cockroaches (adult + nymphs) *Blatta orientalis* – Cockroaches (adult + nymphs) *Lasius niger* – Ants (adult, larvae, nymphs and queen) *Dermatophagoides pteronyssinus* – Mites (adult) *Ixodes ricinus* – Ticks (adult + nymphs) *Rhipicephalus sanguineus* – Ticks (adult + nymphs) *Lepisma saccharina* – Silverfish (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)	Dusting
Application rate(s) and frequency	App. Rate: 10 g/m² (RTU product, dilution is not applicable) Up to 2 applications per year. This use is intended to be applied only summer season where insect infestations are more common.
Category(ies) of users	Professional (trained and non-trained)
Pack sizes and packaging material	Tube/bottle, plastic. >= 50 g - <= 5 Kg Bag, aluminium+plastic. >= 50 g - <= 25 Kg Bag (plastic) inside case (cardboard). >= 50 g - <= 25 Kg

Table 7. Use # 7 – Outdoor –Around paved and rain protected buildings – 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 intended to be applied around buildings on small surfaces as spots and crack and crevice paved surfaces where insects stay or wander around. These intended locations to be treated must be located on places protected to the rain, floods and cleaning water.
Target organism (including development stage)	*Blattella germanica* – Cockroaches (adult + nymphs) *Blatta orientalis* – Cockroaches (adult + nymphs) *Lasius niger* – Ants (adult, larvae, nymphs and queen) *Dermatophagoides pteronyssinus* – Mites (adult) *Ixodes ricinus* – Ticks (adult + nymphs) *Rhipicephalus sanguineus* – Ticks (adult + nymphs) *Lepisma saccharina* – Silverfish (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)	Dusting
Application rate(s) and frequency	App. Rate: 10 g/m² (RTU product, dilution is not applicable) (equivalent to 20 rotations/m² with the dust dispenser)

	Up to 2 applications per year. This use is intended to be applied only summer season where insect infestations are more common.
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	Bag, plastic. <= 500 g Bag, aluminium+plastic. <= 500 g Tube/ bottle, plastic. <= 500 g

3.2.2 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	Massocide T05: 0.5 % w/w Batch: 010216	Initially: Solid (Powder)	Brioschi, M. CH-111/2016
		Massocide T05: 0.5 % w/w Batch: 010216	After 14 days at 54ºC: Solid (Powder)	Brioschi, M. CH-114/2016
		Permetrina Dust 0.5 % w/w Batch: LAB20150909A	Initially: Solid (Powder)	Brioschi, M. CH-613/2015
		Permetrina Dust 0.5 % w/w Batch: LAB20150909A	After 14 days at 54ºC: Solid (Powder)	Brioschi, M. CH-616/2015
		Permetrina Dust 0.5 % w/w Batch: LAB20150909A.	After 3 years at ambient wharehouse temperature: Solid (Powder)	Brioschi, M. CH-617/2015
		Permetrina Dust 0.5 % w/w Batch: Lab160112.	Initially and after 3 years at ambient wharehouse temperature: Solid (Powder)	Brioschi, M. CH-035/2016
Colour at 20 °C and 101.3 kPa	EPA OPPTS 830.6303	Massocide T05: 0.5 % w/w Batch: 010216	Initially: White	Brioschi, M. CH-111/2016
		Massocide T05: 0.5 % w/w Batch: 010216	After 14 days at 54ºC: White	Brioschi, M. CH-114/2016
		Permetrina Dust 0.5 % w/w Batch: LAB20150909A	Initially: White	Brioschi, M. CH-613/2015
		Permetrina Dust 0.5 % w/w Batch: LAB20150909A	After 14 days at 54ºC: White	Brioschi, M. CH-616/2015
		Permetrina Dust 0.5 % w/w Batch: LAB20150909A.	After 3 years at ambient wharehouse temperature: White	Brioschi, M. CH-617/2015
		Permetrina Dust 0.5 % w/w Batch: Lab160112.	Initially: White After 3 years at ambient wharehouse temperature: White	Brioschi, M. CH-035/2016

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
Odour at 20 °C and 101.3 kPa	EPA OPPTS 830.6304	Massocide T05: 0.5 % w/w Batch: 010216	Initially: Characteristic odour	Brioschi, M. CH-111/2016
		Massocide T05: 0.5 % w/w Batch: 010216	After 14 days at 54ºC: Characteristic odour	Brioschi, M. CH-114/2016
		Permetrina Dust 0.5 % w/w Batch: LAB20150909A.	Initially: Characteristic odour	Brioschi, M. CH-613/2015
		Permetrina Dust 0.5 % w/w Batch: LAB20150909A	After 14 days at 54ºC: Characteristic odour	Brioschi, M. CH-616/2015
		Permetrina Dust 0.5 % w/w Batch: LAB20150909A.	After 3 years at ambient wharehouse temperature: Characteristic odour	Brioschi, M. CH-617/2015
		Permetrina Dust 0.5 % w/w Batch: Lab160112.	Initially and after 3 years at ambient wharehouse temperature: Characteristic odour	Brioschi, M. CH-035/2016
Acidity / alkalinity	-	-	Not applicable.	-
Relative density / bulk density	CIPAC MT 186	Massocide T05: 0.5 % w/w Batch: 010216	Pour density: 0.71g/mL bulk density: 0.94g/mL	Brioschi, M. CH-111/2016
Storage stability test – **accelerated storage**	CIPAC MT 46.3	Permetrina Dust 0.5 % w/w Batch: LAB20150909A	The product is stable after 14 days at 54°C in a PE bottle with a screw cap.	Brioschi, M. CH-616/2015
Active substance content	HPLC-UV		Initially: Sum: 0.53±0.01% w/w Cis: 0.14±0.01% w/w Trans: 0.39±0.01% w/w	
			After 2 weaks at 54ºC: Sum: 0.52±0.01% w/w Cis: 0.14±0.01% w/w Trans: 0.38±0.01% w/w Differences: Sum: -1.89 % w/w Cis: 0.00 % w/w Trans: -2.56 % w/w	Brioschi, M. CH-616/2015
Homogeneity of application			Not available.	Brioschi, M. CH-616/2015
Appearance and stability of the package			No changes were observed.	Brioschi, M. CH-616/2015

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
Storage stability test – **accelerated storage**	CIPAC MT 46.3	Massocide T05: 0.5 % w/w Batch: 010216	The product is stable after 14 days at 54°C in a plastic bottle with a screw cup.	Brioschi, M. CH-114/2016
Active substance content	HPLC-UV		<u>Initially:</u> Sum: 0.50±0.01% w/w Cis: 0.11±0.01% w/w Trans: 0.39±0.01% w/w <u>After 2 weaks at 54ºC:</u> Sum: 0.50±0.01% w/w Cis: 0.12±0.01% w/w Trans: 0.38±0.01% w/w Differences: Sum: 0.00 % w/w Cis: 9,09 % w/w Trans: -2.56 % w/w	
Homogeneity of application			Not available.	
Appearance and stability of the package			No changes were observed.	
Storage stability test – **long term storage at ambient temperature**	GIFAP Monograph No. 17	Permetrina Dust 0.5 % w/w Batch: LAB20150909A.	The product is stable after 3 years at ambient wharehouse temperature packed in a PE bottle with a screw cap.	Brioschi, M. CH-617/2015
Active substance content	HPLC-UV		<u>Initially:</u> Sum: 0.53±0.01% w/w Cis: 0.14±0.01% w/w Trans: 0.39±0.01% w/w	CH-615/2015
			<u>After 3 year at ambient wharehouse temperature:</u> Sum: 0.54±0.01% w/w Cis: 0.14±0.01 % w/w Trans: 0.40±0.01 % w/w Differences: Sum: 1.89 % w/w Cis: 0.00 % w/w Trans: 2.56 % w/w	Brioschi, M. CH-617/2015
Homogeneity of application			Not available.	Brioschi, M. CH-617/2015

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
Appearance and stability of the package			No changes were observed.	Brioschi, M. CH-617/2015
Storage stability test – **long term storage at ambient temperature**	GIFAP Monograph No. 17 (Stacked test)	Permetrina Dust 0.5 % w/w Batch: Lab160112.	The product is stable after 36 months at ambient wharehouse temperature packed in 1 kg plastic laminated bag.	Brioschi, M. CH-035/2016
Active substance content	HPLC-UV		Initially: Sum: 0.52±0.01% w/w Cis: 0.10±0.01 % w/w Trans: 0.43±0.01% w/w After 3 years at ambient wharehouse temperature: Sum: 0.52±0.01% w/w Cis: 0.10±0.01 % w/w Trans: 0.43±0.01% w/w Differences: Sum: 0.00 % w/w Cis: 0.00 % w/w Trans: 0.00 % w/w	
Homogeneity of application			Not available.	
Appearance and stability of the package			No changes were observed.	
Storage stability test – **low temperature stability test for liquids**		-	Not applicable.	-
Effects on content of the active substance and technical characteristics of the biocidal product - **light**		-	Not applicable.	

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**			No changes were observed.	Brioschi, M. CH-616/2015 CH-617/2015 CH-035/2016
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**			No changes were observed.	Brioschi, M. CH-616/2015 CH-617/2015 CH-035/2016
Wettability			Not applicable.	-
Suspensibility, spontaneity and dispersion stability			Not applicable.	-
Wet sieve analysis and dry sieve test			Not required.	-
Emulsifiability, re-emulsifiability and emulsion stability			Not applicable.	-
Disintegration time			Not applicable.	
Particle size distribution, content of dust/fines, attrition, friability	CIPAC MT 187	Massocide T05: 0.5 % w/w Batch: 010216	<u>Initially:</u> Dv 10: 2.04 µm Dv 50: 5.89 µm Dv 90: 20.6 µm % > 50 µm: 94.01 % < 75 µm: 1.97	Brioschi, M. CH-111/2016
		Massocide T05: 0.5 % w/w Batch: 010216	<u>After 14 days at 54ºC:</u> Dv 10: 2.01 µm Dv 50: 5.83 µm Dv 90: 19.3 µm % > 50 µm: 94.27 % < 75 µm: 1.72	Brioschi, M. CH-114/2016

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
		Permetrina Dust 0.5 % w/w Batch: LAB20150909A.	Initially: Dv 10: 4.98 µm Dv 50: 11.3 µm Dv 90: 24.4 µm % > 50 µm: 100.00 % < 75 µm: 0.00	Brioschi, M. CH-613/2015
		Permetrina Dust 0.5 % w/w Batch: LAB20150909A	After 14 days at 54ºC: Dv 10: 4.19 µm Dv 50: 10.4 µm Dv 90: 25.5 µm % > 50 µm: 99.94 % < 75 µm: 0.00	Brioschi, M. CH-616/2015
		Permetrina Dust 0.5 % w/w Batch: LAB20150909A.	After 3 years at ambient wharehouse temperature: Dv 10: 2.21 µm Dv 50: 9.26 µm Dv 90: 27.8 µm % > 50 µm: 98.38 % < 75 µm: 0.00	Brioschi, M. CH-617/2015
		Permetrina Dust 0.5 % w/w Batch: Lab160112.	Initially: Dv 10: 2.51 µm Dv 50: 9.18 µm Dv 90: 24.9 µm % > 50 µm: 99.71 % < 75 µm: 0.00 After 3 years at ambient wharehouse temperature: Dv 10: 2.54 µm Dv 50: 9.71 µm Dv 90: 28.7 µm % > 50 µm: 96.39 % < 75 µm: 1.14	Brioschi, M. CH-035/2016
Persistent foaming			Not applicable.	-
Flowability/Pourability/Dustability			Not required.	
Burning rate — smoke generators			Not applicable.	
Burning completeness — smoke generators			Not applicable.	
Composition of smoke — smoke generators			Not applicable.	
Spraying pattern — aerosols			Not applicable.	

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
Physical compatibility			Not applicable.	
Chemical compatibility			Not applicable.	
Degree of dissolution and dilution stability			Not applicable.	-
Surface tension			Not applicable.	-
Viscosity			Not applicable.	-

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

NOTE:
The applicant has noted that the Accelerated Stability and Physical & Chemical Properties have been studied for Massocide T05 to find the same results of Permetrina dust 0,5%.

Appearance
The product is a white solid (powder) with a characteristic odour.

Acidity / alkalinity
The pH is determined previous dilution in water at a 1% concentration (9.6). Therefore, The test are not required for a ready to use dust formulation since the pH value ranged from 4 to 10.

Relative density
The relative density was measured using CIPAC method MT 186.

Accelerated storage
Study CH-616/2015: The container didn't present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena. No significant changes in particle size distribution was found in the formulation stored in PE bottle with a screw cap for 14 days of storage at 54°C.
Study CH-114/2016: After 14 days at 54ºC the permethrin active ingridient content and the physical-chemical properties of the test item are comparable to the relevant values obtained in the initial charaterisation.

Long term storage at ambient temperature
Study CH-617/2015: No change in the sample appearance, colour, odour and weight variation was found for the test item stored in PE bottle with a screw cap for 36 months of storage under ambient warehouse temperature conditions, and no variation was found in colour or in either the internal or external configuration, or loss of sample or evident corrosion phenomena of packaging.
Study CH-035/2016: No change in the sample appearance, colour, odour and weight variation was found for the test item stored in plastic laminated bags for 36 months of storage under ambient warehouse temperature conditions, and no variation was found in colour or in either the internal or external configuration, or loss of sample or evident corrosion phenomena of packaging.

Low temperature stability test for liquids
The study does not need to be conducted because the formulation is a ready-to-use powder.

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.

Effects of temperature and humidity
The product is not affected by temperature and humidity after storage studies.

Effects of reactivity towards container material
The product is not affected by reactivity towards container material after storage studies.

Technical characteristics of the biocidal
Particle size distribution: no changes were observed after storage studies. About 98% particles have a diameter lower than 75 µm, thus no additional information on the separation of the active substance from the carrier is required (trigger value >5%).
Dry sieve test: data from the particle size distribution can be used. No particular device should be used as the product is a ready-to-use and will be used directly from the packaging.
Dustability: the study does not need to be conducted because the formulation is a ready-to-use powder.
For the application of the product, the following characteristics are not relevant: wettability, suspensibility, emulsifiability, persistent foaming and other technical characteristics. The studies do not need to be conducted because the formulation is powder.

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 study does not need to be conducted because the formulation is a ready-to-use powder.

Viscosity
The study does not need to be conducted because the formulation is a ready-to-use powder.

Conclusions
The preparation MASSOCIDE T05 is a white solid (powder) with a characteristic odour, containing 0.5 % w/w of permethrtin. Its bulk density is 0.94 g/mL and its pH is 9.6.
There is no effect at high temperature on the stability of the formulation, since neither the active ingredient content nor the technical properties were changed.
No significant changes in particle size distribution was found for the tests item stored in both packagings.
After storage at 54°C for 14 days, the test items did not show any significant difference in terms of active ingredient content, aspect and particle size, respect the initial conditions. Thus the test items can be considered stable and a shelf life of two years is proposed.
Moreover, two storage stability studies at ambient temperature are finished and from the obtained results it can be concluded that no significant change was found in the Permethrin active ingredient content for the samples stored in plastic laminated bags and in PE bottle with a screw cap for 36 months of storage under ambient warehouse temperature conditions, comparing the obtained results at the beginning of the storage stability, that it complies with the tolerance and it is in accordance with the declared value.
Therefore, noting the same behaviour in the accelerated storage studies for both products, a self life of three years could be deemed for the biocidal product MASSOCIDE T05.

