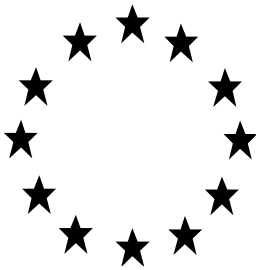
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



MASSOCIDE AD04

Product type 18

Alpha-cypermethrin as included in the Union list of approved active substances

Case Number in R4BP: BC-YY025228-97

Evaluating Competent Authority: SPAIN

Date: July 2023

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Monday, 17 August 2020

Endocrine Disruptor Certificate

Whom may concern

According to CLP classification and product's formulation no further substances of concern than the active substance has been identified in MASSOCIDE AD 0.4 formulation.

Following active substance's CAR, Alpha-cypermethrin has not been shown to have toxic effect on endocrine organs and has not been identified as having endocrine disrupting properties, non of the other ingredients are considered to pose any risk or have any potential endocrine system effect they are inorganic carriers with a low bioavailability potential.

Any of the ingredients present in MASSOCIDE AD04 is the ECHA´s **Endocrine disruptor assessment list published on ECHA´s Website .** ECHA's endocrine disruptor (ED) assessment list includes the substances undergoing an ED assessment under REACH or the Biocidal Products Regulation that have been brought for discussion to ECHA's ED Expert Group.

Non of the substances present in MASSOCIDE AD04 have neither similar profile nor chemical structure equivalent to the 93 substances included in the above list , that may lead any potential endocrine disruption properties

COMERCIAL QUMICA MASSO , SA
PDO. Rosana MARIN

Rosana Marin Sanchez

Regulatory Affairs Manager

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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-YY025228-97	July 2023	Initial assessment

NA-AAT	ES	BC-JE087816-31	August 2023	Amended only Spanish authorisation; typographic mistake

1 CONCLUSION

The biocidal product MASSOCIDE AD04 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 and technical properties
The biocidal product contains 0.4 %w/w Alpha-cypermethrin 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 Alpha-cypermethrin in the biocidal product. Validated analytical methods are also available for the determination of Alpha-cypermethrin in soil, water and air matrices. Other analytical methods are not required.

Efficacy
The biocidal product is effective against *Lasius niger* outdoors.

Human Health
The biocidal product contains the active substance alpha-cypermethrin (0.4%) 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 is taken into account.
According to the CAR and BPC's documents of the active substance alpha-cypermethrin 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.
Finally, evaluating the exposure and characterizing the risk to human health of the biocidal products according to the pattern of use requested by the applicant, the conclusions for each scenario are:

Summary table risk assessment for human health			
Scenario	**Scenario**	**Conclusion**	**Exposed group**
1.	Scattering application	A **safe** situation has been identified for dusting application in outdoor areas when the corresponding instruction for use is used.	Professional / Trained professional users
2.	Mixing and loading	A **safe** situation has been identified for loading of product into application device when the corresponding instruction for use is used.	Non-professional users
3.	Scattering application	A **safe** situation has been identified for dusting application in outdoor areas when the corresponding instruction for use is used.	Non-professional users
Combined scenarios 2 + 3.	M&L + scattering application	A **safe** situation has been identified for M&L and dusting application in outdoor areas when the corresponding instruction for use is used.	Non-professional users

Summary table risk assessment for human health			
Scenario	**Scenario**	**Conclusion**	**Exposed group**
Combined scenarios 1 + 2 + 3.	M&L + scattering applications	A **safe** situation has been identified for M&L and dusting applications in outdoor areas when the corresponding instruction for use is used.	Non-professional users
4.	Toddler playing on treated surfaces	A **safe** situation has been identified for toddler playing and/or crawling on treated surfaces when the corresponding instruction for use and RMM are used.	General public (toddler-chronic)
5.	Laundering	A **safe** situation has been identified for adults laundering contaminated normal/work clothing when the corresponding instruction for use and RMM are used.	General public (adult-chronic)
Combined scenarios 1 + 5	scattering application + laundering	A **safe** situation has been identified for M&L. dusting application in indoor areas and laundering contaminated work clothing when the corresponding instruction for use and RMM are used.	General public (adult-chronic)
Combined scenarios 1 + 2 + 3 + 5	M&L + scattering applications + laundering	A **safe** situation has been identified for M&L. dusting application in indoor areas and laundering contaminated work clothing when the corresponding instruction for use and RMM are used.	General public (adult-chronic)

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

Environment:
A coformulant has been identify as substance of concern for the environment, hence the environmental assessment has been accomplished for the a.s as well as for the SoC.

Despite the fact that the applicant has requested to evaluate the B.P. for indoors disinfestation of domestic and industrial premises, disinfestation of breeding premises and disinfestation of outdoor foundations and soil around the buildings in urban and rural areas, by not providing efficacy studies in this regard, ES CA has only carried out the environmental assessment for the scenario 4, disinfestation of ant nests (due to lack of effective dose to assess the above scenarios):

- 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 use of MASSOCIDE AD04 is 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 AD04, 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 – Outdoor – Directly application in ant nests – Professionals / Trained Professionals	Black ant (*Lasius niger)* – adults.	Professionals / Trained Professionals	Dose: 1.7 g per nest Apply 1.7 g per nest (in 0.14 m^2, e.g. 37cm*37cm), (application rate: 12.14 g/m^2). If no reduction is observed, 1.7 g must be reapplied after 14 days.	Do not spread directly on people, animals or bedding. Do not use/apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock/pets. Keep cats away from treated surfaces. Due to their particular sensitivity to pyrethroids, the product can cause severe adverse reactions in cats. Contains Alpha-Cypermethrin, may be dangerous/toxic to pets (e.g. cats, bees, fish and other aquatic organisms). Keep out of reach of children and non-target animals/pets. All accidental emissions to aquatic or soil compartment should be avoided.
Use # 2 – Outdoor – Directly application in ant nests – General public (non-professional users)	Black ant (*Lasius niger)* – adults.	General public (non-professional users)	Dose: 1.7 g per nest Apply 1.7 g per nest (in 0.14 m^2, e.g. 37cm*37cm), equivalent to 11 rotations per nest when the duster dispenser is used (application rate: 12.14 g/m^2). If no reduction is observed, 1.7 g must be reapplied after 14 days.	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 Alpha-cypermethrin. Alternate with products containing different active substances.

Uses	Target organisms	User categories	Authorised application rates	Use conditions: risk mitigations measures
				When the infestation persists contact a (trained) professional.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier[1]	**Country (if relevant)**
MASSOCIDE AD04 PAPARRIN DP ALFAMITE DP	Spain

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	COMERCIAL QUIMICA MASSÓ SA
	Address	Viladomat 321 , 5º 08029 BARCELONA SPAIN
Authorisation number	ES-APP(NA)-2023-18-00885	
Date of the authorisation	12/07/2023	
Expiry date of the authorisation	12/07/2033	

2.1.1.3 Manufacturer(s) of the product

Name of manufacturer	COMERCIAL QUIMICA MASSÓ SA
Address of manufacturer	Viladomat 321 , 5º 08029 BARCELONA SPAIN
Location of manufacturing sites	Avda. Cadi 12-14 Pol. Ind. Sant Pere Molanta 08799 Olerdola- Barcelona SPAIN

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

Active substance	Alpha-cypermethrin
Name of manufacturer	BASF Agro B.V. Arnhem (NL) Freienbach Branch
Address of manufacturer	Huobstrasse 3, 8808 Pfäffikon SZ Switzerland
Location of manufacturing site 1	Tagros Chemicals India Ltd. A-4/1&2, Sipcot Industrial Complex Pachayankuppam 607 005 Cuddalore-607005 India

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

Location of manufacturing site 2	Bayer Vapi Private Ltd. (formerly Bilag Industries Private Ltd.) Plot No. 306/3; II Phase GIDC, Vapi-396195 Gujarat India

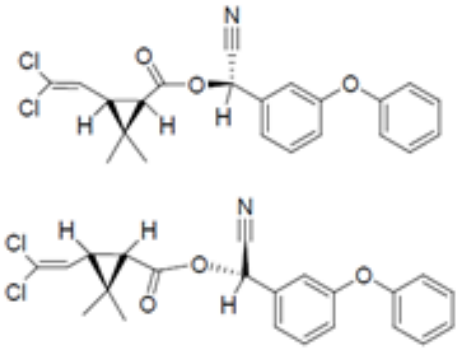
2.1.2 Product composition and formulation

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

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

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	Alpha-Cypermethrin
IUPAC or EC name	Reaction mass of (S)-α-cyano-3-phenoxybenzyl-(1R,3R)-3-(2,2 dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate and (R)-α-cyano-3-phenoxybenzyl-(1S,3S)-3-(2,2-dichlorovinyl)-2,2 imethylcyclopropanecarboxylate (1:1)
EC number	Not available
CAS number	67375-30-8
Index number in Annex VI of CLP	607-422-00-X
Minimum purity / content	930 g/kg (93.0% w/w) Sum of the isomers in a 1:1 ratio
Structural formula	$C_{22}H_{19}Cl_2NO_3$ 

2.1.2.2 Candidate for substitution

According to SANTE-2018-11525 Rev 3 (17 July 2019), the active substance alpha-cypermethrin is considered candidate for substitution. It fulfils the criteria of Article 10 point 1-c of BPR, which claims that a substance could be considered as candidate for substitution if its acceptable daily intake, acute reference dose or acceptable operator exposure level, as appropriate, is significantly lower than those of the majority of approved active substances for the same product-type and use scenario.
On the other hand, the applicant desires to point out that this affirmation has not been included yet under BPR until active substance renewal.

Note: The substitution criteria in BPR Article 10(1)a-f are not met.

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Alpha-Cypermethrin	Reaction mass of (S)-α-cyano-3-phe-noxybenzyl-(1R,3R)-3-(2,2 dichlorovi-nyl)-2,2-dimethylcyclopropanecarbox-ylate and (R)-α-cyano-3-phenoxyben-zyl-(1S,3S)-3-(2,2-dichlorovinyl)-2,2 imethylcyclopropanecarboxylate (1:1)	Active substance	67375-30-8	--	0.4 %
Silicon Dioxide, Amorphous Synthetic	Silicon dioxide	Non-active substance	112926-00-8	231-545-4	0.1%
For further details on product composition please refer to Confidential PAR.					

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

2.1.2.4 Information on technical equivalence

The active substance supplier of alpha-cypermethrin in this application dossier is the original notifier of inclusion into Annex I of BPD. Thus, the technical equivalence information is not applicable.

2.1.2.5 Information on the substance(s) of concern

According to the definition of a substance of concern laid down in the Guidance on the BPR Volume III Human Health- Assessment & Evaluation– Part B and C Risk Assessment (Version 4.0 December 2017), MASSOCIDE AD04 does not contain any substance of concern.
Regarding the environmental assessment, there is a coformulant that could be considered as SoC.

Please see the confidential annex for further details.

2.1.2.6 Type of formulation

DP - dustable powder

2.1.3 Hazard and precautionary statements

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

Classification	
Hazard category	Aquatic acute 1; Aquatic Chronic 1
Hazard statement	H410: very toxic to aquatic life with long lasting effects.
Labelling	
Pictogram	 GHS09
Signal words	Warning
Hazard statements	H410: Very toxic to aquatic life with long lasting effects.
Precautionary statements	P102: Keep out of reach of children. P103: Read label before use. P273: Avoid release to the environment. P391: Collect spillage. P501: • Trained professional users: Dispose of contents/container as hazardous waste to a registered establishment or undertaking, in accordance with current regulations. • Professionals and Non-professional users: Dispose of content and / or its container as hazardous waste according to the regulations in force.
Note	

2.1.4 Authorised use(s)

2.1.4.1 Use # 1 – Outdoor – Directly application in ant nests by professional users (Trained and non-trained professional)

Table 1. Use # 1 – Outdoor – Directly application in ant nests by professional users (Trained and non-trained 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 ant nests.
Target organism (including development stage)	Black ant (*Lasius niger*) – adults.
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 The product is intended to be applied directly from the packaging into the ant nest. It cannot be applied aerially.
Application rate(s) and frequency	Dose: 1.7 g per nest Apply 1.7 g per nest (in 0.14 m^2, e.g. 37cm*37cm), equivalent to 11 rotations per nest when the duster dispenser is used (application rate: 12.14 g/m^2). If no reduction is observed, 1.7 g must be reapplied after 14 days.
Category(ies) of users	Professional / Trained Professionals users
Pack sizes and packaging material	Professional: 250, 350, 500 g plastic dust dispenser(PET-PP) Trained Professional: 100, 250, 500 g and 1kg, 5 kg (PET) bag/sac (combined packaging up to 20 kg net weight) 100, 250, 500 g and 1 kg (PET) bag/sac (combined packaging up to 1 kg net weight)

2.1.4.1.1 Use-specific instructions for use

For professionals equivalent to spread the surface during 11 rotations (ant nest) when using dust dispenser. Refer to general direction of use (section 2.1.5)

2.1.4.1.2 Use-specific risk mitigation measures

Refer to general direction of use (section 2.1.5)

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

Refer to general direction of use (section 2.1.5)

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

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.

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

Refer to general direction of use (section 2.1.5)

2.1.4.2 Use # 2 – Outdoor – Directly application in ant nests by Non-professional users

Table 2. Use # 2 – Outdoor – Directly application in ant nests by 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.
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 The product is intended to be applied directly from the packaging into the ant nest or by using proper devices (dust dispenser). It cannot be applied aerially.
Application rate(s) and frequency	Dose: 1.7 g per nest Apply 1.7 g per nest (in 0.14 m^2, e.g. 37cm*37cm), equivalent to 11 rotations per nest when the duster dispenser is used (application rate: 12.14 g/m^2). If no reduction is observed, 1.7 g must be reapplied after 14 days.
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	250, 350, 500 g plastic dust dispenser(PET-PP)

2.1.4.2.1 Use-specific instructions for use

For non-professionals equivalent to spread the surface during 11 rotations (ant nest) when using dust dispenser. Refer to general direction of use (section 2.1.5)

2.1.4.2.2 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 Alpha-cypermethrin. Alternate with products containing different active substances. When the infestation persists contact a (trained) professional.

Refer to general direction of use (section 2.1.5)

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

Refer to general direction of use (section 2.1.5)

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

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

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

Refer to general direction of use (section 2.1.5)

2.1.5 General directions for use

2.1.5.1 Instructions for use

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

The product should be applied at 12.14 g/m².

To achieve full effect, identify the ant nest's location carefully and dust the product directly into the nest.

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

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

Do not apply close to blooming plants/cultures.

The total kill of ants is obtained at 28 days after application and no repetition is deemed necessary once the ant nest is eradicated.

In case of ants, dose is an average per nest, which can be slightly reduced taking into account level of infection and nest size.

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

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

2.1.5.2 Risk mitigation measures

Do not spread directly on people, animals or bedding.

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

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

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

All accidental emissions to aquatic or soil compartment should be avoided.

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

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

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

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

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

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

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

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

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

Emergency measures to protect the environment:

Notify authorities if product enters sewers or public waters.

Prevent entry to sewers and public waters.

Avoid release to the environment.

2.1.5.4 Instructions for safe disposal of the product and its packaging

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

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

Shelf life: 2 years.

Storage conditions:

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

Do not store near food, drink and feed.

Keep only in the original container in a cool, well ventilated place.

Keep container closed when not in use.

Incompatible products: Strong acids.
Incompatible materials: Sources of ignition.

2.1.6 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. In this case, for professional and non-professional users the maximum size that can be authorized is 1 kg.

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

2.1.7 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure (s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
bag/sac	100, 250, 500 g y 1, 5 kg (PET) bag/sac (combined packaging up to 20 kg net weight)	(PET Single sheet polyethylene Terephthalate)	-	Trained Professional users	YES

bag/sac	100, 250, 500 g y 1 kg (PET) bag/sac (combined packaging up to 1 kg net weight)	(PET Single sheet polyethylene Terephthalate)	-	Trained Professional users	YES
Dust Dispenser	250, 350, 500 g dispensador de polvo de plástico (PET-PP)	plastic (PE+PP)	-	Professional and Non professional users	YES

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

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

2.1.8.2 Access to documentation

The applicant has submitted a Letter of Access to Alpha-cypermethrin active substance from supplier company BASF Agro B.V. Arnhem (NL) Freienbach Branch (Switzerland), notifier of the appproval of the active substance for PT 18 under BPR (EU) 528/2012 and included in Article 95 List.

2.2 Assessment of the biocidal product

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

Table 1. Intended use # 1 – Indoor – Crawling Insects - Dust scattering in industrial/domestic/public facilities by Professional users (Trained and non-trained professional).

Product Type	PT 18 - Insecticide
Where relevant, an exact description of the authorised use	MASSOCIDE AD 04 is an insecticide intended to be used indoor by professionals to control a broad range of crawling insects in crack and crevices, areas behind furnishings and equipment in domestic/public and industrial premises.
Target organism (including development stage)	*Lasius niger* – ants *Blattella germanica* - cockroaches *Blattella orientalis* -cockroaches
Field of use	Indoor

Application method(s)	The product is applied by dusting with proper devices (dust blower, bulb applicator) The product has to be applied by spreading the powder evenly on the surfaces and making sure to treat corners, crevices and cracks. It cannot be applied aerially.
Application rate(s) and frequency	Dose: 12.5 g product/m^2 (equivalent to 0.05 g a.i./m^2) One application each two months if necessary. Maximum of 3 applications per year with the exception of industrial buildings where 2 applications per year is deemed enough. Outdoors in urban areas (foundations, terraces and soil around buildings) 2 applications per year are deemed enough.(see USE#7#)
Category(ies) of users	Trained professional and professional uses
Pack sizes and packaging material	0.1-5 kg (PET) bag/sac (combined packaging up to 20 kg net weight)

Table 2. Use # 2 - Indoor – Crawling and Arachnids-Household use by general public

Product Type	PT 18 - Insecticide
Where relevant, an exact description of the authorised use	MASSOCIDE AD 04 is an insecticide intended to be used indoor and surrounding areas (such as terrace) by non-professionals to control a broad range of insects (crawling and Arachnids) in crack and crevices, areas behind furnishings and equipment in domestic premises.
Target organism (including development stage)	*Lasius niger* – ants *Ctenocephalides felis* - fleas *Rhipicephalus sanguineus* – ticks *Ixodes ricinus* - ticks *Blattella germanica* - cockroaches *Blattella orientalis* - cockroaches
Field of use	Indoor in domestic premises. Surrounding areas (such as terrace) in domestic premises.
Application method(s)	The product is applied by dusting with proper devices (dust blower, bulb applicator, dust dispenser) The product has to be applied by spreading the powder evenly on the targeted surfaces and making sure to treat corners, crevices and cracks. It cannot be applied aerially.
Application rate(s) and frequency	Dose: 12.5 g product/m^2 (equivalent to 0.05 g a.i./m^2) One application each two months if necessary. Maximum of 3 applications per year. In the case of outdoors in urban areas (foundations, terraces and soil around buildings) 2 applications per year are deemed enough.
Category(ies) of users	Non professional
Pack sizes and packaging material	- <= 500 gr plastic dust dispenser(PET+PP) - <= 0.5 kg PET bag/sac (combined packaging up to 1 kg net weight)

Table 3. Use # 3 - Indoor dust scattering in animal housing facilities by Professional users (Trained and non-trained professional).

Product Type	PT 18 - Insecticide
Where relevant, an exact description of the authorised use	MASSOCIDE AD 04 is an insecticide intended to be used indoor by professional users (trained and non-trained) in animal houses/ shelters including poultry houses and similar places where high levels of hygiene are required.
Target organism (including development stage)	*Lasius niger* – ants *Blattella germanica* - cockroaches *Blattella orientalis* - cockroaches *Dermanyssus gallinae* – poultry mite
Field of use	Indoor in animal houses/ shelters including poultry houses and similar places where high levels of hygiene are required.
Application method(s)	The product is applied by dusting. Chicken manure and straw have to be removed before application. The product has to be applied by spreading the powder evenly on the surfaces and making sure to treat corners, crevices and cracks. It cannot be applied aerially.
Application rate(s) and frequency	Dose: 12.5 g product/m^2 (equivalent to 0.05 g a.i./m^2) Frequency: up to 3 applications per year: **3 applications** for animal housing of beef cattle, veal calves and, laying hens in battery cages with belt drying, with force drying and free range with litter floor. **2 applications** for animal housing of broilers **1 application** for animal housing of dairy cattle, piggeries and laying hens in compact battery cages.
Category(ies) of users	Professional (Trained and non-trained professional users)
Pack sizes and packaging material	- 0.1-5 kg (PET) bag/sac (combined packaging up to 20 kg net weight)

Table 4. Use # 4 - Indoor dust scattering in animal housing facilities by non- professionals.

Product Type	PT 18 - Insecticide
Where relevant, an exact description of the authorised use	MASSOCIDE AD 04 is an insecticide intended to be used indoor by non professional users in animal houses/ shelters including poultry houses and similar places where high levels of hygiene are required. (Domestic premises in rural areas)
Target organism (including development stage)	*Lasius niger* – ants *Ctenocephalides felis* - fleas *Rhipicephalus sanguineus* – ticks *Ixodes ricinus* - ticks *Blattella germanica* - cockroaches *Blattella orientalis* - cockroaches *Dermanyssus gallinae* – poultry mite
Field of use	Indoor in animal houses/ shelters including poultry houses and similar places where high levels of hygiene are required.

Application method(s)	The product is applied by dusting. Chicken manure and straw have to be removed before application. The product has to be applied by spreading the powder evenly on the surfaces and making sure to treat corners, crevices and cracks. It cannot be applied aerially.
Application rate(s) and frequency	Dose: 12.5 g product/m^2 (equivalent to 0.05 g a.i./m^2) Frequency: up to 3 applications per year: **3 applications** for animal housing of beef cattle, veal calves and, laying hens in battery cages with belt drying, with force drying and free range with litter floor. **2 applications** for animal housing of broilers **1 application** for animal housing of dairy cattle, piggeries and laying hens in compact battery cages.
Category(ies) of users	Non-professional users.
Pack sizes and packaging material	- < = 500 gr plastic (PET+PP) - < = 0.5 kg (PET) bag/sac(combined packaging up to 1kg net weight)

Table 5. Use # 5 - Outdoor – Directly application in ant nests by professional users (Trained and non-trained professional) -.

Product Type	PT 18 - Insecticide
Where relevant, an exact description of the authorised use	MASSOCIDE AD 04 is an insecticide intended to be applied directly into ant's nests by professionals.
Target organism (including development stage)	*Lasius niger* – ants
Field of use	Outdoor Around houses on paved ways, balconies and terraces where ant nests are located.
Application method(s)	Dusting The product is intended to be applied directly from the packaging into the ant nest or by using proper devices (dust blower , bulb applicator, dust dispenser). It cannot be applied aerially.
Application rate(s) and frequency	Dose:1.7 g per nest The total kill of ants is obtained at 28 days after application and no repetition is deemed necessary once the ant nest is eradicated In case of ants, dose is an average per nest, which can be slightly reduced taking into account level of infection and nest size.
Category(ies) of users	Professional (Trained and non-trained professional users)
Pack sizes and packaging material	- 0.1-5 kg (PET) bag/sac (combiened packaging up to 20 kg net weight)

Table 6. Use # 6 - Outdoor – Directly application in ant nests by non-professional users.

Product Type	PT 18 - Insecticide
Where relevant, an exact description of the authorised use	MASSOCIDE AD 04 is an insecticide intended to be applied directly into ant's nests by non- professionals.
Target organism (including development stage)	*Lasius niger* – ants
Field of use	Outdoor Around houses on paved ways, balconies and terraces where ant nests are located.
Application method(s)	Dusting The product is intended to be applied directly from the packaging into the ant nest. It cannot be applied aerially.
Application rate(s) and frequency	Dose:1.7 g per nest The total kill of ants is obtained at 28 days after application and no repetition is deemed necessary once the ant nest is eradicated In case of ants, dose is an average per nest, which can be slightly reduced taking into account level of infection and nest size.
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	- 250-500 gr plastic dust dispenser(PET-PP) - 0.1-0.5 kg PET bag/sac (combined packaging up to 1 kg net weight)

Table 7. Use # 7 - Outdoor – Crawling insects -Dust scattering around paved and rain protected areas of buildings – Professional users (Trained and non-trained professional).

Product Type	PT 18 - Insecticide
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 crawling 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)	*Lasius niger* – ants *Blattella germanica* - cockroaches *Blattella Orientalis* -cockroaches
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 The product is applied by dusting with proper devices (dust blower , bulb applicator, dust dispenser) The product has to be applied by spreading the powder evenly on the surfaces and making sure to treat corners, crevices and cracks. It cannot be applied aerially.
Application rate(s) and frequency	Dose: 12.5 g product/m^2 (equivalent to 0.05 g a.i./m^2) One application each two months if necessary. 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 professional users)
Pack sizes and packaging material	- 0.1-5 kg (PET) bag/sac (combined packaging up to 20 kg net weight)

Table 8. Use # 8 - Outdoor – Crawling insects -Dust scattering around paved and rain protected areas of buildings – non-Professional users.

Product Type	PT 18 - Insecticide
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 crawling 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)	*Lasius niger* – ants *Blattella germanica* - cockroaches *Blattella Orientalis* -cockroaches
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 The product is applied by dusting with proper devices (dust blower , bulb applicator, dust dispenser) The product has to be applied by spreading the powder evenly on the surfaces and making sure to treat corners, crevices and cracks. It cannot be applied aerially.
Application rate(s) and frequency	Dose: 12.5 g product/m^2 (equivalent to 0.05 g a.i./m^2) One application each two months if necessary. 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	- < = 500 gr plastic (PET+PP) - <= 0.5 kg (PET) bag/sac (combined packaging up ot 1 kg net weight)

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	EPA OPPTS OPPTS 830.6303	MASSOCIDE AD04: 0.4% w/w Batch: E230-98/4	Initially: Solid (powder)	CH-071/2016
		MASSOCIDE AD04: 0.4% w/w Batch: 070616	After 18 weeks at 30ºC: Solid (powder)	CH-408/2016
		MASSOCIDE AD04: 0.4% w/w Batch: 070616	After 2 years at warehouse temperature: Solid (powder)	CH-075/2016
Colour at 20 °C and 101.3 kPa	EPA OPPTS OPPTS 830.6302	MASSOCIDE AD04: 0.4% w/w Batch: E230-98/4	Initially: White	CH-071/2016
		MASSOCIDE AD04: 0.4% w/w Batch: 070616	After 18 weeks at 30ºC: White	CH-408/2016
		MASSOCIDE AD04: 0.4% w/w Batch: not available	After 2 years at warehouse temperature: White	CH-075/2016
Odour at 20 °C and 101.3 kPa	EPA OPPTS OPPTS 830.6304	MASSOCIDE AD04: 0.4% w/w Batch: E230-98/4	Initially: Characteristic odour	CH-071/2016
		MASSOCIDE AD04: 0.4% w/w Batch: 070616	After 18 weeks at 30ºC: Characteristic odour	CH-408/2016
		MASSOCIDE AD04: 0.4% w/w Batch: 070616	After 2 years at warehouse temperature: Characteristic odour	CH-075/2016
Acidity / alkalinity			Not applicable.	CH-071/2016
Relative density / bulk density	Bulk density CIPAC MT186	MASSOCIDE AD04: 0.4% w/w Batch: E230-98/4	Pour density: 0.78 g/mL Tap density: 1.02 g/mL	CH-071/2016
Storage stability test – **accelerated storage**	GIFAP Monograph No. 17	MASSOCIDE AD04: 0.4% w/w Batch: 070616	Stable after 18 weeks stored in PE bottle with a screw cap at 30ºC.	CH-408/2016
Active substance content	HPLC-UV		Initially: 0.40 ± 0.01 % w/w After 2 years at 20ºC: 0.40 ± 0.01 % w/w Difference: 0.00 % w/w	

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
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		Stable after 2 years stored in PE bottle with a screw cap at warehouse temperature.	CH-075/2016
Active substance content	GC-FID	MASSOCIDE AD04: 0.4% w/w Batch: 070616	Initially: 0.40 ± 0.01 % w/w	CH-408/2016
		MASSOCIDE AD04: 0.4% w/w Batch: 070616	After 2 years at warehouse temperature: 0.38 ± 0.01 % w/w Difference: -5.00 % w/w	CH-075/2016
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**			No changes are expected.	
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**			No changes are expected if stored at room temperature.	
Effects on content of the active substance and technical characteristics of			No changes were observed.	CH-075/2016

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
the biocidal product - **reactivity towards container material**				
Wettability			Not applicable	
Suspensibility, spontaneity and dispersion stability			Not applicable	
Wet sieve analysis and dry sieve test			Not applicable	
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 AD04: 0.4% w/w Batch: E230-98/4	Initially: Dv 10(µm): 1.89 µm Dv 50(µm): 5.32 µm Dv 90(µm): 12.5 µm %<45 µm: 98.7% %>75 µm:0.02%	CH-071/2016
		MASSOCIDE AD04: 0.4% w/w Batch: 070616	After 18 weeks at 30ºC: Dv 10(µm): 2.01 µm Dv 50(µm): 6.83 µm Dv 90(µm): 21.3 µm %<45 µm: 99.8% %>75 µm:0.00%	CH-408/2016
		MASSOCIDE AD04: 0.4% w/w Batch: 070616	After 2 years at warehouse temperature: Dv 10(µm): 2.24 µm Dv 50(µm): 7.42 µm Dv 90(µm): 22.9 µm %<45 µm: 98.1% %>75 µm:0.94%	CH-075/2016
Persistent foaming			Not applicable	
Flowability/Pourability/Dustability			Not applicable	
Burning rate — smoke generators			Not applicable	

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
Burning completeness — smoke generators			Not applicable	
Composition of smoke — smoke generators			Not applicable	
Spraying pattern — aerosols			Not applicable	
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

Appearance
The preparation is a white powder solid formulation with a characteristic odour.