3.2.3 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)	Massocide T05: 0.5 % w/w Batch: 010216	Should not exhibit explosive properties	Brioschi, M. CH-112/2016
Flammable gases			Not applicable.	
Flammable aerosols			Not applicable.	
Oxidising gases			Not applicable.	
Gases under pressure			Not applicable.	
Flammable liquids			Not applicable.	
Flammable solids	EC 440/2008 No. A.10	Massocide T05: 0.5 % w/w Batch: 010216	Not highly flammable	Brioschi, M. CH-111/2016
Self-reactive substances and mixtures			Not applicable.	
Pyrophoric liquids			Not applicable.	
Pyrophoric solids			Not applicable.	
Self-heating substances and mixtures			Not applicable.	
Substances and mixtures which in contact with water emit flammable gases			Not applicable.	
Oxidising liquids			Not applicable.	
Oxidising solids	CHETAH software (Chemical Thermodynamic And Hazard evaluation)	Massocide T05: 0.5 % w/w Batch: 010216	Should not exhibit an oxidizing behaviour	Brioschi, M. CH-112/2016
Organic peroxides			Not applicable.	
Corrosive to metals			Not applicable.	
Auto-ignition temperatures of products (liquids and gases)			Not applicable.	
Relative self-ignition temperature for solids	EU Method A.16	Massocide T05: 0.5 % w/w Batch: 010216	>400°C at 1010 mbar	Mazzei N., 2015, 156
Dust explosion hazard			Not applicable.	

Conclusion on the physical hazards and respective characteristics of the product
Explosives

From the criteria results obtained with CHETAH software based on the molecular structure of the active ingredient and main co-formulant of the test item, it can be concluded that the Massocide T05 sample should not exhibit an explosive behaviour.

Flammability
Two preliminary test were performed and the same sample behaviour was observed. The test item, a white powder, did not ignite when Bunsen burner flame came close. Since test item did not propagate combustion, no further testing was required.
From the obtained experimental data according to the A.10 method in Council Regulation (EC) No 440/2008 of 30 May 2008, it can be concluded that the MASSOCIDE T05 sample is not highly flammable substance.

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

Pyrophoric solids
The study does not need to be conducted because experience in manufacture or handling shows that the product does not ignite spontaneously on coming into contact with air at normal temperatures and hence, the classification procedure does not need to be applied.

Self-heating substances and mixtures
EEC Method A.16 is not strictly comparable to "UN Test N.4" as specified in the BPR and CLP guidances; however, given that the sample did not exhibit any signs of self-ignition during heating to 400 °C it can be considered unlikely that self-ignition will occur at temperatures of 140 °C used in UN Test N.4. Therefore, the classification procedure does not need to be applied.

Substances and mixtures which in contact with water emit flammable gases
The study does not need to be conducted because experience in handling and use shows that the substance or mixture does not react with water.

Oxidising properties
From the criteria results obtained with CHETAH software based on the molecular structure of the active ingredient and main co-formulant of the test item, it can be concluded that the MASSOCIDE T05 sample should not exhibit an oxidizing behaviour.

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
The study does not need to be conducted because the formulation is a powder without self-ignition properties.

Relative self-ignition temperature for solids
According to method A.16 the sample labelled as Massocide T05 was found not to have a relative self-ignition temperature bellow 400°C.

Dust explosion hazard

The study does not need to be conducted because the test item has no explosive properties as neither the active ingredient nor other components, did not contain any "plosophore" grouping.

Conclusions
The product MASSOCIDE T05 is not expected to present a significant hazard for explosive and oxidising properties, corrosion and auto-flammability.

3.2.4 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: sum of isomers	HPLC-UV	75 % of the nominal concentration of active ingredient / 2	78.8 – 315.2 μg/mL (±60% of the nominal concentration in sample solutions) $y = 137996x + 45785$ $r^2 = 0.9996$ (n = 5)	Any interference from other substances present in the preparation not be more than 3 % to the total peak area measured for each substance.	100.35-100.54	100.4	1.04	--	Brioschi, M. 2016 CH-113/2016
		100 % of the nominal concentration of active ingredient / 2			98.24-100.43	99.3			
		125 % of the nominal concentration of active ingredient / 2			98.93-98.12	98.5			
Permethrin: sum of isomers	HPLC-UV	75 % of the nominal concentration of active ingredient / 2	118.5 – 276.6 μg/mL (±40% of the nominal concentration in sample solutions) $y = 150119x - 367662$ $r^2 = 0.99985$ (n = 5)	Any interference from other substances present in the preparation not be more than 3 % to the total peak area measured for each substance.	98.71-98.26	98.5	0.84		Brioschi, M. 2015 CH-615/2015
		100 % of the nominal concentration of active ingredient / 2			98.43-97.26	97.8			
		125 % of the nominal concentration of active ingredient / 2			99.33-97.31	98.3			
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	A.R.(addendum 2016)

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		
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 1R-trans Permethrin (R,S) 1.91 %w - 12.8 %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) 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)	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% 1S-trans Permethrin (S,R) 97.5 – 99.5% 1R-trans Permethrin (R,S) 96.6 – 99.1%	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 % 1R-cis Permethrin (R,R) (n = 2) Recovery level (0.69 %w): 98.6 % Recovery level (2.30	Six samples (single injection) from 1 batch – 1S-cis Permethrin (S,S): 0.46 %. 1R-cis Permethrin (R,R): 0.41 % 1S-trans Permethrin (S,R): 0.34 % 1R-trans Permethrin (R,S): 0.62 %	Not applicable	A.R.(addendum 2016)

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		
						%w): 99.5 % Recovery level (4.59 %w):98.2% <u>1S-trans Permethrin (S,R) (n = 2)</u> Recovery level (1.93 %w): 97.5 % Recovery level (6.43 %w): 99.5 % Recovery level (12.9 %w): 98.1 % <u>1R-trans Permethrin (R,S) (n = 2)</u> Recovery level (1.91 %w): 96.6 %			

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 (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 1R-trans Permethrin (R,S) 2.72 %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% 1R-trans Permethrin (R,S) 99.4 – 101.0%	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 %	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 % 1R-trans Permethrin	Not applicable	A.R.(addendum 2016)

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		
						<u>1R-cis Permethrin (R,R)</u> Recovery level (0.98% w/w): 98.0 % Recovery level (3.26%): 100.8 % Recovery level (6.52%): 101.4 % <u>1S-trans Permethrin (S,R)</u> Recovery level (2.74%): 99.3 % Recovery level (9.13%): 100.9 % Recovery level (18.3% w/w): 100.8 %	(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		
						1R-trans Permethrin (R,S) Recovery level (2.72% w/w): 99.4 % Recovery level (9.05% w/w): 101.0 % Recovery level (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	No data provided	No data provided	No data provided	Not applicable	A.R.(addendum 2016)

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		
				or higher number of common co-formulants found in wood preservatives					
Impurities in Permethrin	GC-FID, HPLC-UV, and GC-MS								A. R. (2014)
* 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)	No signals / peaks interfering with	70-110		<20	5.0 µg/kg	A. R. (2014)

			r > 0.9992	the detection of the analyte were observed in extracts of untreated blank control specimens.					

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	A. R. (2014)
	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	A. R. (2014)

Analytical methods for animal and human body fluids and tissues									
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 identificationof the product
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 methods submitted by the applicant for analysing the active substance in the biocidal product can 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 tissues** 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 analitycal methods tested were found to be validated according to the SANCO guideline, therefore it is considered acceptable for the determination of the active substance permethrin in the test material. No other substances of concern are present in the biocidal product MASSOCIDE T05 except for the active ingredients. Thus no further method is required either for the determination of the co-formulants in the biocidal product or for monitoring. All methods submitted are considered fully validated and useful for the purpose.

3.2.5 Efficacy against target organisms

3.2.5.1 Function and field of use

Main group 03: Pest control

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

The biocidal product MASSOCIDE T05 is a dust preparation to be used against cockroaches, silverfishes, ants and ticks 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.

3.2.5.2 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), as spot application in hiding places (including crack and crevices) indoors.

-cockroaches (*Blatella germanica* and *Blatta orientalis*, adults and nymphs), ants (*Lasius niger*, adults), silverfishes (*Lepisma saccharina*, adults) and ticks (*Ixodes ricinus* and *Rhipicephalus sanguineus*, adults and nymphs) as a surface application 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.

3.2.5.3 Effects on target organisms, including unacceptable suffering

MASSOCIDE T05 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.

3.2.5.4 Mode of action, including time delay

MASSOCIDE T05 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.

3.2.5.1 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 DUST 0.5%	*Blatta orientalis*, adults	Laboratory test: Residual efficacy According to TNsG 18-19	Non- porous (ceramic tile - side up) and porous surfaces (ceramic tile - side down) 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 (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 groups). Application rate: 10 g/m^2	<u>Non-porous surfaces:</u> T0, T1 and T2: 100% knockdown (25 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: 96 % knockdown (25 minutes) and 100% knockdown (30 minutes) T1: 96 % knockdown (35 minutes) and 100% knockdown (50 minutes) T2: 88% knockdown (60 minutes) T3: 92% knockdown (50 minutes) and 96% knockdown (60 minutes) Mortality (T0, T1, T2 and T3, after 24 hours): 100% Controls: 0% knockdown, 0% mortality **The efficacy is demonstrated against *Blatta orientalis* (adults) until 3 weeks on porous and non-porous surfaces in laboratory conditions at the application rate of 10 g/m^2.**	Test report: CHEPED011015 – 01 See confidential annex
Insecticide	Indoors	MASSOCIDE T05	*Blatta orientalis,* adults	Laboratory test: Residual efficacy According to TNsG 18-19	Non- porous (ceramic tile - side up) surfaces were treated with the product. Temperature: 25±1°C Relative humidity: 60±5%.	<u>Non-porous surfaces:</u> T0: 100% knockdown (50 minutes) T1: 90% knockdown (60 minutes) T2: 92% knockdown (50 minutes) and 100% knockdown (60 minutes) T3: 94% knockdown (60 minutes) Mortality (T0, T1, T2 and T3, after 24 hours): 100%	Test report: CHET 05071215 -01 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**
					Knockdown (2, 5, 7, 10, 15, 20, 25, 30, 35, 40, 50 and 60 minutes) and mortality (24 hours) were assessed after treatment (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: 10 g/m^2	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 10 g/m^2.**	
Insecticide	Indoors	PERMETRINA DUST 0.5%	*Blatella germanica,* adults	Laboratory test: Residual efficacy According to TNsG 18-19	Non- porous (ceramic tile - side up) and porous surfaces (ceramic tile - side down) 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 (T0), one week after the treatment (T1), two weeks after the treatment (T2) and three	<u>Non-porous surfaces:</u> T0 and T1: 100% knockdown (5 minutes) T2:96% knockdown (5 minutes) and 100% knockdown (7 minutes) T3: 92% knockdown (5 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 and T1: 100% knockdown (5 minutes) T2: 100% knockdown (10 minutes) T3: 100% knockdown (20 minutes) Mortality (T0, T1, T2 and T3, after 24 hours): 100% Controls: 0% knockdown, 0% mortality	Test report: CHEPED011015 – 02 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**
					weeks after treatment (T3). 5 replicates (10 insects per both treated and control groups). Application rate: 10 g/m^2	**The efficacy is demonstrated against *Blatella germanica* (adults) until 3 weeks on porous and non-porous surfaces in laboratory conditions at the application rate of 10 g/m^2.**	
Insecticida	Indoors	MASSOCIDE T05	*Blattella germanica,* adults	Laboratory test: Residual efficacy According to TNsG 18-19	Non- porous (ceramic tile - side up) surfaces 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 (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: 10 g/m^2	Non-porous surfaces: T0: 96% knockdown (7 minutes) and 100% knockdown (10 minutes) T1: 92% knockdown (7 minutes) and 100% knockdown (10 minutes) T2: 94% knockdown (7 minutes) and 100% knockdown (10 minutes) T3: 94% knockdown (7 minutes) and 100% knockdown (10 minutes) Mortality (T0, T1, T2 and T3, after 24 hours): 100% Controls: 0% knockdown, 0% mortality **The efficacy is demonstrated against *Blatella germanica* (adults) until 3 weeks on non-porous surfaces in laboratory conditions at the application rate of 10 g/m^2.**	Test report: CHET 0507 1 215 – 02 See confidential annex
Insecticide	Indoors	PERMETRINA DUST 0.5%	*Lasius niger,* adults	Laboratory test:	Non- porous (ceramic tile - side up) and porous surfaces (ceramic tile -	Non-porous surfaces: T0, T1 and T2: 100% knockdown (5 minutes)	Test report: CHEPED01101 5 – 03

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	side down) 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 (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 groups). Application rate: 10 g/m2	T3: 96% knockdown (5 minutes) and 100% knockdown (7 minutes) Mortality (T0, T1, T2 and T3, after 24 hours): 100% Controls: 0% knockdown, 0% mortality <u>Porous surfaces:</u> T0: 96% knockdown (5 minutes) and 100% knockdown (7 minutes) T1: 97% knockdown (5 minutes) and 100% knockdown (7 minutes) T2 and T3: 100% knockdown (10 minutes) Mortality (T0, T1, T2 and T3, after 24 hours): 100% 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 rate of 10 g/m².**	See confidential annex
Insecticide	Indoors	PERMETRINA DUST 0.5%	*Ctenocephalides s felis,* adults	Laboratory test: Residual efficacy According to TNsG 18-19	Non- porous (ceramic side –side up) and porous surfaces (ceramic tile- side down) 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	<u>Non-porous surfaces:</u> T0 and T1: 100% knockdown (2 minutes) T2: 100% knockdown (5 minutes) T3: 100% knockdown (10 minutes) Mortality (T0, T1, T2 and T3, after 24 hours): 100% Controls: <6% knockdown, <4% mortality <u>Porous surfaces:</u> T0: 100% knockdown (5 minutes). T1: 98% knockdown (15 minutes). T2: 100% knockdown (10 minutes)	Test report: CHEPED011015 – 04 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**
					assessed after treatment (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 groups). Application rate: 10 g/m^2	T3: 100% knockdown (15 minutes) Mortality (T0, T1, T2 and T3, after 24 hours): 100% Controls: 0% knockdown, <4% mortality **The efficacy is demonstrated against *Ctenocephalides felis* (adults) until 3 weeks on porous and non-porous surfaces in laboratory conditions at the application rate of 10 g/m^2.**	
Insecticide	Indoors	PERMETRINA DUST 0.5%	*Lepisma saccharina,* adults	Laboratory test: Residual efficacy According to TNsG 18-19	Non- porous (ceramic side –side up) and porous surfaces (ceramic tile- side down) 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 (T0), one week after the treatment (T1), two weeks after the treatment (T2) and three weeks after treatment (T3).	<u>Non-porous surfaces:</u> T0, T1 and T3: 100% knockdown (5 minutes) T2: 96% knockdown (5 minutes) and 100% knockdown (7 minutes) Mortality (T0, T1, T2 and T3, after 24 hours): 100% Controls: 0% knockdown, 0% mortality <u>Porous surfaces:</u> T0: 94% knockdown (7 minutes) and 100% knockdown (10 minutes). T1: 100% knockdown (10 minutes). T2: 100% knockdown (15 minutes) T3: 98% knockdown (15 minutes) and 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 and**	Test report: CHEPED011015 – 01 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**
					5 replicates (10 insects per both treated and control groups). Application rate: 10 g/m^2	**porous surfaces in laboratory conditions at the application rate of 10 g/m^2.**	
Insecticide	Indoors	PERMETRINA DUST 0.5%	*Dermatophagoides pteronyssinus,* adults	Laboratory test: No-choice test According to TNsG 18-19	Non-porous (ceramic tile - side up) and porous (marble) surfaces 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 groups). Application rate: 16 g/m^2	100 % mortality for both surfaces. Controls: 0% mortality **The efficacy is demonstrated against *Dermatophagoides pteronyssinus* (adults) on non-porous and porous surfaces in laboratory conditions at the application rate of 16 g/m^2.**	Test report: CHEPED011015 – 06 See confidential annex
Insecticide	Indoors	PERMETRINA DUST 0.5%	*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 (1, 2, 3, 4, 5, 7, 10, 20 and 30 minutes) and mortality (24 hours) were assessed after treatment.	<u>Non-porous surfaces</u> 90% knockdown (2 minutes) and 100% knockdown (4 minutes) 100% mortality Controls: 0% knockdown, 0% mortality <u>Porous surfaces</u> 90% knockdown (2 minutes) and 100% knockdown (7 minutes) 100% mortality Controls: 0% knockdown, 0% mortality **The efficacy is demonstrated against *Ixodes ricinus* (adults) in laboratory**	Test report: CHEPED011015 – 07 See confidential annex

<table>
<tr><th colspan="8">Experimental data on the efficacy of the biocidal product against target organism(s)</th></tr>
<tr><th>Function</th><th>Field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test method</th><th>Test system / concentrations applied / exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td>5 replicates (10 insects per both treated and control groups).
Application rate: 16 g/m^2</td><td>conditions on non-porous and porous surfaces in laboratory conditions at the application rate of 16 g/m^2.</td><td></td></tr>
<tr><td>Insecticide</td><td>Indoors</td><td>PERTRIN DUST – 0.5% permethrin</td><td>Blattella germanica, adults (BGa) and nymphs (BGn)
Blatta orientalis, adults (BOa) and nymphs (BOn)
Lasius niger, adults (LNa)
Lepisma saccharina, adults (LSa)
Ctenocephalides felis, adults (CFa) and larvae (CFl)
Ixodes Ricinus, adults (IRa) and nymphs (IRn)
Ripicephalus sanguineus, adults (RSa) and nymphs (RSn)</td><td>Guidance on the Biocidal Products Regulation - Volume II Efficacy – Assessment and Evaluation (Parts B&C) – Version 1.0 - February 2017</td><td>Two trials were conducted: on non-porous (ceramic tiles) and on porous surfaces (blocks of concrete).
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, 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.</td><td>100% knockdown in non-porous and porous surfaces
<table><tr><th></th><th>Non-porous surfaces (min)</th><th>Porous surfaces (min)</th></tr><tr><td>BGa</td><td>30</td><td>30</td></tr><tr><td>BGn</td><td>30</td><td>30</td></tr><tr><td>BOa</td><td>40</td><td>30</td></tr><tr><td>BOn</td><td>30</td><td>30</td></tr><tr><td>LNa</td><td>10</td><td>10</td></tr><tr><td>LSa</td><td>10</td><td>10</td></tr><tr><td>CFa</td><td>20</td><td>20</td></tr><tr><td>CFl[1]</td><td>20</td><td>10</td></tr><tr><td>IRa</td><td>10</td><td>10</td></tr><tr><td>IRn</td><td>10</td><td>10</td></tr><tr><td>RSa</td><td>30</td><td>30</td></tr><tr><td>RSn</td><td>30</td><td>10</td></tr><tr><td>DPan</td><td>30</td><td>30</td></tr><tr><td>ASan</td><td>30</td><td>30</td></tr></table>[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)</td><td>Test report: 2296–DUST-SIM/0118-03

See confidential annex</td></tr>
</table>

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**
			Dermatophagoides pteronyssinus, adults+nymphs (DPan) *Acarus siro,* adults+nymphs (ASan)		Application rate: 10 g/m² (using a duster dispenser).	**in simulated use conditions on porous and non-porous surfaces at the application rate of 10 g/m².**	
Insecticide	Indoors	PERTRIN DUST – 0.5% 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). High level of infestation. 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	Blattella germanica-Population reduction: D1: 83.3% D7: 93.4% D14: 95.8% D28: 95.7% Control groups≤4.6 % Blatta orientalis-Population reduction: D1: 89% D7: 95.7% D14: 97.6% D28: 98.3% Control groups ≤2.4% **The field test demonstrates the efficacy of the product against cockroaches at the application rate of 10 g/m².**	Test report: 2296-DUST-FIELDCO/0118-03 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**
					harborage for cockroaches). Application rate: 10 g/m² (The product was applied using a professional duster) Assessments were carried out 1, 7, 14 and 28 days after treatment.		
Insecticide	Ant nests	PERTRIN DUST - 0.5% 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 the nest was open after 4 weeks Temperature: average 21.7 ºC Rain : 169 mm Hours fo sun: 237 The observation was done in a square of 1 m² around the main nest entry. Application rate: 10 g/m². Nests and surrounding areas were treated with 2.5g (0.25 m²) and 1g (0.1 m²). (The product was applied using a duster dispenser direct to the nest)	<u>Population reduction-</u> Test product: 90.6% (day 1 after the treatment) and 100% (days 21 and 28 after the treatment) After 4 weeks the nest was open, 100% mortality. Control groups≤2.5 % For control groups > 500 larvae / nymphs / queen were found alive. **The field test demonstrates the efficacy of the product as nest ants application (and surrounding areas) at the application rate of 10 g/m².**	Test report: 2296-DUST-FIELDANT/0118-04 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**
					5 nests were monitored (as for the untreated controls). 6 assessments were done: -1, and +1, 7, 14, 21, 28 days after treatment.		
Insecticide	Indoors	PERTRIN DUST - 0.5% permethrin w/w	*Ctenocephalides s 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 1.0 - February 2017	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	<u>Fleas (adults), mites (adults, nymphs) and ticks (adults, nymphs):</u> 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 and wood at the application rate of 10 g/m².**	Test report: 2296–DUST-SIM-HDMFT /0118R 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**
					and nymphs/larvae for surface and for specie. Application rate: 10 g/m2 (the product was applied using a duster dispenser).		
Insecticide	-	MASSOCIDE T05	-	The aim of this study is to determine the amount of product applied in each discharge (container rotation)	10 plastic dust powder containers were filled with the test item. Each bottle was weighed in 10 times (1 measurement =10 container rotations)	The mean value of product discharged in each rotation is 0.5 g (1 measurement = 5g) **The number of rotations to reach the application rate of 10 g/m^2 are 20.**	See confidential annex

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.

The applicant has provided 2 tests with MASSOCIDE T05 and 11 with PERMETRINA DUST 0.5% (or PERTRIN DUST 0.5%) to demonstrate the efficacy of MASSOCIDE T05. ES CA has accepted the tests with both formulations taken into account that the formulations are similar (see confidential PAR).

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

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

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

- The product has shown KD > 90% in 25-50 minutes for adult *Blattela germanica* and in 5-7 minutes (for adult *Blatta orientalis*) and a mortality of 100% (24 hours) for both cockroaches on porous and non-porous surfaces (ceramic tiles, side down and side up) and residual efficacy until 3 weeks.
- The simulated-use test 2296–DUST-SIM/0118-03 resulted in 100% knockdown (within 30-40 minutes) and 100% mortality after 24h at an application rate of 10 g/m^2 (on ceramic tiles and blocks of concrete) for both adult and nymph cockroaches.
- In the field test 2296-DUST-FIELDCO/0118-03, the product was applied as spot application and crack and crevices treatment in apartments of 60-80 m^2 (treated area (kitchen): 12-15 m²) at an application rate of 10 g/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).

- The use as superficial treatment for the general public and professional users (laboratory tests and simulated-use tests showed > 90% knockdown and mortality ≥90% in 24 hours).

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.

Therefore, the eCA concludes that the product MASSOCIDE T05 is effective against crawling insects, cockroaches (*Blattella germanica* and *Blatta orientalis,* adults and nymphs*),* by dusting as a general surface treatment for the general public and professional users (indoors) and as spot to surface in hiding places (including crack and crevices) for the general public and 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 5 minutes and mortality of 100% in 24 hours on porous and non-porous surfaces (ceramic tiles, side down and side up) and residual efficacy until 3 weeks.
- In the simulated-use test, 2296–DUST-SIM/0118-03, 100% knockdown in 10 minutes and 100% mortality after 24h were achieved on ceramic tiles and blocks of concrete with an application rate of 10 g/m^2 against adult black ants. This test demonstrated the efficacy of the product as superficial application indoors.
- The field trial 2296-DUST-FIELDANT/0118R investigated the efficacy of the product applied by dusting 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 10 g/m^2 (2.5 g maximum per nest (in 0.25 m^2, e.g. 50cm*50cm).

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 requeriments 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.

The eCA concludes that the product MASSOCIDE T05 is effective against *Lasius niger* by dusting as a general surface treatment 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).

In laboratory and simulated-use (2296–DUST-SIM/0118-03) tests were obtained 100% mortality and 100% KD in few minutes on non-porous and porous surfaces and residual efficacy (until 3 weeks on both surfaces) at an application rate of 10 g/m^2.

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.

The eCA concludes that the product MASSOCIDE T05 is effective against adult silverfishes (*Lepisma saccharina)* by dusting as a general surface treatment indoors.

Efficacy against cat fleas *(Ctenocephalides felis)*

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

- The laboratory test has shown 100% KD in few minutes and 100% mortality (24 hours) on non-porous and porous surfaces with residual efficacy until 3 weeks.
- Two simulated-use tests (test reports 2296–DUST-SIM/0118-03 and 2296–DUST-SIM-HDMFT /0118R) were provided by the applicant to demonstrate the efficacy against cat fleas at an application rate of 10 g/m^2. The test report 2296–DUST-SIM/0118-03 demonstrated the efficacy of the product against adult fleas on ceramic tiles and blocks of concrete (100% KD and 100% mortality in 24 hours). 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–DUST-SIM-HDMFT /0118R), 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 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).

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.

The eCA concludes that the product MASSOCIDE T05 is effective against adult cat fleas (*Ctenocephalides felis)* by dusting on non-washable textile surfaces for general public.

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* on ceramic tiles and marble (100% mortality).
- Two simulated-use tests (test reports 2296–DUST-SIM/0118-03 and 2296–DUST-SIM-HDMFT /0118R) were submitted at an application rate of 10 g/m^2. The test report 2296–DUST-SIM/0118-03 was carried out on ceramic and concrete surfaces against *Dermatophagoides pteronyssinus* and *Acarus siro.* 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 16 g/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 MASSOCIDE T05 is effective against house dust mites (*Dermatophagoides pteronyssinus,* adults and nymphs) by dusting 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 4 minutes on porous surfaces and 7 minutes on non-porous surfaces. 100% mortality in 24 hours).
- Two simulated-use tests (test reports 2296–DUST-SIM/0118-03 and 2296–DUST-SIM-HDMFT /0118R) were submitted at an application rate of 10 g/m^2: one of them on ceramic and concrete surfaces and the other one on wood and carpet. The two tests demonstrated the efficacy against *Rhipicephalus sanguineus* and *Ixodes ricinus* (100% KD in 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 16 g/m2. 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 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.

The eCA concludes that the product MASSOCIDE T05 is effective against ticks (*Rhipicephalus sanguineus and Ixodes ricinus,* adults and nymphs) by dusting as a surface application for general public, professionals and trained professionals and 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 powder container rotations to apply 10 g /m^2 of biocidal product. The number of rotations required are 20.

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*),* as spot to surface in hiding places (including crack and crevices) for the general public, professionals and trained professionals (indoor). The tests were performed against two keys species, one small (*Blatella germanica*) and one larger specie (*Blatta orientalis*).
- Use against cockroaches (*B. germanica* and *B. orientalis*, adults and nymphs), ants (*Lasius niger*, adults), silverfishes (*Lepisma saccharina*, adults) and ticks (*Ixodes ricinus* and *Rhipicephalus sanguineus*, adults and nymphs) as a surface treatment indoors.
- Use against *Lasius niger* (adults, larvae, nymphs and queens) as nest application and surrounding areas for the general public, professionals and trained professionals.
- Use against adult cat fleas (*Ctenocephalides felis),* house dust mite (*Dermatophagoides pteronyssinus*) and ticks (*Rhipicephalus sanguineus* and *Ixodes ricinus*) by dusting on non-washable textile surfaces for the general public.

3.2.5.2 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 (trained) professional."

3.2.5.3 Known limitations

None.

3.2.5.4 Evaluation of the label claims

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*),* as spot to surface in hiding places (including crack and crevices) for the general public, professionals and trained professionals (indoor). The tests were

performed against two keys species, one small (*Blatella germanica*) and one larger specie (*Blatta orientalis*).
- Use against cockroaches (*B. germanica* and *B. orientalis*, adults and nymphs), ants (*Lasius niger*, adults), silverfishes (*Lepisma saccharina*, adults) and ticks (*Ixodes ricinus* and *Rhipicephalus sanguineus*, adults and nymphs) as a surface treatment indoors.
- Use against *Lasius niger* (adults, larvae, nymphs and queens) as nest application and surrounding areas for the general public, professionals and trained professionals.
- Use against adult cat fleas (*Ctenocephalides felis),* house dust mite (*Dermatophagoides pteronyssinus*) and ticks (*Rhipicephalus sanguineus* and *Ixodes ricinus*) by dusting on non-washable textile surfaces for the general public.

For information, based on the environmental risk assessment, only the following uses will be authorised:
- Use against crawling insects, cockroaches (*B. germanica* and *B. orientalis,* adults and nymphs*),* as spot to surface in hiding places (including crack and crevices) for the general public, professionals and trained professionals (indoor).
- Use against *Lasius niger* (adults, larvae, nymphs and queens) as nest application and surrounding areas for the general public, professionals and trained professionals.
- Use against adult cat fleas (*Ctenocephalides felis),* house dust mite (*Dermatophagoides pteronyssinus*) and ticks (*Rhipicephalus sanguineus* and *Ixodes ricinus*) by dusting on non-washable textile surfaces for the general public.