Acidity / alkalinity
The pH is determined previous dilution in water at a 1% concentration (9.7). 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 density using CIPAC method MT 186.

Accelerated storage
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 18 weeks of storage at 30°C.

Long term storage at ambient temperature
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 24 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 product application is not affected by light. According with the experience of the registrant, effects of light in the product stability are not expected.

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

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: test under the CIPAC MT 59.1 has not performed. However, data from the particular size distribution performed by the Laser, show that the less than 1% of the preparation should be retained on a 75 µm sieve, thus it is not expected any separation from the carrier and additional test is not required.
Dustability data from the particular size distribution performed by the laser technique (CIPAC MT 187), show that the Dv90 is 22 µm, which means that the preparation should be considered as dusty. Thus the potential risk to operator and bystander has been evaluated in the Human Risk Assessment.
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 product Massodice AD04 is a white solid (powder) with characteristic odour, containing 0.4% w/w of alpha-cypermethrin. Its bulk density is 1.02 g/cc and the pH is 9.7.
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.
After storage at 30°C for 18 weeks, 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, one storage stability studies at ambient temperature is finished and from the obtained results it can be concluded that no significant change was found in the alpha-

cypermethrin active ingredient content for the samples stored in PE bottle with a screw cap for 24 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 storage studies, a self-life of two years is accepted for the biocidal product MASSOCIDE AD04.
The SoC was identified and not included in the storage study because the SoC is thermally stable according to its Assessment Report as active substance (FR CA, 2014).

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
Explosives	CHETAH software	MASSOCIDE AD04: 0.4% w/w Batch: E230-98/4	Non explosive properties.	CH-072/2016
Flammable gases			Not applicable.	
Flammable aerosols			Not applicable.	
Oxidising gases			Not applicable.	
Gases under pressure			Not applicable.	
Flammable liquids			Not applicable.	
Flammable solids	EU Method A.10	MASSOCIDE AD04: 0.4% w/w Batch: E230-98/4	Not highly flammable.	CH-071/2016
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	MASSOCIDE AD04: 0.4% w/w Batch: E230-98/4	Non oxidising properties	CH-072/2016
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 AD04: 0.4% w/w Batch: E230-98/4	Massocide AD04 was found not to have a relative self-ignition temperature bellow 400 ºC	201600851
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 AD04 sample should not exhibit an explosive behaviour.
In addition,

Flammability
Two preliminary test were performed and the same sample behaviour was observed. The test item, a white powder, did not ignite; the solid sample became grey 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 AD04 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 molecule 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 AD04 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
No exothermic effects was observing during the tests. Therefore , according to method A.16, the sample labelled as MASSOCIDE AD04 was found not to have a relative self-ignition temperature bellow 400ºC.

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 AD04 is not explosive, flammable, corrosive and has no oxidising properties. Its physical and respective characteristics are acceptable for a DP formulation safe use.

2.2.4 Methods for detection and identification

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Alpha-cypermethrin	HPLC-DAD	75%, 100 % and 125% / 6	30.4 to 71.0 µg/mL y = 139817x + 77271 r^2 >99907	Specific for the quantitative determination of Alpha-cypermethrin	100.11-104.07	102.6	--	--	CH-073/2016
Alpha-cypermethrin	HRGC-FID	--	0.5-1.5 mg/mL y = 0.181649x + 0.137894, r^2 = 0.9990	Yes	--	--	--	..	CAR (2014)

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		
Alpha-cypermethrin	GC-ECD	0.05 mg/kg / 4	0.0126-0.251 µg/mL $y = 117418.557x + 478.68$, $r^2 = 0.9984$	yes	83-99	90	6.1	0.05 mg/kg	CAR (2014)
		50 mg/kg / 5			83-99	88	4.7		
Alpha-cypermethrin	GC-MSD	50 ppb / 5	0.0025-0.04 µg/mL r > 0.9997	yes	--	--	--	50 ppb	CAR (2014)
Alpha-cypermethrin	LC-MS/MS (HPLC and UPLC)	0.001 mg/kg / 5	0.1-10 ng/mL r > 0.99	yes	64–131	71–110	0.7–16.0	0.001 mg/kg	CAR (2014)
		0.01 mg/kg / 5							

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		
Alpha-cypermethrin	GC-NPD	0.02 µg/m³ / 5	0.01-0.5 µg/mL $y = \exp(1.07 \ln x + 0.000040$	Yes	--	104.6	7.84	0.02 µg/m^3	CAR (2014)
		0.1 µg/m³ / 5			--	92.6	8.14		
		0.5 µg/m³ / 5			--	83	9.21		

		0.2 µg/m³ / 4	2), *r* = 0.9984		--	92.5	1.40		
Alpha-cypermethrin	GC-MS	1.4 µg/m³ / 5	0.01-0.3 µg/mL y = 0.00798237 + 0.00248815x r = 0.9980	Yes	..	102	6	1.4 µg/m³	CAR (2014)
		14 µg/m³ / 5			--	86	12		

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		
Alpha-cypermethrin *Surface water*	GC-ECD	0.05 µg/L / 5	0.0126-0.502 µg/mL y = 90114.01 x + 504.08 r² = 0.9926	Yes	78-107	88	8.9	0.05 µg/L	CAR (2014)
		0.5 µg/L / 5			78-107	89	12		
Alpha-cypermethrin *Destilled water*	GC-ECD	0.01 µg/L / 2	0.00503-0.503 µg/mL y =2626x + -20.092, r = 0.9997	Yes	--	88.6	--	0.01 µg/L	CAR (2014)
		0.05 µg/L / 2			--	95.6	--		
		0.1 µg/L / 2			--	84.6	--		
		1.0 µg/L / 2			--	96.8	--		
		10 µg/L / 2			--	91.1	--		
Alpha-cypermethrin *Pond water*		0.01 µg/L / 1			--	74.4	--		
		0.02 µg/L / 1			--	105.5	--		
		0.05 µg/L / 2			--	107.6	--		
		0.1 µg/L / 2			--	90.5	--		
		1.0 µg/L / 2			--	88.5	--		
		10 µg/L / 2			--	84.8	--		
Alpha-cypermethrin *Ground water*	GC-MSD	0.05 ppb / 3	0.0025-0.04 µg/mL r > 0.9997		--	--	--	0.05 ppb (µg/L)	CAR (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		
Alpha-cypermethrin *Animal Blood*	GC-ECD	0.005 mg/L / 5	0.00250-0.0998 µg/L y = 98647 x – 29.0 r = 0.9996	Yes	98-103	1105	4.1	0.005 mg/L	CAR (2014)
		0.05 mg/L/ 5			98-107	101	3.4		
Alpha-cypermethrin *Animal Urine*		0.005 mg/L / 5			90-105	96	6.3		
		0.05 mg/L / 5			92.99	95			
Alpha-cypermethrin *Cattle muscle*	GC-ECD	50 ppb / 3	0.002-0.02 µg/mL y = 12428237 x + 23138.23 r = 0.999714	Yes	92.1-105	97.1	7.2	50 ppb	CAR (2014)
		100 ppb / 3			106-109	108	1.4		
		200 ppb / 3			92.7-107	99.9	7.2		
Alpha-cypermethrin *Cattle fat*		50 ppb / 3			78.4-89.4	84.4	6.6		
		100 ppb / 3			104-108	106	1.9		
		200 ppb / 3			95.3-97.2	96.2	1-0		
Alpha-cypermethrin *Cattle liver*		50 ppb / 3			78.3-83.7	81.6	3.5		
		100 ppb / 3			98.9-101	100	1.1		
		200 ppb / 3			89.8-93	91.5	1.8		
Alpha-cypermethrin		50 ppb / 3			98.3-106	101	4.2		

Cattle kidney		100 ppb / 3			81.8-84.9	83.5	1.9		
		200 ppb / 3			97.7-105	101	3.6		
Alpha-cypermethrin *Milk*		10 ppb / 3			83.6-85.8	84.7	1.3	10 ppb	
		20 ppb / 3			101 - 104	103	1.5		
		40 ppb / 3			106 - 115	110	4.3		
Alpha-cypermethrin *Bovine blood*	GC-MSD	5 ppb / 3	0.0025-0.04 µg/mL r > 0.9997	Yes	--	--	--	5 ppb (µg/mL)	CAR (2014)

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

Analytical methods for the detection and identification of the active substance (alpha-cypermethrin) in technical grade material are presented and validated in CAR. The analytical techniques were validated and were generally found to be linear, with adequate repeatability and reproducibility (RSDs generally in the acceptable range).

The method submitted by the applicant for analising the active substance in the biocidal product is considered acceptable.

The SoC was identified and not included in the storage study because the SoC is thermally stable according to its Assessment Report as active substance (FR CA, 2014). Therefore, an analytical method for the SoC is not necessary according to the BPR Guidance and TAB.

Analytical methods for soil

Acceptable validated methods for residues of alpha-cypermethrin in soil were presented.

Analytical methods for air
Acceptable validated methods were provided for residues of alpha-cypermethrin in air.

Analytical methods for water
Acceptable validated methods were provided for residues of alpha-cypermethrin in water.

Analytical methods for animal and human body fluids and tissues
Acceptable validated methods were provided for residues of alpha-cypermethrin in animal and human body fluids and tissues.

Analytical methods for monitoring of active substances and residues in food and feeding stuff
Food and feeding stuff will not be exposed to Alpha-cypermethrin 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 BASF for information on analytical methods for the alpha-cypermethrin active substance.
Finally, the analytical method submitted for the analyses of the active substance in the formulation submitted by the applicant is deemed sufficiently specific and precise.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

Main group 03: Pest control
Product type 18: Insecticides, acaricides and products to control other arthropods.
The biocidal product MASSOCIDE AD04 is a dust preparation to be used against adult ants in nests outdoors.

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

The organisms to be controlled are:
- adult ants (*Lasius niger*) as nest application outdoors.

2.2.5.3 Effects on target organisms, including unacceptable suffering

MASSOCIDE AD04 is formulated with the active substance alpha-cypermethrin, a synthetic pyrethroid. According to the CAR, Alpha-cypermethrin intoxication results in a rapid knockdown and resultant mortality. The affected insect shows uncoordinated movements and finally dies. It is not possible to assess unacceptable suffering.

2.2.5.4 Mode of action, including time delay

According to the CAR, alpha-cypermethrin acts by preventing transmission of impulses along nerves on adult insects. This effect is brought about by blocking the passage of positive

sodium ions through sodium channels in nerve membranes, thus preventing action potentials passing down axons.

2.2.5.5 Efficacy data

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Insecticide	Indoor Outdoor	Massocide AD04	*Blattella germanica,* adults *Alphitobius diaperinus,* adults *Rhipicephalus sanguineus,* adults *Lasius niger,* adults *Ctenocephalides felis* adults *Cimex lectularius*, adults *Dermanyssus gallinae*, adults	Laboratory test TNsG for PT 18-19, 2012	Test treatments were applied directly to the test arthropods on the base of a plastic container (diameter 0.0225m^2). In the case of bird mites, the treatment was carried out before introducing the mites into the container. Temperature: 19.2-21.7ºC Relative humidity: 40.6 – 52.3%. Knockdown and mortality were recorded at 5, 10, 15, 20, 30, 45 and 60 minutes and 2, 4, 24 and 48 hours after the treatment. The insects were provided with food and water where appropriate, following the 2 hour assessment. 10 insects per both treated and control group (4 replicates). Application rate: 50 mg/m2 (1.1 mg /0.0225m2)	***-Blatella germanica*:** 95% knockdown (20 minutes) and 100% knockdown (30 minutes) Mortality (24 hours): 0% Mortality (48 hours): 57.5% Controls: 0% knockdown, 0% mortality **The laboratory test does NOT demonstrate the efficacy of the product against *Blattella germanica*** ***-Alphitobius diaperinus:*** 95% knockdown (10 minutes) and 100% knockdown (15 minutes) Mortality (24 hours): 15% Mortality (48 hours): 17.2% Controls: 0% knockdown, 0% mortality **The applicant withdrew this claim** ***-Rhipicephalus sanguineus:*** 95% knockdown (45 minutes) and 100% knockdown (60 minutes) Mortality (24 hours): 42.5% Controls: 0% knockdown, 0% mortality	Study Code 15/381 See confidential PAR

						The laboratory test does NOT demonstrate the efficacy of the product against *Rhipicephalus sanguineus* ***-Lasius niger:*** 100% knockdown (10 minutes) Mortality (24 hours): 100% Controls: 0% knockdown, 0% mortality **The laboratory test demonstrates the efficacy of the product against *Lasius niger*** ***Ctenocephalides felis:*** 97.5% knockdown (10 minutes) and 100% knockdown (15 minutes) Mortality (24 hours): 35% Mortality (48 hours): 72.5% Controls: 0% knockdown, 0% mortality **The laboratory test does NOT demonstrate the efficacy of the product against *Ctenocephalides felis*** **- Cimex lectularius** 92.5% knockdown (20 minutes) and 100% knockdown (30 minutes) Mortality (24 hours): 100% Controls: 0% knockdown, 0% mortality **The applicant withdrew this claim.** ***- Dermanyssus gallinae:***	

						90.5% knockdown (30 minutes) and 93% knockdown (45 minutes) Mortality (24 hours): 100% Controls: 0% knockdown, 10% mortality (24 hours) **The laboratory test demonstrates the efficacy of the product against *Dermanyssus gallinae***	
Insecticide	Indoor Outdoor	Massocide AD04	*Blattella germanica*	Field test – TNsG for PT 18-19, 2012	The trial was started in February/ March 2016 in Girona (Spain). 3 Apartments treated Pre-monitoring assessment: 7 or 9 monitoring traps. The number of cockroaches trapped was recorded over a period from 24 to 72 hours later, at 2 days prior to application. Product application:50 mg/m^2 as cracks and crevices and spot treatment using a bulb type dust blower. A further set of monitoring traps were placed at the same location as for the pre-monitoring assessment and assessed at weekly interval for a total of 8 weeks (at 1, 2, 3, 4, 6 and 8 weeks)	*Population reduction: ≤90 %* **The field test does NOT demonstrate the efficacy of the product against *Blattella germanica*** Study Code 15/382 See confidential PAR
Insecticide	Outdoor	Massocide AD04	*Lasius niger*	Field test – TNsG for PT 18-19, 2012	The study was set up in the UK in spring 2016. A pre-monitoring assessment was conducted to establish the infestation level at the site by visual means. All nests were located in soil underneath objects (3 control nests + 3 treated nests) Application rate: 1.7 g/nest (37cm x 37cm (0.14m^2)). The treatment was re-applied at nest 3 at 14 days with	Population reduction (nest entrance and surrounding surface): -Test product: 100% at days 21 and 28 after the treatment for nests 1 and 2. For nest 3: 100 % at day 28. Control nets: no mortality neither knockdown were observed. For control groups > 1500 ants were found alive.	Study Code 15/383 See confidential PAR

					1.7 g due to insufficient reduction in ant numbers. The treatment was applied as a light dusting using a bottle with a small hole in the lid to all visible entrances to each nest. Assessments were done at 3, 7, 14, 21 and 28 days by visual means.	**The field test demonstrates the efficacy of the product against adult ants as nest application at the application rate of 1.7 g/nest (with a re-application of 1.7/nest, if necessary)**	
Insecticide	Indoor	Massocide AD04	*Ixodes ricinus* *Rhipicephalus sanguineus*	Simulated-use test Guidance on the Biocidal Products Regulation, Volume II Efficacy - Assessment and Evaluation (Parts B+C), Version 3.0 (2018)	Two trials were conducted: on porous (carpet) or non-porous (glazed ceramic) surfaces. The test arena comprised a 0.5m^2 arena (61.3 x 81.5 cm) with walls 15 cm tall. The carpet provided sufficient harbourage, glazed ceramic tiles were partially covered by stripes of a corrugated sheet to provide sufficient shelter. Assessments of knockdown/mortality were made at 15, 30 and 45 minutes and 1, 2, 4, 8, and 24 hours post initial introduction of the insects into the arena (in treated and non-treated groups) After exposure, the alive ticks were taken individually and subjected to a trial to investigate whether host attachment remains viable (test area of the volunteer's skin). 2 replicates of 20 ticks for each surface and specie. Application rate: 12.5 g/m^2 (dust dispenser). The product was applied around the edges of the arena (10% of the area).	Mortality (24 hours): -*Ixodes ricinus*: 100% on porous and non-porous surfaces. - *Rhipicephalus sanguineus:*85% on non-porous surfaces and 60% on porous surfaces. **The simulated-use test demonstrates the efficacy of the product against *Ixodes ricinus* at the application rate of 12.5 g/m^2**	Study code 21/201 See confidential PAR
Insecticide	Indoor Outdoor	Massocide AD04	*Blatta orientalis* *Ctenocephalides felis*	Simulated-use test Guidance on the	Two trials were conducted: on porous and non-porous surfaces. For cockroaches: ceramic (non-porous) and plywood (porous) surfaces /For fleas: ceramic (non-	***Blatta orientalis*:** -Non-porous surfaces: 100% knockdown (2 hours) and 96.3% mortality (2 days)	Study Code 21/207

				Biocidal Products Regulation, Volume II Efficacy - Assessment and Evaluation (Parts B+C), Version 3.0 (2018)	porous) and carpet surfaces (porous). The simulation arena comprised of a 1m2 arena with walls measuring approximately 15cm tall (cockroaches) or 1m tall (cat fleas). For cockroaches, food and water was placed in the centre of the test arena. For cat fleas, no provision for food or water was necessary. Temperature: 24-25.4ºC Relative humidity: 19 – 46%. Application rate: 12.5 g/m^2 (ready to use container). (treated surface: 10% of the arena). Replicates: 4 for treated and non-treated groups (20 insects/group) A negative control (untreated) was also conducted alongside the product efficacy tests as a measure of batch fitness in test groups. Assessments of knockdown/mortality were made at 15, 30 and 45 minutes and at 1, 2 and 4 hours and at 1, 2, 3 and 7 (only for fleas) days post initial introduction of the insects into the arena.	-Porous surfaces: 64.85% knockdown (4 hours) and 100% mortality (3 days) Controls: ≤1.1 % knockdown, 0% mortality ***Ctenocephalides felis:*** -Non-porous surfaces: 97.5% mortality (7 days) -Porous surfaces: 93.8% mortality (7 days) Controls: ≤2.1 % knockdown, ≤1.8 % mortality **The simulated-use test does NOT demonstrate the efficacy of the product against *Blattella orientalis* and *Ctenocephalides felis*** See confidential PAR
Insecticide	Indoor	Massocide AD04	*Dermanyssus gallinae*	Field test – TNsG for PT 18-19, 2012	The trial was conducted at hobby hen houses and chicken houses in South Bohemia, Czech Republic. The test was carried out in three sites. Chicken manure and straw were removed before application. Pre-treatment: 10 monitoring traps were placed at various locations overnight. Treatment: 3 treated sites (one with high infestation)	Population reduction: ≥90% in two of three sites tested. **The field test does NOT demonstrate the efficacy of the product against *Dermanyssus gallinae*** Study code 15/354 See confidential PAR

					-site 1: 4 m x 4 m x 3m →treatment: 6 g -site 2: 2.5 m x 1 m x 1.8 m →treatment: 2 g -site 3: 2.5 m x 2 m x 1.8 m →treatment: 2 g The treated sites were subdivided by various vertical or horizontal dividers and contained beams, niches and crevices). Product was applied to floor, walls as well as all inner surfaces accessible (e.g. nesting compartments). In case of small home-made wooden chicken houses, outer surfaces containing crevices visibly used as hiding places for the chicken mites, were also treated. Post-treatment: The same procedure as pre-treatment was applied for post-treatment assessments at 1, 3 and 7 days post-treatment.		
Insecticide	-	Massocide AD (0.4% Alphacypermethrin)	*Alphitobius diaperinus*	Field test – TNsG for PT 18-19, 2012	The trial was conducted in chicken farms (Zhoř-Zbyslav and Přeštěnice, Czech Republic) that had a 2 month chicken breeding cycle, (the breeding cycle starts in section 1, barrier is removed and area expanded to section 2 etc.), after which sanitation/desinsection was conducted, the manure removed, and the floor washed with water. During this period, the farms were not heated. Pre-treatment: 15 samples of 20 adult beetles were sampled at each of the test sites from the surface and crevices of walls and columns and from the floor just under the walls and columns (cold immobilised beetles), using	Application of Masssocide AD at 50 mg/m2 resulted in 65%, 17% and 59% efficacy compared to pre-treatment levels. **The applicant withdrew this claim**	Study code 15/385 See confidential PAR

					entomological forceps. The samples were warmed to approximately 20ºC and number of live/affected (knocked down or dead) beetles was estimated. Treatment (applied as crack and crevice treatment): • test site 1: 15 g (196 m^2) • test site 2: 102 g (518 m^2) • test site 3: 14 g (64 m^2) Application device: Bulb applicator (Killgerm) Post-treatment: The same procedure as pre-treatment was applied for post-treatment assessments at 1, 3 and 7 days post-treatment. NOTE: Traps would represent an unsuitable monitoring method because sticky traps would be destroyed during by regular sanitation, the sites are not heated during this sanitation and beetles are immobilised. As manure is removed during the sanitation, the abundance of beetles is changing in time.		
Insecticide	-	MASSOCIDE AD 0.4 %	-	The aim of this study is to determine the amount of product applied in each discharge (container rotation)	The mean value of product discharged in each rotation is 0.15 g.	For the application rate of 1.7 g/ant nest = 11 container rotations	See confidential PAR

Conclusion on the efficacy of the product

The applicant has provided 7 test to demonstrate the efficacy of the product: laboratory, simulated-use and field tests. Furthermore, a laboratory test was provided to determinate the amount of product applied in each container rotation of the packaging ready-to-use.

In the efficacy table are included efficacy results against *Alphitobius diaperinus* (Study code 15/385) and *Cimex lectularius* (Study Code 15/381) but are not taken into account in the assessment of the product because the applicant withdrew the claims for these species.

Note that some of the tests provided were carried out with MASSOCIDE AD 04 and with another product. For the assessment of MASSOCIDE AD04, only the results of the tests carried out with MASSOCIDE AD 04 were taken into account. Therefore, the efficacy table and conclusions only show the results obtained with MASSOCIDE AD04.

According to the evaluation of the results of the efficacy table, the eCA concludes that:

Efficacy against *Lasius niger*

The requirements and criteria of the TNsG on product evaluation for PT18/19 (2012) are met for the use against *Lasius niger* as nest application by dusting. The applicant has provided:

- A field test in ant nests (Study Code 15/383). The efficacy against ants was performed in 3 treated nests. Three non-treated nests were used as a negative control to test nest activity. All nests were protected under objects. In nests 1, 2 and 3 was observed 100% reduction population in nest entrance at day 28 at an application rate of 1.7 g/ant nest. The treatment was re-applied at nest 3 at 14 days due to insufficient reduction of adult ants.
- A laboratory test for direct contact (Study Code 15/381) without residual efficacy in which was observed 100% knockdown in 10 minutes and 100% mortality in 24 hours. In this test, fewer ants were used than the recommended by the guidance, 10 ants per replicate (4), 40 ants. Nonetheless, the results clearly show that there was not mortality or knockdown in control groups and that in the treated groups a strong knockdown and mortality was observed, leading to the conclusion of a rapid insecticidal effect. Furthermore, these effects were confirmed by the field test, considering in this way a complete package data for this claim.

The applicant also requested the use against ants in crack and crevices and spot treatments indoor and outdoor but no field tests were provided for these claims. The efficacy was not demonstrated for these uses.

The requirements and criteria of the TNsG on product evaluation for PT18/19 (2012) are not met for:

-*Blatella germanica**:*** The applicant has submitted a laboratory test (Study Code 15/381) showing knockdown (95% in 20 minutes and 100% in 30 minutes). However, no mortality (24 hours) was observed according to the guidance. Regarding the field test (Study Code 15/382), it shows the population reduction taking into account the number of cockroaches calculated per day instead of the number of cockroaches in each measurement. ES CA considers that this calculation overestimates the population

reduction. If we take into account the number of cockroaches on each day of observation, the reduction ≥90% is not reached.

-*Blatta orientalis:* One simulated-use test has been provided where the mortality is reached in 48 - 72 days depending on the surface instead of 24 hours (Study Code: 21/207). Neither laboratory tests nor field trials have been submitted. Therefore, the efficacy against *Blatta orientalis* is not demonstrated.

-*Ctenocephalides felis:* For laboratory and simulated-use tests were not demonstrated neither 100% knockdown within 24 hours nor ≥90% mortality within 48 hours for adult fleas (Study Codes 15/381 and 21/207).

-*Ixodes ricinus:* Laboratory and simulated-use tests are required according to the guidance. The simulated-use test showed 100% mortality on porous and non-porous surfaces (Study code 21/201). However, a laboratory tests was not provided and the efficacy of the product against *Ixodes ricinus* is not demonstrated.

-*Rhipicephalus sanguineus:* For laboratory and simulated-use tests is not demonstrated ≥95% mortality according to the guidance (Study Codes 15/381 and 21/201).

-*Dermanyssus gallinae:* According to the guidance both laboratory and field test are necessary to demonstrate the efficacy against *Dermanyssus gallinae*. The applicant has submitted a laboratory test showing ≥90% mortality in 24 hours (Study Code 15/381). However, the field test (Study code15/354) shows ≥90% population reduction in two of three sites tested. The site with high infestation did not shown the population reduction ≥90%. ES CA considers that two sites are insufficient to determinate the efficacy of the product. Therefore, the field test did not demonstrate the efficacy of the product.

Application rate:
The applicant has provided the test report to determinate the number of powder container rotations to apply 1.7 g of biocidal product. The number of rotations required are 11.

ES CA concludes that MASSOCIDE AD04 is effective against *Lasius niger* as ant nest application.

2.2.5.6 Occurrence of resistance and resistance management

According to the CAR, development of resistance against alpha-cypermethrin is in principle possible in a wide range of insect taxa. Due to the common mode of action of pyrethroids cross-resistance may be of importance. However, actual resistance (including cross-resistance) has to date only been observed in agricultural pest insects, which are the targets of large-scale applications of insecticides, thus increasing the likelihood of resistance development. Biocidal treatments, in contrast, are typically targeted on relatively small populations of pest insects forming more or less closed populations. Good treatment practice will most likely results in high control levels which in turn reduces the likelihood of resistance development. In the literature search, *Blattela germanica* is identified as susceptible to alpha-cypermethrin, with no indications of resistance. Any records related to *Periplaneta americana* or to fleas (Siphonaptera) were not identified

by the literature search. This suggests that both the American cockroach and the whole order of fleas (Siphonaptera) resistance has to date not been detected.

The continued threat of resistance must be managed in order to prevent its manifestation in species where it has already developed and in order to minimize the risk of resistance developing in species which have not yet developed resistance to the synthetic pyrethroids. For this reason, strategies such as alteration of insecticides with different modes of action, mixtures of insecticides with different modes of action and avoidance of frequent and repeated use are standard practice.

The proposed resistance management strategy includes the following actions:

- The incorporation of a label warning: 'Use products at recommended doses and intervals'.
- To avoid the potential for insect resistance, the product should be used in alternation with other products not containing the same a.s. to avoid resistant populations.
- If resistance is confirmed, stop the use of the product and rotate to an insecticide with alternative mode of action.
- The authorisation holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management.

2.2.5.7 Known limitations

No known limitation

2.2.5.8 Evaluation of the label claims

The following claimed use is compliant with the requirements of the TNsG on product evaluation for PT18/19 (2012): Use against *Lasius niger* (adults) as nest application for consumers and professionals.

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

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

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

MASSOCIDE AD04 is a dustable powder containing 0.4 % alpha-cypermethrin.

No animal or human data on toxicological properties have been generated, but 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 alpha-cypermethrin assessment report. 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 AD04 has been provided in the confidential annex.

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	MASSOCIDE AD04 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 AD04.
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

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	MASSOCIDE AD04 is not irritating to eyes.
Justification for the value/conclusion	Based on the classification of the active substance and the co-formulants and their final content in the formulation. There is one co-formulant, without harmonised classification, which is classified as causing eye damage in its SDS. However, the concentration of this co-formulant in the preparation is well below the classification limit set in Regulation (EC) Nº 1272/2008. Thus, the biocidal product does not meet the criteria to be classified for serious eye damage/eye irritation.
Classification of the product according to CLP	No classification required according to CLP.