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

MASSOCIDE T05 is not intended to be use with other biocidal products.

3.2.6 Risk assessment for human health

The current application is for MASSOCIDE T05, a ready to use dust formulation containing 0.5% w/w Permethrin, for the indoor and outdoor treatments by professional, trained professionals and non-professional users for the control of crawling insects (ants, fleas, mites and ticks) (Product Type 18).

3.2.6.1 Assessment of effects on Human Health

No animal or human data on toxicological properties has been generated. However, an in vitro eye irritation study has been provided by the applicant. This study has been performed using a similar formulation containing 0.5% w/w permethrin. The applicant proposes to read across from this study for the MASSOCIDE T05 formulation. Both formulations have the same content of active substance with slight variations in the content of the co-formulants. The variations between the formulations are in inert components that are not expected to affect toxicology. ES CA accepts the data generated for this product can be referred to the product MASSOCIDE T05 (see confidential annex).

For the others toxicology endpoints a calculation of toxicological properties according to CLP criteria has been carried out, taking into account the amount of each ingredient in the product. Active substance effects and critical concentrations are described in the permethrin assessment report (Ireland, 2014). Information on co-formulants are found on the ECHA dissemination website and in the SDSs submitted. Therefore, new studies with the biocidal product are scientifically not justified.

The full composition of the product MASSOCIDE T05 has been provided in the confidential annex.

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	MASSOCIDE T05 is neither irritant nor corrosive to the skin.
Justification for the value/conclusion	Based on the classification of the active substance and the co-formulants and their respective content in the final formulation. None of the components of the product are classified for skin corrosion or irritation. Therefore, the product does not meet the criteria for classification for skin corrosion or irritation according to Regulation (EC) Nº 1272/2008.
Classification of the product according to CLP	No classification required according to CLP.

Data waiving	
Information requirement	No dermal irritation study has been conducted with MASSOCIDE T05.
Justification	The composition of the product is known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the product. In addition, synergistic effects between any of the components are not expected. Consequently, classification of the mixture can be made according to the rules laid down in Regulation (EC) No 1272/2008, therefore this study does not need to be conducted.

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 Yes Reliable	Fresh bovine corneas / *Bos primigenius* Taurus / 9 corneas (3 for each treatment group)	PERMETRIN A 0.5% DUST / 4h	4h cornea opacity score IVIS: 0.92 → Test item 1.87 → Neg control 84.22 → Pos control Max score test item: 4.45 Reversability: not specified	None	See confidential annex

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	MASSOCIDE T05 is not irritant to eyes.

Justification for the value/conclusion	The test item PERMETRINA 0.5% DUST showed no effects on the cornea of the bovine eye. The calculated IVIS (in vitro irritancy score) is 0.92 at time point 4h. The experiment is considered as sufficient for the classification of the test item, because two of the three replicates of the test item lead to the same assessment. The applicant proposes to read-across from the results of the study using PERMETRINA DUST 0.5% to the product MASSOCIDE T05. ES CA accepts that data generated for this product can be referred to the product MASSOCIDE T05. Therefore, the biocidal product MASSOCIDE T05 is not an eye irritant and is not classified.
Classification of the product according to CLP Regulation	MASSOCIDE T05 is not classified as irritating to skin.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	MASSOCIDE T05 is not a respiratory tract irritant.
Justification for the conclusion	Based on the classification of the active substance and the co-formulants and their respective content in the final formulation. None of the components of the product are classified as respiratory tract irritants. Therefore, the product does not meet the criteria for classification as a respiratory tract irritant according to Regulation (EC) Nº 1272/2008
Classification of the product according to CLP	No classification is required.

Data waiving	
Information requirement	Respiratory tract irritation data.
Justification	There are valid data available on each of the components in the product MASSOCIDE T05 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. None of the components in the formulation are irritant to respiratory tract.

Skin sensitization

onclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not skin sensitizer
Justification for the value/conclusion	Based on the classification of permethrin and the co-formulants and its final content in the formulation. MASSOCIDE T05 contains 0.5 % permethrin, which is classified as skin sensitive, category 1. This concentration is not sufficient for classification, but exceeds the trigger value for elicitation in already sensitized individuals. The rest of the co-formulants are not classified as skin sensitive.

Classification of the product according to CLP	No classification for skin sensitization is required. Supplemental hazard statement EUH208: "Contains permethrin. May produce an allergic reaction" is required.

Data waiving	
Information requirement	Skin sensitization study
Justification	The composition of the products in the family is known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the product. In addition, synergistic effects between any of the components are not expected. Consequently, classification of the mixture can be made according to the rules laid down in Regulation (EC) No 1272/2008, therefore this study does not need to be conducted.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	MASSOCIDE T05 is not respiratory sensitizer.
Justification for the value/conclusion	Based on the classification of permethrin and the different co-formulants and, their respective final content in the formulation. None of the components of the product are classified for respiratory sensitization. Therefore, the product does not meet the criteria for classification for respiratory sensitization according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP	No classification required according to CLP.

Data waiving	
Information requirement	No study regarding respiratory sensitation with MASOCIDE T05 has been conducted and performing a new study is scientifically unjustified.
Justification	For the biocidal product the composition is known. Sufficient data on the intrinsic properties of the components are available from safety data sheets and other information for each of the individual components in the product. Consequently, classification of the mixture can be made according to the rules laid down in Regulation (EC) No 1272/2008. None of the ingredients are classified as respiratory sensitizers, so the product is not classified.

Acute toxicity

The assessment of the acute toxicological properties of MASOCIDE T05 is derived from the classification of the active substance and co-formulants as agreed in the Annex VI of the CLP regulation or, when not available, as agreed in the Classification and Labelling notification at ECHA. This information is included in their safety data sheets. For confidentiality reasons, the names and percentages of co-formulants are disclosed in PAR confidential annex document.

According to Regulation (EC) No 1272/2008 classification of mixtures based on ingredients of the mixture is determined by calculation from the ATE values (ATE_{mix}):

$$\frac{100}{ATE_{mix}} = \sum_{r} \frac{C_i}{ATE_i}$$

or

$$\frac{100 - (\sum C_{unknown} if > 10\%)}{ATE_{mix}} = \sum_{r} \frac{C_i}{ATE_i}$$

where:

C_i = concentration of ingredient i (% w/w or % v/v)
i = the individual ingredient from 1 to n
n = the number of ingredients
ATE_i = Acute Toxicity Estimate of ingredient i.

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	DL_{50}>2000mg/kg bw
Justification for the selected value	According to annex VI of CLP Regulation, permethrin is classified for acute oral toxicity as Acute tox 4*; H302. According to the SDS of permethrin, the LD50 value is 554 mg/kg bw. The calculated oral ATE for MASOCIDE T05 is higher than 2000mg/kg bw. Therefore the product does not meet the criteria for classification for acute oral toxicity according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP	No classification required according to CLP.

Data waiving	
Information requirement	No study regarding acute toxicity by oral route with the MASSOCIDE T05 has been conducted and performing a new study is scientifically unjustified.
Justification	No vertebrate studies have been performed with the formulated product in order to avoid unnecessary testing with vertebrates. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the product. In addition, synergistic effects between any of the components are not expected. Consequently, classification of the mixture can be made according to the rules laid down in Regulation (EC) No 1272/2008, therefore this study does not need to be conducted.

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	CL_{50}:>5mg/l
Justification for the selected value	According to annex VI of CLP Regulation, permethrin is classified for acute inhalation toxicity as Acute tox 4*; H332. According to the SDS of permethrin, the LC50 value is 4.638 mg/l. The calculation of ATEmix for inhalatory toxicity is >5mg/l. Therefore, the products do not meet the criteria for

	classification for acute inhalation toxicity according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP	No classification required according to CLP.

Data waiving	
Information requirement	No study regarding acute toxicity by inhalation route with the MASSOCIDE T05 has been conducted and performing a new study is scientifically unjustified.
Justification	No studies have been performed with the biocidal product in order to avoid unnecessary testing with vertebrates. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the product. In addition, synergistic effects between any of the components are not expected. Consequently, classification of the mixture can be made according to the rules laid down in Regulation (EC) No 1272/2008, therefore this study does not need to be conducted.

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	MASSOCIDE T05 is not harmful by dermal route.
Justification for the selected value	Based on the classification of permethrin and the different co-formulants and their respective final content in the formulation. None of the components of the product is classified as harmful by dermal route. Therefore, the product does not meet the criteria for classification for acute toxicity by dermal route according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP	No classification required according to CLP.

Data waiving	
Information requirement	No study regarding acute toxicity by dermal route with the MASSOCIDE T05 has been conducted and performing a new study is scientifically unjustified.
Justification	No studies have been performed with the biocidal product in order to avoid unnecessary testing with vertebrates. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the product. In addition, synergistic effects between any of the components are not expected. Consequently, classification of the mixture can be made according to the rules laid down in Regulation (EC) No 1272/2008, therefore this study does not need to be conducted.

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Permethrin
Value	50 %
Justification for the selected value	Default value from EFSA guidance on dermal absorption for solid formulations (EFSA Journal 2017; 15(6):4873).

Data waiving	
Information requirement	Dermal absorption study
Justification	There is no experimental data available on the dermal absorption of MASSOCIDE T05 since no study has been conducted thus far. As a result, risk assessment calculations for human exposure have been made according to the EFSA guidance on dermal absorption (EFSA Journal, 2017;15(6):4873) using a default value of 50% dermal absorption for this product.

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

The formulation contains some co-formulants, one of which is classified for human toxicity according to its SDS. However, the concentration of this substance in the preparation is well below the classification limits set out in Regulation (EC) Nº 1272/2008 and the biocidal product is not classified based on its presence in the preparation. Please see the confidential annex for further details.

Available toxicological data relating to a mixture

Not relevant.

Endocrine disrupting properties

Endocrine disrupting properties assessment of active substance and co-formulants is mandatory from 7 June 2018, date when the Regulation (EU) 2017/2100 came into force, according to the article 19 of BPR.

Assessment of the ED properties of the active substances:

The biocidal product family contains only one active substance. According to the CAR and BPC Opinion (April 2014), permethrin is not considered to have endocrine disrupting properties. 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):

After reviewing the potential ED properties of co-formulants (please refer to the Confidential Annex), none of them are subject to an on-going evaluation or a decision regarding their ED properties. Based on the available information, ES CA considers that there is no concern regarding the ED properties of these co-formulants.

Overall conclusion on the biocidal product regarding ED properties:

Based on the existing knowledge and the data provided in permethrin assessment report, there is no indication of concern regarding the ED properties of the substances used in the MASSOCIDE T05 biocidal product.

If one or several components are identified as having ED properties in the future, the conditions for granting the biocidal product authorization will be revised.

Other

Not relevant.

3.2.6.2 Exposure assessment

General Remarks
The assessment of occupational exposure towards permethrin as insecticide is based on information provided by the Applicant. In the absence of human exposure data, the exposure estimation to BIT 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.
If no appropriate models are available in the BHHEM, surrogate models are chosen and a justification is provided.
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).
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.

MASSOCIDE T05 is a ready to use dust formulation containing 0.5% w/w permethrin intended for the indoor and outdoor use by (trained) professionals and non-professionals. The recommended usage concentration of the dust formulation is 10 g bp/m^2 (equivalent to 50 mg permethrin per m^2). For the indoor use it is applied by spreading the powder evenly on the surfaces and making sure to treat corners, hiding places (including crevices and cracks) and over textiles. And outdoor use can be developed by dusting directly into ant's nests, around houses on paved ways, balconies, and terraces where ant nests are located.

Whenever it is possible, it is indicated that the product should be applied directly from the packaging with the spreader in a homogeneous way in corners, hiding places (including cracks and crevices), nests and in the perimeters or where the infestation must be eliminated.

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	Yes	Yes	Yes	n.a.
Dermal	n.a.	Yes	Yes	Yes	Yes	Yes	n.a.
Oral	n.a.	No	No	No	No	Yes	n.a.

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 handheld duster, bulb duster or a powder container. (Professional Use & Consumer Use).
- Professional and non-professional use of biocidal product by dusting (Professional Use & Consumer Use).

SECONDARY EXPOSURE

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

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
1.	Mixing and loading	**Primary exposure.** Loading product in application device.	Professional / Trained professional
2.	Application	**Primary exposure.** Indoor application by dusting.	Professional / Trained professional
3.	Application	**Primary exposure.** Outdoor application of product in ant's nest entries.	Professional / Trained professional
4.	Mixing and loading	**Primary exposure.** Loading product in application device.	Non-professional
5.	Application	**Primary exposure.** Indoor application by dusting.	Non-professional
6.	Application	**Primary exposure.** Outdoor application of product in ant's nest entries.	Non-professional
7.	Post-application	**Secundary exposure.** General population accidentally rubbing treated surfaces. In the case of toddlers possible hand-to-mouth transference is likely	General public
8.	Post-application	**Secondary exposure.** Persons laundering contaminated work clothing	General pubic

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 and it is not considered since adequate protective clothing and equipment are used to prevent exposure of the workforce.

Professional exposure

Scenario [1] – Mixing and loading

Description of Scenario [1]			
The biocidal product used as spot and superficial treatment is applied using a handheld duster, bulb duster or a powder container. Exposure of this application method can be assessed with the exposure scenario **Mixing and loading Model 7 for powders. (TNsG 2007).** Duration of exposure is 10 minutes. Only hands are exposed during touching of contaminated surfaces, package (only accidentally). Inhalation exposure to permethrin during manual transfer is considered negligible, because of low vapour pressure. In Tier 2 PPE (gloves) are considered. Further values regarded in the current assessment can be found below:			
	Parameters	**Value**	**Justification / Source**
Tier 1	Weight fraction of active substance	0.5	Section 2.1.2.
	Body weight	60 kg	Recommendation no. 14, 2017
	Expected duration of actual exposure	10 minutes	HEEG Opinion 1
	Dermal exposure		
	Hand exposure	305 mg/min	HEEG Opinion 1
	Dermal Absorption	50%	Guidance on Dermal Absorption (EFSA, 2017)
	Inhalation exposure		
	Indicative inhalation exposure	7.2 mg/m^3	HEEG Opinion 1
	Inhalation rate	1.25 m^3/h	Recommendation no. 14, 2017
	Inhalation Absorption	100%	Default value.
Tier 2	Hand exposure under gloves and clothes	3.05 mg/min	HEEG Opinion 1

Calculations for Scenario [1]

Summary table: estimated exposure from professional uses					
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 [1]	1/no PPE	1.25E-04	1.27E-01	--	1.27E-01
Scenario [1]	2/gloves and clothes	1.25E-04	1.27E-03	--	1.40E-03

See more information in Annex 3.2.

Further information and considerations on scenario [1]
Not applicable.

Scenario [2] – Indoor application

Description of Scenario [2]

The biocidal product is applied by spreading the powder evenly on the surfaces and making sure to treat corners, crevices and cracks and over textiles for the indoor use. Exposure of this application method can be assessed with the exposure scenario **Scattering powder against ants from a hand held flexible duster/hand-held consumers and professionals. (TNsG 2007)**

The model from the TNsG 2007 is derived from the following simulated volunteer study: Includes crack and crevice treatment for ants in a kitchen (skirting, shelves, horizontal laminate floors) using a fine powder (45% of particles less than 75 μm) and broadcast flea treatment (carpet) using coarse granules (95% of particles greater than 180 μm). Application is not hand-held flexible duster but a spoon. Therefore, inhalation exposure is assumed negligible compared to dermal exposure. The value 2.73 + 2.74 is assumed to be the worst case, but there is no other data/model available.

Professional users are expected to use the biocidal product on a daily basis for 230 working days in the year. However, it is not a realistic worst case to assume 230 days/year working with permethrin based products. According to the TNsG on Human Exposure (2002), daily use is anticipated with several applications per day but workers are peripatetic and much time is spent travelling to treatment sites and surveying. Therefore, duration of exposure is 120 minutes.

In Tier 2 PPE (gloves) are considered.

Further values regarded in the current assessment can be found below:

	Parameters	**Value**	**Justification / Source**
Tier 1	Weight fraction of active substance	0.5	Section 2.1.2.
	Body weight	60 kg	Recommendation no. 14, 2017
	Expected duration of actual exposure	120 minutes	Recommendation no. 6, 2020 – BHHEM, 2015
	Dermal exposure		
	Potential legs/feet/face exposure	2.74 mg/min	Recommendation no. 6, 2020
	Potential hand/forearm exposure	2.73 mg/min	Recommendation no. 6, 2020
	Dermal Absorption	50%	Guidance on Dermal Absorption (EFSA, 2012)
	Inhalation exposure		
	Indicative inhalation exposure	2.47 mg/m^3	Recommendation no. 6, 2020
	Inhalation rate	1.25 m^3/h	Recommendation no. 14, 2017
	Inhalation Absorption	100%	Default value.
Tier 2	PPE (protective gloves)	10% penetration	HEEG Opinion 9

Calculations for Scenario [2]

Summary table: estimated exposure from professional uses					
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 [2]	1/no PPE	5.15E-04	2.74E-02	--	2.79E-02
Scenario [2]	2/protective gloves	5.15E-04	1.51E-02	--	1.56E-02

See more information in Annex 3.2.

Further information and considerations on scenario [2]

Not applicable.

Scenario [3] – Outdoor application

Description of Scenario [3]			
The biocidal product 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 of this application method can be assessed with the exposure scenario **Scattering powder against ants from a hand held flexible duster/hand-held consumers and professionals. (TNsG 2007)** The model from the TNsG 2007 is derived from the following simulated volunteer study: Includes crack and crevice treatment for ants in a kitchen (skirting, shelves, horizontal laminate floors) using a fine powder (45% of particles less than 75 μm) and broadcast flea treatment (carpet) using coarse granules (95% of particles greater than 180 μm). Application is not hand-held flexible duster but a spoon. Therefore, inhalation exposure is assumed negligible compared to dermal exposure. The value 2.73 + 2.74 is assumed to be the worst case, but there is no other data/model available. Professional users are expected to use the biocidal product on a daily basis for 230 working days in the year. However, it is not a realistic worst case to assume 230 days/year working with permethrin based products. According to the TNsG on Human Exposure (2002), daily use is anticipated with several applications per day but workers are peripatetic and much time is spent travelling to treatment sites and surveying. For treatment of ant nests (spot application) an exposure duration of 60 min may be assumed. In Tier 2 PPE (gloves) are considered. Further values regarded in the current assessment can be found below:			
	Parameters	**Value**	**Justification / Source**
Tier 1	Weight fraction of active substance	0.5	Section 2.1.2.
	Body weight	60 kg	Recommendation no. 14, 2017
	Expected duration of actual exposure	60 minutes	Recommendation no. 6, 2020
	Dermal exposure		
	Potential legs/feet/face exposure	2.74 mg/min	Recommendation no. 6, 2020
	Potential hand/forearm exposure	2.73 mg/min	Recommendation no. 6, 2020

	Dermal Absorption	50%	Guidance on Dermal Absorption (EFSA, 2017)
	Inhalation exposure		
	Indicative inhalation exposure	2.47 mg/m^3	Recommendation no. 6, 2020
	Inhalation rate	1.25 m^3/h	Recommendation no. 14, 2017
	Inhalation Absorption	100%	Default value.
Tier 2	PPE (protective gloves)	10% penetration	HEEG Opinion 9

Calculations for Scenario [3]

Summary table: estimated exposure from professional uses					
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 [3]	1/no PPE	2.57E-04	1.37E-02	--	1.39E-02
Scenario [3]	2/protective gloves	2.57E-04	7.53E-03	--	7.79E-03

See more information in Annex 3.2.

Further information and considerations on scenario [3]
Not applicable.

Combined scenarios

There is the possibility that the scenarios 1 and 2 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					
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 [1, 2]	1/no PPE	6.40E-04	1.54E-01	--	1.55E-01
Scenarios [1, 2]	2/protective gloves	6.40E-04	1.63E-02	--	1.70E-02
Scenarios [1, 2, 3]	1/no PPE	8.97E-04	1.68E-01	--	1.69E-01
Scenarios [1, 2, 3]	2/protective gloves	8.97E-04	2.39E-02	--	2.48E-02

Non-professional exposure

Scenario [4] – Mixing and loading

Description of Scenario [4]			
Although the product is intended to be applied directly from the packaging-applicator (e.g. directly into ant nests). There is the likely that the user loads the product from the package to another applicator device (e.g. bulb dust blower or flexible dusters). These last application types require the loading task from the container to the applicator device. Although they are performed for small product amounts, they must be considered as an exposure scenario. Hence, the estimation of the loading task as worst case is performed using the model from **RIVM ConsExpo Web, version 1.1.0 (Pest Control Products Fact Sheet) scenario: 2.4 Exposure to powder and granules during mixing and loading**. Further values regarded in the current assessment can be found below:			
	Parameters	**Value**	**Justification / Source**
Tier 1	Weight fraction of active substance	0.5	Section 2.1.2.
	Body weight	60 kg	Recommendation no. 14, 2017
	Frequency	3 per year	RIVM report 320005002/2006 Pest Control Products Fact Sheet
	Exposed area	1950 cm^2	Recommendation no. 14, 2017 (hands and forearms)
	Contact rate	0.033 mg/min	RIVM report 320005002/2006 Pest Control Products Fact Sheet
	Release duration	1.33 min	RIVM report 320005002/2006 Pest Control Products Fact Sheet
	Inhalation rate	1.25 m^3/h	Recommendation no. 14, 2017
	Dermal Absorption	50%	Guidance on Dermal Absorption (EFSA, 2017)

Calculations for Scenario [4]

Summary table: estimated exposure from non-professional uses					
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 [4]	1/no PPE	--	1.83E-06	--	1.83E-06

See more information in Annex 3.2.

Further information and considerations on scenario [4]
Not applicable.

Scenario [5] – Indoor application over textile surfaces by dusting

Description of Scenario [5]			
The biocidal product is applied by spreading the powder evenly on the surfaces and over textiles for the indoor use. Exposure of this application method can be assessed with the exposure scenario **Scattering powder against ants from a hand held flexible duster/hand-held consumers and professionals. (TNsG 2007)** The model from the TNsG 2007 is derived from the following simulated volunteer study: Includes crack and crevice treatment for ants in a kitchen (skirting, shelves, horizontal laminate floors) using a fine powder (45% of particles less than 75 μm) and broadcast flea treatment (carpet) using coarse granules (95% of particles greater than 180 μm). Application is not hand-held flexible duster but a spoon. Therefore, inhalation exposure is assumed negligible compared to dermal exposure. The value 2.73 + 2.74 is assumed to be the worst case, but there is no other data/model available. Duration of exposure is 5 minutes. Further values regarded in the current assessment can be found below:			
	Parameters	**Value**	**Justification / Source**
Tier 1	Weight fraction of active substance	0.5	Section 2.1.2.
	Body weight	60 kg	Recommendation no. 14, 2017
	Expected duration of actual exposure	5 minutes	Recommendation no. 6, 2020
	Dermal exposure		
	Potential legs/feet/face exposure	2.74 mg/min	Recommendation no. 6, 2020
	Potential hand/forearm exposure	2.73 mg/min	Recommendation no. 6, 2020
	Dermal Absorption	50%	Guidance on Dermal Absorption (EFSA, 2012)
	Inhalation exposure		
	Indicative inhalation exposure	2.47 mg/m^3	Recommendation no. 6, 2020
	Inhalation rate	1.25 m^3/h	Recommendation no. 14, 2017
	Inhalation Absorption	100%	Default value.

Calculations for Scenario [5]

Summary table: estimated exposure from non-professional uses					
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 [5]	1/no PPE	2.14E-05	1.14E-03	--	1.16E-03

See more information in Annex 3.2.

Further information and considerations on scenario [5]
Not applicable.

Scenario [6] – Outdoor application

Description of Scenario [6]
The biocidal product 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 of this application method can be assessed with the exposure scenario **Scattering powder against ants from a hand held flexible duster/hand-held consumers and professionals. (TNsG 2007)** The model from the TNsG 2007 is derived from the following simulated volunteer study: Includes crack and crevice treatment for ants in a kitchen (skirting, shelves, horizontal laminate floors) using a fine powder (45% of particles less than 75 μm) and broadcast flea treatment (carpet) using coarse granules (95% of particles greater than 180 μm). Application is not hand-held flexible duster but a spoon. Therefore, inhalation exposure is assumed negligible compared to dermal exposure. The value 2.73 + 2.74 is assumed to be the worst case, but there is no other data/model available. Duration of exposure is 5 minutes. Further values regarded in the current assessment can be found below:

	Parameters	**Value**	**Justification / Source**
Tier 1	Weight fraction of active substance	0.5	Section 2.1.2.
	Body weight	60 kg	Recommendation no. 14, 2017
	Expected duration of actual exposure	5 minutes	Recommendation no. 6, 2020
	Dermal exposure		
	Potential legs/feet/face exposure	2.74 mg/min	Recommendation no. 6, 2020
	Potential hand/forearm exposure	2.73 mg/min	Recommendation no. 6, 2020
	Dermal Absorption	50%	Guidance on Dermal Absorption (EFSA, 2017)
	Inhalation exposure		
	Indicative inhalation exposure	2.47 mg/m^3	Recommendation no. 6, 2020
	Inhalation rate	1.25 m^3/h	Recommendation no. 14, 2017
	Dermal Absorption	100%	Default value.

Calculations for Scenario [6]

Summary table: estimated exposure from non-professional uses					
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 [6]	1/no PPE	2.14E-05	1.14E-03	--	1.16E-03

See more information in Annex 3.2.

Further information and considerations on scenario [6]
Not applicable.

Combined scenarios

Summary table: combined systemic exposure from non-professional uses					
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 [4, 5]	1/no PPE	2.14E-05	1.14E-03	--	1.16E-03
Scenarios [4, 5, 6]	1/no PPE	4.29E-05	2.28E-03	--	2.32E-03

Exposure of the general public

Scenario [7] – Toddlers playing in treated areas

Description of Scenario [7]
Subsequent to the use of the biocidal product at domestic pest control, the exposure to the general public is possible via the dermal and the oral route. Dermal and oral exposure could be relevant for toddlers, when they crawl over a floor after treatment. Considering this case, direct dermal contact and oral ingestion by hand-to-mouth contact are conceivable for toddlers. Secondary exposure is usually not relevant for adults as intense dermal and oral contacts with contaminated surfaces are less likely than for toddlers. It is assumed that toddlers would not be permitted to be present during the dusting operation and therefore there would be no acute exposure. Exposure estimation has been calculated using **RIVM ConsExpo Web, version 1.1.0 scenarios (Pest Control Products – Dusting Powders – post application)**. The main route of exposure is via accidental dermal contamination by rubbing off treated surfaces. To account for this, the weight fraction compound is set to 1 (100 %) since the measured values refers to the active substance and not to biocidal product. The ConsExpo model gives a transfer coefficient of 0.6 m²/h but a transfer factor of 0.20 m²/h according to the Recommendation for indoor transfer coefficients no. 12 (2016) is considered. The dislodgeable amount is set to 30 % (ConsExpo Pest Control Product Fact Sheet, 2006) but a transfer coeffiencient of 6% (transfer efficiency of powder from a smooth surface – BHHEM, 2015) is deemed. The default room floor surface is 1 m² and the exposure duration proposed in the corresponding fact sheet is only 60 min. To our case, the parameters chosen are the following: - Application dose: 50 mg permethrin/m^2 (10 g bp/m^2) according to the section B.2 Considering a deposition value of 85% (RIVM scenario assumption), the amount deposited on the floor will be: • Permethrin: 50 mg/m^2 x 0.85 = 42.5 mg/m^2 Assuming that 6% thereof will be dislodgeable, a dislodgeable amount of • Permethrin: 42.5 mg/m^2 x 0.06 = 2.55 mg/m^2 is calculated. Considering that 10 % of dermal load (see Consexpo reports in the attached excel file) will be ingested by hand-to-mouth transfer, the ingestion rate is calculated as • Permethrin: 2.55 mg/m^2 x 0.20 m^2/h x 0.1 / 60 min = 8.50E-04 mg/min

Description of Scenario [7]			
for Tier 1. Further values regarded in the current assessment can be found below:			
	Parameters	**Value**	**Justification / Source**
Tier 1	Weight fraction substance	100%	
	Application rate	50 mg/m^2	Section 2.2.5.
	Frequency	70 per year	RIVM report 320005002/2006 - Pest Control Products Fact Sheet
	Body weight	10 kg	Recommendation no. 14, 2017.
	Dermal exposure		
	Exposed area	2150 cm^2	Recommendation no. 14, 2017. (hands, arms, legs, feet of a toddler)
	Deposition rate on floor	85%	RIVM report 320005002/2006 - Pest Control Products Fact Sheet
	Dislodgeable residue	6%	BHHEM, 2015
	Dislodgeable amount	2.55 mg/m^2	Calculated value.
	Contact time	60 min	RIVM report 320005002/2006 - Pest Control Products Fact Sheet
	Contact surface	1 m^2	RIVM report 320005002/2006 - Pest Control Products Fact Sheet
	Release duration	1 m^2	RIVM report 320005002/2006 - Pest Control Products Fact Sheet
	Dermal absorption	50%	Guidance on Dermal Absorption (EFSA, 2017)
	Oral exposure		
	Transfer coefficient	0.20 m^2/h	Recommendation no. 12, 2016.
	Transfer hand to mouth	10%	RIVM report 320005002/2006 - Pest Control Products Fact Sheet
	Exposure duration	60 min	RIVM report 320005002/2006 - Pest Control Products Fact Sheet
	Oral absorption	100%	Default value.
	Ingestion rate	8.50E-04 mg/min	Calculated value.

Calculations for Scenario [7]

Summary table: systemic exposure from non-professional uses					
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 [7]	1/no PPE	--	2.55E-02	5.10E-03	3.06E-02

Further information and considerations on scenario [7]
Not applicable.