Data waiving	
Information requirement	No eye irritation study has been conducted with MASSOCIDE AD04.
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.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	MASSOCIDE AD04 is not a respiratory tract irritant.
Justification for the conclusion	The active substance alpha-cypermethrin (0.4 %) is deemed as STOT SE 3 (H335: May cause respiratory irritation) whilst the rest of the co-formulants are not classified as respiratory tract irritants. However, the concentration of the active substance in the preparation is well below of the classification limit (20%) set in Regulation (EC) Nº 1272/2008. Therefore, the biocidal product does not meet the criteria for classification as a respiratory tract irritant.
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 AD04 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

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	MASSOCIDE AD04 is not a skin sensitiser.
Justification for the value/conclusion	Based on the classification of the alpha-cypermethrin and the co-formulants and their final content in the formulation. None of the components of the product are classified for skin sensitisation. Therefore, the product does not meet the criteria for classification for skin sensitisation 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 skin sensitation with MASOCIDE AD04 has been conducted and performing a new study is scientifically unjustified.
Justification	Testing on the product does not need to be conducted if there are valid data available on each of the components in the mixture

	sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. Therefore, no skin sensitization test has been conducted because data on the active substance and each co-formulants are available (please refer to the MSDS attached in the IUCLID dossier) and none of them are classified as skin sensitizer. Hence, according to the CLP regulation, the biocidal product is not classified and the study is not necessary.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	MASSOCIDE AD04 is not respiratory sensitizer.
Justification for the value/conclusion	Based on the classification of alpha-cypermethrin 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 data regarding respiratory sensitation with MASOCIDE AD04 has been provided.
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 AD04 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	The classification of the biocidal product was conducted using endpoints included in Assessment Report (PT18) of alpha-cypermethrin and the SDSs of the other components. According to Assessment Report, the worst case acute oral LD_{50} for alpha-cypermethrin is 57 mg/kg bw. The calculated oral ATE for MASOCIDE AD04 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 AD04 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	MASSOCIDE AD04 is not harmful by inhalation route.
Justification for the selected value	Based on the classification of alpha-cypermethrin 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 inhalation route. 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 acute toxicity by inhalation route with the MASSOCIDE AD04 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 AD04 is not harmful by dermal route.
Justification for the selected value	Based on the classification of alpha-cypermethrin and the different co-formulants and, their respective final content in the formulation. None of the components of the product are 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 AD04 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.

Available toxicological data relating to other endpoints:

Specific target organ toxicity, repeated exposure (STOT RE)

Value used in the Risk Assessment – STOT RE	
Value	The product does not cause organ damage through prolonged or repeated exposure.
Justification for the selected value	The active substance Alpha-cypermethrin may cause damage to the Central Nervous System (CNS) through prolonged or repeated exposure (STOT RE 2) whilst the co-formulants do not have this classification. However, the concentration of the active substance in

	the preparation is well below of the classification limit (10%) set in Regulation (EC) Nº 1272/2008. Therefore, the biocidal product does not meet the criteria for classification as a specific target organ toxicant.
Classification of the product according to CLP	No classification required according to CLP.

Data waiving	
Information requirement	Specific target organ toxicity (repeated exposure) study.
Justification	No studies have been performed with the biocidal product in order to avoid unnecessary testing with vertebrates. The composition of the product is known and there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP Regulation), and synergistic effects between any of the components are not expected Therefore, this study does not need to be conducted.

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Alpha-cypermethrin
Value*	14.2 %
Justification for the selected value	Alpha-cypermethrin's CAR value of a diluted reference solution.

* No dermal absorption study on MASSOCIDE AD04 is submitted.

Data waiving	
Information requirement	Not required.
Justification	Alpha-cypermethrin was assessed for its dermal absorption properties under BPR taken as a reference formulation a suspension concentrate (SC). BASF was the owner of such formulation named TENOPA and they are also the suppliers of the active substance for MASSOCIDE AD04 (see LoA's). Dermal studies developed by BASF set dermal absorption values of 1.9% and 14.2% for alpha-cypermethrin at concentrate (2%) and diluted SC (0.018%) formulations respectively (Belgium, AR document). The dermal absorption value set in the alpha-cypermethrin CAR for a diluted formulation (14.2 %) was chosen for dermal absorption value of MASSOCIDE AD04 taking into account the following points: 1. MASSOCIDE AD 04 does not contain any co-formulant that can have any influence in the dermal absorption. Two co-formulants (> 99%) are inert substance and the third co-formulant is present in a no-relevant concentration to affect

	absorption (please refer to the confidential annex for the composition details). 2. TENOPA is a water-soluble concentrate formulation whereas MASSOCIDE AD04 is an inorganic solid formulation. In the chapter 7.2.3 from the OECD Guidance Notes on dermal absorption (2011) it is stated: "*Because of physicochemical considerations, it may be assumed that skin penetration of water-based plant protection or biocide formulations or of solid materials (such as granules) will be equal to or less than for organic solvent-based formulations of the same active compound at the same concentration level, although there may be exceptions. Provided there are no further co-formulants contained that might alter dermal uptake, experimental data obtained with an organic solvent-based test preparation may be considered as a worst case*". Neither of the two formulations are a solvent-based formulation, therefore dermal absorption value of the two biocides could be similar since there is no co-formulants that could alter the dermal absorption values. 3. In the dermal absorption assay carried out with diluted TENOPA, the concentration of the A.S. is 0.018%, whereas the A.S. concentration in MASSOCIDE AD04 is 0.4%. The 'Guidance on dermal absorption' (EFSA Journal 2017;15(6):4873) states: "*Review of available data on pesticide formulations and new human in vitro studies indicates that (see EFSA PPR Panel, 2011, section 4 and Appendix B): … • relative absorption (e.g. expressed as a percentage of the applied dose) is generally inversely related to the concentration of the active substance. Exceptions may include irritant and volatile compounds, and the presence of co-formulants that strongly affect absorption*". This product does not have skin irritant or volatile compounds, and there is no co-formulants that affect absorption. According to this point, it could be proposed that the dermal absorption value will be lower than 14.2% in the MASSOCIDE AD04 biocidal product. But, in the absence of any dermal penetration study with this formulation, ESCA chose 14.2% value as a worst-case.

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 MASSOCIDE AD04 contains only one active substance. Assessment report of alpha-cypermethrin (Belgium, 2014) indicates that active substance is not classified as Carc. 2 or Repr. 2 and has not been identified as having endocrine disrupting properties. However, a comprehensive ED-assessment of 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 alpha-cypermethrin assessment report, there is no indication of concern regarding the ED properties of the substances used in the MASSOCIDE ADO04 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.

2.2.6.2 Exposure assessment

General Remarks
The assessment of occupational exposure towards alpha-cypermethrin as insecticide is based on information provided by the Applicant. In the absence of human exposure data, the exposure estimation to alpha-cypermethrin 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 alpha-cypermethrin 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 AD04 is a dust formulation containing 0.4% w/w alpha-cypermethrin intended for the outdoor in domestic areas used by (trained) professional and non-professional users. The recommended usage concentration of the dust formulation is 12.14 g bp/m^2 (equivalent to 48.57 mg Alpha-cypermethrin per m^2), which is deemed as worst case in the current assessment. For the outdoor and surroundings use it is applied by spreading the powder evenly on the surfaces and making sure to treat nests. Exposure for the (trained) professional user is only during application since, being a ready to use formulation, no mixing and loading is foreseen.

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

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

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

PRIMARY EXPOSURE

- Loading of biocidal product into a handheld duster, bulb duster or a powder container. (Consumer Use)
- Application of biocidal product by dusting. (Professional Use & Consumer Use)

SECONDARY EXPOSURE

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

List of scenarios

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

Industrial exposure

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

Professional exposure

Scenario [1] – Outdoor application

Description of Scenario [1]

The biocidal product is applied directly to the ant nests, around houses on paved ways, balconies, and terraces where ant nests are located for the outdoor use. Exposure for the (trained) professional user is only during application since, being a ready to use formulation, no mixing and loading is foreseen.
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 Alpha-cypermethrin 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	0.4	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	14.2%	Section 2.2.6.1.
	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%	AR/CAR
Tier 2	PPE (protective gloves)	10% penetration	HEEG Opinion 9

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	2.06E-04	3.11E-03	--	3.31E-03
Scenario [1]	2/protective gloves	2.06E-04	1.71E-03	--	1.92E-03

See more information in Annex 3.2.

Further information and considerations on scenario [1]

Not applicable.

Combined scenarios
Not applicable.

Non-professional exposure

Scenario [2] – Mixing and loading

Description of Scenario [2]			
The biocidal product used as spot and superficial treatment is applied using a handheld duster, bulb duster or a powder container. The estimation of the loading task 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	0.4	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	14.2%	Section 2.2.6.1.

Calculations for Scenario [2]

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 [2]	1/no PPE	--	4.15E-07	--	4.15E-07

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 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	0.4	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	14.2%	Section 2.2.6.1.
	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 [3]

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 [3]	1/no PPE	1.72E-05	2.59E-04	--	2.76E-04

See more information in Annex 3.2.

Further information and considerations on scenario [3]

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 [2, 3]	1/no PPE	1.72E-05	2.59E-04	--	2.76E-04
Scenarios [1, 2, 3]	1/no PPE	2.23E-04	3.37E-03	--	3.59E-03

Exposure of the general public

Scenario [4] – Toddlers playing in treated areas

Description of Scenario [4]
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

Description of Scenario [4]

(2016) is considered. The dislodgeable amount is set to 30 % (ConsExpo Pest Control Product Fact Sheet, 2006). 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: 48.57 mg alpha-cypermethrin/m^2 (12.14 g bp/m^2) according to the section 2.2.5.

Considering a deposition value of 85% (RIVM scenario assumption), the amount deposited on the floor will be:

- Alpha-cypermethrin: 48.57 mg/m^2 x 0.85 = 41.29 mg/m^2

Assuming that 30% thereof will be dislodgeable, a dislodgeable amount of

- Alpha-cypermethrin: 41.29 mg/m^2 x 0.3 = 12.39 mg/m^2

is calculated.

Finally, considering that 10 % of dermal load (ConsExpo Pest Control Product Fact Sheet, 2006) will be ingested by hand-to-mouth transfer, the ingestion rate is calculated as

- Alpha-cypermethrin: 12.39 mg/m^2 x 0.20 m^2/h / 60 min x 0.1 = 4.13E-03 mg/min

for Tier 1.

For Tier 2, a transfer coefficient of 6% (transfer efficiency of powder from a smooth surface – BHHEM, 2015) is deemed for refining:

- Alpha-cypermethrin: 41.29 mg/m^2 x 0.06 = 2.48 mg/m^2 as dislodgeable amount
- Alpha-cypermethrin: 2.48 mg/m^2 x 0.20 m^2/h / 60 min x 0.1 = 8.26E-04 mg/min as ingestion rate.

For Tier 3, a 57 % of the product will be extracted by saliva (US EPA Residential SOPs - 2012) could be deemed for refining:

- Alpha-cypermethrin: 2.48 mg/m^2 x 0.20 m^2/h / 60 min x 0.1 x 0.57 = 4.71E-04 mg/min as ingestion rate.

For Tier 4, considering that 40 % of the palms (recommendation no. 5 - 2015) will be in contact with the product could be deemed for refining:

- Alpha-cypermethrin: 2.48 mg/m^2 x 0.20 m^2/h / 60 min x 0.1 x 0.57 x 0.40 = 1.88E-04 mg/min as ingestion rate.

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

	Parameters	**Value**	**Justification / Source**
Tier 1	Weight fraction of substance	100%	
	Application dose	48.57 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	30%	RIVM report 320005002/2006 - Pest Control Products Fact Sheet
	Dislodgeable amount	12.39 mg/m^2	Calculated value.

Description of Scenario [4]			
	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	14.2%	Section 2.2.6.1.
	Oral exposure		
	Transfer coefficient	0.20 m^2/h	Recommendation no. 12, 2016.
	Exposure duration	60 min	RIVM report 320005002/2006 - Pest Control Products Fact Sheet
	Transfer hand to mouth	10%	RIVM report 320005002/2006 - Pest Control Products Fact Sheet
	Ingestion rate	4.13E-03 mg/min	Calculated value.
	Oral absorption	45%	CAR/AR, 2014
Tier 2	Dislodgeable residue	6%	BHHEM 2015
	Dislodgeable amount	2.48 mg/m^2	Calculated value.
	Ingestion rate	8.26E-04 mg/min	Calculated value.
Tier 3	Fraction of Pesticide Extracted by Saliva	57%	Standard Operating Procedures for Residential Pesticide Exposure Assessment - October 2012
	Ingestion rate	4.71E-04 mg/min	Calculated value.
Tier 4	Proportion of palms of hand in contact	40%	Recommendation no. 5, 2015.
	Ingestion rate	1.88E-04 mg/min	Calculated value.

Calculations for Scenario [4]

Summary table: systemic exposure from general public					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake [mg/kg bw/d]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated oral uptake [mg/kg bw/d]**	**Estimated total uptake [mg/kg bw/d]**
Scenario [4]	1/no PPE	--	3.52E-02	1.12E-02	4.63E-02
Scenario [4]	2/no PPE	--	7.04E-03	2.23E-03	9.27E-03
Scenario [4]	3/no PPE	--	7.04E-03	1.27E-03	8.31E-03
Scenario [4]	4/no PPE	--	7.04E-03	5.08E-04	7.55E-03

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

Scenario [5] – Laundering work clothes

Description of Scenario [5]			
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 scattering from which the tier that shows safe use is tier 1 where no PPEs are worn. It is assumed that applicator wear regular clothes which, according to HEEG opinion 9, have a Default Protection Factor of 50%.			
	Parameters	**Value**	**Justification / Source**
Tier 1	Weight fraction of active substance	0.4	Section 2.1.2.
	Body weight	60 kg	Recommendation no. 14, 2017
	Dermal exposure		
	Indicative value from model	82.20 mg/d	Application (nests) for (trained) professionals
	Surface medium-sized coverall	22700 cm^2	Estimated parameter usually accepted
	Regular clothes penetration	50 %	HEEG opinion 9
	Dermal Absorption	14.2%	Section 2.2.6.1.
	Skin surface area in contact	820 cm^2	For an adult, the total area of both hands (front and back) is 820 cm^2 (Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure Default human factor values for use in exposure assessments for biocidal products (revision of HEEG opinion 17 agreed at the Human Health Working Group III on 12 June 2017))
	Transfer coefficient	30 %	BHHEM, 2015 - Cotton, knitwear, plastic, wood Dried fluid - wet hand

Calculations for Scenario [5]

Summary table: systemic exposure from general public					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake [mg/kg bw/d]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated oral uptake [mg/kg bw/d]**	**Estimated total uptake [mg/kg bw/d]**
Scenario [5]	1/no PPE	--	4.22E-05	--	4.22E-05

Further information and considerations on scenario [5]
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, 5]	2.06E-04	3.15E-03	--	3.35E-03
Scenarios [1, 2, 3, 5]	2.23E-04	3.41E-03	--	3.63E-03

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

According to SANTE-2018-11525 Rev 3 (17 July 2019), the active substance alpha-cypermethrin is considered candidate for substitution. It fulfils the criteria of Article 10 point 1-c of BPR, which claims that a substance could be considered as candidate for substitution if its acceptable daily intake, acute reference dose or acceptable operator exposure level, as appropriate, is significantly lower than those of the majority of approved active substances for the same product-type and use scenario.
On the other hand, the applicant desires to point out that this affirmation has not been included yet under BPR until active substance renewal.

Summary table of other (non-biocidal) uses			
	Sector of use	**Intended use**	**Reference value(s)**

Summary table of other (non-biocidal) uses			
1. alpha-cypermethrin	Plant protection products	IN - Insecticide	Withdraw (1)
2. alpha-cypermethrin	Veterinary use	Antiparasitic agents/Agents againstectoparasites	(2)

(1) COMMISSION IMPLEMENTING REGULATION (EU) 2021/795 of 17 May 2021 withdrawing the approval of the active substance alpha-cypermethrin in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011.
Commission Implementing Regulation (EU) 2019/1690 renewed the approval of the active substance alpha-cypermethrin as a candidate for substitution. Consequently, that active substance was listed in part E of the Annex to Commission Implementing Regulation (EU) No 540/2011.
Implementing Regulation (EU) 2019/1690 required that the applicant submitted to the Commission, the Member States and the Authority confirmatory information as regards the toxicological profile of certain metabolites by 30 October 2020. In addition, confirmatory information had been required for three other points by other deadlines set out in the Annex I of the Implementing Regulation (EU) 2019/1690.In October 2020, the applicant informed the Commission, the rapporteur Member State and the Authority that it would not submit any confirmatory data for any of the four points where confirmatory information were requested. Consequently, it is appropriate to withdraw the approval of that active substance.

(2) 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.

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
Alpha-cypermethrin	Cypermethrin (sum of isomers)	Bovine, ovine	20 µg/kg 200 µg/kg 20 µg/kg 20 µg/kg 20 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 AD04 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 AD04 is expected since the product is not applied in such a way that food or feeding stuffs could be contaminated. Therefore, there is no requirement to assess potential residues on foodstuffs.

According to Guidance on the BPR: Volume III Parts B+C Version 4.0 December 2017, 5. Guidance on Estimating Dietary Risk from Transfer of Biocidal Active Substances into

Foods – Non-professional Uses, the following risk mitigation measures are added to PAR required:

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

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

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

Aggregated exposure

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

Summary of exposure assessment

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake [mg/kg bw/d]**
1. Outdoor application	Professionals / Trained professionals	Tier 1 / no PPE	3.31E-03
		Tier 2 / protective gloves	1.92E-03
2. Mixing and loading	Non-professionals	Tier 1 / no PPE	4.15E-07
3. Outdoor application	Non-professionals	Tier 1 / no PPE	2.76E-04
3 + 2.	Non-professionals	Tier 1 / no PPE	2.76E-04
1 + 2 + 3.	Non-professionals	Tier 1 / no PPE	3.59E-03
4. Toddlers playing on treated area	General public	Tier 1 / no PPE	4.63E-02
		Tier 2 / no PPE	9.27E-02
		Tier 3 / no PPE	8.31E-03
		Tier 4 / no PPE	7.55E-03
5. Laundering working clothes	General public	Tier 1 / no PPE	4.22E-05
1 + 5.	General public	Tier 1 / no PPE	3.35E-03
1 + 2 + 3 + 5.	General public	Tier 1 / no PPE	3.63E-03

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation (alpha-cypermethrin)

Reference	Study	NOAEL (LOAEL)	AF[1]	Correction for oral absorption	Value [mg/kg bw/d]
$AEL_{short\text{-}term}$	Acute neurotoxicity study	NOAEL = 4 mg/kg bw/d	100	Yes (45%)	0.018
$AEL_{medium\text{-}term}$	90 days oral dog study	NOAEL = 3.5 mg/kg bw/d	100	Yes (45%)	0.016
$AEL_{long\text{-}term}$	1-year oral dog study	NOAEL = 2.0 mg/kg bw/d	100	Yes (45%)	0.009
ARfD	Rat, acute neurotoxicity study	NOAEL = 4.0 mg/kg bw/d	100	No	0.04
ADI	--	--	--	--	--

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

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	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
1. Outdoor application	Tier 1 / no PPE	0.009	3.31E-03	36.8	Yes
	Tier 2 / protective gloves	0.009	1.92E-03	21.3	Yes

No unacceptable risk has been identified for considered task with or without protective gloves.

Combined scenarios
Not applicable

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

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

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

Therefore, no local effects are foreseen from the application of MASSOCIDE AD04 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	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
2. Mixing and loading	Tier 1 / no PPE	0.009	4.15E-07	0.005	Yes
3. Outdoor application	Tier 1 / no PPE	0.009	2.76E-04	3.1	Yes

No unacceptable risk has been identified for different tasks considered.

Combined scenarios

Scenarios combined	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
2 + 3.	Tier 1 / no PPE	0.009	2.76E-04	3.1	Yes
1 + 2 + 3.	Tier 1 / no PPE	0.009	3.59E-03	39.9	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 alpha-cypermethrin (synthetic pyrethroid). DO NOT USE if under medical advice NOT to work with such compounds; and/or

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

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

Conclusion
Based on the results obtained in the risk assessment, the exposure of non-professional users 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	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
4. Toddlers playing on treated area	Tier 1 / no PPE	0.009	4.63E-02	514.4	**No**
	Tier 2 / no PPE	0.009	9.27E-03	103.0	**No**
	Tier 3 / no PPE	0.009	8.31E-03	92.3	Yes
	Tier 4 / no PPE	0.009	7.55E-03	83.9	Yes
5. Laundering working clothes	Tier 1 / no PPE	0.009	4.22E-05	0.47	Yes

No unacceptable risk has been identified for different tasks considered.

Combined scenarios

Scenarios combined	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
1 + 5	Tier 1 / no PPE	0.009	3.35E-03	37.3	Yes
1 + 2 + 3+ 5	Tier 1 / no PPE	0.009	3.63E-03	40.4	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 alpha-cypermethrin (synthetic pyrethroid). DO NOT USE if under medical advice NOT to work with such compounds; and/or

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

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

Conclusion

The risk derived from the use of MASSOCIDE AD04 by general public as secondary exposure appears not to be acceptable when the exposure of the user to alpha-cypermethrin is compared to its chronic AEL. Moreover the biocidal product MASSOCIDE AD04 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 is therefore assigned:

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

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 AD04 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 RMM is therefore assigned:

- *Do not (use/apply) directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock/pets.*
- Keep out of reach of children and non-target animals/pets.

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

The product MASSOCIDE AD04 does not contain any further active substance or substance of concern so a combined exposure is not expected.

2.2.7 Risk assessment for animal health

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

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

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

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

2.2.8 Risk assessment for the environment

2.2.8.1 Effects assessment on the environment

ES CA:
The risk assessment for the environment is reported as submitted by the Applicant. The ES CA assessment is presented in separate boxes on a green background.

ES CA:
MASSOCIDE AD04 is an insecticide biocidal product applied by the applicant for different intended uses (indoor in crack and crevices and behind furnishings, around buildings on paved areas protected from rain and direct application in ant nests) against crawling insects for use by non professional, professional and trained professional users in urban pest control (Domestic/Households/Private Areas) as well as in rural hygiene (Animal Houses/Shelters). The application method is by dusting.

The following data have been obtained from the active substance's CAR for the different compartments:

Aquatic compartment

Alpha-cypermethrin substance is considered toxic to aquatic organisms. Alpha-cypermethrin is relatively stable (DT_{50} =564.4 d, 12 °C, pH =7) and stable to hydrolysis (DT_{50} > 1 year, 50 °C, pH =4). Aqueous photolysis contributes to degradation of alpha-cypermethrin in water. Water/sediment studies showed that alpha-cypermethrin moved rapidly from the water phase to the sediment phase with a DT_{50} in the water ranging between 0.88 and 4 days and in sediment between 12 and 67 days at the reference temperature of 12 °C.

The following table summarizes the toxicity data for aquatic species (most sensitive species of each group) obtained from active substance's CAR.

Species	Time-scale	Endpoint	Toxicity
Fish			
Pimephales promelas	96h	Mortality (LC_{50})	0.93 µg/L (measured)
Pimephales promelas	34 d	Overall mortality across development stages (NOEC)	0.03 µg/L (measured)
Invertebrates			
Daphnia magna	48 h	Immobilisation (EC_{50})	0.3 µg/L (nominal)
Daphnia magna	21 d	Reproduction (NOEC)	0.03 µg/L (nominal)
Alage			
Pseudokirchneriella subcapitata	72 h	Cell multiplication inhibition (E_rC_{50})	> 1.0 mg/L (nominal)
Microorganisms			

Activated sludge microorganisms	3 h	Respiration inhibition (EC_{50})	> 1000 mg/L (nominal)

According to active substance's CAR, the table below shows the toxicity data for aquatic species exposed to major metabolites from alpha-cypermethrin.

Species	Time-scale	Endpoint	Toxicity
Fish			
Lepomis macrochirus: Metabolite CL 912554 Metabolite CL 206128	 96h 96h	 Mortality (LC_{50}) Mortality (LC_{50})	>102.8 mg/L (measured) >103.2 mg/L (measured)
Invertebrates			
Daphnia magna: Metabolite CL 912554 Metabolite CL 206128 Metabolite CL 206969	 48 h 48 h 48 h	 Immobilisation (EC_{50}) NOEC Immobilisation (EC_{50}) NOEC Immobilisation (EC_{50}) NOEC	 61.9 mg/L (nominal) 25 mg/L (nominal) 39 mg/L (nominal) 12.5 mg/L (nominal) 0.8 mg/L (measured) 0.286 mg/L (measured)
Alage			
Pseudokirchneriella subcapitata Metabolite CL 912554 Metabolite CL 206128	72 h	 E_rC_{50} E_bC_{50} E_rC_{50} E_bC_{50}	 70 mg/L (nominal) 31.6 mg/L (nominal) 85 mg/L (nominal) 38.1 mg/L (nominal)
Microorganisms			
Activated sludge microorganisms	3 h	Respiration inhibition (EC_{50})	> 1000 mg/L (nominal)

In the table below, a summary of the PNEC values is shown for the active substance:

Active substance	Aquatic compartment		
	$PNEC_{sw}$	**$PNEC_{sed}$**	**$PNEC_{stp}$**
Alpha-cypermethrin	$4.8x10^{-6}$ mg/L	$9.78x10^{-4}$ mg/kg wwt	100 mg/L

Atmosphere

According to the TGD on Risk Assessment (ECB Part II, 2003), there is currently no appropriate guidance to calculate a $PNEC_{air}$. The physical-chemical properties of the active substance in the environment, such as vapour pressure (<0.1 mPa), and molecular weight (416.3 g/mol), indicate that alpha-cypermethrin will not readily volatilise into the atmosphere at ambient temperature and pressure. On the other hand, Alpha-cypermethrin's CAR estimates a DT_{50} [OH rad] of 3.4 hours. Thus, in conclusion, due to the rapid degradation of the active substance in the atmosphere , no risk is expected from the use of MASSO's product on the atmosphere, birds and non-target insects. In addition, it is important to bear in mind that the product is intended to be used only in indoor premises, so the presence of volatile residue in the outdoor environment is really unlikely.

Terrestrial compartment

Alpha-cypermethrin degraded slowly in soil (DT_{50}, sandy silty loam soil, 12 °C =113.5 days) with 3-phenoxybenzoic acid as a major product of degradation and 3-phenoxybenzaldehyde as a minor product of degradation.

According to active substance's CAR, field studies in sandy loam soil on the degradation of alpha-cypermethrin were conducted and included single annual applications for up to three years. DT_{50} ranged from < 14 to 112 days and in all of these studies 90 % of the dissipation occurred within a year.

On the other hand, based on reliable adsorption/desorption data, it can be concluded that alpha-cypermethrin is strongly adsorbed by soil components (K_{oc} = 26 492 – 144 652, n = 3, mean value = 76 344 mL/g). Therefore, leaching is not expected to occur.

PNEC values obtained from active substance's CAR are summarized in the following table:

Species	**Time-scale**	**Endpoint**	**Toxicity**
Earthworms			
Eisenia foetida	14 d	LC_{50} (Acute tox.)	> 1000 mg/kg dry soil
Soil micro-organisms			
(Nitrogen mineralization)	28 d 28 d	EC50 NOEC	> 100 mg/kg > 100 mg/kg
(Carbon mineralization)	28 d 28 d	EC50 NOEC	> 100 mg/kg > 100 mg/kg
Terrestrial vertebrates			
Mammals (rat)	-	LD_{50} (Acute tox.)	57 mg a.s./kg bw
Colinus virginianus (bird)	-	LD_{50} (Acute tox.)	> 2025 mg a.s./kg bw
Colinus virginianus (bird)	5 d	LC_{50} (Diet. Tox.)	> 5000 mg a.s./kg feed
Colinus virginianus (bird)	22 weeks	NOEC (Rep. Tox.)	> 150 mg a.s./kg feed

Taken into account the values above and according to active substance's CAR, the following PNEC value is used to assess the risk of soil compartment:

Active substance	**Terrestrial compartment**
	$PNEC_{soil}$
Alpha-cypermethrin	>0.882 mg/kg wwt

ES CA:

Degradation of alpha-cypermethrin in the different environmental compartments

Degradation of alpha-cypermethrin in the aquatic compartment (including sediment)

Alpha-cypermethrin has been shown to be stable at pH 4 and hydrolyse very slowly under environmental temperature of 12°C and pH 7 with predicted DT_{50} of 564.4 days. Whereas, at more alkaline pH (pH 9) alpha-cypermethrin showed a DT_{50} of 9.9 days (Van Dijk, 1993). A major metabolite was identified as 3-phenoxybenzaldehyde (CAS-no. 39515-51-0). Photolysis will contribute to degradation of alpha-cypermethrin with a DT_{50} of 4.85 days predicted from the available data after adjustment for natural sunlight (Concha *et al*., 2001). Alpha-cypermethrin is not readily biodegradable according to OECD 301 B and D guidelines (Stone and Watkinson, 1983).

In the water-sediment degradation studies using samples from natural aquatic systems, alpha-cypermethrin incubated in the dark disappeared rapidly from the water phase due to strong adsorption to the sediment and metabolisation. Alpha-cypermethrin was also readily eliminated in the sediment phase, by metabolisation and formation of bound

residues. Alpha-cypermethrin quickly moves from the water phase into the sediment with DT_{50} in water ranging between 0.8 and 4 days, and in sediment between 12 and 67 days. BE CA recalculated DT_{50} water of 2.22 days and DT_{50} sediment of 28.13 days at 12 °C (TGD, Part B, , formula 25).
The main degradation products formed were cis-2,2-dimethyl-3-(2',2'-dichlorovinyl)cyclopropane carboxylic acid isomers (CL 912554) and 3-phenoxybenzoic acid (CL 206128), both of which underwent further degradation to $^{14}CO_2$. The DT_{50} of CL 912554 in the total system ranged between 27 and 70 days, and the DT_{50} of CL 206128 ranged between 4 and 6 days.
Although there is no direct exposure, surface water and sediment are assessed for the environmental risk and PEC values calculated to cover the effects of alpha-cypermethrin residues in the STP effluent.
Information on the metabolites is available in the Assessment Report. The ecotoxicity data show that the metabolites are far less toxic to aquatic organisms compared to parent alpha-cypermethrin:

- The 48 h EC_{50} (immobilisation) of cis-2,2-dimethyl-3-(2',2'-dichlorovinyl)cyclopropane carboxylic acid isomers (CL 912554) towards invertebrates *(Daphnia magna)* is 62 mg/L.
- The 48 h EC_{50} (immobilisation) of 3-phenoxybenzoic acid (CL 206128) towards invertebrates *(Daphnia magna)* is 39 mg/L.
- The 48 h EC_{50} (immobilisation) of 3-phenoxybenzaldehyde CL 206969 towards invertebrates *(Daphnia magna)* is 0.8 mg/L.

While the 48 h EC_{50} (immobilisation) of alpha-cypermethrin (also *Daphnia magna*) is much lower (0.3 µg/L).

Mobility of alpha-cypermethrin metabolites was shown to be minimal in laboratory leaching studies with alpha-cypermethrin.

Thus, it is demonstrated that the aqueous metabolites of alpha-cypermethrin are of less ecotoxicological significance than the parent compound with respect to invertebrate toxicity.

<u>*Degradation of alpha-cypermethrin in soils*</u>
Degradation of alpha-cypermethrin was investigated under aerobic conditions in a sandy loam soil (Gedik and Keirs, 2001). Alpha-cypermethrin seems to degrade in this type of soil with DT_{50} of 39.1 days at 12°C with CO_2 as the principal degradation product (~35% at 12°C). Four minor degradation products, including 3-phenoxybenzoic acid (CL 206128) (≤5.44% AR) and three unknowns, as well as polar materials, were also extracted from the soil (<9% of AR).
In addition to laboratory studies, field soil dissipation studies were also conducted (Doc. III-A7.2.2.2/01-09). Alpha-cypermethrin degradation was followed during three years with one application of EC alpha-cypermethrin formulation (0.5 kg a.s./ha). DT_{50} values ranged from <14 to 112 days. In all of these studies, 90% of the dissipation occurred within a year. The degradation product, 3-phenoxybenzoic acid (CL 206128), is degraded more rapidly than the parent compound.
Based on reliable adsorption/desorption data (Hill, 1993) it can be concluded that alpha-cypermethrin is strongly adsorbed in soil (Koc range 26492 to 144652, mean 76344ml/g, n = 12). Based on common mobility classification schemes (McCall *et al*., 1983; Fate of

Chemicals in the Environment, ACS, pp. 105-123) alpha-cypermethrin is classified as immobile in soil (Koc > 5000).
A further study of the effect of sunlight on a soil surface indicated that alpha-cypermethrin is not rapidly degraded through photodegradation on soil surfaces with DT_{50} of 113.5 days at 12°C. The major product of photodegradation is 3-phenoxybenzoic acid (CL 206128) (16.4% AR) and 3-phenoxybenzaldehyde (CL 206969) is a minor degradation product (<3%).

Degradation of alpha-cypermethrin in the atmosphere
Based on the vapour pressure (3.4×10^{-7} Pa at 25°C) and the Henry's law constant (0.069 Pa×m³/mol at 25°C), volatilisation of alpha-cypermethrin is negligible. The fate of alpha-cypermethrin in air was investigated using the quantitative structure activity relationship estimation method (QSAR; TGD, 2003) (Mangels, 1995), which considers the reaction with the daily air concentrations of hydroxyl radicals (OH•) and with the help of the software AOPWIN. The half-life was calculated at 3.47 hours. Therefore, alpha-cypermethrin is rapidly degraded by photochemical processes and due to its low vapour pressure alpha-cypermethrin is not considered as volatile. The air compartment is thus not considered further within the following exposure assessment.

* Taking together all this information, it is justified to **disregard the metabolites in the environmental exposure and risk assessment and to base the assessment solely on alpha-cypermethrin**.

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

No studies have been performed with the formulated product and the classification presented in this report relies on the ecotoxicity data available for the active substance. The following table summarizes the ecotoxicological data available in the active substance's CAR:

Ecotoxicological values from active substance's CAR		**AF**	**PNEC**
NOEC for fish and invertebrates	0.03 µg/L	-	$PNEC_{aquatic}$ = 0.024/ 5 = 0.0048 µg/L = 4.8E-06 mg/L
EAC mesocosmos	0.015 µg/L	-	
28 d-NOEC	0.024 µg/L	5	
$NOEC_{microorganisms}$	1000 mg/L	10	$PNEC_{micro\text{-}organisms\ (STP)}$ = 100 mg/L
NOECdevelopment rate or *Chironomus riparus*	0.0225 mg/kg dwt	5 (and 4.6 from dwt to wwt)	$PNEC_{sediment}$ =0.0225 /5 = 4.5E-03 mg/kg dwt / 4.6 = 9.78E-04 mg /kg wwt
NOEC long-term studies on soil microorganisms	>100 $mg/kg_{dry\ soil}$	100	>0.882 mg/kgwwt

NOEC diet Northern bobwhite quail	150 mg/kg diet	30	$PNEC_{birds}$ = 5 mg/kg feed
NOEC study in dogs (1-year)	80 mg/kg bw/d	30	$PNEC_{mammal}$ =2.67 mg/kg food

Further information about product composition can be seen in the confidential annex of the present dossier.

The product does not contain substances of concern for the environment.

ES CA:
MASSOCIDE AD04 is a formulation containing Alpha-Cypermethrin as active substance (a.s.) (0.4%). This a.s. is classified as Aquatic Acute 1 M=1000, Aquatic Chronic 1 M=1000 according to their entry in Annex VI of Regulation (EC) No. 1272/2008.

MASSOCIDE AD04 has other co-formulants in the formulation. ES CA analised the information available on the co-formulants (i.e. Safety Data Sheets, C&L Inventory, REACH Registration dossiers, REACH Evaluation Reports and CARs of approved biocidal active substances). Some of the co-formulants are not classified for environmental hazards and therefore do not contribute to the classification or possible risks of the mixture. Only one co-formulant carry environmental hazard classification. However it is below the concentration limits specified in Regulation (EC) No. 1272/2008 leading the product to be regarded as hazardous. Therefore it doesn`t contribute to the classification of the biocidal product for environmental hazards.

The product MASSOCIDE AD04 contains the coformulant Silicon Dioxide. Synthetic amorphous silicon dioxide doesn't have an harmonised classification and labelling according to Reg. (EC) No 1272/2008. In the AR (FR, 2014) a classification for STOT RE 2 (inhalative route, H373) is proposed but no classification is warranted for dangers to the aquatic environment. Therefore synthetic amorphous silicon dioxide present in the product does not contribute to the C&L of the biocidal product based on its danger to the environment, nor does it meet the criteria for being a PBT or vPvB substance. However, as Silicon Dioxide is an active substance from other product types contained in the product for which a draft final Competent Authority Report is available it should be considered as SoCs according to the Guidance on the BPR, Volume IV Environment – Assessment and Evaluation (Part B+C) as it is present in the biocidal product at a concentration ≥ 0.1%.

Therefore the risk assessment of the product MASSOCIDE AD04 is based on the information provided in the Assessment Report of alpha-cypermethrin as included in the Assessment Reports of PT18 uses (final CAR of July 2014) and on the information provided in the Assessment Report of Synthetic amorphous silicon dioxide PT18 (March 2014) which is identified as a substance of concern.

The application of MASSOCIDE AD04, as applied by the applicant, on the Domestic/Households/Private Areas and also on Animal Houses/Shelters ranged from 1

to 3 applications per year. The application dose is 12.5 g product/m^2 (0.05 g a.i./m^2). The dose for the direct application in ant nests is 1.7 g per nest.

ES CA:

PNEC derivation- Substance of Concern

PNEC values were proposed in the Assessment Report of Synthetic amorphous silicon dioxide PT18.

Summary table on PNEC for Synthetic amorphous silicon dioxide	
Environmental compartment	**PNEC value**
PNEC STP	100 $mg.L^{-1}$
Surface water	8.6E-02 $mg.L^{-1}$
Freshwater sediment *	2.19 $mg.kg_{wwt}^{-1}$*
Soil *	706 $g.kg_{dwt}^{-1}$ = 625 $g.kg_{wwt}^{-1}$*

* According to the CAR, the PNEC cannot be calculated with the partitioning method from PNEC water. Therefore, as agreed during TMIII10, PNEC is replaced by silica background in the considered compartment.

As explained in the Assessment Report of Synthetic amorphous silicon dioxide PT18, it is not necessary to perform an assessment of secondary poisoning.

ES CA:

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.

No further ecotoxicological studies are available for MASSOCIDE AD04. The product was not tested for potential endocrine disruption properties. MASSOCIDE AD04 contains the active substance Alpha-Cypermethrin 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.

For the co-formulants a screening was performed by consulting:
- ECHA data for identification of ED and PBT, under REACH, 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=yand https://wedocs.unep.org/bitstream/handle/20.500.11822/25635/edc_report2_factsheet.pdf?sequence=1&isAllowed=y)

During screening performance none of the co-formulant triggered an alert for ED property thus, ES CA considered that there is no concerned regarding the ED properties of this coformulants.

Further Ecotoxicological studies

No data is available on the product. Please refer to the data on the active substance's CAR.

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

No data is available on the product. Please refer to the data on the active substance's CAR.

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

No data is available on the product. Please refer to the data on the active substance's CAR.

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

No more data than mentioned in Alpha-cypermethrin's CAR is available.

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

Not applicable.

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

The main emission route of the active substance through its use in MASSO's product-DP (Alpha-cypermethrin 0.4% w/w) is via wastewater to sewage water treatment plants (STP) and subsequent release via effluents to surface water and sediment after the cleaning of the treated areas or the treated materials or washing of applicator cloths. There are no direct emissions to surface water or sediment, and aquatic or sediment organisms are not directly exposed to the active substance. Direct exposures to the environment via the pathways air, soil or groundwater are considered to be negligible. However, STP sludge might be applied to soil and contaminate soil. Therefore, the risk was calculated also for soil and groundwater. In addition, secondary poisoning was assessed in the present assessment.

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

No further studies are necessary. Data available on the active substance is sufficient.

ES CA:
New environmental fate and behaviour on the a.s. or product specific data are not available as they are not considered necessary. All agreed endpoints have been taken from the CAR of the a.s. in PT 18 as well as from the Substance of Concern, Synthetic amorphous silicon dioxide.

Leaching behaviour (ADS)

No new data is deemed necessary.

Testing for distribution and dissipation in soil (ADS)

No new data is deemed necessary.

ES CA:
Additional data on distribution and dissipation in soil of the a.s. or the biocidal product are not necessary. New data are not available.

The data on the distribution and dissipation of the a.s. gives sufficient information and there are no indications of risk due to specific properties of the b.p..
The emissions to soil exclusively occur via sewage sludge or slurry/manure applications. Several field and laboratory degradation studies in soil are available for alpha-cypermethrin, showing aerobic degradation of the a.s. with half-lives ranging from < 14 to 112 days (12°C). CO_2 was the only detected major metabolite. All other metabolites formed were minor metabolites (formed in amounts < 10%). In all of the studies, 90 % of dissipation occurred within a year. Alpha-cypermethrin will therefore not persist in soil. Furthermore, the components of the biocidal product do not influence the distribution characteristics of the a.s.. The formulation types are not expected to change the model of action of the a.s or its bioavailability.
Further testing for distribution and dissipation in the environment is therefore not deemed reasonable.

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

No new data is deemed necessary.

ES CA:
Additional data on distribution and dissipation in water and sediment of the a.s. or the biocidal product are not necessary. New data are not available.

The data on the distribution and dissipation of the a.s. gives sufficient information and there are no indications of risk due to specific properties of the b.p..
The emissions to sediment exclusively occur via sewage sludge or slurry/manure applications. Higher tier water-sediment degradation studies are available for alpha-cypermethrin showing that alpha-cypermethrin moved rapidly from the water phase to the sediment phase with a DT_{50} in the water phase of between 0.88 and 4 days and in sediment between 12 and 67 days (12°C). The main degradation products formed were cis-2,2-dimethyl-3-(2',2'-dichlorovinyl)cyclopropane carboxylic acid isomers (DT_{50} 27-70 days) and 3-phenoxybenzoic acid (DT_{50} 4-6 days), both of which underwent further degradation to CO_2, showing aerobic degradation of the a.s. with half-lives ranging from < 14 to 112 days (12°C). Alpha-cypermethrin will therefore not persist in sediment.
Furthermore, the components of the product do not influence the distribution characteristics of the a.s..
Further testing for distribution and dissipation in the environment is therefore not deemed reasonable.

Testing for distribution and dissipation in air (ADS)

No new data is deemed necessary.

ES CA:
Additional data on distribution and dissipation in air of the a.s. or the biocidal product are not necessary. New data are not available.

Volatilisation to the atmosphere following normal biocidal use of the b.p. is limited due to the very low vapour pressure (3.4×10^{-7} Pa at room temperature). Accumulation in air does not occur due to the low air photolysis DT_{50} of 10.4 h.
Thus, accumulation and transport in air can be excluded and further testing is not deemed reasonable.

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

The biocidal product is not intended to be sprayed near to surface water, so this study is not required. Outdoor use is limited and controlled for ant nest treatment near buildings.

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

The biocidal product is not intended to be sprayed outside so no further studies are required.

ES CA:
Based on the use pattern of the biocidal product MASSOCIDE AD04 the outdoor use against ants will not affect plants or flower beds. Treated areas are specifically ants nests and therefore they are not visited by bees. Exposure to bees or other arthropods would be limited and of limited extension. Therefore, no risk to bees or other non-target arthropods is anticipated and therefore no additional studies performed with bees or other arthropods are deemed necessary.

In addition, the biocidal product MASSOCIDE AD04 does not contain in its formulation any co-formulant that could be attractive to bees. However, to prevent possible bee access to the product, the sentence "*Do not apply close to blooming plants/cultures*" must be included for outdoor use as an instruction for use.

2.2.8.2 Exposure assessment

MASSO's powder-product (Alpha-cypermethrin at 0.4% w/w) is a PT-18 intended to be used indoors in domestic, public and livestock premises and in surrounding areas in houses. The environmental exposure of this product has been assessed in accordance with the recommendations of EUSES 2.2.0 model calculations, the Technical Guidance Document (TGD) on risk assessment (ECB Part II, 2003), the OECD "Emission Scenario Document for Insecticides, Acaricides and Products to control other Arthropods (PT18) for household and professional uses" (July 2008) and OECD "Emission Scenario Document for Stables and Manure Storage Systems" (January 2006).

ES CA:
For the environmental exposure assessment also the technical agreements reached for the evaluation of biocidal products "Technical Agreements for Biocides"- Environment (ENV)- February 2021, has been used.

General information

Assessed PT	PT 18
Assessed scenarios	**Scenario 1**: Disinfestation of domestic and industrial premises (crack and crevice or broadcast areas of domestic premises, bedrooms, kitchens, garage and annexes connected to STP) **Scenario 2:** Disinfestation of breeding premises without the presence of animals during the application. **Scenario 3:** Disinfestation of outdoor foundations and soil around the buildings in urban and rural areas. **Scenario 4:** Disinfestation of ant nests.
ESD(s) used	*Emission Scenario Documents for Product Type 18:* - *Emission Scenario Document for insecticides, acaricides and products to control other arthropods for household and professional uses (OECD Nº18, 2008).* - *Emission Scenario Document for insecticides for stables and manure storage systems (OECD Nº14, 2006).*
Approach	***Scenario 1:*** *Average consumption: Considering 3 as the highest number of events per year.* The powder-product with 0.4% w/w concentration of alpha-Cypermethrin is directly applied by spreading method. Under this consideration, two scopes of application have been taken in account in the present environmental assessment: • *Surface dusting crack and crevice (Scenario 1.a)* • *Surface dusting broadcast (Scenario 1.b)* In addition, in function of the intended user, private and industrial use should be deemed in the assessment. Furthermore, dry and wet cleaning methods used after product application have been also considered in order to establish the environmental risk assessment. Due that the product is also intended to be applied by non-professional users, "washable coverall" has been deemed as default. Wet cleaning methods are considered in the assessment despite dry cleaning methods should be used to remove any product residue when accessible to the cleaning equipment. Therefore, eight likely scenarios are foreseeable for domestic premises: • <u>*Crack & crevice (scenario 1.a)*</u> - (*Scenario 1.a-Private-wet*) Surface dusting crack and crevice application in private buildings with wet cleaning methods after product's treatment. - (*Scenario 1.a-Private-dry*) Surface dusting crack and crevice application in private buildings with dry cleaning methods

	after product's treatment. - (*Scenario 1.a-Indust-wet*) Surface dusting crack and crevice application in industrial buildings with wet cleaning methods after product's treatment. - (*Scenario 1.a-Indust-dry*) Surface dusting crack and crevice application in industrial buildings with dry cleaning methods after product's treatment. • <u>*Surfaces (broadcast) (scenario 1.b)*</u> - (*Scenario1.b-Private-wet*) Surface dusting broadcast application with wet cleaning methods in private buildings after product's treatment. - (*Scenario 1.b-Private-dry*) Surface dusting broadcast application with dry cleaning methods in private buildings after product's treatment. - (*Scenario1.b-Indust-wet*) Surface dusting broadcast application with wet cleaning methods in industrial buildings after product's treatment. - (*Scenario 1.b-Indust-dry*) Surface dusting broadcast application with dry cleaning methods in industrial buildings after product's treatment. ***Scenario 2:*** *Average consumption: Considering the following intended number of events per year:* **3 applications** for animal housing of beef cattle, veal calves and, laying hens in battery cages with belt drying, with force drying and free range with litter floor. **2 applications** for animal housing of broilers **1 application** for animal housing of dairy cattle, piggeries and laying hens in compact battery cages.. Furthermore, the assessment of this scenario was evaluated with the concentration of the active substance for the main species of animals to be protected. Several sub-scenarios are assessed for this scenario: • Dairy cows • Beef cattle • Veal Calves • Sows in individual pens • Sows in groups • Fattening pigs • Laying hens in battery cages without treatment • Laying hens in battery cages with aeration (Belt drying) • Laying hens battery cages with force drying • Laying hens compact battery cages • Laying hens in free range with litter floor • Broilers in free range with litter floor • Laying hens in free range with grating floor (aviary system) • Parent broilers in free range with grating floor • Parent broilers in rearing with grating floor • Turkeys in free range with litter floor • Ducks in free range with litter floor • Geese in free range with litter floor

	Scenario 3: *Average consumption: Considering 2 as the highest number of events per year.* As in the case of Scenario 1, private and industrial division is done in function of the intended user. In addition, distinction between rural and urban areas has also be taken into account. ***Scenario 4:*** *Average consumption: Considering 2 as the highest number of events per year*
Distribution in the environment	Emission scenarios have been developed according ESD guidances No.18 and No. 14 for PT18. These calculations can be seen in the attached documents
Groundwater simulation	No further model was developed.
Confidential Annexes	Yes
Life cycle steps assessed	*- Scenarios 1, 2, 3 and 4:* Production: No Formulation No Use: Yes Service life: No
Remarks	- Outdoor use into ant's nests (Scenario 4) is done by pouring directly the powder into the ant nest and then, the nest must be covered by plastic tarp in order to avoid any loss of powder from the nest by air or rainfall.

ES CA:
Some modifications have been added to the table below.

Despite the fact that the applicant has requested to evaluate the B.P. for indoors disinfestation of domestic and industrial premises, disinfestation of breeding premises and disinfestation of outdoor foundations and soil around the buildings in urban and rural areas, by not providing efficacy studies in this regard, ES CA has only carried out scenario 4, disinfestation of ant nests (due to lack of effective dose to assess the above scenarios).

Assessed PT	PT 18
Assessed scenarios	***Scenario 4:*** *Outdoor - Ant nests* a) Private houses b) Larger buildings
ESD(s) used (*)	○ *Emission Scenario Document for insecticides, acaricides and products to control other arthropods for household and professional uses (OECD Nº18, 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 the BPR, Vol. IV, Part B+C (2017) • Technical Agreements for Biocides (TAB) – ENV v.2.1
Groundwater simulation	No further model was developed.
Confidential Annexes	No
Life cycle steps assessed	*Scenario 4* Production: No Formulation No Use: Yes Service life: No
Remarks	-

The following parameters obtained from Alpha-cypermethrin's CAR have been considered in the environmental risk assessment:

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	***Value***	***Unit***	***Remarks***
Molecular weight	416.3		
Melting point	82.3	°C	
Boiling point	None	°C	decomposes before boiling at atmospheric pressure
Vapour pressure (at XC)	5.60E-07	Pa	
Water solubility (at X°C)	4.59E-03	mg/l	at pH4 (5.8E-3 mg/L at pH 7 and 7.87E-3 mg/L at pH 9)
Log Octanol/water partition coefficient	5.5	Log 10	(log P_{ow}) No relevant pH-dependence due to absence of dissociating groups. Therefore, alpha-cypermethrin is not considered to be a bioaccumulable substance with a BCF_{fish} value of 910 L/kg.

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	***Value***	***Unit***	***Remarks***
Organic carbon/water partition coefficient (Koc)	76344	L/kg	median. (*Therefore, leaching is not expected to occur*)
Henry's Law Constant (at X C)*[if measured data available]*	6.90E-02	$Pa/m^3/mol$	
Biodegradability	*Not readily biodegradable*		
Rate constant for STP *[if measured data available]*		h^{-1}	
DT_{50} for biodegradation in surface water		d or h (at 12ºC)	
DT_{50} for hydrolysis in surface water	4 d (water) and 67 d (sediment) as worst cases	d or h (at 12ºC /pH)	alpha-cypermethrin moved rapidly from the water phase to the sediment phase with a DT_{50} in the water ranging between 0.88 and 4 days and in sediment between 12 and 67 days at the reference. The main degradation products formed were cis-2,2-dimethyl-3-(2',2'dichlorovinyl) cyclopropane carboxylic acid isomers (DT50 ranged 27 - 70 days) and 3-phenoxybenzoic acid (DT_{50} ranged 4 - 6 days), both of which underwent further degradation to $C0_2$.

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	***Value***	***Unit***	***Remarks***
DT_{50} for photolysis in surface water		d or h	Aqueous photolysis contributes to degradation of alpha-cypermethrin in water. Three resulting metabolites were formed: 3-phenoxybenzaldehyde, 3-phenoxybenzoic acid and cis + trans-2,2-dimethyl-3-(2',2'-ichlorovinyl)cyclopropane carboxylic acid isomers. The former two metabolites are also sensitive to photodegradation. The latter metabolite demonstrated to be less sensitive. Nevertheless, increasing amounts of carbon dioxide were formed, suggesting that alphacypermethrin and its hotolytic transformation products are rapidly degraded, involving partial photochemical oxidation to $C0_2$.
DT_{50} for degradation in soil	39.1 35	d or h (at 12ºC)	temperature of 12 °C. *Alpha-cypermethrin degraded slowly in soil*
DT_{50} for degradation in air	Not required	d or h	According to CAR's results (t1; 2 < 2 days), alpha-cypermethrin is rapidly degraded by photochemical processes in air and no accumulation of alpha-cypermethrin in the air is to be expected

ES CA:
After reviewing the parameters proposed by the applicant, some modifications have been made that are shown in the next table (also the Synthetic amorphous silicon dioxide parameters have been added):

Parameter	Value	Unit
Molecular weight	416.3	g/mol
Melting point	82.3	°C
Boiling point	None (decomposes before boiling at atmospheric pressure)	°C
Vapour pressure (at 25 °C)	$2.5*10^{-7}$ (20°C) $5.6*10^{-7}$ (25°C, extrapolated)	Pa
Water solubility (at 20 °C)	5.8 (pH 7)	µg/L
Log Octanol/water partition coefficient	5.5	Log 10
Organic carbon/water partition coefficient (Koc)	76344	L/kg
Kp soil	1527	L/kg
Kp susp.	7634	L/kg
Henry's Law Constant (at 25°C)	0.069	Pa/m3/mol
Biodegradability	Not readily biodegradable	-
Rate constant for STP	0	h^{-1}
DT_{50} for biodegradation in surface water (at 12 ºC)	2.22	d
DT_{50} for hydrolysis in surface water (at 12 ºC)	564 (pH 7)	d
DT_{50} for photolysis in surface water	3.4 – 6.3	d
DT_{50} for degradation in soil (at 12 ºC)	112	d
DT_{50} for degradation in air	3.47	0

Synthetic amorphous silicon dioxide

Input parameters used in the environmental exposure assessments according to the CAR (March, 2014)		
Input	Value	Unit
CAS number	112926-00-8	-
Molecular weight	60.08	$g.mol^{-1}$
Vapour pressure	Not applicable as melting point>300°C	Pa
Water solubility (at 21°C)	Not soluble	$mg.L^{-1}$
Partition coefficient (log P_{OW}) (pH 7)	Not applicable	Log 10
Biodegradability	Not biodegradable	
Degradation in water/sediment (DT_{50}) (at 12°C)	Not relevant	days
Degradation in soil (DT_{50}) (at 12°C)	Not relevant	days
Adsorption / desorption Koc	Not relevant	$L.kg^{-1}$
Henry's Law Constant (at 20°C)	Not applicable	$Pa.m^{-3}.mol^{-1}$
Photo-oxidative degradation in air (DT_{50})	Not relevant	h
Total rate constant for removal from top soil (k_{TOT})	6.93E-07 (No degradation)	$days^{-1}$
BCF fish	Not expected to have an intrinsic potential for bioconcentration	$L.kg^{-1}$
BMF fish		-
BCF earthworms		$L.kg^{-1}$

As mentioned above, considering that all the uses requested by the applicant cannot be approved, the environmental assessment of the a.s. and the SoC has only been carried out for scenario 4, for the use of "direct application on ant´s nest by professional and non-professional users".

Assessed scenarios: Intended uses and application rates for MASSOCIDE AD 0.4

Scenarios	Uses #[1]	Indoor / Outdoor	User	Type of application	Target pest	Product's application rate	Application rate (a.i.)
1	01 and 02	Indoor	Professional and General public	Dusting powder in voids/cavities (1a) (cracks and crevices) and broadcast surfaces (1b)	Crawling insects[2]	12.5 g/m^2	50 mg/m^2
2	03 and 04	Indoor	Professional and General public	Dusting powder into animal housing[3]	Crawling insects	12.5 g/m2	50 mg/m^2
3	07 and 08	Outdoor	Professional and General public	Dusting powder in voids/cavities of paved surfaces and roof-covered areas	Crawling insects[2]	12.5 g/m2	50 mg/m^2
4	05 and 06	Outdoor	Professional and General public	Dusting powder on ant's nest	Ants	12.5 g/m2	50 mg/m^2

[1] As indicated in the section 2.1.4 Authorized uses

[2] Cockroaches deemed as worst case

[3] Following OECD ESD No.14 Spraying application has been used for this assessment as the most appropriate method of application available in the the guidance.

ES CA:

Scenarios	Uses #[1]	Active substance	Indoor/Outdoor	User	Type of application	Target pest	Product's application rate	Application rate (a.i.)
4	05 and 06	alpha-cypermethrin	Outdoor	Professional and General public	Dusting powder on ant's nest	Ants	1.7 g/nest	12,14 g/m^2

[1] As indicated in the section 2.2.1 Intended use as applied for by the applicant

Emission estimation

As the product is applied in an indoor environment (domestic, industrial, public, animal housing), direct emission to the environment is not likely. In addition, the use outdoors at surrounding areas must be targeted to crack and crevice places hence, it can be considered as spot application and its emission can be also deemed as unlikely. Similar case can be considered for application into ant nests, where the product is applied directly into the nest and then covered by a plastic trap in order to avoid any release by air or rainfall. However, in this scenario (ant nest) direcy emission to soil is developed although it must be considered as localized and restricted emission to addressed area. Therefore, no indirect emission to surface water or STP is expected from this scenario and the potential groundwater emission should be deemed as negligible.

Indirect emission occurs during cleaning out of residues (domestic/ public premises) or manure (animal housing).

Scenarios [1.a]

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario:**1.a - Disinfestation by manual dusting on crack and crevice surfaces of domestic and industrial premises**			
Quantity of commercial product applied	1.25E-02	Kg/m^2	*S*
Concentration of active substance in the product:	0.004	-	*S*
Area treated with the product in standard house (surface dusting crack and crevice)	2	m^2	*D*
Area treated with the product in large building (surface dusting crack and crevice)	9.3	m^2	This value is used according to ENV142 of TAB-ENV (Feb 2021)
Frequency of application	3-11 times a year		*S*
Coverall is considered	washable	-	*S*
Mixing and loading	Not considered*		*S*

S: data set by the applicant; D: default value; P: Pick list.
* As the product is a ready-to-use formulation, no emission from mixing and loading task is deemed in the Environmental Risk Assessment.

Note: According to Technical Agreements for Biocides (TAB) – ENV (February 2021), an efficiency of 0.25 for wet cleaning treatment was considered for crack and crevice use as MASSOCICE AD04 is a powder formulation.