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 fogging from which the tier that shows safe use is tier 2 using protective gloves and coated coverall. 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	0.5%	Section 2.1.2.
	Body weight	60 kg	Recommendation no. 14, 2017
	Dermal exposure		
	Indicative value from model	246.60 mg/day	Application 1 + Application 2 (nests)
	Surface medium-sized coverall	22700 cm^2	Estimated parameter usually accepted
	Regular clothes penetration	50 %	HEEG opinion 9
	Dermal Absorption	50 %	Guidance on Dermal Absorption (EFSA, 2017)
	Skin surface area in contact	1640 cm^2	Twice with palms of both hands and once with the total hands surface. Recommendation no. 14, 2017.
	Transfer coefficient	30 %	BHHEM, 2015 - Cotton, knitwear, plastic, wood Dried fluid - wet hand

Calculations for Scenario [8]

Summary table: systemic exposure from non-professional uses					
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	--	1.11E-03	--	1.11E-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, 2, 3, 8]	8.97E-04	2.50E-02	--	2.59E-02
Scenarios [1, 2, 3, 4, 5, 6, 8]	9.40E-04	2.73E-02	--	2.82E-02

Monitoring data

No monitoring data available.

Dietary exposure

Dietary exposure is considered as not relevant, as the biocidal product is not intended to be applied in the presence of food or animals destined for human consumption. In addition, the treatment on places where the food/feed is stored must to be avoided. Hence, any quantitatively relevant exposure of humans via the food chain can be safely excluded.

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] 2000/817/EC: 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 (notified under document number C(2000) 4140).
[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. OJ L 15, 20.1.2010, p. 1-72.

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 MASSOCIDE T05 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 MASSOCIDE T05 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 animals.*

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			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake [mg/kg bw/d]**
1. Mixing and loading	Professionals / Trained professionals	Tier 1 / no PPE	1.27E-01
		Tier 2 / gloves and clothes	1.40E-03
2. Indoor application	Professionals / Trained professionals	Tier 1 / no PPE	2.79E-02
		Tier 2 / protective gloves	1.56E-02
3. Outdoor application	Professionals / Trained professionals	Tier 1 / no PPE	1.39E-02
		Tier 2 / protective gloves	7.79E-03
1 + 2.	Professionals / Trained professionals	Tier 1 / no PPE	1.51E-01
		Tier 2 / protective gloves	1.70E-02
1 + 2 + 3.	Professionals / Trained professionals	Tier 1 / no PPE	1.69E-01
		Tier 2 / protective gloves	2.48E-02
4. Mixing and loading	Non-professionals	Tier 1 / no PPE	1.83E-06
5. Indoor application	Non-professionals	Tier 1 / no PPE	1.16E-03
6. Outdoor application	Non-professionals	Tier 1 / no PPE	1.16E-03
4 + 5.	Non-professionals	Tier 1 / no PPE	1.16E-03
4 + 5 + 6.	Non-professionals	Tier 1 / no PPE	2.32E-03
7. Toddlers playing on treated area	General public	Tier 1 / no PPE	3.06E-02
8. Laundering working clothes	General public	Tier 1 / no PPE	1.11E-03
1 + 2 + 3 + 8.	General public	Tier 1 / no PPE	2.59E-02
1 + 2 + 3+ 4 + 5 + 6 + 8.	General public	Tier 1 / no PPE	2.82E-02

3.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation

Reference	**Study**	**NOAEL (LOAEL)**	**AF[1]**	**Correction for oral absorption**	**Value**
$AEL_{short\text{-}term}$	2-year rat toxicity study	NOAEL = 50 mg/kg bw/d	100	No	0.5

$AEL_{medium-term/long-term}$	1-year dog chronic toxicity study	NOAEL = 5 mg/kg bw/d	100	No	0.05
ARfD	2-year rat toxicity study	NOAEL = 50 mg/kg bw/d	100	No	0.5
ADI	1-year dog study	NOAEL = 5 mg/kg bw/d	100	No	0.05

[1] Please explain background and reason for assessment factor.

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

Risk for industrial users

No risk exposure is foreseen because as previously stated, no relevant exposure is foreseen, the product is intended to be manufactured but not to be used by industrial users. And considering that industrial users are adequately trained in the safe handling and manufacturing 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 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. Mixing and loading	Tier 1 / no PPE	5	0.05	1.27E-01	254.4	**No**
	Tier 2 / gloves and clothes	5	0.05	1.40E-03	2.8	Yes
2. Indoor application	Tier 1 / no PPE	5	0.05	2.79E-02	55.7	Yes
	Tier 2 / gloves and clothes	5	0.05	1.56E-02	31.2	Yes
3. Outdoor application	Tier 1 / no PPE	5	0.05	1.39E-02	27.9	Yes
	Tier 2 / protective gloves	5	0.05	7.79E-03	15.6	Yes

No unacceptable risk has been identified for different tasks considered when workers wear gloves and clothes.

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 + 2.	Tier 1 / no PPE	5	0.05	1.55E-01	310.2	**No**
	Tier 2 / protective gloves	5	0.05	1.70E-02	34.0	Yes
1 + 2 + 3.	Tier 1 / no PPE	5	0.05	1.69E-01	338.0	**No**
	Tier 2 / protective gloves	5	0.05	2.48E-02	49.5	Yes

No unacceptable risk has been identified for different combined tasks considered when workers wear gloves and clothes.

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 5000 ppm.

Therefore, no local effects are foreseen from the application of MASSOCIDE T05 product under label instructions.

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 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)
4. Mixing and loading	Tier 1 / no PPE	5	0.05	1.83E-06	0.01	Yes
5. Indoor application	Tier 1 / no PPE	5	0.05	1.16E-03	2.3	Yes

6. Outdoor application	Tier 1 / no PPE	5	0.05	1.16E-03	2.3	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)
4 + 5.	Tier 1 / no PPE	5	0.05	1.16E-03	2.3	Yes
4 + 5 + 6.	Tier 1 / no PPE	5	0.05	2.32E-03	4.7	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 5000 ppm.

Therefore, no local effects are foreseen from the application of MASSOCIDE T05 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. Toddlers playing on treated area	Tier 1 / no PPE	5	0.05	3.06E-02	61.2	Yes

8. Laundering working clothes	Tier 1 / no PPE	5	0.05	1.11E-03	2.2	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 + 2 + 3 + 8	Tier 1 / no PPE	5	0.05	2.59E-02	51.8	Yes
1 + 2 + 3+ 4 + 5 + 6 + 8	Tier 1 / no PPE	5	0.05	2.82E-02	56.4	Yes

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

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 5000 ppm.

Therefore, no local effects are foreseen from the application of MASSOCIDE T05 product under label instructions.

Conclusion

The risk derived from the use of MASSOCIDE T05 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 MASSOCIDE T05 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, the following RMM was therefore assigned:

- *Keep children away from treated surfaces.*

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

Risk for consumers via residues in food

MASSOCIDE T05 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.*
- *Keep children away from treated surfaces.*

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

The product MASSOCIDE T05 does not contain any further active substance or substance of concern so a combined exposure is not expected.

3.2.7 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.*

In addition, to prevent any exposure of animals the following RMMs are included:

- *Do not spread onto people and 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 animals.*

3.2.8 Risk assessment for the environmental

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

Summary on PNEC used for the risk assessment							
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

3.2.8.1 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

The biocidal product contains a single active substance, Permethrin. Further details of the composition of the biocidal product are given in the Confidential PAR. Synergistic effects between any of the components are not expected. 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. Therefore, the available data on the active substance Permethrin, as summarised in the Assessment Report (2014), are considered sufficient to enable a decision to be made concerning the classification of the biocidal product.

PermethrinNo aquatic, terrestrial or secondary poisoning toxicity studies were conducted with the product MASSOCIDE T05, 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 environmental classification of the product is Aquatic acute 1 (H400) and aquatic chronic 1 (H410).

Further Ecotoxicological studies

Data waiving	
Information requirement	-
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 MASSOCIDE T05. However, results of these tests, does not modify 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 MASSOCIDE T05 formulation which are of ecotoxicological relevance (see Confidential PAR), therefore no additional studies were performed and reference is made to the CAR, document IIA, section 4.2.

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 studies are deemed necessary.

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

Data waiving	
Information requirement	No data required
Justification	No further studies are deemed necessary.

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 studies are deemed necessary.

Endocrine disruption activity of non-active substances

The Commission Delegated Regulation (EU) 2017/2100 specifying the scientific criteria for the determination of endocrine-disrupting properties (ED criteria) under Regulation (EU) No 528/2012 (BPR) establishes that the ED criteria become applicable by 7 June 2018 for biocides (https://www.ctgb.nl/onderwerpen/hormoon-verstoorders).

No further ecotoxicological studies are available for MASSOCIDE T05. The product was not tested for potential endocrine disruption properties. MASSOCIDE T05 contains the active substance Permethrin and various co-formulants (see confidential PAR).

For the active substance, no ED assessment is required because for active substances which have been approved, the EU assessment should be followed. As discussed in the Assessment Report for Permethrin (April 2014), acute and chronic exposure to Permethrin was highly toxic to the three groups of aquatic organisms, affecting reproduction and survival in fish and D*aphnia* (Daphnia was the most sensitive species in the acute and chronic tests). Permethrin does not have an endocrine effect on fish.

For the co-formulants a screening was performed by consulting:

- ECHA data for identification of ED and PBT, under REACH or BPR or CLP
- Identified as ED by United States EPA (https://comptox.epa.gov/dashboard/)
- Identified as ED by the United Nations Environment (July 2017) Programme(http://wedocs.unep.org/bitstream/handle/20.500.11822/25634/edc_report2.pdf?sequence=1&isAllowed=y and https://wedocs.unep.org/bitstream/handle/20.500.11822/25635/edc_report2_factsheet.pdf?sequence=1&isAllowed=y)

During screening performance any co-formulant triggered an alert for ED property (See confidential PAR for further details).

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

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.	++	++	+	+	(+)
Outdoors applications	+	+	n.r.	n.r.	++	+	++	+	(+)

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

PermethrinPermethrinPermethrinPermethrinPermethrinPermethrin

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

Data waiving	
Information requirement	-
Justification	No further studies are deemed necessary.

Leaching behaviour (ADS)

Data waiving	
Information requirement	-
Justification	No further studies are deemed necessary.

Testing for distribution and dissipation in soil (ADS)

Data waiving	
Information requirement	-
Justification	No testing for dissipation and distribution in soil has been conducted on MASSOCIDE T05. 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. No further studies are deemed necessary.

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

Data waiving	
Information requirement	-

Justification	No testing for dissipation and distribution in water and sediment has been conducted on MASSOCIDE T05. 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. No further studies are deemed necessary.

Testing for distribution and dissipation in air (ADS)

Data waiving	
Information requirement	-
Justification	No testing for dissipation and distribution in air has been conducted on MASSOCIDE T05. 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. No further studies are deemed necessary.

3.2.8.2 Exposure assessment

The biocidal product MASSOCIDE T05 is an insecticidal dust formulation containing 0.5 % (w/w) of the active substance Permethrin. The b.p. is intended to be used indoors and outdoors by professionals and by non-professionals to control crawling insects in and around domestic premises and public or commercial buidlings.

Formulation and use of the insecticide MASSOCIDE T05 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 uses (OECD, 2008) as well as the technical agreements reached for the evaluation of biocidal products "Technical Agreements for Biocides" v.2.1) and based on the information relating to the intended uses of MASSOCIDE T05.

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

The assessed scenarios cover the intended uses by the applicant. In addition, efficacy studies supported an extra use not initialy intended by the applicant: general surface treatment by dusting applied by general public and professional users. In order to asses the environmental viability of this use, it has been included in the ERA of the product MASSOCIDE T05.

Assessed PT	PT18
Assessed scenarios	Scenario 1: Indoor – surface treatment in hiding places a) Professional b) Non-professional

	Scenario 2: Indoor – surface treatment a) Professional b) Non-professional Scenario 3: Indoor – Non-washable textile surfaces a) Professional b) Non-professional Scenario 4: Outdoor - Ant nests a) Large buildings b) Private houses
ESD(s) used	Emission Scenario Document for insecticides, acaricides and products to control arthropods (PT18) for household and professional uses (OECD, 2008)
Approach	All scenarios by average consumption
Distribution in the environment	Calculated based on: • Emission Scenario Document for insecticides, acaricides and products to control arthropods (PT18) for household and professional use (OECD, 2008) • Guidance on BPR Vol IV Part B+C (2017) • Technical Agreements for Biocides (TAB) – ENV v.2.1
Groundwater simulation	FOCUS PEARL 4.4.4.
Confidential Annexes	NO
Life cycle steps assessed	For all scenarios: Production: No Formulation No Use: Yes Service life: No
Remarks	-

Assessed scenarios: Intended uses and application rates for MASSOCIDE T05

Scenarios	Uses	Indoor / Outdoor	User	Type of application	Target pest	Application rate (a.i.)
1	01 and 02	Indoor	Professional and general public	Dusting powder in hiding places	Crawling insects*	50 mg/m^2
3	03 and 04	Indoor	Professional and general public	Dusting powder on non-washable textile surfaces by wet cleaning methods	Mites, bed bugs	50 mg/m^2
4	05 and 06	Outdoor	Professional and general public	Dusting powder on ant's nest around houses and commercial buildings on paved areas, balconies and terraces	Ants	50 mg/m^2

** Cockroaches deemed as worst case

Intended uses 06 and 07 have not been considered into the risk assessment due to lack of efficacy support. Nevertheless, the following uses 01´and 02´ were furhter supported by efficacy tests although not initially intended by the applicant. Therefore, they have been evaluated.

Scenarios	Uses	Indoor / Outdoor	User	Type of application	Target pest	Application rate (a.i.)
2	01´ and 02´*	Indoor	Professional and general public	Dusting powder (surface treatment)	Crawling insects*	50 mg/m^2

* Cockroaches deemed as the worst case.

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 following the Guidance on the BPR, Vol. IV, Part B+C (2017) and using the parameters 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 - Dusting powder in hiding places

According to the efficacy tests, the product is applied as spot application in hiding places where crawling insects are looking for food, paying special attention to grooves and cracks and areas behind or under machinery, kitchen equipment or pipes. As when this application was submitted no difference between voids and cavities and crack and crevice existed. According to the OECD ESD No. 18 as well as TAB v. 2.1 (ENV 149), for the envisaged application to voids and cavities a cleaning efficiency of 0 % is considered. In addition, a Restriction in Use with only dry-cleaning procedures has been considered.