Calculations for Scenarios [*1.a*]

Resulting local emission to relevant environmental compartments					
Compartment	**Local emission (Elocal$_{compartment}$) [kg/d]**				**Remarks**
	Scenario 1.a-standard house – wet cleaning	*Scenario 1.a-standard house -dry cleaning*	*Scenario 1.a-large building – wet cleaning*	*Scenario 1.a-large building -dry cleaning*	
Emission via application					
Emission to air	2.00E-06	2.00E-06	9.30E-06	9.30E-09	*O*
Emission to floor	1.80E-05	1.80E-05	8.37E-05	8.37E-05	*O*
Emission to applicator	-	-	-	-	*O*
Emission to treated area	8.00E-05	8.00E-05	3.72E-04	3.72E-04	*O*
Emission via cleaning					
From the applicator	-	-	-	-	*O*
From the floor	4.50E-06	4.50E-06	2.09E-05	2.09E-05	*O*
Emission to wastewater from wet cleaning the treated surfaces	2.00E-05	-	9.3E-05	-	*O*
Emission to solid waste from dry cleaning the treated surfaces	-	2.00E-05	-	9.3E-05	*O*
Total emission	***Scenario 1.a-Private (standard houses)-wet***	***Scenario 1.a-Private (standard houses) -dry***	***Scenario 1.a-Indust (standard houses and large building)-wet***	***Scenario 1.a-Indust (standard houses and large building)-dry***	
Local emission to air	6.52E-05	6.52E-05	8.79E-05	8.79E-05	*O*
Local emission to wastewater	7.99E-04	1.47E-04	1.08E-03	1.98E-04	*O*
Local emission to solid waste	0	0	0	8.79E-04	*O*

O: Output

Further data calculations of each scenario can be found in attached documents at Annex section 3.2.

Scenarios [1.b]

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario:**1.b - Disinfestation by manual dusting on broadcast surfaces of domestic and industrial premises**			
Quantity of commercial product applied	1.25E-02	Kg/m^2	*S*
Concentration of active substance in the product:	4	g/Kg	*S*
Area treated with the product in standard house (surface dusting crack and crevice)	22	m^2	*D*
Area treated with the product in large building (surface dusting crack and crevice)	609	m^2	This value is used according to ENV146 of TAB-ENV v.2.1.
Frequency of application	3-11 times a year		*P/S*
Coverall is considered	washable	-	*P*
Mixing and loading	Not considered*		*P*
Cleaning efficiency	0.5	-	*D*

S: data set by the applicant; D: default value; P: Pick list.
* As the product is a ready-to-use formulation, no emission from mixing and loading task is deemed in the Environmental Risk Assessment.

Calculations for Scenario *[1.b]*

Resulting local emission to relevant environmental compartments					
Compartment	**Local emission (Elocal$_{compartment}$) [kg/d]**				**Remarks**
	Scenario 1.b-standard house – wet cleaning	*Scenario 1.b-standard house -dry cleaning*	*Scenario 1.b-large building – wet cleaning*	*Scenario 1.b-large building -dry cleaning*	
Emission via application					
Emission to air	2.20E-05	2.20E-05	6.09E-04	6.09E-04	*O*
Emission to floor	1.98E-04	1.98E-04	5.48E-03	5.48E-03	*O*
Emission to applicator	-	-	-	-	*O*
Emission to treated area	8.80E-04	8.80E-04	2.44E-02	2.44E-02	*O*
Emission via cleaning					
From the applicator	-	-	-	-	*O*
Emission to wastewater from wet cleaning the floor	9.90E-05	9.90E-05	2.74E-03	2.74E-03	*O*

Resulting local emission to relevant environmental compartments					
Compartment	**Local emission (Elocal$_{compartment}$) [kg/d]**				**Remarks**
	Scenario 1.b-standard house – wet cleaning	*Scenario 1.b-standard house -dry cleaning*	*Scenario 1.b-large building – wet cleaning*	*Scenario 1.b-large building -dry cleaning*	
Emission to wastewater from wet cleaning the treated surfaces	4.40E-04	-	1.22E-02	-	*O*
Emission to solid waste from dry cleaning the treated surfaces	-	4.40E-04	-	1.22E-02	*O*
Total emission	***Scenario 1.b-Private (standard houses)-wet***	***Scenario 1.b-Private (standard houses) -dry***	***Scenario 1.b-Indust (standard houses and large building)-wet***	***Scenario 1.b-Indust (standard houses and large building)-dry***	
Local emission to air	7.17E-04	7.17E-04	2.21E-03	2.21E-03	*O*
Local emission to wastewater	1.76E-02	3.23E-03	5.41E-02	9.93E-03	*O*
Local emission to solid waste	-	-	-	4.41E-02	*O*

O: Output

ES CA:
As stated previously, Scenario 1 (Disinfestation by manual dusting of domestic and industrial premises) has not been considered into the risk assessment by ES CA due to lack of efficacy support.

Therefore, all the scenario 1 evaluation included by the applicant has not been reviewed.

Scenario [2] - Disinfestation of breeding premises

Following the ESD for PT 18 (OECD, Series on Emission Scenario Documents No. 14, Emission Scenario Document for Insecticides for Stables and Manure Storage Systems; cited in the following as "ESD for PT 18 No. 14"), spreadsheets have been used according to the specifications related on TAB – ENV (February 2021) , to calculate the PEC values for each compartment derived from the intended use of MASSOCIDE AD04 product.

The releases of MASSOCIDE AD 0.4 to the environment are assessed by applying emission models to soil after manure applications on grassland and arable land followed by emission models to groundwater and surface water.

It is intended to be used in all animal categories (i1=18) according to the ESD for Insecticides for Stables and Manure Storage Systems in PT18 (2006).

In the following table the concerned animal subcategories and manure storage types are presented. These different categories are referenced with the appropriate number.

Sub-cat. (*i1*)	Number of animals	Floor area	Wall and Roof area	total area (incl. slats, other areas and manure area)	Housing volume
	[-]	[m²]	[m²]	m²	m³
(1) Dairy cows	100	1170	1670	3230	9630
(2) Beef cattle	125	370	1000	1750	3063
(3) Veal calves	80	160	330	650	590
(4) Sows, in individual pens	132	560	910	1930	1960
(5) Sows in groups	132	710	1160	2200	2480
(6) Fattening pigs	400	600	970	2020	2110
(7) Laying hens in battery cages without treatment	21000	750	1100	4410	2810
(8) Laying hens in battery cages with aeration (belt drying)	21000	750	1100	4410	2810
(9) Laying hens in batters cages with forced drying (deep pit, high rise)	21000	750	1100	3810	2810
(10) Laying hens in compact battery cages	21000	750	1100	3510	2810
(11) Laying hens in free range with litter floor (partly litter floor, partly slatted)	10000	1430	2030	4610	5360
(12) Broilers in free range with litter floor	20000	1110	1600	2730	4170
(13) Laying hens in free range with grating floor (aviary system)	20000	1270	1822	4992	4780
(14) Parent broilers in free range with grating floor	7000	390	600	1290	1458
(15) Parent broilers in rearing with grating floor	9000	500	750	1640	1880
(16) Turkeys in free range with litter floor	10000	3330	4650	8040	12500
(17) Ducks in free range with litter floor	10000	2000	2820	4880	7500
(18) Geese in free range with litter floor	10000	2500	3500	6060	9380

Calculations for Scenario [2] – Use in animal housing (livestock)

The input parameter used for the environmental exposure assessment for professional use in rural hygiene (stables i.e. animal houses/shelters) is taken from the ESD for Insecticides for Stables and Manure Storage Systems in PT18 (OECD ESD No.14) and the Technical Agreements for Biocides (TAB) – ENV (February 2021). Additional calculations were performed according to the Guidance on the biocidal products Regulation. Volume IV Environment - Part B Risk Assessment (active substances) (BPR, ECHA, 2015b), as well as from output values given by EUSES and Simple Treat 4.0 (according to AHEE-1 2016, RIVM-VSP report 14245c02).

Default values regarding e.g. number of animals (see table below), the fractions of a.s. released to the relevant streams, number of disinfectant applications etc. were directly used in accordance with the ESD No.14 (2006) and associated documents. The treated area in the stables, which is used for calculations, is the total area of the housing (floor, walls and ceiling) plus the slatted areas and other areas, taken the worst case scenario.

Calculations were done for all animal sub-categories (i1 = 1-18) and for i2 = 2 (Insecticide (adulticide) against other insects or arthropods (blood sucking pests). The

mode of application was spraying (i3 = 1), it was considered as the most suitable from available application methods and the exposure streams considered were all [(i4= 1 (manure), i4= 2 (waste water) and i4= 3 (slurry)].

The following input parameters were used to calculate the local emissions to soil.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Content of active ingredient in formulation (product)	4	*g/kg*	S
Area to be treated with amount prescribed	1	m^2	S
Amount of product prescribed to be used for area specified	12.5	$g.m^{-2}$	S
Number of repeated treatments prescribed by the applicant per year: (i1=1, 4, 5, 6 and 10) (i1=12, 14 and 15) (i1=2, 3, 7, 8, 9, 11, 13, 16, 17 and 18)	 1 2 3	 - - -	S
Period between biocide treatments (i1=1, 4, 5, 6 and 10) (i1=12, 14 and 15) (i1=2, 3, 7, 8, 9, 11, 13, 16, 17 and 18)	 365 61 61	 *d* *d* *d*	S
Number of land application - on grassland - on arable land	 4 1	 Yr^{-1} Yr^{-1}	 D D
Manure storage time - grassland - arable land	 53 212	 *d* *d*	 D D
Number of biocide application during manure storage period of application for <u>arable land</u>: (i1=1, 4, 5, 6 and 10) (i1=12, 14 and 15) (i1=2, 3, 7, 8, 9, 11, 13, 16, 17 and 18)	 1 3 3	 - - -	 O O O
Number of biocide application during manure storage period of application for <u>grassland</u>: (i1=1, 4, 5, 6 and 10) (i1=12, 14 and 15) (i1=2, 3, 7, 8, 9, 11, 13, 16, 17 and 18)	 1 1 1	 - - -	 O O O
Half-life for biodegradation in soil ($DT50_{bio\_Soil}$)	35	*d*	D*
For those sub-scenarios where the emission is developed via wwtp the following fractions of a.s. emission taken from Simple Treat 4.0 is considered: - Fraction of emission directed to water by STP:	9.754	%	O
- Fraction of emission directed to sludge by STP:	29.16	%	O

* Considered as median value from field studies in a.s.'s CAR.

Outputs from Simple Treat 4.0 can be found at annex section 3.2 of the current dosier.

As MASSOCIDE AD04 is intended to be used as insecticide in all breeding areas, the emission calculation was conducted for all of relevant categories and subcategories (see annex section 3.2.2). In dependence of the relevant emission streams different exposure pathway scenarios exist:

In case of livestock, the relevant emission stream is only slurry. Contrary, the relevant emission stream of housing systems for poultry is depicted by:

- discharge of stable cleaning water to the municipal STP and slurry (battery cages with aeration)
- manure and liquid waste (free-range system with litter floor)
- solely slurry (free-range with grating floor, battery cages without treatment and compact battery cages) and
- solely manure (battery cages with forced drying).

In case that the poultry housing system is not connected to the local sewer system, the waste water from the housing would remain on site and be stored in a specific collection tank. Then, waste water will be mixed with slurry/manure and will commonly be applied to agricultural land.

In case that the animal housing is connected to the local sewer system, a fraction of a.s. could be released with waste water to the local STP whilst another fraction of a.s. could be applied to agricultural land after a period of storage in manure/slurry (ref. to ESD PT 3, p. 19f., EN 2011). Thus, two different scenarios must be assessed for the receiving as well as secondarily affected environmental compartments for the life cycle stage 'professional use phase' according to the ESD PT3 (2011). In the following table both scenarios, poultry housing connected to the local sewer system ("via STP") and cattle, swine and poultry housing which not connected to the local sewer system ("via manure/slurry"), with the relevant receiving compartments are summarised.

Identification of relevant receiving compartments based on the exposure pathway						
Discharge	**Wastewater (STP)**	**Surface water**	**Sediment**	**Soil**	**Groundwater**	**Air**
via STP	Yes	Yes (indirect)	Yes (indirect)	Yes (indirect)	Yes (indirect)	Not relevant
via manure/slurry	No	Yes (indirect)	Yes (indirect)	Yes (direct)	Yes (direct)	Not relevant

Calculation of PEC values

Phosphorous immission standards were not considered in the current assessment since they are unique in the Netherlands and therefore not applicable EU wide. At the technical meeting I/08 it was decided to use the Nitrogen immission standards from the EC Nitrates Directive (91/676/EEC) of 170 kg N $ha^{-1}.yr^{-1}$ for all soils (arable land and grassland).

Calculation of PEC in aquatic compartments *(incl. sewage treatment plant).*

Furthermore, in function of the animal housing different emission pathway are foreseen so different PECs are estimated for each way:

- ***Local PEC values for the emission pathway via manure/slurry***

The estimation of the local PECs for the aquatic compartment includes PECs for surface water and sediment:

- $PEC_{surfacewater}$ according to equation 27 and 29 of OECD ESD No. 14
- $PEC_{local\_sediment}$ according to equation 50, chapter 2.3.8.4, Guidance BPR IV ENV B (2015).

- **Surface water**

(sub-cat. i1= 1-18)	**PEC sw (mg/L)**		**PEC sed (mg/kg)**	
	Alpha-cypermethrin		**Alpha-cypermethrin**	
	grass	**arable**	**grass**	**arable**
(i1= 1)	6.04E-07	1.51E-08	1.00E-03	2.51E-05
(i1= 2)	5.39E-07	1.35E-08	8.95E-04	2.24E-05
(i1= 3)	4.41E-06	1.10E-07	7.32E-03	1.83E-04
(i1= 4)	1.04E-06	2.61E-08	1.73E-03	4.34E-05
(i1= 5)	1.32E-06	3.31E-08	2.20E-03	5.50E-05
(i1= 6)	8.63E-07	2.16E-08	1.43E-03	3.58E-05
(i1= 7)	9.28E-07	2.32E-08	1.54E-03	3.85E-05
(i1= 8)	1.04E-06	2.59E-08	1.72E-03	4.30E-05
(i1= 9)	1.66E-06	4.14E-08	2.75E-03	6.88E-05
(i1= 10)	3.45E-07	8.63E-09	5.73E-04	1.43E-05
(i1= 11)	2.63E-06	6.59E-08	4.37E-03	1.09E-04
(i1= 12)	7.47E-07	2.80E-08	1.24E-03	4.65E-05
(i1= 13)	1.95E-06	4.88E-08	3.24E-03	8.09E-05
(i1= 14)	6.54E-07	2.45E-08	1.09E-03	4.08E-05
(i1= 15)	1.42E-06	5.32E-08	2.36E-03	8.84E-05
(i1= 16)	2.18E-06	5.44E-08	3.61E-03	9.04E-05
(i1= 17)	1.63E-06	4.09E-08	2.71E-03	6.78E-05
(i1= 18)	2.30E-06	5.75E-08	3.82E-03	9.55E-05

➢ ***Local PEC values for the emission pathway via STP***

In this case, the estimation of the local PECs for the aquatic compartment includes PECs for sewage treatment plant (STP), surface water and sediment:

- PEC_{STP} (= $Clocal_{inf}$) according to equation 39, chapter 2.3.7.1, Guidance BPR IV ENV B (2015);
- $PEC_{local\_surfacewater}$ according to equation 48, chapter 2.3.8.3, Guidance BPR IV ENV B (2015);
- $PEC_{local\_sediment}$ according to equation 50, chapter 2.3.8.4, Guidance BPR IV ENV B (2015)

In some animal housing systems, particularly for poultry (category-subcategory 8, 11, 12, 16-18) a fraction of the applied biocidal product can be released to waste water that is later discharged to a STP. Release fractions to waste water for these animal categories were calculated according to OECD ESD No. 14. Further calculation of influent and effluent concentration in STP, PEC_{STP}, $PEC_{surface\_water}$ were carried out by assuming that only one farm releases liquid wastes into the sewer at one day.

Due that no studies are available on active substance's CAR for biodegradation in seawater or anaerobic biodegradation in STP, no biodegradation has been considered in Simple Treat 4.0 calculation, in view of that 9.754% is considered to be emitted to surface water whilst 29.16% is considered emitted to sludge by STP.

Avian systems (i1=8, 11, 12, 16-18)	Clocal_inf [mg.l^{-1}]	Clocal_eff [mg.l^{-1}]	PECstp [mg.l^{-1}]	PECsw [mg.l^{-1}]	PECsed [mg.kg^{-1}]
Tier I					
(i1= 8)	3.75E-03	3.66E-04	3.75E-03	3.28E-05	5.45E-02
(i1= 11)	7.15E-03	6.97E-04	7.15E-03	6.26E-05	1.04E-01
(i1= 12)	5.55E-03	5.41E-04	5.55E-03	4.86E-05	8.07E-02
(i1= 16)	1.67E-02	1.62E-03	1.67E-02	1.46E-04	2.42E-01
(i1= 17)	1.25E-02	1.22E-03	1.25E-02	1.09E-04	1.82E-01
(i1= 18)	1.00E-02	9.75E-04	1.00E-02	8.75E-05	1.45E-01

Calculation of PEC in soil compartments

- ***Local PEC values for the emission pathway via manure/slurry***

The estimation of the local PECs for the terrestrial compartment includes PEC_{soil} according to equation 24 b and 25 b of the Recommendation of the AHEE, Addendum to OECD ESD No. 14 considering recent decisions concerning the parameters $Tgr\text{-}int_{no\_manure}$ (365 d instead 206 d) and k_{leach} (according to eq. 58, Guidance on the BPR, Vol. IV, Part B (2015)). In addition, four manure applicaton events per year are considered for grassland following endpoint 3.3 of the mentioned AHEE Addendum before.

Predicted environmental concentrations due to the application of the biocide and after 10 years of successive manure application in stables have been estimated. Concentrations are based on the nitrogen immision standards. Degradation of the active substance in soils is included.

PEC soil (mg/kgwwt)						
(sub-cat. i1=1-18)	***PECsoil after one manure application on arable or four manure applications on grassland <u>without degradation</u> OPP***		***PECsoil after one manure application on arable or four manure applications on grassland <u>with degradation</u>***		***PECsoil after 10 year consecutive application, degradation in soil included***	
	grass	**arable**	**grass**	**arable**	**grass**	**arable**
(i1= 1)	8.14E-04	2.04E-04	8.14E-04	2.04E-04	8.14E-03	9.08E-37
(i1= 2)	7.27E-04	1.82E-04	7.27E-04	1.82E-04	7.27E-03	8.10E-37
(i1= 3)	5.94E-03	1.49E-03	5.94E-03	1.49E-03	5.94E-02	6.62E-36
(i1= 4)	1.41E-03	3.52E-04	1.41E-03	3.52E-04	1.41E-02	1.57E-36
(i1= 5)	1.79E-03	4.46E-04	1.79E-03	4.46E-04	1.78E-02	1.99E-36
(i1= 6)	1.16E-03	2.91E-04	1.16E-03	2.91E-04	1.16E-02	1.30E-36
(i1= 7)	1.25E-03	3.13E-04	1.25E-03	3.13E-04	1.25E-02	1.39E-36
(i1= 8)	1.40E-03	3.49E-04	1.40E-03	3.49E-04	1.40E-02	1.56E-36
(i1= 9)	2.23E-03	5.58E-04	2.23E-03	5.58E-04	2.23E-02	2.49E-36
(i1= 10)	4.65E-04	1.16E-04	4.65E-04	1.16E-04	4.65E-03	5.19E-37
(i1= 11)	3.55E-03	8.88E-04	3.55E-03	8.88E-04	3.55E-02	3.96E-36
(i1= 12)	1.01E-03	3.78E-04	1.01E-03	3.78E-04	1.01E-02	1.68E-36
(i1= 13)	2.63E-03	6.57E-04	2.63E-03	6.57E-04	2.63E-02	2.93E-36
(i1= 14)	8.82E-04	3.31E-04	8.82E-04	3.31E-04	8.82E-03	1.47E-36
(i1= 15)	1.91E-03	7.17E-04	1.91E-03	7.17E-04	1.91E-02	3.20E-36
(i1= 16)	2.93E-03	7.33E-04	2.93E-03	7.33E-04	2.93E-02	3.27E-36
(i1= 17)	2.20E-03	5.50E-04	2.20E-03	5.50E-04	2.20E-02	2.45E-36
(i1= 18)	3.10E-03	7.75E-04	3.10E-03	7.75E-04	3.10E-02	3.45E-36

➢ ***Local PEC values for the emission pathway via STP***

The estimation of the local PECs for the terrestrial compartment includes PECs for soil and groundwater:

- PEC $_{local\_soil}$ according to equation 66, chapter 2.3.8.5, Guidance BPR IV ENV B (2015);

Avian systems (i1=8, 11, 12, 16-18)	**Alpha-cypermethrin**	
	Csludge	**PEClocal$_{soil}$**
	[mg.kg^{-1}]	**[mg.kg^{-1}]**
(i1= 8)	3.64E-03	3.64E-02
(i1= 11)	6.95E-03	6.94E-02
(i1= 12)	5.39E-03	5.38E-02
(i1= 16)	1.62E-02	1.62E-01
(i1= 17)	1.21E-02	1.21E-01
(i1= 18)	9.72E-03	9.70E-02

Calculation of PEC in groundwater

➢ ***Local PEC values for the emission pathway via manure/slurry***

The estimation of the local PECs for the terrestrial compartment includes groundwater. PEC $_{groundwater}$ according to equation 26 and 28 of OECD ESD No. 14 on and adapted to equation 37 of the Recommendation of the AHEE, Addendum to OECD ESD No. 14.

(sub-cat. i1=1-18)	**PECgroundwater (µg/L)**	
	Alpha-cypermethrin	
	grass	**arable**
(i1= 1)	6.04E-03	6.74E-37
(i1= 2)	5.39E-03	6.01E-37
(i1= 3)	4.41E-02	4.92E-36
(i1= 4)	1.04E-02	1.16E-36
(i1= 5)	1.32E-02	1.48E-36
(i1= 6)	8.63E-03	9.62E-37
(i1= 7)	9.28E-03	1.03E-36
(i1= 8)	1.04E-02	1.16E-36
(i1= 9)	1.66E-02	1.85E-36
(i1= 10)	3.45E-03	3.85E-37
(i1= 11)	2.63E-02	2.94E-36
(i1= 12)	7.47E-03	1.25E-36
(i1= 13)	1.95E-02	2.17E-36
(i1= 14)	6.54E-03	1.09E-36
(i1= 15)	1.42E-02	2.37E-36
(i1= 16)	2.18E-02	2.43E-36
(i1= 17)	1.63E-02	1.82E-36
(i1= 18)	2.30E-02	2.56E-36

Values on bold are considered above the trigger value 0.1 µg/L for groundwater.

The table above shows that no risk is expected for groundwater from product's application in animal housing where emission is developed via manure/slurry.

➢ ***Local PEC values for the emission pathway via STP***

The estimation of the local PECs for the terrestrial compartment includes PECs for groundwater:

- PEC $_{local\_groundwater}$ according to equation 68, chapter 2.3.8.6, Guidance BPR IV ENV B (2015) as a first worst-case estimation.

Avian systems (i1=8, 11, 12, 16-18)	**PEClocal$_{groundwater}$ [µg.L-1]**
	Alpha-cypermethrin
Tier I	
(i1= 8)	2.70E-02
(i1= 11)	5.15E-02
(i1= 12)	4.00E-02
(i1= 16)	**1.20E-01**
(i1= 17)	9.00E-02
(i1= 18)	7.20E-02

Values on bold are considered above the trigger value 0.1 µg/L for groundwater.

Outputs above show an acceptable risk for groundwater compartment for the active substance alpha-cypermethrin with the exception of "Turkeys in free range with litter floor" sub-scenario (i1=16) which is slightly above the trigger value.

ES CA:
As stated previously, Scenario 2 (Disinfestation of breeding premises) has not been considered into the risk assessment by ES CA due to lack of efficacy support.

Therefore, all the scenario 2 evaluation included by the applicant has not been reviewed.

Scenario [3]

This scenario considers the application of MASSOCIDE AD04 to control insects around buildings. According to OECD No. 18, ESD for dust applications, the same scenario of spray application around building can be considered to assess the local emission.

The table bellow shows the parameter used in the ECHA's PT18 spreadsheet for the default scenario „Outdoor spray.–crawling insects":

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario **3 - Disinfestation of crawling insects outdoor at foundations and soil around buildings by manual dusting application on urban and rural areas.**			
Quantity of product applied	1.25E-02	Kg/m^2	S
Concentration of active substance in the product:	0.004	-	S
Frequency of application (large buildings and standard houses)	1-2	Times/year	P
Mixing and loading	Not considered*		P
Number of standard houses contributing to the same STP	2500	-	D
Number of large buildings contributing to the same STP	300	-	D
Bulk density of soil	1700	kg$_{ww}$.m^{-3}	D

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario **3 - Disinfestation of crawling insects outdoor at foundations and soil around buildings by manual dusting application on urban and rural areas.**			
Area of foundation treated per day - Private house - Public/commercial/industrial building	 25 125	 $m^2.d^{-1}$ $m^2.d^{-1}$	 D D
Area of soil treated per day - Private house - Public/commercial/industrial building	 26 126	 $m^2.d^{-1}$ $m^2.d^{-1}$	 D D
Area of untreated zone - Private house - Public/commercial/industrial building	 28 128	 $m^2.d^{-1}$ $m^2.d^{-1}$	 D D
Soil volume for deposition and application at 0.5 m (treated) - Private house - Public/commercial/industrial building	 13 63	 $m^3.d^{-1}$ $m^3.d^{-1}$	 D D
Soil volume for deposition and application (untreated) - Private house - Public/commercial/industrial building	 14 64	 $m^3.d^{-1}$ $m^3.d^{-1}$	 D D
Fraction emitted to soil during outdoor foundation spray application	0.3	-	D
Fraction emitted to soil during outdoor ground spray application - Private house - Public/commercial/industrial building	 0.99 0.0042	 - -	 D D
Fraction emitted to soil due to wash-off by rainfall	0.5	-	D
Multiple application factor**	1.2	-	S
Application specific factor, acute exposure	1.15	-	D
Application specific factor, short term exposure	1.4	-	D
Effective application rate, acute exposure	5.75E-08	$Kg.m^{-2}$	O
Effective application rate, short-term exposure	7.00E-08	$Kg.m^{-2}$	O
Bioconcentration factor for earthworms	3796	$l.kg_{wwt}^{-1}$	S (CAR)
Additional factor to translate Tappl for 1 ha	1E-04	$ha.kg^{-1}$	D
Density of solid phase	2500	$kg.m^{-3}$	D
Volume fraction of solids in soil	0.6	$m^3.m^{-3}$	D
Fraction of gut loading in worm	0.1	$kg_{dwt}.kg_{wwt}^{-1}$	D
Soil-water partition coefficient	2290.52	$m^3.m^{-3}$	S
Conversion factor for soil concentration wet - dry weight soil	1.13	$kg_{wwt}.kg_{dwt}^{-1}$	O
Half-life for biodegradation in soil	35	Days	S (CAR)

S: data set by the applicant; D: default value; P: Pick list; O: outputs.
* As the product is a ready-to-use formulation, no emission from mixing and loading task is deemed in the Environmental Risk Assessment.

** Taken into account the number of intended applications per year and according to table 5.2-8 of OECD ESD No.18, the value of 1.2 has been chosen as worst case.

Calculations for Scenarios [*3*]

Resulting local emission to relevant environmental compartments				
Compartment	**Local emission (Elocal$_{compartment}$) [kg/d]**			**Remarks**
	Standard house / non-professional users	Standard house / professional users	Large building / professional users	
Emission via application				
Due to application on foundations	3.75E-04	3.75E-04	1.88E-03	*O*
Due to application on soil, treated area	1.29E-03	1.29E-03	6.24E-03	*O*
Due to application on soil, untreated area	5.88E-06	5.88E-06	2.69E-05	*O*
Emission via cleaning				
Due to wash-off (from foundations)	6.25E-04	6.25E-04	3.13E-03	*O*

S: data set by the applicant; D: default value; P: Pick list; O: outputs.

The following table shows the **total emission** outputs for each user at each area (urban or rural)

Outputs	**Non-professional users (standard houses)**	**Professional users (standard houses and large buildings)**	Remarks
Urban environment			
Local emission to wastewater	1.17E-02	1.86E-02	*O*
Total release in rural area			
Local emission to soil, treated area	1.17E-02	1.86E-02	*O*
Local emission to soil, untreated area	3.00E-05	4.65E-05	*O*

The following table shows the estimated concentrations in soil at rural areas after product application:

Concentration in soil (rural area) (Kg/kg$_{ww}$)	**Standard houses**	**Large buildings**
Concentration of active ingredient in treated soil at 0.5 m from the house due to foundation and ground application against crawling insects	1.03E-7	1.05E-7
Concentration of active ingredient in untreated soil due to foundation and ground application against crawling insects	2.47E-10	2.47E-10

Further data calculations of each scenario can be found in attached documents at Annex section 3.2.

ES CA:
As stated previously, Scenario 3 (Disinfestation of crawling insects outdoor at foundations and soil around buildings by manual dusting application on urban and rural areas) has not been considered into the risk assessment by ES CA due to lack of efficacy support.

Therefore, all the scenario 3 evaluation included by the applicant has not been reviewed.

Scenario [4]

Following ESD PT18 No.18, it is expected that direct powdering on nest would lead to more limited releases than spray application and should be considered as spot application on soil. In this case, the possible receiving compartments are the soil and to a lesser extent, the air. Release to the air is considered negligible. It is not current practice to collect unconsumed product. Therefore, it is considered that the fraction released during powder application to the environment is 90%, either directly or through ultimate releases after target insect death.