No mixing and loading is deemed for general public (non-professional users) as the product is furnished as a ready-to-use. However, for professional users, 2 preparations of 50 g per day in a large building (50 g x 2 = 100 g) is deemed sufficient as the area considered to be treated in commercial buildings is 9.3 m^2.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 1: Indoor – Dusting powder in hiding places			
Application rate of biocidal product	10	g/m²	
Concentration of active substance in the product	0.5	% w/w	
Area treated, house	2	m^2	
Area treated, larger building	9.3*	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	2	d^{-1}	
Quantity of commercial product used per preparation	50	g	Only considered in mixing/loading for professional users
Fraction emmited to floor during mixing and loading (only for professional users)	0.01	-	

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 1: Indoor – Dusting powder in hiding places			
Frequency of application in standard houses and large buildings	3-11 (Profesional) 12 (Non-profesional)	Times a year	
Simultaneity factor for indoor uses of insecticide in standard houses and large buildings	0.00815 (Profesional) 0.01386 (Non-prof.)	-	
Fraction emitted to air during application	0.02	-	default
Fraction emitted to floor during application	0.18	-	default
Fraction emitted to applicator during application	0	-	default
Fraction emitted to treated surfaces	0.8	-	default
Cleaning efficiency	0[1]	-	default
Number of houses per STP	4000	-	default
Number of buildings per STP	300	-	Not relevant for non-professional user

* 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 can be deemed as spot application, 9.3 m^2 has been considered as the most realistic value.

[1] The value for cleaning efficiency in located applications of dust/powders is set following the ESD PT18 ENV/JM/MONO(2008)14, with a Fce = 0. At the time this PAR was firstly submitted, any distinction between crack/crevices and voids/cavities was reflected in the TAB and the value from the ESD only considered voids/cavities. The value for voids/cavities has been used into the assessment.

Calculations for Scenario 1

The following table summarizes the obtained local emission rates to the environment:

Local emission [kg.d^{-1}]	**Type of area treated**		
	Professional users		***Geneal public***
	Standard houses	Large buildings	Standard houses
Emissions during Mixing/loading (only considered for professional users)			
Local emission to floor	2.5E-06	5E-06	-
Emissions during product's application			
Local emission to air	2E-06	9.3E-06	2E-06
Local emission to applicator	0	0	0
Local emission to floor	1.8E-05	8.37E-05	1.8E-05

Local emission to treated surfaces	8E-05	3.72E-04	8E-05
Emissions during cleaning residues derived from mixing/loading (only for professional users)			
Local emission to wastewater from wet cleaning the floor	2.5E-06	5E-06	0
Emissions during cleaning after application			
Local emission to wastewater from washing applicator's 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 surfaces	0	0	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**
	Private use	**Industrial use**	
Freshwater	-	-	None
Freshwater sediment	-	-	None
Seawater	-	-	None
Seawater sediment	-	-	None
STP	0	9.37E-05	None
Air	1.11E-04	8.79E-05	None
Soil	-	-	None
Groundwater	-	-	None

Scenario 2 - Dusting powder (surface treatment)

No mixing and loading is deemed for non-professional users as the product is furnished as ready-to-use. However, due to the area considered to be treated, for professional users a total amount of 11 kg is needed. The use of dry cleaning methods here has not been considered realistic.

Considering the frequency of application supported by efficacy studies, the product has been deemed as effective with a single use and no post application is needed. Thus, a single application has been used in the assessment.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 1: Indoor – Dusting powder (surface treatment)			
Application rate of biocidal product	10	g/m²	
Concentration of active substance in the product	0.5	% w/w	
Area treated, house	22	m^2	Default
Area treated, larger building	3280	m^2	Default
Number of applications per day, house	1	d^{-1}	
Number of applications per day, large building	3	d^{-1}	
Fraction emmited to floor during mixing and loading (only for professional users)	0.01	-	
Frequency of application in standard houses and large buildings	1-2	Times a year	
Simultaneity factor for indoor uses of insecticide in standard houses and large buildings	0.00204	-	
Fraction emitted to air during application	0.02	-	Default
Fraction emitted to floor during application	0.18	-	Default
Fraction emitted to applicator during application	0	-	Default
Fraction emitted to treated surfaces	0.8	-	Default
Cleaning efficiency	0.5	-	Default
Number of houses per STP	4000	-	Default
Number of buildings per STP	300	-	Default. Not relevant for non-professional user

Calculations for Scenario 2

The following table summarizes the obtained local emission rates to the environment:

Local emission [kg.d^{-1}]	**Type of area treated**		
	Professional users		***Geneal public***
	Standard houses	Large buildings	Standard houses
Emissions during Mixing/loading (only considered for professional users)			
Local emission to floor	5.50E-04	1.65E-03	-
Emissions during product's application			
Local emission to air	2.2E-05	9.84E-03	2.20E-05

Local emission to applicator	0	0	0
Local emission to floor	1.98E-04	8.86E-02	1.98E-04
Local emission to treated surfaces	8.80E-04	3.94E-01	8.80E-04
Emissions during cleaning residues derived from mixing/loading (only for professional users)			
Local emission to wastewater from wet cleaning the floor	5.50E-04	1.65E-03	0
Emissions during cleaning after application			
Local emission to wastewater from washing applicator's coveralls	0	0	0
Local emission to wastewater from wet cleaning the floor	9.90E-05	4.43E-02	9.90E-05
Local emission to wastewater from wet cleaning the treated surfaces	4.40E-04	1.97E-01	4.40E-04

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**
	Private use	**Industrial use**	
Freshwater	-	-	None
Freshwater sediment	-	-	None
Seawater	-	-	None
Seawater sediment	-	-	None
STP	4.40E-03	1.58E-01	None
Air	1.80E-04	6.21E-03	None
Soil	-	-	None
Groundwater	-	-	None

Scenario 3 - Dusting powder on non-washable textile surfaces

In order to assess the use of MASSOCIDE T05 on soft furnishings (e.g. against mites or fleas) which are not routinely wet cleaned, the exposure scenario presented in TAB entry ENV 147 (treatment against cat fleas or bedbugs) has been considered.

All relevant input parameters to calculate the local emissions to STP are shown in the following table for Tier 1.

Input parameters for calculating the local emission – Tier 1			
Input	**Value**	**Unit**	**Remarks**
Scenario 3: Indoor – Dusting powder on non-washable textile surfaces			
Application rate of biocidal product	10	g/m²	
Concentration of active substance in the product	0.5	% w/w	
Area treated (large building)	93	m^2	default
Area treated (standard house)	22	m^2	default
Area subject to be wet cleaned in a large building (barrier)	27	m^2	default
Area subject to be wet cleaned in a domestic home (barrier)	5.9	m^2	default
Number of applications per day, house	1	d^{-1}	
Number of applications per day, large building	2	d^{-1}	
Quantity of commercial product used per preparation	50	g	Only considered in mixing/loading for professional users
Frequency of application in standard houses and large buildings	1-2	Times a year	
Simultaneity factor for indoor uses of insecticide in standard houses and large buildings	0.00204	-	
Fraction emitted to air during application	0.02	-	default
Fraction emitted to floor during application	0.18	-	default
Fraction emitted to applicator during application	0	-	default
Fraction emitted to treated surfaces	0.8	-	default
Cleaning efficiency	0.5	-	default
Number of houses per STP	4000	-	default
Number of buildings per STP	300	-	Not relevant for non-professional user

Calculations for Scenario 3

Tier 1

Resulting local emission to relevant environmental compartments – Tier 1		
Scenario 3: Indoor – Dusting powder on non-washable textile surfaces		
Output	**Value**	
	Non-professional users (standard houses)	Professional users (standard houses and large buildings)
Local emission to air [$kg.d^{-1}$]	1.8E-04	2.37E-04
Local emission to wastewater [$kg.d^{-1}$]	2.17E-04	5.05E-03

Tier 2

According to label instructions, dry cleaning methods are mandatory. Therefore, the cleaning efficiency has been set to 0 and no emission to the STP has been considered in Tier 2.

Resulting local emission to relevant environmental compartments – Tier 2		
Scenario 3: Indoor – Dusting powder on non-washable textile surfaces – Dry cleaning		
Output	**Value**	
	Non-professional users (standard houses)	Professional users (standard houses and large buildings)
Local emission to air [kg.d^{-1}]	1.8E-04	2.37E-04
Local emission to wastewater [kg.d^{-1}]	0	0

Scenario 4 - Dusting powder on ant's nest

Following ESD PT18 No.18 and considering the proposed use pattern of the b.p., direct powdering on ants´ nest can be described as spot application. Release to the air is considered negligible and environmental exposure may only arise following flooding from a rain event over treated areas. These emissions may enter directly into the surrounding soil or will be released to a STP system with subsequent indirect release to the environmental compartments surface water, sediment, soil (via sludge application) and groundwater. The label instructions state that the use of MASSOCIDE T05 is restricted to paved surfaces of terraces or balconies and not on bare soil. Consequently, the emission to soil due to application on unpaved soil has not been considered. It is presumed that outdoor areas of private houses, such as gardens, terraces and balconies, are not connected to an STP system. Therefore, release to STP is only considered for b.p. application around larger buildings.

According to the ESD for PT18 (2008), when the b.p. is used outdoors the mixing/loading step may be performed inside or outside a building nearby. For worst case considerations it is assumed that the product is prepared outside the building. The product label gives risk mitigation measure that the soil is covered during preparation for the professional user. It is presumed that the professional user of MASSOCIDE T05 is instructed by the label to prevent spilling to the floor during mixing/loading by appropriate measures, e.g., covering the floor with a plastic sheet before mixing and application. Regarding the use of the b.p. by general public, MASSOCIDE T05 is furnished as a RTU product. Therefore, no emissions to the environment are expected during mixing/loading.

The input values for determining the releases from b.p. applications on paved surfaces in the course of spot application around larger buildings and private houses as well as the calculated emission rates are summarised bellow. It is not current practice to collect unconsumed product and therefore, it is considered that 90% of the used product may end-up in the adjacent soil or STP.

Estimation of releases from b.p. applications on paved surfaces

The input values for determining the releases from b.p. applications on paved surfaces in the course of spot application around larger buildings and private houses, respectively, as well as the calculated emission rates are summarised bellow. An application rate of 10 $g.m^{-2}$ is prescribed in label instructions of the biocidal product. Using this value we can derive the amount of product applied for both private houses and larger building scenarios. In this regard, the generic treatment areas to each specific pest as assigned at the WG-I-2018 and at TAB entries ENV 155 and 159 were used.

In the case of private houses, ants´ nest treatment must be assessed by using the terrace scenario, which entails 4 applications and a default receiving area of 8.5 m^2 (ENV 155 and ENV 159). Following the ESD PT18 description of receiving compartment, as spot application ant´s nest can be simplified as a square surface portion with dimension of 0.5 x 0.5 m (0.25 m^2). This area is considered as a realistic approach to the expected dimensions of an ant´s nest entrance.

According to this model, the quantity of biocidal product to be applied per nest is equal to 2.5 g b.p., and gives a total of 10 g b.p. applied on a terrace of private houses.

According to ESD PT18 No. 18 (2008), equivalent information is not available for larger public or industrial buildings and data needs to be extrapolated from house model. A default perimeter of 100 m is proposed for outdoor applications of insecticides around larger buildings (TAB v. 2.1 ENV 159). Therefore, considering the default values set for a private house terrace, the application rate for larger buildings can be derived following two different approaches:

a) a total amount of 10 g b.p. is applied on a terrace which side adjacent to the house has a length of 6 m, therefore the application rate per perimeter unit is 1.67 g b.p. m^{-1}.
b) 4 applications are expected on a terrace with 6 m of side length, therefore the numer of nests per perimeter unit is 0.67.

Regardless which approach is followed, an overall application of 166.67 g b.p. around a larger building is obtained.

The application of the b.p. in an outdoor larger building scenario results in a release to paved soil surfaces of **7.50E-01** g Permethrin. In case of application of the b.p. around private houses, the terrace scenario leads to calculated release of **4.50E-02** g Permethrin to surrounding receiving soil area.

Calculations for Scenario 4

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: Outdoor – Spot application into ant's nest			
Application rate of commercial product	10	$g \cdot m^{-2}$	
Quantity of commercial product applied per nest	2.5	g	

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: Outdoor – Spot application into ant's nest			
Fraction of active substance in the product	0.005	-	
Fraction emitted to soil during application	0.9	-	Default
Number of application sites	4	-	Default (terrace)
Number of applications during a campaign	1	-	Default
Area exposed to insecticide	8.5	m^2	Default (terrace)
Treated perimeter around larger buildings	100	m	Default
Depth of exposed soil	0.5	m	Default
Volume of exposed soil	0.125	m^3	Default
Bulk density of soil	1700	Kgwwt. m^{-3}	Default
Output			
Local direct emission rate to receiving soil area - terrace scenario (paved surfaces) in private houses	4.50E-02	$g.d^{-1}$	
Local direct emission rate to paved surfaces around larger buildings	7.50E-01	g.d-1	

Estimation of release to soil due to direct release after a campaign

Local concentration in soil:

$$C_{spot,soil} = \frac{E_{spot,\ soil}}{AREA_{exposed} \times DEPTH_{soil} \times RHO_{soil}} = 6.23E\text{-}03\ mg.kg^{-1}$$

Estimation of release to sewage treatment plants from commercial buildings

In frame of BPR, estimates of potential exposures resulting from STPs are carried out according to the Guidance on BPR, Vol. IV, Parts B+C (Version 2.0, 2017). According to this, the further receiving environmental compartments are surface water and sediment (after STP), soil and groundwater (from sludge application), and the outdoor air.

The input values for determining releases to STP in the course of spot application as well as the calculated emission rates are summarised bellow. Outgoing from a maximum application of 1-2 times per year a simultaneity factor of 0.204% (F_{sim} = 0.00204) was applied.

Determinants of the emission scenario	**Value**
Local direct emission rate to paved surfaces - larger buildings	7.50E-01 $g.d^{-1}$
Number of larger buildings connected to STP	300

- larger buildings	
Simultaneity factor outdoor	0.00204228
Output	
Simultaneous emission to STP	4.59E-04 $g.d^{-1}$

The application of the b.p. in a typical scenario around commercial buildings results in a simultaneous release of **4,59E-04** $g.d^{-1}$ Permetrhin to the STP.

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway							
	Fresh-water	**Freshwater sediment**	**STP**	**Air**	**Soil**	**Ground-water**	**Secondary poisoning**
Scenario 1	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Scenario 2	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Scenario 3	Yes*	Yes*	Yes*	Yes	Yes*	Yes*	Yes*
Scenario 4	Yes**	Yes**	Yes**	Yes	Yes	Yes	Yes

* Considered only for Tier 1.

** Considered only for large buildings.

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 20ºC)	2.155E-6	Pa	
Water solubility (at 20°C)	0.18	mg/l	
Log Octanol/water partition coefficient (at 25°C)	4.67	Log 10	
Organic carbon/water partition coefficient (Koc)	26930	l/kg	arithmetic mean, n=10
Henry's Law Constant (at 20º C)	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
Bioconcentration factor	23.8 (earthworm) 20700 (fish)	L/Kg	Estimated values by USES, AR.

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

Calculated fate and distribution in the STP		
Compartment	**Percentage [%]**	**Remarks**
Air	negligible	-
Water	26.19	-
Sludge	73.81	-
Degraded in STP	0	-

Metabolites

According to the AR for the a.s. Permethrin (2014) two major metabolites need to be considered for the aquatic and terrestrial compartment, which are DCVA and PBA. The metabolites are far less toxic to aquatic organisms than the parent a.s. and are, according to the AR (2014), not ecotoxicologically relevant. The same applies for the soil compartment. However, the quantitative risk assessments for the major water will be calculated for completness.