ES CA:
Local emissions are calculated for the active substance alpha-cypermethrin and also for the substance of concern silicon dioxide.

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 AD04 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.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: Outdoor – Spot application into ant's nest			
Quantity of commercial product applied per nest	1.7	g	S
Concentration of active substance in the product	0.004	-	S

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: Outdoor – Spot application into ant's nest			
Fraction emitted to soil during application due to deposition	0.9	-	D
Number of nests treated per day	1	-	D
Area exposed to insecticide (50 cm diameter circular surface)	0.1963	m^2	D
Depth of exposed soil	0.5	m	D
Volume of exposed soil	0.1	m^3	D
Bulk density of soil	1700	Kgwwt. m^{-3}	default
Multiple application factor*	1.2	-	S
Application specific factor, acute exposure for secondary poisoning**	1.15	-	S
Application specific factor, short-term exposure for secondary poisoning**	1.4	-	S
Effective application rate, for acute exposure	3.98E-05	Kg.m^{-2}	O
Effective application rate, for short-term exposure	4.85E-05	Kg.m^{-2}	O
Bioconcentration factor for earthworms	3796	l.kgwwt^{-1}	S
Additional factor to translate Tappl for 1 ha	1.00E-04	ha.kg^{-1}	D
Density of solid phase	2500	Kgwwt. m^{-3}	D
Volume fraction of solids in soil	0.6	m^3.m^{-3}	D
Fraction of gut loading in worm	0.1	Kgdwt.kgdwt^{-1}	
Soil-water partition coefficient	2.29E+03	m^3.m^{-3}	S
Conversion factor for soil concentration wet-dry weight soil	1.133	Kgwwt.kgdwt^{-1}	O

S: data set by the applicant; D: default value; P: Pick list; O: outputs.
* Taken into account the number of intended applications per year and according to table 5.2-8 of OECD ESD No.18, the value of 1.2 has been chosen as worst case.
** The same values deemed by default for scenario 3 were used for this scenario.

ES CA:
MASSOCIDE AD04 is furnished as a RTU product. Therefore, no emissions to the environment are expected during mixing/loading.

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 below. 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. An application rate of 12.14 g.m^{-2} is

prescribed in label instructions of the biocidal product and confirmed by the efficacy team. 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 1.7 g b.p., and gives a total of 6.8 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 6.8 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 1.13 g b.p. m^{-1}.
b) 4 applications are expected on a terrace with 6 m of side length, therefore the number of nests per perimeter unit is 0.67.

Regardless which approach is followed, an overall application of 113.33 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 **6.49E-01** g alpha-cypermethrin and **1.73E-01** g silicon dioxide . In case of application of the b.p. around private houses, the terrace scenario leads to calculated release of **2.45E-02** g alpha-cypermethrin and **6.12E-03** g silicon dioxide to csurrounding receiving soil area.

Input values to calculate biocide release to relevant environmental compartments are summarised in the table below.

Input	**Symbol**	**Value**	**Unit**
Scenario: Outdoor – Spot application into ant's nest			
Quantity of commercial product applied	Q_{prod}	1.7	g
Concentration of active substance in the product	$F_{AI, alphapermethrin}$	0.004	-
Concentration of substance of concern in the product	$F_{AI, silicon\ dioxide}$	0.001	-
Fraction emitted to soil during application	$F_{outdoor, nest\ powder, soil}$	0.9	-
Number of application sites (terrace)	N_{sites}	4	-
Number of application sites (perimeter)	N_{sites}	113.33	-
Number of applications during a campaign	N_{appl}	1	-
Area exposed to insecticide (terrace)	$AREA_{exposed}$	8.5	m^2
Treated perimeter around larger buildings	Perimeter	100	m
Depth of exposed soil	$Depth_{soil}$	0.5	m
Volume of exposed soil	$Volume_{soil}$	0.125	m^3
Bulk density of soil	RHO_{soil}	1700	Kgwwt. m^{-3}
Output for the active substance:			
Local direct emission rate to receiving soil area - terrace scenario (paved surfaces) in private houses		2,45E-02	$g.d^{-1}$
Local direct emission rate to paved surfaces around larger buildings		6,94E-01	$g.d^{-1}$
Output for the substance of concern:			
Local direct emission rate to receiving soil area - terrace scenario (paved surfaces) in private houses		6,12E-03	$g.d^{-1}$
Local direct emission rate to paved surfaces around larger buildings		1,73E-01	$g.d^{-1}$

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

The equations for local releases to air and to soil during spot application would be:

$E_{spot, soil} = Q_{prod} \times F_{AI} \times N_{sites} \times N_{appl} \times F_{outdoor, nest\ powder, soil}$ (eq. 58, 59)

Concentrations in the soil around the spot application after direct release can be estimated by the equation:

$C_{spot,soil} = E_{spot,soil} / (AREA_{exposed} * DEPTH_{soil} * RHO_{soil})$ (eq. 60)

$C_{spot,soil}$ = 3.39E-03 $mg.kg^{-1}$ for alpha-cypermethrin and 8.47E-04 $mg.kg^{-1}$ for silicon dioxide.

Estimation of release to sewage treatment plants

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 (g.d-1) - alpha-cypermethrin	6,94E-01
Local direct emission rate to paved surfaces - larger buildings (g.d-1) - silicon dioxide	1,73E-01
Number of larger buildings connected to STP -larger buildings	300
Simultaneity factor outdoor	0.00204228
Output	
Simultaneous emission to STP (g.d-1) - alpha-cypermethrin	4,25E-04
Simultaneous emission to STP (g.d-1) - silicon dioxide	1,06E-04

The application of the b.p. in a typical scenario around commercial buildings results in a simultaneous release of **4.25E-04** g.d-1 Cypermethrin and **1.06E-04** g.d-1 silicon dioxide to the STP.

Calculations for Scenario 4

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/campaign]**	**Remarks**
Soil	2.04E-06	None

Other outputs obtained from ECHA's spreadsheets are:

Local concentration in soil (PECsoil)	2.88E-08	Kg.kgwwt^{-1}
Local concentration in porewater (PECgw)	2.14E-11	Kg.L^{-1}
Concentration in earthworm	0.076	mg.kgwt earthworm^{-1}

Fate and distribution in exposed environmental compartments

In the table below a summary of the likely fate and distribution in environmental compartments is shown.

	Fresh-water	**Freshwater sediment**	**Sea-water**	**Seawater sediment**	**STP/ WWTP**	**Air**	**Soil**	**Ground-water**
Scenarios 1	Yes	Yes	n.r.	n.r.	Yes	n.r.	Yes	Yes
Scenarios 2	Yes	Yes	n.r.	n.r.	Yes & No*	n.r.	Yes	Yes
Scenarios 3	Yes	Yes	n.r.	n.r.	Yes	n.r.	Yes	Yes
Scenario 4	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	Yes	Yes

"n.r." means Not relevant
*Applicable for those livestock premises not connected to WWTP.

The following parameters have been considered in the environmental risk assessment for the active substance Alpha-cypermethrin:

Calculated fate and distribution in the STP					
Compartment	Percentage [%]				Remarks
	Scenarios 1	Scenarios 2*	Scenario 3a	Scenario 4	
Air	8.42E-03	1.372E-02	8.42E-03	-	
Water	14.86	9.754	14.86	-	
Primary settler	61.07	61.07	61.07	-	
Sludge	24.05	29.16	24.05	-	
Degraded in STP	0	0	0	-	

* Simple Treat 4.0 estimation.

ES CA:
Fate and distribution in environmental compartments:

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

* Considered only for large buildings.

The parameters that have been considered in the environmental risk assessment for the active substance Alpha-cypermethrin, has been according to the model SimpleTreat 4.0 obtained by EUSES:

Calculated fate and distribution in the STP		
Compartment	**Percentage [%]**	**Remarks**
Air	8.42E-03	-
Water	14.86	-
Sludge	85.12	-
Degraded in STP	0	-

The parameters that have been considered in the environmental risk assessment for the substance of concern silicon dioxide, has been according to the model SimpleTreat 4.0 obtained by EUSES:

Calculated fate and distribution of Synthetic amorphous silicon dioxide in the STP		
Compartment	**Percentage [%]**	**Remarks**
Air	0	-
Water	0	-
Sludge	100	-
Degraded in STP	0	-

It should be noted that for the synthetic amorphous silicon dioxide, when it released into the environment, these forms are expected to combine with soil or sediment organic matter and adopt the same behavior as natural silica. Therefore, it is not expected that the nanoform of this substance remains in the environment.

Calculated PEC values

Estimated PEC values are shown below for the active substance:

Summary table on calculated PEC values for Alpha-cypermethrin substance								
Scenario	**PEC_{STP}**	**PEC_{water}**	**PEC_{sed}**	**$PEC_{soil\ 30d\_agric}$**	**$PEC_{soil\ 180d\_agric}$**	**$PEC_{soil\ 180d\_grass}$**	**PEC_{GW}**	**PEC_{air}**
	[mg/l]	[mg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[mg/l]	[mg/m^3]
Scenario 1 (3-11 applications)								
[1.a-Priv-wet]	5.94E-05	5.33E-06	8.84E-03	1.22E-02	1.22E-02	4.87E-03	9.06E-06	1.81E-08
[1.a-Priv-dry]	1.09E-05	9.78E-07	1.62E-03	2.25E-03	2.25E-03	9.05E-04	1.67E-06	1.81E-08
[1.a-Ind-wet]	8.01E-05	7.18E-06	1.19E-02	1.65E-02	1.65E-02	6.56E-03	1.22E-05	2.01E-08
[1.a-Ind-dry]	1.47E-05	1.32E-06	2.19E-03	3.03E-03	3.03E-03	1.22E-03	2.25E-06	2.01E-08
[1.b-Priv-wet]	1.31E-03	1.17E-04	1.95E-01	2.68E-01	2.68E-01	1.07E-01	**1.99E-04**	1.99E-07
[1.b-Priv-dry]	2.40E-04	2.15E-05	3.57E-02	4.94E-02	4.93E-02	1.98E-02	3.66E-05	1.99E-07
[1.b-Ind-wet]	4.02E-03	3.60E-04	5.98E-01	8.26E-01	8.25E-01	3.29E-01	**6.13E-04**	5.04E-07
[1.b-Ind-dry]	7.38E-04	6.62E-05	1.10E-01	1.52E-01	1.52E-01	6.07E-02	**1.13E-04**	5.04E-07
Scenario 1 (1-2 applications)								
[1.a-Priv-wet]	1.49E-05	1.33E-06	2.22E-03	3.06E-03	3.06E-03	1.22E-03	2.27E-06	4.54E-09
[1.a-Priv-dry]	2.73E-06	2.45E-07	4.07E-04	5.63E-04	5.63E-04	2.27E-04	4.18E-07	4.54E-09
[1.a-Ind-wet]	2.01E-05	1.80E-06	2.99E-03	4.12E-03	4.12E-03	1.64E-03	3.06E-06	5.03E-09
[1.a-Ind-dry]	3.68E-06	3.31E-07	5.49E-04	7.59E-04	7.59E-04	3.05E-04	5.63E-07	5.03E-09
[1.b-Priv-wet]	3.27E-04	2.94E-05	4.87E-02	6.72E-02	6.72E-02	2.68E-02	4.99E-05	5.00E-08
[1.b-Priv-dry]	6.01E-05	5.39E-06	8.95E-03	1.24E-02	1.24E-02	4.95E-03	9.18E-06	5.00E-08
[1.b-Ind-wet]	1.01E-03	9.03E-05	1.50E-01	2.07E-01	2.07E-01	8.23E-02	**1.53E-04**	1.26E-07
[1.b-Ind-dry]	1.85E-04	1.66E-05	2.75E-02	3.80E-02	3.80E-02	1.52E-02	2.82E-05	1.26E-07
Scenario 2 (residues via STP)								
(i1= 8)	3.75E-03	3.28E-05	5.45E-02	3.64E-02	-	-	2.70E-05	-
(i1= 11)	7.15E-03	6.26E-05	1.04E-01	6.94E-02	-	-	5.15E-05	-
(i1= 12)	5.55E-03	4.86E-05	8.07E-02	5.38E-02	-	-	4.00E-05	-
(i1= 16)	1.67E-02	1.46E-04	2.42E-01	1.62E-01	-	-	**1.20E-04**	-
(i1= 17)	1.25E-02	1.09E-04	1.82E-01	1.21E-01	-	-	9.00E-05	-
(i1= 18)	1.00E-02	8.75E-05	1.45E-01	9.70E-02	-	-	7.20E-05	-
Scenario 3 (outdoor application around buildings)								
[3.a-Priv]	8.70E-04	7.80E-05	1.30E-01	1.79E-01	1.79E-01	7.11E-02	**1.33E-04**	2.74E-10
[3.a-Ind]	1.38E-03	1.24E-04	2.06E-01	2.84E-01	2.84E-01	1.13E-01	**2.11E-04**	3.58E-10
[3.b-Priv]	-	-	-	1.03E-01	-	-	7.68E-05	-
[3.b-Ind]	-	-	-	1.05E-01	-	-	7.79E-05	-
Scenario 4 (Ant nest)								
[4] – ant nest	-	-	-	0.0288	-	-	2.14E-05	-

ES CA:
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 Ksoil-water is calculated according to the guidance (2290.5 $m^3 \cdot m^{-3}$). The concentrations in groundwater are derived from the concentration in agricultural soil at 180 days.

Estimated PEC values for all the scenarios are shown in the table below:

Summary table on calculated PEC values for the different scenarios					
Scenario	**PEC STP (mg/l)**	**PEC SW (mg/l)**	**PEC SED (mg/kg_{wwt})**	**PEC SOIL (mg/kg_{wwt})**	**PEC GW (ug/L)**
Scenario 4 (Ant nest) Alpha-cypermethrin					
Private house (Non-professional)	Not relevant	Not relevant	Not relevant	3,39E-03	2,51E-03
Large buildings (Professional)	3,16E-08	2,83E-09	4,70E-06	5,19E-07	3,85E-07
Scenario 4 (Ant nest) Silicon dioxide					
Private house (Non-professional)	Not relevant	Not relevant	Not relevant	8,47E-04	Not relevant
Large buildings (Professional)	Not relevant	Not relevant	Not relevant	1,98E-06	Not relevant

For the synthetic amorphous silicon dioxide, as it is stated in the CAR, due to its limited water solubility in natural conditions and extremely low vapour pressure, it is expected to be distributed mainly into soils/sediments, weakly into water and probably not at all in the air. This compound is expected to combine indistinguishably with the soil layer and sediment due to its chemical identity with inorganic soil matter. Whatever its origin, man-made or natural, and whatever its structure, once released and diluted into the environment, no distinction can be made between the initial forms of silica.

Therefore, no PEC values are calculated for surface water sediment, groundwater and STP compartments. Indeed, based on its physico-chemical properties (hydrophobicity, inert and inorganic character...), the distribution of silicon dioxide over the solid and liquid phase will be controlled by the precipitation of the agglomerated particles.

Thus, only the PEC soil is calculated for the substance of concern of the product MASSOCIDE AD04.

Primary and secondary poisoning

Primary poisoning

According to the ESD for PT 18 primary poisoning is only a matter of concern if insecticides are applied together with food attractants. As this is not the intended use of the product, the assessment is not required. In addition, direct uptake of Alpha-Cypermethrin after application of MASSO's product at small confined surfaces (i.e.: voids, crevices, cracks and crevices…) is not likely; therefore primary poisoning should not be relevant.

ES CA:
Agree with the applicant. Primary poisoning is very unlikely for the biocidal product MASSOCIDE AD 0.4.

Secondary poisoning

Although, as it was mentioned before, direct uptake of the active substance after product's application is not likely, there is a slight possibility that the product reaches environmental compartments such as water or soil, which leads to specific compartment organisms such as fish and earthworms. Secondary poisoning is of special relevance for substances with a log $K_{ow} \geq 4.5$, such as the case of alpha-cypermethrin (log P_{ow} =5.5), which indicates a high potential for bioaccumulation in organisms. In addition, aquatic and soil-dwelling organisms may be exposed to active substance indirectly emitted to water and soil. Therefore, a risk assessment has been performed for secondary poisoning on fish and earthworms as representative organisms in water and soil compartments, respectively.

- Calculations for **Scenarios 1 and 2**

Summary table on estimated theoretical exposition (ETE)		
Scenario	**Alpha-cypermethrin**	
	$ETE_{earthworms}$	**ETE_{fish}**
	[mg/kg*d^{-1}]	[mg/kg*d^{-1}]
Scenario 1 (3-11 applications)		
[1.a-Priv-wet]	0.016	0.251
[1.a-Priv-dry]	2.96E-03	4.62E-02
[1.a-Ind-wet]	0.0216	0.2787
[1.a-Ind-dry]	3.99E-03	5.12E-02
[1.b-Priv-wet]	3.53E-01	5.53
[1.b-Priv-dry]	6.49E-02	1.02
[1.b-Ind-wet]	1.09	14
[1.b-Ind-dry]	0.2	2.57
Scenario 1 (1-2 applications)		
[1.a-Priv-wet]	4.02E-03	6.3E-02
[1.a-Priv-dry]	7.41E-04	1.16E-02
[1.a-Ind-wet]	5.42E-03	6.98E-02
[1.a-Ind-dry]	9.99E-04	1.28E-02
[1.b-Priv-wet]	8.85E-02	1.39
[1.b-Priv-dry]	1.63E-02	2.55E-01

Summary table on estimated theoretical exposition (ETE)		
Scenario	**Alpha-cypermethrin**	
	$ETE_{earthworms}$	**ETE_{fish}**
	[mg/kg*d^{-1}]	[mg/kg*d^{-1}]
[1.b-Ind-wet]	0.272	3.5
[1.b-Ind-dry]	5.00E-02	6.43E-01
Scenario 2 (residues via slurry/manure)		
(i1= 1)	2.07E-02	1.25E-01
(i1= 2)	1.85E-02	1.12E-01
(i1= 3)	1.51E-01	9.13E-01
(i1= 4)	3.58E-02	2.16E-01
(i1= 5)	4.54E-02	2.74E-01
(i1= 6)	2.95E-02	1.79E-01
(i1= 7)	3.18E-02	1.92E-01
(i1= 8)	3.55E-02	2.14E-01
(i1= 9)	5.68E-02	3.43E-01
(i1= 10)	1.18E-02	7.15E-02
(i1= 11)	9.02E-02	5.45E-01
(i1= 12)	2.56E-02	1.55E-01
(i1= 13)	6.68E-02	4.04E-01
(i1= 14)	2.24E-02	2.94E-01
(i1= 15)	4.86E-02	1.35E-01
(i1= 16)	7.45E-02	4.51E-01
(i1= 17)	5.60E-02	3.38E-01
(i1= 18)	7.87E-02	4.76E-01
Scenario 2 (residues via STP)		
(i1= 8)	9.58E-02	6.79
(i1= 11)	1.83E-01	12.95
(i1= 12)	1.42E-01	10.05
(i1= 16)	4.25E-01	30.16
(i1= 17)	3.19E-01	22.65
(i1= 18)	2.55E-01	18.12

* Concentration in earthworms from agricultural soil is considered negligible instead of it, as a worst case, the concentration in earthworm in treated area from application and wash-off is taken into account in the assessment.

On the other hand, the risk derived from outdoor scenarios 3 and 4 is estimated for each potential specie considered in the ESD PT18 by ECHA's spreadsheets.

- Calculations for **Scenario 3**

The following table summarizes the outputs obtained for this scenario:

Concentrations due to "application treatment around the building - application on the foundations and on the soil around the house and wash-off the treated surfaces by rainfall"				
	Area		**Units**	**Remarks**
	Standard house	**Large building**		

Local concentration in soil in treated area around the house/building, from application	7.52E-8	7.57E-8	kg.kg $_{wwt}^{-1}$	*O*
Local concentration in soil in treated area around the house/building, from application and wash-off by rainfall	1.03E-7	1.05E-7	kg.kg $_{wwt}^{-1}$	*O*
Local concentration in soil in untreated area around the house/building, from application	2.47E-10	2.47E-10	kg.kg $_{wwt}^{-1}$	*O*
Local concentration in porewater in soil in treated area around the house/building, from application	5.58E-11	5.62E-11	$kg.l^{-1}$	*O*
Local concentration in porewater in soil in treated area around the house/building, from application and wash-off by rainfall	7.68E-11	7.79E-11	$kg.l^{-1}$	*O*
Local concentration in porewater in soil in untreated area around the house/building, from application	1.83E-13	1.83E-13	$kg.l^{-1}$	*O*
Concentration in earthworm in soil in treated area around the house/building, from application	1.98E-01	1.99E-01	$mg.kg_{wet\ earthworm}^{-1}$	*O*
Concentration in earthworm in soil in treated area around the house/building, from application and wash-off by rainfall	2.72E-01	2.76E-01	$mg.kg_{wet\ earthworm}^{-1}$	*O*
Concentration in earthworm in soil in untreated area around the house/building, from application	6.50E-04	6.50E-04	$mg.kg_{wet\ earthworm}^{-1}$	*O*

The following table summarizes the estimated theoretical exposure (ETE) for secondary poisoning for each indicator species at scenario 3 obtained from ECHA's spreadsheets:

From application on a **standard house**

Representative specie	ETE (mg.kg^{-1}.d^{-1})															
	Insectivorous				Herbivorous				Mammals eating worms				Birds eating worms			
	Acute exposure		Short-term exposure		Acute exposure		Short-term exposure		Acute exposure		Short-term exposure		Acute exposure		Short-term exposure	
	Treated area	Untreated area	Treated area	Untreated area	Treated area	Untreated area	Treated area	Untreated area	Treated area	Untreated area	Treated area	Untreated area	Treated area	Untreated area	Treated area	Untreated area
Small insectivorous mammal 1 (pipistrelle) – 7.6 g *	5.51E-04	5.51E-04	2.44E-04	2.44E-04	-	-	-	-	-		-	-	-	-	-	-
Small insectivorous mammal 2 (mole) – 85 g	-	-	-	-	-	-	-	-	1.43E-01	4.68E-04	1.96E-01	-	-	-	-	-
Medium insectivorous mammal – 1100 g – hedgehog *	1.26E-04	1.26E-04	5.59E-05	5.59E-05	-	-	-	-	6.73E-02	2.21E-04	9.27E-02	-	-	-	-	-
Large insectivorous mammal – 10100 g (badger) *	6.55E-05	6.55E-05	2.91E-05	2.91E-05	-	-	-	-	3.50E-02	1.15E-04	4.82E-02	-	-	-	-	-
Medium herbivorous mammal – 1500 g (rabbit) *	-	-	-	-	1.29E-03	1.29E-03	8.68E-04	8.68E-04	-	-	-	-	-	-	-	-
Small Insectivorous bird (Tree sparrow, robin) – 22 g	2.45E-03	2.45E-03	1.66E-03	1.66E-03	-	-	-	-	-	-	-	-	-	-	-	-

Representative specie	ETE (mg.kg^{-1}.d^{-1})															
	Insectivorous				Herbivorous				Mammals eating worms				Birds eating worms			
	Acute exposure		Short-term exposure		Acute exposure		Short-term exposure		Acute exposure		Short-term exposure		Acute exposure		Short-term exposure	
	Treated area	Untreated area	Treated area	Untreated area	Treated area	Untreated area	Treated area	Untreated area	Treated area	Untreated area	Treated area	Untreated area	Treated area	Untreated area	Treated area	Untreated area
Medium Insectivorous bird – 113 g (blackbird) *	6.20E-04	6.20E-04	2.75E-04	2.75E-04	-	-	-	-	-	-	-	-	-	-	-	-
Omnivorous bird – 225 g (Black-billed magpie) *	6.20E-04	6.20E-04	2.75E-04	2.75E-04	-	-	-	-	-	-	-	-	1.77E-01	5.81E-04	2.43E-01	-

*Indicator species considered as relevant for lawn/garden.

From application on a **large building**

Representative specie	ETE (mg.kg^{-1}.d^{-1})															
	Insectivorous				Herbivorous				Mammals eating worms				Birds eating worms			
	Acute exposure		Short-term exposure		Acute exposure		Short-term exposure		Acute exposure		Short-term exposure		Acute exposure		Short-term exposure	
	Treated area	Untreated area	Treated area	Untreated area	Treated area	Untreated area	Treated area	Untreated area	Treated area	Untreated area	Treated area	Untreated area	Treated area	Untreated area	Treated area	Untreated area
Small insectivorous mammal 1 (pipistrelle) – 7.6 g *	5.51E-04	5.51E-04	2.44E-04	2.44E-04	-	-	-	-	-	-	-	-	-	-	-	-
Small insectivorous mammal 2 (mole) – 85 g	-	-	-	-	-	-	-	-	1.44E-01	4.68E-04	1.99E-01	-	-	-	-	-

Representative specie	ETE (mg.kg^{-1}.d^{-1})															
	Insectivorous				Herbivorous				Mammals eating worms				Birds eating worms			
	Acute exposure		Short-term exposure		Acute exposure		Short-term exposure		Acute exposure		Short-term exposure		Acute exposure		Short-term exposure	
	Treated area	Untreated area	Treated area	Untreated area	Treated area	Untreated area	Treated area	Untreated area	Treated area	Untreated area	Treated area	Untreated area	Treated area	Untreated area	Treated area	Untreated area
Medium insectivorous mammal – 1100 g – hedgehog *	1.26E-04	1.26E-04	5.59E-05	5.59E-05	-	-	-	-	6.78E-02	2.21E-04	9.40E-02	-	-	-	-	-
Large insectivorous mammal – 10100 g (badger) *	6.55E-05	6.55E-05	2.91E-05	2.91E-05	-	-	-	-	3.53E-02	1.15E-04	4.89E-02	-	-	-	-	-
Medium herbivorous mammal – 1500 g (rabbit) *	-	-	-	-	1.29E-03	1.29E-03	8.68E-04	8.68E-04	-	-	-	-	-	-	-	-
Small Insectivorous bird (Tree sparrow, robin) – 22 g	2.45E-03	2.45E-03	1.66E-03	1.66E-03	-	-	-	-	-	-	-	-	-	-	-	-
Medium Insectivorous bird – 113 g (blackbird) *	6.20E-04	6.20E-04	2.75E-04	2.75E-04	-	-	-	-	-	-	-	-	-	-	-	-
Omnivorous bird – 225 g (Black-billed magpie) *	6.20E-04	6.20E-04	2.75E-04	2.75E-04	-	-	-	-	-	-	-	-	1.78E-01	5.81E-04	2.47E-01	-

*Indicator species considered as relevant for lawn/garden.

- Calculations for **Scenario 4**

The following table summarizes the estimated theoretical exposure (ETE) for secondary poisoning for each indicator species at scenario 4 obtained from ESD spreadsheet from ECHA.

Representative specie	ETE ($mg.kg^{-1}.d^{-1}$)							
	Insectivorous		Herbivorous		Mammals eating worms		Birds eating worms	
	Acute exposure	Short-term exposure	Acute exposure	Short-term exposure	Acute exposure	Short-term exposure	Acute exposure	Short-term exposure
Small insectivorous mammal 1 (pipistrelle) – 7.6 g *	3E-04	1.33E-04	-	-	-	-	-	-
Small insectivorous mammal 2 (mole) – 85 g	-	-	-	-	0.055	0.055	-	-
Medium insectivorous mammal – 1100 g – hedgehog *	6.85E-05	3.04E-05	-	-	0.026	0.026	-	-
Large insectivorous mammal – 10100 g (badger) *	3.56E-05	1.58E-05	-	-	0.013	0.013	-	-
Medium herbivorous mammal – 1500 g (rabbit) *	-	-	7.03E-04	4.72E-04	-	-	-	-
Small Insectivorous bird (Tree sparrow, robin) – 22 g	1.33E-03	9.04E-04	-	-	-	-	-	-
Medium Insectivorous bird – 113 g (blackbird) *	3.38E-04	1.5E-04	-	-	-	-	-	-
Omnivorous bird – 225 g (Black-billed magpie) *	1.8E-04	7.98E-05	-	-	-	-	0.068	0.068

*Indicator species considered as relevant for lawn/garden.

ES CA:
For all the reasons detailed in the CAR of the synthetic amorphous silicon dioxide, it is not necessary to perform an assessment of secondary poisoning for this substance of concern.