The two major metabolites (DCVA and PBA) are expected to be more mobile in soil with mean Koc 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 after distribution of sewage sludge or manure. Therefore, the risk for the groundwater is quantitatively assessed for the major metabolite DCVA (worst case DT50 soil [12°C]: 175 d). Aquatic and soil metabolite DCVA is presented for completeness. Considering that PBA is less persistent (DT50 in soils is 2.5 d (12°C) and less mobile, the risk assessment for DCVA covers the risks for PBA. The concentrations in groundwater result from the terrestrial PEC. The latter was calculated by correcting the concentration active substance for the differences in molar weight (209.07/391.3=0.534) and the observed maximum fraction in soils (11.3%).

Input parameters (only set values) for calculating the fate and distribution in the environment				
Input	DCVA	PBA	Unit	Remarks
Molecular weight	209.07	214.22	g/mol	
DT50 for degradation in soil (at 12ºC)	175	2.5	d	
Molecular correction factor	0.534[a]	0.548[a]	-	
Percentage metabolite in soil	11.3	15	%	
Percentage metabolite in water	62.6	28.8	%	
Percentage metabolite in sediment	21.7	16.4	%	

a = mol. $weight_{metabolite}$ / mol. $weight_{Permethrin}$

Calculated PEC values

- **Permethrin**

Concentrations in groundwater are assumed to be identical to concentrations in soil porewater and were calculated according to equation (70) of the Guidance on BPR IV/B+C (2017), whereby the soil-water partitioning coefficient $K_{soil\text{-}water}$ is calculated according to the guidance (808.1 $m^3 \cdot m^{-3}$). The concentrations in groundwater are derived from the concentration in agricultural soil at 180 days.

Summary table on calculated PEC values						
Scenarios		**PEC_{STP}**	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{GW}**
		[mg/L]	[mg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/L]
Scenario 1						
Professional		1.23E-05	1.18E-06	6.92E-04	1.29E-04	1.75E-04
Non-professional		0	0	0	0	0
Scenario 2						
Professional		2.06E-02	1.98E-03	1.16E+00	2.17E-01	**2.95E-01**
Non-professional		5.77E-04	5.54E-05	3.25E-02	6.05E-03	8.23E-03
Scenario 3						
Tier1	Professional	6.61E-04	6.35E-05	3.73E-02	6.94E-03	9,44E-03
	Non-professional	2.84E-05	2.73E-06	1.60E-03	2.98E-04	4,06E-04
Tier2	Professional	-	-	-		
	Non-professional	-	-	-		
Scenario 4						
Private house (Non-professional)		-	-	-	6.23E-03	1.31E-02
Large buildings (Professional)		6.02E-08	5.78E-09	3.39E-06	6.31E-07	8.59E-07

Predicted environmental concentration in pore water for Scenario 2 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.

- **Metabolites**

As mentioned, 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 for DCVA					
Scenarios		**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{GW}**
		[mg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/L]
Scenario 1					
Professional		3.94E-07	1.11E-06	7.77E-06	2.85E-03
Non-professional		0	0	0	0
Scenario 2					
Professional		6.63E-04	1.35E-01	1.31E-02	**4.80**
Non-professional		1.85E-05	3.76E-03	3.65E-04	**1.34E-01**
Scenario 3					
Tier1	Professional	2.12E-05	4.32E-03	4.18E-04	**1.54E-01**
	Non-professional	9.13E-07	1.85E-04	1.80E-05	6.60E-03
Tier2	Professional	-	-	-	-
	Non-professional	-	-	-	-
Scenario 4					
Private house (Non-professional)		-	-	3.76E-04	**2.13E-01**
Large buildings (Professional)		1.93E-09	3.93E-07	3.81E-08	1.40E-05

Predicted environmental concentrations for DCVA in pore water for Scenarios 2, 3 and 4 (private houses) 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.

Primary and secondary poisoning

Primary poisoning

According to the Emission Scenario Document for PT 18 (ESD PT 18), the direct consumption of insecticidal products by birds and mammals mainly occurs when insecticides are applied together with food attractants or are applied as granular formulation. Both does not apply for MASSOCIDE T05. Therefore, the assessment of primary poisoning has not been addressed for MASSOCIDE T05.

Secondary poisoning

The log Kow of Permethrin (4.67) is above the trigger value of 3 suggesting that the substance may have significant potential for bioconcentration in both aquatic and terrestrial biota.

Scenarios 1 (for non-professionals) and 3 (Tier 2) disclose a potential emission to wastewater due to label instructions. These scenarios consider by default an emission to

wastewater by wet cleaning treatment which is not the intended use of the product and secondary poisoning is not expected to these scenarios.

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			
Professional		4.88E-02	1.63E-02
Non-professional		0	0
Scenario 2			
Professional		8.21E+01	2.75E+01
Non-professional		2.29	7.67E-01
Scenario 3			
Tier1	Professional	2.63	8.79E-01
	Non-professional	1.13E-01	3.78E-02
Tier2	Professional	-	-
	Non-professional	-	-
Scenario 4			
Private house (Non-professional)		-	-
Large buildings (Professional)		2.39E-04	8.00E-05
Terrestrial food chain		**PEC $_{oral.predator.terrestrial}$ (mg/kg)**	
Scenario 1			
Professional		1.22E-05	2.66E-06
Non-professional		0	0
Scenario 2			
Professional		2.06E-02	4.48E-03
Non-professional		5.74E-04	1.25E-04
Scenario 3			
Tier1	Professional	6.59E-04	1.44E-04
	Non-professional	2.83E-05	6.17E-06

Tier2	Professional	-	-
	Non-professional	-	-
Scenario 4			
Private house (Non-professional)		9.14E-04	1.99E-04
Large buildings (Professional)		5.99E-08	1.31E-08

3.2.8.3 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). 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 for DCVA in water, sediment and soil has been performed for the sake of completeness (risk of PBA is considered covered by DCVA). No assessment on PB alcohol can be performed as no data on PNEC value are available.

Atmosphere

Conclusion:

The formulation type of the product (DP), 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.

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 $PEC/PNEC_{STP}$			
		Permethrin	**DCVA**
Scenario 1			
Professional		7.76E-03	-
Non-professional		5.29E-03	-
Scenario 2			
Professional		**4.17**	-
Non-professional		1.16E-01	-
Scenario 3			
Tier1	Professional	1.34E-01	-

	Non-professional	5.74E-03	-
Tier2	Professional	-	-
	Non-professional	-	-
Scenario 4			
Private house (Non-professional)		-	-
Large buildings (Professional)		1.22E-05	-

Conclusion:

The obtained PEC/PNEC ratios in this assessment discloses potential risk due to emission to STP from Scenario 2 (by professional use).

According to the obtained PEC/PNEC ratios for the other assessed scenarios, the use of MASSOCIDE T05 is safe for the microorganisms involved in biodegradation processes in the STP, since the ratio between PEC/PNEC is lower than 1.

Therefore, the emission to STP derived from surface dust treatment by professional user poses un unacceptable risk to the environment and this use cannot be granted.

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 $PNEC_{sed}$.

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

Summary table on PEC/PNEC					
		$PEC/PNEC_{water}$		**$PEC/PNEC_{sed}$**	
		Permethrin	**DCVA**	**Permethrin**	**DCVA**
Scenario 1					
Professional		**2.51**	2,63E-05	**3.19**	6,68E-03
Non-professional		**0**	0	**0**	0
Scenario 2					
Professional		**4.22E+03**	4.42E-02	**5.36E+03**	**1.12E+01**
Non-professional		**1.18E+02**	1.24E-03	**1.50E+02**	3.14E-01
Scenario 3					
Tier 1	Professional	**1.35E+02**	1.42E-03	**1.72E+02**	3.60E-01
	Non-professional	**5.81**	6.08E-05	**7.37**	1.55E-02
Tier 2	Professional	-	-	-	-
	Non-professional	-	-	-	-
Scenario 4					
Private house (Non-professional)		-	-	-	-
Large buildings (Professional)		1.23E-02	1.29E-07	1.56E-02	3.27E-05

Conclusion for aquatic compartment:

The assessment of scenario 1 showed an unacceptable risk for surface water compartment for both professional and non-professional users. However, this risk can be reduced to acceptable levels or prevented by imposing the following RMM: Cover the soil with a plastic sheet before mixing and loading the biocidal product prior to application. Therefore, this use is considered to be acceptable.

An unacceptable risk is foreseen at scenario 2. This risk cannot be reduced or prevented by RMM and is not considered to be acceptable.

On the other hand, an unacceptable risk is foreseen at scenario 3 during Tier 1. However, this risk is removed at Tier 2 when, following label instructions, dry cleaning methods are considered.

When the product is applied outdoors to treat ant nests (scenario 4), emission to STP is only expected for large buildings and acceptable risk is foreseen to the aquatic compartment for both Permethrin and DCVA.

Taking into account the mandatory label instructions of the b.p. MASSOCIDE T05, acceptable risk is expected for the aquatic compartment for scenarios 3 and 4. General surface treatment by dusting or treatment of hiding areas cannot be accepted.

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 $PEC/PNEC_{Soil}$			
		Permethrin	**DCVA**
Scenario 1			
Professional		7.36E-04	1.69E-06
Non-professional		0	0
Scenario 2			
Professional		**1.24**	2.84E-03
Non-professional		3.46E-02	7.93E-05
Scenario 3			
Tier1	Professional	3.96E-02	9.10E-05
	Non-professional	1.70E-03	3.91E-06
Tier2	Professional	-	-
	Non-professional	-	-
Scenario 4			
Private house (Non-professional)		3.56E-02	6.94E-04

Large buildings (Professional)	3.61E-06	8.28E-09

Conclusion:

An unacceptable risk is foreseen at scenario 2 for professional user. This risk cannot be reduced or prevented by RMM implementation and therefore this use is not considered to be acceptable.

According to the obtained PEC/PNEC ratio, the use of MASSOCIDE T05 is safe for the soil compartment for the rest of assessed scenarios.

Groundwater

Summary table on PEC_{GW} [µg/L]			
		Permethrin	**DCVA**
Scenario 1			
Professional		1.75E-04	2.85E-03
Non-professional		0	0
Scenario 2			
Professional		**2.95E-01**	**4.80**
Non-professional		8.23E-03	**1.34E-01**
Scenario 3			
Tier1	Professional	9.44E-03	**1.54E-01**
	Non-professional	4.06E-04	6.60E-03
Tier2	Professional	-	-
	Non-professional	-	-
Scenario 4			
Private house (Non-professional)		1.31E-02	**2.13E-01**
Large buildings (Professional)		8.59E-07	1.40E-05

Values on bold are above the trigger value (1E-04 mg/L) and deemed of concern.

Conclusion:

According to the obtained PEC_{GW}, the use of MASSOCIDE T05 is safe for the groundwater compartment in scenarios 1 and 3 (Tier 2, following label instructions), since the final PEC_{GW} expected is lower than the trigger value for drinking water of 0.1 µ/L for both Permethrin and the metabolite DCVA.

The values obtained for scenario 2 are above the trigger value of 0.1 µg/L and denote an unacceptable risk to the environment derived from this scenario. Considering the unacceptable risk values also obtained for this scenario in other environmental compartments, further refinement is not deemed necesary for this scenario as this use is not granted.

Regarding scenario 4, direct emission to soil from private houses leads to groundwater values above the limit for DCVA. Thus, 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	<0.000001	<0.000001
Hamburg	<0.000001	<0.000001
Jokioinen	<0.000001	<0.000001
Kremsmünster	<0.000001	<0.000001
Okehampton	<0.000001	<0.000001
Piacenza	<0.000001	<0.000001
Porto	<0.000001	<0.000001
Sevilla	<0.000001	<0.000001
Thiva	<0.000001	<0.000001

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

Primary and secondary poisoning

Primary poisoning

Not relevant

Secondary poisoning

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 from the potential PEC in surface water and the estimated bioconcentration factor for fish.

The risk to predators 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 and DCVA 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			
		Permethrin	**DCVA**
Aquatic food chain		**PEC $_{oral,predator,aquatic}$ (mg/kg)**	
Scenario 1			
Professional		2.92E-03	9.78E-04
Non-professional		0	0
Scenario 2			
Professional		**4.92**	**1.64**
Non-professional		1.37E-01	4.59E-02
Scenario 3			
Tier1	Professional	1.58E-01	5.27E-02
	Non-professional	6.77E-03	2.26E-03
Tier2	Professional	-	-
	Non-professional	-	-
Scenario 4			
Private house (Non-professional)		-	-
Large buildings (Professional)		1.43E-05	4.79E-06
Terrestrial food chain		**PEC $_{oral.predator.terrestrial}$ (mg/kg)**	
Scenario 1			
Professional		7.32E-07	1.60E-07
Non-professional		0	0
Scenario 2			
Professional		1.23E-03	2.68E-04
Non-professional		3.44E-05	7.49E-06
Scenario 3			
Tier1	Professional	3.94E-05	8.59E-06
	Non-professional	1.69E-06	3.69E-07
Tier2	Professional	-	-
	Non-professional	-	-

Scenario 4		
Private house (Non-professional)	5.47E-05	1.19E-05
Large buildings (Professional)	3.59E-09	7.82E-10

Conclusion:

As it can be observed, the PEC/PNEC ratio is lower than 1 for Permethrin and DCVA for all the assessed scenarios except for profesional user in scenario 2, indicating acceptable risk of secondary poisoning throught the terrestrial food-chain via earthworm and aquatic food chain via fish for all assessed scenarios except por scenario 2.

Mixture toxicity

The b.p. contains only one a.s. There are no substances of concern with regards to the environment. An assessment of the mixture toxicity is therefore not necessary.

Aggregated exposure (combined for relevant emission sources)

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

Overall conclusion

Overall conclusion on the risk assessment for the environment of the product
An acceptable risk is foreseen at assessed compartments for scenarios 1, 3 and 4, when the claimed application processes on product's label are followed for each scenario or RMM are applied Indoor scenario 2 (surface dusting powder) and scenario 3 (tier I, dusting powder over non washable textile surfaces) shows an unacceptable risk for the environment when consider a default emission to STP. According to the risk values obtained, the application of MASSOCIDE T05 by surface dusting (general surface) cannot be granted. Regarding scenario 3, the emission to STP should be prevented by label instructions and RMM application. When the product is applied outdoors to treat ant nests on paved surfaces such as terraces or balconies (Scenario 4), an unacceptable risk for the environment is not expected.

3.2.9 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.

3.2.10 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.

3.2.11 Comparative assessment

Not relevant

4 ANNEXES

4.1 List of studies for the biocidal product (family)

Please, see confidential PAR.

4.2 Model used and exposure calculations

4.2.1 Human exposure model

Human Exposure Calculations_MASSC

4.3 New information on the active substance

None.

4.4 Residue behaviour

Not required.

4.5 Summaries of the efficacy studies

See summary table of efficacy tests. section 2.2.5.5.

4.6 Confidential annex

Please, see confidential PAR.