Alpha-cypermethrin has a potential for bioaccumulation in aquatic and terrestrial non-target organisms (log K_{OW} 5.5). Thus, an estimation of the theoretical exposure of top predators via the aquatic and terrestrial food chain has been performed and is presented in the following tables. In accordance with the ECHA Guidance on the BPR (Volume IV Environment –Version 2.0, October 2017), the predicted environmental concentration in fish- and earthworm-eating top predators has been estimated according to the following relationships:

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

Where:

Variable/parameter (unit)	Symbol	Unit	Value	Source
Predicted Environmental Concentration in fish-eating predators	$PEC_{oral,\ fish\text{-}eating\ predator}$	$[mg.kg_{wet\ fish}^{-1}]$	-	Output
Predicted Environmental Concentration in surface water	$PEC_{surface\ water}$	$[mg.L^{-1}]$	[1]	Input
Bioconcentration Factor for fish on wet weight basis	BCF_{fish}	$[L.kg_{wet\ fish}^{-1}]$	910	Input
Biomagnification factor in fish	*BMF*	[-]	1	Default

[1]PECwater for the different scenarios.
BCF_{fish} According to alpha-cypermethrin CAR.
BMF According to alpha-cypermethrin CAR and Table 23 of ECHA Guidance on the BPR (Volume IV Environment –Version 2.0, October 2017)

$PEC_{oral,\ earthworm\text{-}eating\ predator} =$
$C_{earthworm} = (BCF_{earthworm} \times C_{porewater} + C_{soil} \times F_{gut} \times CONV_{soil}) / (1 + F_{gut} \times CONV_{soil})$

Where:

Variable/parameter (unit)	Symbol	Unit	Value	Source
Predicted Environmental Concentration in earthworm-eating predators	$PEC_{oral,\ earthworm\text{-}eating\ predator}$	[$mg.kg_{wet\ earthworm}^{-1}$]	-	Output
Concentration in earthworm on wet weight basis	$C_{earthworm}$	[$mg.kg_{wet\ earthworm}^{-1}$]	-	Output
Bioconcentration Factor for earthworms on wet weight basis	$BCF_{earthworm}$	[$mg.kg_{wet\ earthworm}^{-1}$]	3796	Input
Concentration in porewater	$C_{porewater}$	[$mg.L^{-1}$]	[2]	Input
Concentration in soil	C_{soil}	[$mg.kg_{wwt}^{-1}$]	[3]	Input
Fraction of gut loading in worm	F_{gut}	[$kg_{dwt}.kg_{wwt}^{-1}$]	0.1 [4]	Default
Conversion factor for soil concentration wet-dry weight soil	$CONV_{soil}$	[$kg_{wwt}.kg_{dwt}^{-1}$]	1.13 [4]	Default

$BCF_{earthworm}$ According to alpha- cypermethrin CAR.

[2] PECporewater for the different scenarios.

[3] 180 days PECsoil for the different scenarios.

[4] Default values were obtained from ECHA Guidance on the BPR (October 2017).

Based on the above the Predicted Environmental Concentration in fish-eating and earthworm-eating predators are presented in the following tables.

Summary table on secondary poisoning via the aquatic food chain	
Scenario 4 (Ant nest) Alpha-cypermethrin	***PEC oral, fish-eating predator***
Private house (Non-professional)	-
Large buildings (Professional)	2,58E-06
Summary table on secondary poisoning via the terrestrial food chain	
Scenario 4 (Ant nest) Alpha-cypermethrin	***PEC oral, earthworm-eating predator***
Private house (Non-professional)	8,92E-03
Large buildings (Professional)	1,37E-06

2.2.8.3 Risk characterisation

ES CA:
As explained before, the risk characterisation is only done for the scenario 4.

Atmosphere

Conclusion:

As the product is applied in an indoor environment and surrounding areas direct emission to the environment is not likely. Emissions to air are unlikely considering the low volatility of alpha-cypermethrin (vapour pressure: <0.1 mPa at 25°C). Moreover the product is

commonly applied in stables limiting even further the direct emission to air. Exposure of the air compartment is negligible. Consequently, the risk is acceptable for this compartment.

ES CA:
No risk characterisation for air was conducted for the a.s. as exposure to air is considered negligible.

According to the CAR of the SoC, Silicon dioxide is not volatile, and therefore exposure via the atmospheric compartment is not considered relevant.

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values	
Scenario	**PEC/PNEC$_{STP}$**
Scenario 1 (3-11 applications)	
[1.a-Priv-wet]	5.94E-07
[1.a-Priv-dry]	1.09E-07
[1.a-Ind-wet]	8.01E-07
[1.a-Ind-dry]	1.47E-07
[1.b-Priv-wet]	1.31E-05
[1.b-Priv-dry]	2.40E-06
[1.b-Ind-wet]	4.02E-05
[1.b-Ind-dry]	7.38E-06
Scenario 1 (1-2 applications)	
[1.a-Priv-wet]	1.49E-07
[1.a-Priv-dry]	2.73E-08
[1.a-Ind-wet]	2.01E-07
[1.a-Ind-dry]	3.68E-08
[1.b-Priv-wet]	3.27E-06
[1.b-Priv-dry]	6.01E-07
[1.b-Ind-wet]	1.01E-05
[1.b-Ind-dry]	1.85E-06
Scenario 2 (residues via STP)	
(i1= 8)	3.75E-05
(i1= 11)	7.15E-05
(i1= 12)	5.55E-05
(i1= 16)	1.67E-04
(i1= 17)	1.25E-04
(i1= 18)	1.00E-04
Scenario 3a (urban area)	
[3.a-Priv]	8.70E-06
[3.a-Ind]	1.38E-05

Conclusion:

There is no risk posed to micro-organisms in a sewage treatment plant (STP/WWTP) resulting from product residue's losses after application and cleaning in any of the treatment scenarios with MASSO's product (DP).The PEC/PNEC ratios ranged between $3.68x10^{-8}$ and

0, and thus these results indicate acceptable concentrations of the active substance in local STPs.

ES CA:

Summary table on calculated PEC/PNEC values for MASSOCIDE AD 04	
Scenario	**PEC/PNEC STP**
Scenario 4 (Ant nest) Alpha-cypermethrin	
Private house (Non-professional)	-
Large buildings (Professional)	3,16E-10
Scenario 4 (Ant nest) Silicon dioxide	
Private house (Non-professional)	-
Large buildings (Professional)	-

For the active substance, when the product is applied outdoors to treat directly ant nests (scenario 4), no emission to STP is expected on private houses as this compartment is not exposed.

For the substance of concern, according to the explanation given previously, no risks to the aquatic environment as well as STP microorganisms after cleaning operations are expected. Moreover, as demonstrated in the CAR of the synthetic amorphous silicon dioxide, the SoC is not toxic at all for the STP microorganisms.

Conclusion:

As the PEC/ PNEC value is less than 1, an acceptable level of risk to STP is predicted from the application scenario.

Aquatic compartment

Summary table on calculated PEC/PNEC values		
Scenario	**PEC/PNEC$_{water}$**	**PEC/PNEC$_{sed}$**
Scenario 1 (3-11 applications)		
[1.a-Priv-wet]	**1.11**	**9.04**
[1.a-Priv-dry]	0.20	**1.66**
[1.a-Ind-wet]	**1.50**	**12.20**
[1.a-Ind-dry]	0.27	**2.24**
[1.b-Priv-wet]	**24.41**	**198.94**
[1.b-Priv-dry]	**4.48**	**36.54**
[1.b-Ind-wet]	**75.09**	**611.95**
[1.b-Ind-dry]	**13.79**	**112.40**
Scenario 1 (1-2 applications)		
[1.a-Priv-wet]	0.28	**2.27**
[1.a-Priv-dry]	0.05	0.42

Summary table on calculated PEC/PNEC values				
Scenario	**PEC/PNEC$_{water}$**		**PEC/PNEC$_{sed}$**	
[1.a-Ind-wet]	0.37		**3.06**	
[1.a-Ind-dry]	0.07		0.56	
[1.b-Priv-wet]	**6.12**		**49.84**	
[1.b-Priv-dry]	**1.12**		**9.15**	
[1.b-Ind-wet]	**18.81**		**153.31**	
[1.b-Ind-dry]	**3.46**		**28.16**	
Scenario 2 (residues via STP)				
(i1= 8)	**6.84**		**55.72**	
(i1= 11)	**13.04**		**106.24**	
(i1= 12)	**10.12**		**82.47**	
(i1= 16)	**30.36**		**247.40**	
(i1= 17)	**22.79**		**185.73**	
(i1= 18)	**18.23**		**148.59**	
Scenario 2 (residues via Slurry / manure)				
	Grassland	**Arable land**	**Grassland**	**Arable land**
(i1= 1)	0.13	0.00	**1.03**	0.03
(i1= 2)	0.11	0.00	0.92	0.02
(i1= 3)	0.92	0.02	**7.48**	0.19
(i1= 4)	0.22	0.01	**1.77**	0.04
(i1= 5)	0.28	0.01	**2.25**	0.06
(i1= 6)	0.18	0.00	**1.46**	0.04
(i1= 7)	0.19	0.00	**1.58**	0.04
(i1= 8)	0.22	0.01	**1.76**	0.04
(i1= 9)	0.35	0.01	**2.81**	0.07
(i1= 10)	0.07	0.00	0.59	0.01
(i1= 11)	0.55	0.01	**4.47**	0.11
(i1= 12)	0.16	0.01	**1.27**	0.05
(i1= 13)	0.41	0.01	**3.31**	0.08
(i1= 14)	0.14	0.01	**1.11**	0.04
(i1= 15)	0.30	0.01	**2.41**	0.09
(i1= 16)	0.45	0.01	**3.70**	0.09
(i1= 17)	0.34	0.01	**2.77**	0.07
(i1= 18)	0.48	0.01	**3.90**	0.10
Scenario 3a (urban area)				
[3.a-Priv]	**16.26**		**132.50**	
[3.a-Ind]	**25.84**		**210.62**	

Conclusion:

The PEC/PNEC ratios indicate that when 1-2 applications per year are undertaken there is an acceptable risk for crack & crevice application at indoor areas intended to be cleaned by dry methods regardless the application user (Scenario 1). The application in animal housing (Scenario 2) pose risk in those sub-scenarios connected to STP. However, when emission is done via slurry/manure, no risk is expected at sediment compartment derived from arable land emission whilst slightly risk is expected from grassland emission.

When the product is applied outdoors, around buildings in urban areas (Scenario 3a) (i.e.application on the foundations and on the soil around the house, which are exposed to

wash-off the treated surfaces by rainfall), unacceptable risk is expected for aquatic compartment. However, this risk can be avoided if the product is applied in areas protected to rain and flood and not connected to waste water. No risk is expected for aquatic compartments for outdoor applications at rural areas (Scenario 3b) nor at ant nest (scenario 4).

ES CA:

Summary table on calculated PEC/PNEC values for MASSOCIDE AD 04		
Scenario	**PEC/PNEC SW**	**PEC/PNEC SED**
Scenario 4 (Ant nest) Alpha-cypermethrin		
Private house (Non-professional)	-	-
Large buildings (Professional)	5,90E-04	4,81E-03
Scenario 4 (Ant nest) Silicon dioxide		
Private house (Non-professional)	-	-
Large buildings (Professional)	-	-

For the active substance, no emission to the aquatic compartment (surface water and sediment) is expected on private houses as this compartment is not exposed.

For the substance of concern, according to the explanation given previously, the exposure to the aquatic compartment (surface water and sediment) can be discarded; no emission to the aquatic environment after the use of the product is expected. Moreover, as demonstrated in the CAR of the synthetic amorphous silicon dioxide, the active substance is not toxic for the aquatic organisms.

Conclusion:
An acceptable level of risk to SW and SED is predicted from large buildings when b.p. is applied to ant nests.

Terrestrial compartment

Summary table on calculated PEC/PNEC values			
Scenario	**PECsoil /PNEC$_{soil}$**	**PEC$_{180d_agric}$ /PNEC$_{soil}$**	**PEC$_{180d_grass}$/PNEC$_{soil}$**
Scenario 1 (3-11 applications)			
[1.a-Priv-wet]	1.38E-02	1.38E-02	5.52E-03
[1.a-Priv-dry]	2.55E-03	2.55E-03	1.03E-03
[1.a-Ind-wet]	1.87E-02	1.87E-02	7.44E-03
[1.a-Ind-dry]	3.43E-03	3.43E-03	1.38E-03
[1.b-Priv-wet]	3.04E-01	3.04E-01	1.21E-01
[1.b-Priv-dry]	5.60E-02	5.59E-02	2.24E-02
[1.b-Ind-wet]	9.36E-01	9.36E-01	3.73E-01
[1.b-Ind-dry]	1.72E-01	1.72E-01	6.88E-02
Scenario 1 (1-2 applications)			

Summary table on calculated PEC/PNEC values			
Scenario	**PECsoil /PNEC$_{soil}$**	**PEC$_{180d_agric}$ /PNEC$_{soil}$**	**PEC$_{180d_grass}$/PNEC$_{soil}$**
[1.a-Priv-wet]	3.47E-03	3.47E-03	1.38E-03
[1.a-Priv-dry]	6.38E-04	6.38E-04	2.57E-04
[1.a-Ind-wet]	4.67E-03	4.67E-03	1.86E-03
[1.a-Ind-dry]	8.60E-04	8.60E-04	3.46E-04
[1.b-Priv-wet]	7.62E-02	7.62E-02	3.04E-02
[1.b-Priv-dry]	1.40E-02	1.40E-02	5.61E-03
[1.b-Ind-wet]	2.34E-01	2.34E-01	9.34E-02
[1.b-Ind-dry]	4.31E-02	4.31E-02	1.72E-02
Scenario 2 (emission via STP)			
(i1= 8)	4.12E-02	-	-
(i1= 11)	7.86E-02	-	-
(i1= 12)	6.10E-02	-	-
(i1= 16)	1.83E-01	-	-
(i1= 17)	1.37E-01	-	-
(i1= 18)	1.10E-01	-	-
Scenario 3a (urban area)			
[3.a-Priv]	2.03E-01	2.03E-01	8.06E-02
[3.a-Ind]	3.22E-01	3.22E-01	1.28E-01
Scenario 3b (rural area)			
[3.b-Priv]	1.17E-01	-	-
[3.b-Ind]	1.19E-01	-	-
Scenario 4(ant nest)			
[4]	3.27E-02	-	-

Scenario 2 (emission via slurry/manure)						
PEC$_{soil}$ /PNEC$_{soil}$						
(sub-cat. i1=1-18)	***after one manure application on arable or four manure applications on grassland <u>without degradation</u>* OPP**		***after one manure application on arable or four manure applications on grassland <u>with degradation</u>***		***after 10 year consecutive application, degradation in soil included***	
	grass	**arable**	**grass**	**arable**	**grass**	**arable**
(i1= 1)	9.23E-04	2.31E-04	9.23E-04	2.31E-04	9.23E-03	1.03E-36
(i1= 2)	8.24E-04	2.06E-04	8.24E-04	2.06E-04	8.24E-03	9.18E-37
(i1= 3)	6.74E-03	1.68E-03	6.74E-03	1.68E-03	6.73E-02	7.51E-36
(i1= 4)	1.60E-03	3.99E-04	1.60E-03	3.99E-04	1.60E-02	1.78E-36
(i1= 5)	2.02E-03	5.06E-04	2.02E-03	5.06E-04	2.02E-02	2.26E-36
(i1= 6)	1.32E-03	3.30E-04	1.32E-03	3.30E-04	1.32E-02	1.47E-36
(i1= 7)	1.42E-03	3.55E-04	1.42E-03	3.55E-04	1.42E-02	1.58E-36
(i1= 8)	1.58E-03	3.96E-04	1.58E-03	3.96E-04	1.58E-02	1.76E-36
(i1= 9)	2.53E-03	6.33E-04	2.53E-03	6.33E-04	2.53E-02	2.82E-36
(i1= 10)	5.28E-04	1.32E-04	5.28E-04	1.32E-04	5.28E-03	5.88E-37
(i1= 11)	4.03E-03	1.01E-03	4.03E-03	1.01E-03	4.02E-02	4.49E-36
(i1= 12)	1.14E-03	4.28E-04	1.14E-03	4.28E-04	1.14E-02	1.91E-36
(i1= 13)	2.98E-03	7.45E-04	2.98E-03	7.45E-04	2.98E-02	3.32E-36
(i1= 14)	1.00E-03	3.75E-04	1.00E-03	3.75E-04	1.00E-02	1.67E-36
(i1= 15)	2.17E-03	8.13E-04	2.17E-03	8.13E-04	2.17E-02	3.63E-36

Scenario 2 (emission via slurry/manure)						
PEC_{soil} /$PNEC_{soil}$						
(sub-cat. i1=1-18)	***after one manure application on arable or four manure applications on grassland <u>without degradation</u> OPP***		***after one manure application on arable or four manure applications on grassland <u>with degradation</u>***		***after 10 year consecutive application, degradation in soil included***	
	grass	**arable**	**grass**	**arable**	**grass**	**arable**
(i1= 16)	3.33E-03	8.31E-04	3.33E-03	8.31E-04	3.32E-02	3.71E-36
(i1= 17)	2.50E-03	6.24E-04	2.50E-03	6.24E-04	2.50E-02	2.78E-36
(i1= 18)	3.51E-03	8.78E-04	3.51E-03	8.78E-04	3.51E-02	3.92E-36

<u>Conclusion</u>:

The PEC/PNEC ratios indicate that there is an acceptable risk for terrestrial organisms either following the use in <u>domestic/public/industrial premises</u> or <u>breeding premises</u>.
Therefore, no studies with the formulated product are necessary for this environmental compartment.

ES CA:

Summary table on calculated PEC/PNEC values for MASSOCIDE AD 04	
Scenario	**PEC/PNEC SOIL**
Scenario 4 (Ant nest) Alpha-cypermethrin	
Private house (Non-professional)	3,84E-03
Large buildings (Professional)	5,89E-07
Scenario 4 (Ant nest) Silicon dioxide	
Private house (Non-professional)	1,36E-01
Large buildings (Professional)	3,16E-04

<u>Conclusion:</u>

The risk characterisation ratios are below 1 for the active substance and the substance of concern for the soil compartment. Therefore, the risks for the soil compartment are acceptable when using the product MASSOCIDE AD04.

Groundwater

Summary table on calculated PEC values for Alpha-cypermethrin substance	
Scenario	**PEC_{GW}** [mg/l]
Scenario 1 (3-11 applications)	
[1.a-Priv-wet]	9.06E-06
[1.a-Priv-dry]	1.67E-06
[1.a-Ind-wet]	1.22E-05
[1.a-Ind-dry]	2.25E-06
[1.b-Priv-wet]	**1.99E-04**
[1.b-Priv-dry]	3.66E-05

Summary table on calculated PEC values for Alpha-cypermethrin substance	
Scenario	**PEC_{GW}** [mg/l]
[1.b-Ind-wet]	**6.13E-04**
[1.b-Ind-dry]	**1.13E-04**
Scenario 1 (1-2 applications)	
[1.a-Priv-wet]	2.27E-06
[1.a-Priv-dry]	4.18E-07
[1.a-Ind-wet]	3.06E-06
[1.a-Ind-dry]	5.63E-07
[1.b-Priv-wet]	4.99E-05
[1.b-Priv-dry]	9.18E-06
[1.b-Ind-wet]	**1.53E-04**
[1.b-Ind-dry]	2.82E-05
Scenario 2 (residues via STP)	
(i1= 8)	2.70E-05
(i1= 11)	5.15E-05
(i1= 12)	4.00E-05
(i1= 16)	**1.20E-04**
(i1= 17)	9.00E-05
(i1= 18)	7.20E-05
Scenario 3 (outdoor application around buildings)	
[3.a-Priv]	**1.33E-04**
[3.a-Ind]	**2.11E-04**
[3.b-Priv]	7.68E-05
[3.b-Ind]	7.79E-05
Scenario 4 (Ant nest)	
[4] – ant nest	2.14E-05

Outputs above disclose values slightly above the the maximum permissible concentration of 0.1 µg/L at industrial use indoors for broadcast surfaces with wet cleaning treatment (scenario 1), turkeys animal housing connected to stp (sub-scenario i=16 from scenario 2) and outdoor application on urban areas (scenario 3). In view of that, further refinement is necessary so PECgw was calculated using FOCUS PEARL 4.4.4. with the following input data for worst case: Scenario 1.b-Ind-wet (indoor application on broadcast surfaces by industrial users with wet cleaning treatment of treated surfaces).

For this scenario the following estimated parameters were used in the estimation of the application rate to be used in FOCUS program for the estimation of PECgw:

Parameter	**Alpha-cypermethrin**
Elocal (kg/d)	5.41E-02
Csludge (total concentration of chemical in combined sludge) ($mg.kg^{-1}$)	56.48348

For sludge application to agricultural soil, an application rate of 5000 kg/ha dry weight per year is assumed. For grassland a rate of 1000 kg/ha/yr should be used.

$Appl\_rate\ agr/grass = App\ sewage\_sludge_{\_(agr/grass)} \times Csludge \times 10^{-6}$

App_rate to be considered in FOCUS (kg/ha)	**Alpha-cypermethrin**
Grassland	0.0565
Arable land	0.2824

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

Parameter	Value	Unit	Origin
Molar mass	416.3	[g.mol-1]	S
Solubility in water (at test temperature)	5800	[mg.L-1]	S
Molar enthalpy of dissolution	27	[kJ.mol-1]	D
Vapour pressure (at test temperature)	5.6E-07	[Pa]	S
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 (K_{oc} or **K_{om}**) (K_{om} = K_{oc} / 1.724)	76344 (mean K_{oc}) K_{om} = 44283.062	[$dm^3.kg^{-1}$]	S
Exponent of the Freundlich-Isotherm (1/n)	0.9	[-]	D/S
$DT_{50\ soil}$(20°C)	35	[d]	S
Arrhenius activation energy	65.4	[kJ.mol-1]	D
Plant uptake factor	0	[-]	D

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

FOCUS Scenarios ([1.b-Ind-wet])		
Ground land Scenarios	**Concentration closest to the 80th percentile [µg·L^{-1}]**	
	Alfalfa (grassland)	**Maize (arable land)**
Châteaudun	0.000000	0.000000
Hamburg	0.000000	0.000000
Jokioinen	0.000000	-
Kremsmünster	0.000000	0.000000
Okehampton	0.000000	0.000000
Piacenza	0.000000	0.000000
Porto	0.000000	0.000000
Sevilla	0.000000	0.000000
Thiva	0.000000	0.000000

Values on bold are considered above the trigger value 1E-04 mg/L

Conclusion:

Outputs above disclose that no risk is foreseen for the active substance for groundwater compartment by the intended use of the MASSOCIDE AD04. This result can be extrapolated for all intended uses because the assessed Scenario 1.b-Ind-wet can be deemed as the worst-case.

ES CA:

Summary table on calculated PEC/PNEC values for MASSOCIDE AD 04	
Scenario	**GROUNDWATER (ug/L)**
	PNEC
	>0,1
Scenario 4 (Ant nest) Alpha-cypermethrin	
Private house (Non-professional)	2,51E-03
Large buildings (Professional)	3,85E-07
Scenario 4 (Ant nest) Silicon dioxide	
Private house (Non-professional)	-
Large buildings (Professional)	-

For the substance of concern, the amorphous silica is hydrophobic and non-soluble in water, a risk of leaching and contamination of groundwater can be discarded.

Conclusion:

Using the simplistic approach detailed in the ECHA guidance on ERA to calculate the concentration of alpha-cypermethrin in groundwater, levels below the groundwater drinking trigger concentration of 0.1 µg L^{-1} (directive 98/83/EC) were predicted for the active substance alpha-cypermethrin when b.p. is applied directly into ant nests. Hence an acceptable level of risk to groundwater is predicted for this product.

Summary risk characterization table for all the environmental compartments:

Summary table on calculated PEC/PNEC values for MASSOCIDE AD 04									
Scenario	PEC STP (mg/l)	PEC/PNEC STP	SW (mg/l)	PEC/PNEC SW	PEC SED (mg/kgdt)	PEC/PNEC SED	PEC SOIL (mg/kg)	PEC/PNEC SOIL	GROUNDWATER (ug/L)
	PNEC		PNEC		PNEC		PNEC		PNEC
	100		4,80E-06		9,78E-04		0,882		>0,1
	100		8,60E-02		2,19E+00		0,00625		>0,1
Scenario 4 (Ant nest) Alpha-cypermethrin									
Private house (Non-professional)							3,39E-03	**3,84E-03**	**2,51E-03**
Large buildings (Professional)	3,16E-08	**3,16E-10**	2,83E-09	**5,90E-04**	4,70E-06	**4,81E-03**	5,19E-07	**5,89E-07**	**3,85E-07**
Scenario 4 (Ant nest) Silicon dioxide									
Private house (Non-professional)							8,47E-04	**1,36E-01**	
Large buildings (Professional)							1,98E-06	**3,16E-04**	

Primary and secondary poisoning

Primary poisoning

No primary poisoning is foreseeable according to the intended use pattern.

Secondary poisoning

PEC/PNEC ratios were estimated for the active substance as follows:

Summary table on secondary poisoning from Alpha-cypermethrin				
Scenario	**Concentration in fish for secondary poisoning (freshwater)**	**Concentration in earthworms from agricultural soil**	**PEC/PNEC$_{fish}$**	**PEC/PNEC** (birds & mammals)
Scenario 1 (3-11 applications)				
[1.a-Priv-wet]	0.251	0.016	0.09	0.01
[1.a-Priv-dry]	4.62E-02	2.96E-03	0.02	0.00
[1.a-Ind-wet]	0.2787	0.0216	0.10	0.01
[1.a-Ind-dry]	5.12E-02	3.99E-03	0.02	0.00
[1.b-Priv-wet]	5.53	3.53E-01	**2.07**	0.13
[1.b-Priv-dry]	1.02	6.49E-02	0.38	0.02
[1.b-Ind-wet]	14	1.09	**5.24**	0.41
[1.b-Ind-dry]	2.57	0.2	0.96	0.07
Scenario 1 (1-2 applications)				
[1.a-Priv-wet]	6.3E-02	4.02E-03	0.02	0.00
[1.a-Priv-dry]	1.16E-02	7.41E-04	0.00	0.00
[1.a-Ind-wet]	6.98E-02	5.42E-03	0.03	0.00
[1.a-Ind-dry]	1.28E-02	9.99E-04	0.00	0.00
[1.b-Priv-wet]	1.39	8.85E-02	0.52	0.03
[1.b-Priv-dry]	2.55E-01	1.63E-02	0.10	0.01
[1.b-Ind-wet]	3.5	0.272	**1.31**	0.10
[1.b-Ind-dry]	6.43E-01	5.00E-02	0.24	0.02
Scenario 2 (emission via slurry/manure)				
(i1= 1)	1.25E-01	2.07E-02	0.05	0.01
(i1= 2)	1.12E-01	1.85E-02	0.04	0.01
(i1= 3)	9.13E-01	1.51E-01	0.34	0.06
(i1= 4)	2.16E-01	3.58E-02	0.08	0.01
(i1= 5)	2.74E-01	4.54E-02	0.10	0.02
(i1= 6)	1.79E-01	2.95E-02	0.07	0.01
(i1= 7)	1.92E-01	3.18E-02	0.07	0.01
(i1= 8)	2.14E-01	3.55E-02	0.08	0.01
(i1= 9)	3.43E-01	5.68E-02	0.13	0.02
(i1= 10)	7.15E-02	1.18E-02	0.03	0.00
(i1= 11)	5.45E-01	9.02E-02	0.20	0.03
(i1= 12)	1.55E-01	2.56E-02	0.06	0.01
(i1= 13)	4.04E-01	6.68E-02	0.15	0.03
(i1= 14)	2.94E-01	2.24E-02	0.11	0.01
(i1= 15)	1.35E-01	4.86E-02	0.05	0.02
(i1= 16)	4.51E-01	7.45E-02	0.17	0.03
(i1= 17)	3.38E-01	5.60E-02	0.13	0.02
(i1= 18)	4.76E-01	7.87E-02	0.18	0.03
Scenario 2 (emission via STP)				
(i1= 8)	6.79	9.58E-02	**2.54**	0.04
(i1= 11)	12.95	1.83E-01	**4.85**	0.07
(i1= 12)	10.05	1.42E-01	**3.76**	0.05

Summary table on secondary poisoning from Alpha-cypermethrin				
Scenario	**Concentration in fish for secondary poisoning (freshwater)**	**Concentration in earthworms from agricultural soil**	**PEC/PNEC$_{fish}$**	**PEC/PNEC** (birds & mammals)
(i1= 16)	30.16	4.25E-01	**11.30**	0.16
(i1= 17)	22.65	3.19E-01	**8.48**	0.12
(i1= 18)	18.12	2.55E-01	**6.79**	0.10

Outputs above disclose that there is no risk for terrestrial organism by secondary poisoning at scenarios 1 or 2. However, when residue emissions are connected to STP, unacceptable risk is foreseen for aquatic organisms at scenario 2 and at scenario 1 (derived from surface treatment at indoor with wet cleaned treatment).

The risk assessment for specific species by secondary poisoning considered in scenarios 3 and 4 is considered by splitting the ETE with the correspondent PNEC (i.e. bird or mammal value). These quotients are showed in the following tables:

In the case of scenario 3, the case of large building application was used to assess the risk for terrestrial species of secondary poisioning as it is deemed as worse case, covering the application on standard house:

Representative specie	ETE /PNEC$_{oral}$															
	Insectivorous				Herbivorous				Mammals eating worms				Birds eating worms			
	Acute exposure		Short-term exposure		Acute exposure		Short-term exposure		Acute exposure		Short-term exposure		Acute exposure		Short-term exposure	
	Treated area	Untreated area	Treated area	Untreated area	Treated area	Untreated area	Treated area	Untreated area	Treated area	Untreated area	Treated area	Untreated area	Treated area	Untreated area	Treated area	Untreated area
Small insectivorous mammal 1 (pipistrelle) – 7.6 g *	2.06E-04	2.06E-04	9.14E-05	9.14E-05	-	-	-	-	-	-	-	-	-	-	-	-
Small insectivorous mammal 2 (mole) – 85 g	-	-	-	-	-	-	-	-	5.39E-02	1.75E-04	7.45E-02	-	-	-	-	-
Medium insectivorous mammal – 1100 g – hedgehog *	4.72E-05	4.72E-05	2.09E-05	2.09E-05	-	-	-	-	2.54E-02	8.28E-05	3.52E-02	-	-	-	-	-
Large insectivorous mammal – 10100 g (badger) *	2.45E-05	2.45E-05	1.09E-05	1.09E-05	-	-	-	-	1.32E-02	4.31E-05	1.83E-02	-	-	-	-	-
Medium herbivorous mammal – 1500 g (rabbit) *	-	-	-	-	4.83E-04	4.83E-04	3.25E-04	3.25E-04	-	-	-	-	-	-	-	-
Small Insectivorous bird (Tree sparrow, robin) – 22 g	4.90E-04	4.90E-04	3.32E-04	3.32E-04	-	-	-	-	-	-	-	-	-	-	-	-
Medium Insectivorous bird – 113 g (blackbird) *	1.24E-04	1.24E-04	5.50E-05	5.50E-05	-	-	-	-	-	-	-	-	-	-	-	-

Representative specie	ETE /PNEC$_{oral}$															
	Insectivorous				Herbivorous				Mammals eating worms				Birds eating worms			
	Acute exposure		Short-term exposure		Acute exposure		Short-term exposure		Acute exposure		Short-term exposure		Acute exposure		Short-term exposure	
	Treated area	Untreated area	Treated area	Untreated area	Treated area	Untreated area	Treated area	Untreated area	Treated area	Untreated area	Treated area	Untreated area	Treated area	Untreated area	Treated area	Untreated area
Omnivorous bird – 225 g (Black-billed magpie) *	1.24E-04	1.24E-04	5.50E-05	5.50E-05	-	-	-	-	-	-	-	-	3.56E-02	1.16E-04	4.94E-02	-

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

Representative specie	ETE / PNEC							
	Insectivorous		Herbivorous		Mammals eating worms		Birds eating worms	
	Acute exposure	Short-term exposure	Acute exposure	Short-term exposure	Acute exposure	Short-term exposure	Acute exposure	Short-term exposure
Small insectivorous mammal 1 (pipistrelle) – 7.6 g *	1.12E-04	4.98E-05	-	-	-	-	-	-
Small insectivorous mammal 2 (mole) – 85 g	-	-	-	-	2.06E-02	2.06E-02	-	-
Medium insectivorous mammal – 1100 g – hedgehog *	2.57E-05	1.14E-05	-	-	9.74E-03	9.74E-03	-	-
Large insectivorous mammal – 10100 g (badger) *	1.33E-05	5.92E-06	-	-	4.87E-03	4.87E-03	-	-
Medium herbivorous mammal – 1500 g (rabbit) *	-	-	2.63E-04	1.77E-04	-	-	-	-
Small Insectivorous bird (Tree sparrow, robin) – 22 g	2.66E-04	1.81E-04	-	-	-	-	-	-
Medium Insectivorous bird – 113 g (blackbird) *	6.76E-05	3.00E-05	-	-	-	-	-	-

Representative specie	ETE / PNEC							
	Insectivorous		Herbivorous		Mammals eating worms		Birds eating worms	
	Acute exposure	Short-term exposure	Acute exposure	Short-term exposure	Acute exposure	Short-term exposure	Acute exposure	Short-term exposure
Omnivorous bird – 225 g (Black-billed magpie) *	3.60E-05	1.60E-05	-	-	-	-	1.36E-02	1.36E-02

*Indicator species considered as relevant for lawn/garden.

Conclusion:

Risk characterization ratios for secondary poisoning shows an acceptable risk for aquatic organisms at those scenarios not connected to STP. On the other hand, no risk is expected for terrestrial organisms by secondary poisoning at any scenario.

ES CA:
Primary poisoning
Not relevant

Secondary poisoning

As stated previously, it is not necessary to perform an assessment of secondary poisoning for the substance of concern.

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 (PNECoral, fish food chain). The concentration of alpha-cypermethrin 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 (PNE_{Coral}, terrestrial food chain). The concentration of alpha-cypermethrin 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 via the aquatic food chain		
Scenario 4	**PEC/PNECbirds**	**PEC/PNECmammals**
Private house (Non-professional)	-	-
Large buildings (Professional)	5,16E-07	9,66E-07
Summary table on secondary poisoning via the aquatic food chain		
Scenario 4	**PEC/PNECbirds**	**PEC/PNECmammals**
Private house (Non-professional)	1,78E-03	3,34E-03
Large buildings (Professional)	2,73E-07	5,12E-07

Conclusion: The PEC/PNEC ratios are lower than 1. It may be concluded that there are acceptable risks for secondary poisoning through the terrestrial food-chain via earthworm and aquatic food chain via fish from the use of MASSOCIDE AD04.

Mixture toxicity

No mixture toxicity has been assessed considering the risk observed in the present calculations.

ES CA:
As it is stated before, the risk assessment of the product MASSOCIDE AD04 is based both on the information provided in the Assessment Report of alpha-cypermethrin and on the information provided in the Assessment Report of Synthetic amorphous silicon dioxide PT18 (March 2014) which is identified as a substance of concern.

The result of mixture toxicity assessment of the product containing the active substance alpha-cypermethrin and the substance of concern amorphous silicon dioxine is summarised in the following table.

Summary table on calculated ΣPEC/PNEC values - Scenario 4 (Ant nest)					
	$\Sigma PEC/PNEC_{STP}$	$\Sigma PEC/PNEC_{sw}$	$\Sigma PEC/PNEC_{sed}$	$\Sigma PEC/PNEC_{soil}$	ΣPEC_{GW} (µg/L)
Private house (Non-professional)				1,39E-01	2,51E-03
Large buildings (Professional)	3,16E-10	5,90E-04	4,81E-03	3,17E-04	3,85E-07

Conclusion: The sum of RCRs is below 1 for all compartments considered (STP, water, sediment, soil and the groundwater). Therefore, the risk assessment for the environment is acceptable when using the product MASSOCIDE AD04.

Aggregated exposure (combined for relevant emission sources)

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

Overall conclusion

No risk is foreseeable in most of the environmental compartments when MASSO's product DP (0.4% w/w of alpha-cypermethrin) is applied on domestic (private), industrial and breeding premises according to the label instructions.

Only aquatic compartments show RCR values slightly above of the threshold in some of the assessed scenarios for surface water and sediment which indicates a potential risk for these compartments. This potential risk is clearly decreased when the number of applications decrease till an acceptable potential risk for the majority of aquatic compartments.

Relative to private and industrial use, the risk from crack and crevice application in areas to be cleaned by dry methods is considered acceptable for all environmental compartments. On the other hand, environmental risk for aquatic compartment is foreseeable when the product is used on broadcast surfaces and residues are cleaned by wet methods. This scenario is considered as a worse case and the risk may be excluded if the product's label indicates that no wet cleaning methods can be used for cleaning product's residues and that the product is intended to be applied on crack and crevices.

Outdoor application on foundations and soil around buildings is deemed on risk for sediment compartment at urban areas. However, no risk is expected at rural areas. In addition, as it is claimed in the product's label, application outdoors must be addressed to ant nests (direct application) or to voids and cavities onto paved surfaces that are protected to rainfall, floods and wash in order to avoid any potential emission to STP and surfacewaters.

Regarding to breeding premises, risk is foreseeable for aquatic compartments (surface water and sediment) when product's residues are considered as stream of waste water and for sediment compartment at several sub-scenarios where emission by manure/slurry is done at grassland. Therefore, the use of MASSO's product (alpha-cypermethrin 0.4% w/w)

is considered acceptable for breeding premises where residues are not collected to a private WWTP and used at arable land, but it is not considered acceptable for premises connected to WWTP or emitted to grassland.

ES CA:
Overall conclusion on the risk assessment for the environment of the product

MASSOCIDE AD04 is an insecticide biocidal product for the use of "direct application on ant´s nest by non professional, professional and trained professional users". The application method is by dusting.

When the product is applied outdoors to treat ant nests on paved surfaces such as terraces or balconies (Scenario 4), the mixture toxicity has shown no unacceptable risk is expected for exposed compartments; therefore this is considered a safe use for the environment.

2.2.9 Measures to protect man, animals and the environment

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

2.2.10 Assessment of a combination of biocidal products

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

2.2.11 Comparative assessment

Not relevant.

3 ANNEXES[1]

3.1 List of studies for the biocidal product

Please, see confidential PAR.

3.2 Output tables from exposure assessment tools

Human Risk Assessment

Human Exposure Calculations_MASSC

Environmental Risk Assessment

Scenarios 1, 3 and 4

Environmental calculations can be found in the attached Excel document. In order to check the right obtained values, EUSES 2.2.2 and ESD spreadsheets have been used to corroborate the outputs for each scenario.

Outputs from ESD spreadsheet	Outputs from EUSES 2.2.2
ERA-MASSO 0.4-ESD spreadsheet_PAR.xlsx	ERA-MASSO 0.4-EUSES_PAR.xlsx

The spreadsheets above shows the same estimated emission rates for the same assessed scenarios.

Scenario 2

Animal housing disinfection has been estimated according OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 14, Addendum to OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 14 and ENV-TAB (December 2019).

As it was mentioned in section 2.2.8. Two potential emissions have been assessed from housing scenarios: 1-Discharged via manure/slurry to soil and 2-Discharged via waste water (STP). The first one is considered for all housing whilst the second one is only deemed for poultry housing connected to STP. In function of each emission is considered, different calculations are developed:

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

1. Local PEC values for the emission pathway via manure/slurry

In order to cover as many animal scenarios as possible, all the animals contemplated in the guide have been considered in a first stage to calculate the amount of component used in the accommodation or storage of manure for an application. This amount has been calculated as follows:

Qai_prescri= Capacity of fumigant can x Volume of housing / (Volume to be treated with fumigant can x 1000) [Kg] (eq. 12 of OECD ESD. No. 14)

The amount to the manure after one application is estimated following equation 14 of OECD ESD No. 14, which takes into account the fraction release to the manure in function of the type of application and type of animal housing:

Qai = Qai_prescri x Fslurry/manure [kg] (eq. 14 of OECD ESD. No. 14)

The next step consist in the estimation of the substance's amount discharged to the soil over the manure's storage period for grassland and arable land. This estimation takes into account the number of biocides application during manure storage period (Napp_manure) for grass and for arable land which have been estimated according Sections 2.2-2.3 of the OECD ESD No.14 Addendum (2015) and taken into account the use frequency of the biocidal product:

Estimation of number of applications during manure storage (reference: OECD ESD No.14 Sections 2.2-2.3 of the Addendum (2015))

				beef cattle, veal calves and, laying hens in battery cages with belt drying, with force drying and free range with litter floor	Broilers	dairy cattle, piggeries and laying hens in compact battery cages	
ARABLE LAND							
number of land application for arable land	Nlapp_arab	[-]	1				D
number of prescribed maximum repeated biocide treatments	Napp_bioc	[-]		3	2	1	S
land application interval for arable land	Tar_int	[d]	365				D
period between biocide treatments	Tbioc_int	[d]		61	61	365	S
manure storage time arable land in new scenario	Tmanure_int_ar	[d]	212				D
number of biocide applications during manure storage period	**Napp_bio_manure_ar**	[-]		3	3	1	O

				beef cattle, veal calves and, laying hens in battery cages with belt drying, with force drying and free range with litter floor	Broilers	dairy cattle, piggeries and laying hens in compact battery cages	
GRASSLAND							
number of repeated treatments prescribed in grassland	Napp prescr			3	2	1	S
period between biocide treatments	Tbioc_int	[d]		61	61	365	S
land application interval for arable land	Tgr_int	[d]	53				D
maximum number of applications during manure storage period of manure to be spread on grassland	**Napp_manure_gr**	[-]		1	1	1	O

Once Napp_manure are calculated for each soil (grass and arable). The correspondent Qai for grassland and arable land was estimated considering equations 16 and 17 respectively from the OECD ESD No. 14.

Qai_grass = Qai x Napp_manure_gr (eq. 16 of OECD ESD. No. 14)

Qai_arab = Qai x Napp_bio_manure_ar (eq. 17 of OECD ESD. No. 14)

The next step consist to estimate the Nitrogen production (Qnitrog_grass and Qnitrog_arab) during the manure storage period for each housing and soil type. This calculation takes into account the number of animals (Nanimal), the Nitrogen production from each animal (Qnitrog) and the default values of Manure application time interval for grassland

(Tgr_int=53 d) and arable land (Tar_int = 212 d). These estimations are carried on by following the equations 20 and 21 from OECD ESD No.14.

Qnitrog-grass = Nanimal x Qnitrog x Tgr_int (eq. 20 of OECD ESD. No. 14)

Qnitrog-arab = Nanimal x Qnitrog x Tar_int (eq. 21 of OECD ESD. No. 14)

- **Estimation of PEC soil after one manure application on arable land and four manure applications on grassland without degradation.**

Taken into account section 3.2 from OECD ESD No.14 Addendum 2015, the PIECsoil for grassland after four application events without degradation is estimated (PIECgrass_4-N). This calculation takes into account the nitrogen immission standard for one year on grassland (QN_gr), the estimated nitrogen production during the manure storage period (Qnitro-grass), the mixing with soil in grassland (DEPTHgr) and the density of wet bulk soil (RHOsoil).

PIECgrass_4-N = (Qai_grass x QN_gr x 100) / (Qnitro-grass x DEPTHgr x RHOsoil)

(eq. 24a Addendum 2015 of OECD ESD No. 14).

Following ENV162 of TAB ENV (2019), the total initial concentration of the substance in soil after four manure application events considering all prescribed biocide applications and without taking degradation in soil into account is estimated as:

PIECgrass_4-N-total = (PIECgrass_4-N x Napp_presc) / (Napp_manure_gr x Nlapp_grass)

(eq. 24a Addendum 2015 of OECD ESD No. 14 + ENV 162 of TAB-ENV 2019).

Where Nlapp_grass is the default number of manure applications for grassland (4 applications) and Napp_presc is the maximum number of disinfectant applications in one year.

PECsoil after one manure application on arable land is calculated according equation 25 from OECD ESD No.14.

PIECara_N = (Qai_arab x QN_ar x 100) / (Qnitro-arab x Nlapp_arab x DEPTHar x RHOsoil)

(eq. 25 of OECD ESD No. 14).

Where Nlapp_arab is the default number of manure applications for arable land (1 applications).

- **Estimation of PEC soil after one manure application on arable land and four manure applications on grassland with degradation.**

Following section 3.3 of Addendum OECD ESD No. 14, PIEC soil for grassland is calculated by considering degradation process of the substance in soil. To do it the following intermediate equations are followed:

$Kdeg_{soil}$ = Ln(2) / DT50_biosoil (eq. 6 OECD ESD No.14)

$Fsoil_{grass} = (1- (e^{-Kdegsoil \times Tgr\text{-}int})^{Nlapp\_grass}) / (1- e^{-Kdegsoil \times Tgr\text{-}int})$ (eq. 7a Addendum 2015 of OECD ESD No.14)

PIECgrass_4_degr-N = PIECgrass_4-N x $Fsoil_{grass}$ (eq. 9 of OECD ESD No.14, considering the eq.24b Addendum 2015 OECD ESD No.14)

For PIEC of arable land, similar process has been carried on:

$Fsoil_{arab} = (1- (e^{-Kdegsoil \times Tar\text{-}int})^{Nlapp\_arab}) / (1- e^{-Kdegsoil \times Tar\text{-}int})$ (eq. 8 from OECD ESD No.14)

$PIECarab\_degr\text{-}N = PIECarab\_N \times Fsoil_{arab}$ (eq. 9 from OECD ESD No.14)

- **Estimation of PEC soil after 10 year consecutive application, degradation in soil included.**

For **arable land**, the initial concentration in soil of arable land after 10 years of manure application, taking degradation into account has been estimated according to Section 3.4 of Addendum 2015 of OECD ESD No.14.

$Fsoil_{ars\_10} = (1-(e^{(-kbio\_soil \times Tar\_int\_10)Nlapp\_arab\_10}))/(1-e^{(-kbio\_soil*Tar\_int\_10)})$ (eq.8a Addendum 2015 of OECD ESD No.14)

Where $Fsoil_{ars\_10}$ is the fraction of active remaining in arable soil after 10 year of manure application.

Then according to updated eq. 25 of Addendum 2015 of OECD ESD No.14, the initial concentration in soil of arable land after 10 years of manure application, taking degradation into account (PIECars_10_degr-N) is estimated:

$PIECars\_10\_degr\text{-}N = PIECars\text{-}N \times Fsoil_{ars\_10}$ (eq. 25a Addendum 2015 of OECD ESD No.14)

For **grassland**, the initial concentration in soil of grassland after 10 years of manure application, taking degradation into account has been estimated according to Section 3.5 of Addendum 2015 of OECD ESD No.14.

In this case, an interval of 206 days between last (of four) manure application and the first application of a new series (Tgr_int_NoManure) is taken into account.

The fraction of substance remaining in grassland soil, after 365 days after the first (of four) manure spreading events (Fsoilgrs2) is estimated according to eq.35 of Section 3.5 at Addendum 2015 OECD ESD No.14:

$Fsoil_{grs2} = e^{-Kdegsoil \times Tgr\text{-}int\_NoManure}$ (eq.35 Addendum 2015 OECD ESD No.14)

PIECgrs10_degr-N is estimated according eq.36 form Addendum 2015 OECD ESD No.14:

$$PIECgrs_{10\_degr} - N_{i1,i2,i3,i4} = PIECgrs_{4\_degr} - N_{i1,i2,i3,i4} \cdot \left[1 + \sum_{n=1}^{9} Fsoil_{grs2}{}^{n}\right]$$

- **Estimation of PEC groundwater.**

The concentration in porewater is used for the initial groundwater assessment. The PEC in porewater is calculated from PIECgrs10_degr–Ni1,i2,i3,i4 using TGD equations for equilibrium partitioning. These equations are also applied in the ESD for PT18 in Equations 26 – 29. The appropriate equation here is shown for reasons of clarity:

$$PIECgrs_{10\_degr} \text{ - gw - } N_{i1,i2,i3,i4} = \frac{PIECgrs_{10\_degr} - N_{i1,i2,i3,i4} * RHOsoil_{wet}}{K_{soil\text{-}water} * 1000}$$

- **Estimation of PEC surface water.**

The concentration in surface water used for the initial assessment is calculated by dividing PIECgrs10_degr–gw–Ni1,i2,i3,i4 by a dilution factor of 10. This is represented by Equation 27 from the ESD, in which DILUTION run-off is set to a value of 10.

- **Estimation of PEC sediment.**

The concentration in surface water used for the initial assessment is calculated according to equation 50 from chapter 2.3.8.4 of BPR IV-ENV part B (2015).

$$PEClocal_{sed} = \frac{K_{susp\text{-}water}}{RHO_{susp}} \cdot PEClocal_{water} \cdot 1000$$

The following tables, shows the outputs obtained for each substance at scenario [1]:

- **for the emission pathway via manure/slurry**

type of housing	Fraction to the manure	Area	Volume	Number of animals	Nitrogen production/animal	Number of biocides application during manure storage period		Number of prescribed maximum repeated biocides treatments according to information given by the applicant	Amount of active ingredient to be used in housing or manure storage for one application	Amount to the manure after one application	Amount of ai discharged to the soil over the manure's storage period.		Nitrogen production during the manure storage period	
	Fslurry/manure			Nanimal	Qnitrog	Napp-manure		$Napp_{prescr}$	Qai_prescri	Qai	Qai-grass	Qai-arab	Qnitrog-grass	Qnitrog-arab
	(-)	m²	m³	(-)	kg	(-)		(-)	kg	kg	kg	kg	kg	kg
						grass	arable				grass	arable	grass	arable
Dairy cows	0.50	1170	9630	100	3.39E-01	1	1	1	5.85E-02	2.93E-02	2.93E-02	2.93E-02	1796	7185
Beef cattle	0.50	370	3063	125	2.88E-01	1	3	3	1.85E-02	9.25E-03	9.25E-03	2.78E-02	1909	7637
Veal calves	0.50	160	590	80	2.38E-02	1	3	3	8.00E-03	4.00E-03	4.00E-03	1.20E-02	101	404
Sows, in individual pens	0.50	560	1960	132	7.11E-02	1	1	1	2.80E-02	1.40E-02	1.40E-02	1.40E-02	497	1989
Sows in groups	0.50	710	2480	132	7.11E-02	1	1	1	3.55E-02	1.78E-02	1.78E-02	1.78E-02	497	1989
Fattening pigs	0.50	600	2110	400	3.04E-02	1	1	1	3.00E-02	1.50E-02	1.50E-02	1.50E-02	645	2580
Laying hens in battery cages without treatment	0.50	750	2810	21000	2.02E-03	1	3	3	3.75E-02	1.88E-02	1.88E-02	5.63E-02	2248	8993
Laying hens in battery cages with aeration (belt drying)	0.50	750	2810	21000	1.81E-03	1	3	3	3.75E-02	1.88E-02	1.88E-02	5.63E-02	2015	8058
Laying hens in batters cages with forced drying (deep pit, high rise)	0.80	750	2810	21000	1.81E-03	1	3	3	3.75E-02	3.00E-02	3.00E-02	9.00E-02	2015	8058
Laying hens in compact battery cages	0.50	750	2810	21000	1.81E-03	1	1	1	3.75E-02	1.88E-02	1.88E-02	1.88E-02	2015	8058
Laying hens in free range with litter floor (partly litter floor, partly slatted)	0.30	1430	5360	10000	1.71E-03	1	3	3	7.15E-02	2.15E-02	2.15E-02	6.44E-02	906	3625
Broilers in free range with litter floor	0.30	1110	4170	20000	1.56E-03	1	3	2	5.55E-02	1.67E-02	1.67E-02	5.00E-02	1654	6614
Laying hens in free range with grating floor (aviary system)	0.50	1270	4780	20000	1.71E-03	1	3	3	6.35E-02	3.18E-02	3.18E-02	9.53E-02	1813	7250
Parent broilers in free range with grating floor	0.50	390	1458	7000	2.98E-03	1	3	2	1.95E-02	9.75E-03	9.75E-03	2.93E-02	1106	4422
Parent broilers in rearing with grating floor	0.50	500	1880	9000	1.37E-03	1	3	2	2.50E-02	1.25E-02	1.25E-02	3.75E-02	653	2614
Turkeys in free range with litter floor	0.30	3330	12500	10000	4.82E-03	1	3	3	1.67E-01	5.00E-02	5.00E-02	1.50E-01	2555	10218
Geese in free range with litter floor	0.30	2500	9380	10000	4.82E-03	1	3	3	1.25E-01	3.75E-02	3.75E-02	1.13E-01	2555	10218
Ducks in free range with litter floor	0.30	2000	7500	10000	2.74E-03	1	3	3	1.00E-01	3.00E-02	3.00E-02	9.00E-02	1452	5809
Reference										formula 14	formula 16	formula 17	formula 20	formula 21

type of housing	ESD Addendum 2015 3.2 PIECsoil,grassland, four manure application events, no degradation (equation 24a)	PECsoil and PEC/PNEC after one manure application on arable or four manure applications on grassland Without degradation					PECsoil and PEC/PNEC after one manure application on arable or four manure applications on grassland With degradation					PECsoil and PEC/PNEC after 10 year consecutive appliaction, degradation in soil included				
	PIECgrass4-N	based on nitrogen immision standards					based on nitrogen immision standards					based on nitrogen immision standards				
	mg/kg	PIEC (mg/kg wwt)		risk ratio			PIEC (mg/kg wwt)		risk ratio			PIEC (mg/kg wwt)		risk ratio		
	grass	grass	arable	grass	arable	max	grass	arable	grass	arable	RCRmax	grass	arable	grass	arable	RCRmax
Dairy cows	3.26E-03	8.14E-04	2.04E-04	9.23E-04	2.31E-04	9.23E-04	8.14E-04	2.04E-04	9.23E-04	2.31E-04	9.23E-04	8.14E-03	9.08E-37	9.23E-03	1.03E-36	9.23E-03
Beef cattle	9.69E-04	7.27E-04	1.82E-04	8.24E-04	2.06E-04	8.24E-04	7.27E-04	1.82E-04	8.24E-04	2.06E-04	8.24E-04	7.27E-03	8.10E-37	8.24E-03	9.18E-37	8.24E-03
Veal calves	7.92E-03	5.94E-03	1.49E-03	6.74E-03	1.68E-03	6.74E-03	5.94E-03	1.49E-03	6.74E-03	1.68E-03	6.74E-03	5.94E-02	6.62E-36	6.73E-02	7.51E-36	6.73E-02
Sows, in individual pens	5.63E-03	1.41E-03	3.52E-04	1.60E-03	3.99E-04	1.60E-03	1.41E-03	3.52E-04	1.60E-03	3.99E-04	1.60E-03	1.41E-02	1.57E-36	1.60E-02	1.78E-36	1.60E-02
Sows in groups	7.14E-03	1.79E-03	4.46E-04	2.02E-03	5.06E-04	2.02E-03	1.79E-03	4.46E-04	2.02E-03	5.06E-04	2.02E-03	1.78E-02	1.99E-36	2.02E-02	2.26E-36	2.02E-02
Fattening pigs	4.65E-03	1.16E-03	2.91E-04	1.32E-03	3.30E-04	1.32E-03	1.16E-03	2.91E-04	1.32E-03	3.30E-04	1.32E-03	1.16E-02	1.30E-36	1.32E-02	1.47E-36	1.32E-02
Laying hens in battery cages without treatment	1.67E-03	1.25E-03	3.13E-04	1.42E-03	3.55E-04	1.42E-03	1.25E-03	3.13E-04	1.42E-03	3.55E-04	1.42E-03	1.25E-02	1.39E-36	1.42E-02	1.58E-36	1.42E-02
Laying hens in battery cages with aeration (belt drying)	1.86E-03	1.40E-03	3.49E-04	1.58E-03	3.96E-04	1.58E-03	1.40E-03	3.49E-04	1.58E-03	3.96E-04	1.58E-03	1.40E-02	1.56E-36	1.58E-02	1.76E-36	1.58E-02
Laying hens in batters cages with forced drying (deep pit, high rise)	2.98E-03	2.23E-03	5.58E-04	2.53E-03	6.33E-04	2.53E-03	2.23E-03	5.58E-04	2.53E-03	6.33E-04	2.53E-03	2.23E-02	2.49E-36	2.53E-02	2.82E-36	2.53E-02
Laying hens in compact battery cages	1.86E-03	4.65E-04	1.16E-04	5.28E-04	1.32E-04	5.28E-04	4.65E-04	1.16E-04	5.28E-04	1.32E-04	5.28E-04	4.65E-03	5.19E-37	5.28E-03	5.88E-37	5.28E-03
Laying hens in free range with litter floor (partly litter floor, partly slatted)	4.73E-03	3.55E-03	8.88E-04	4.03E-03	1.01E-03	4.03E-03	3.55E-03	8.88E-04	4.03E-03	1.01E-03	4.03E-03	3.55E-02	3.96E-36	4.02E-02	4.49E-36	4.02E-02
Broilers in free range with litter floor	2.01E-03	1.01E-03	3.78E-04	1.14E-03	4.28E-04	1.14E-03	1.01E-03	3.78E-04	1.14E-03	4.28E-04	1.14E-03	1.01E-02	1.68E-36	1.14E-02	1.91E-36	1.14E-02
Laying hens in free range with grating floor (aviary system)	3.50E-03	2.63E-03	6.57E-04	2.98E-03	7.45E-04	2.98E-03	2.63E-03	6.57E-04	2.98E-03	7.45E-04	2.98E-03	2.63E-02	2.93E-36	2.98E-02	3.32E-36	2.98E-02
Parent broilers in free range with grating floor	1.76E-03	8.82E-04	3.31E-04	1.00E-03	3.75E-04	1.00E-03	8.82E-04	3.31E-04	1.00E-03	3.75E-04	1.00E-03	8.82E-03	1.47E-36	1.00E-02	1.67E-36	1.00E-02
Parent broilers in rearing with grating floor	3.83E-03	1.91E-03	7.17E-04	2.17E-03	8.13E-04	2.17E-03	1.91E-03	7.17E-04	2.17E-03	8.13E-04	2.17E-03	1.91E-02	3.20E-36	2.17E-02	3.63E-36	2.17E-02
Turkeys in free range with litter floor	3.91E-03	2.93E-03	7.33E-04	3.33E-03	8.31E-04	3.33E-03	2.93E-03	7.33E-04	3.33E-03	8.31E-04	3.33E-03	2.93E-02	3.27E-36	3.32E-02	3.71E-36	3.32E-02
Geese in free range with litter floor	2.94E-03	2.20E-03	5.50E-04	2.50E-03	6.24E-04	2.50E-03	2.20E-03	5.50E-04	2.50E-03	6.24E-04	2.50E-03	2.20E-02	2.45E-36	2.50E-02	2.78E-36	2.50E-02
Ducks in free range with litter floor	4.13E-03	3.10E-03	7.75E-04	3.51E-03	8.78E-04	3.51E-03	3.10E-03	7.75E-04	3.51E-03	8.78E-04	3.51E-03	3.10E-02	3.45E-36	3.51E-02	3.92E-36	3.51E-02
Reference	formula 24a	formula 24a + ENV162	formula 25										Equation 25a - page 12.			

type of housing	based on nitrogen immision standards	based on nitrogen immision standards	PIEC surface water (mg/L) for grassland	Risk ratio surfacewater	PIEC surface water (mg/L) for arable land	Risk ratio surfacewater	PIEC sediment (mg/kg dwt) for grassland	Risk ratio sediment	PIEC sediment (mg/kg dwt) for arable land	Risk ratio sediment
	PIEC groundwater (µg/L)	PIEC groundwater (µg/L)								
	Grassland	Arable	derived from surfacewater by using an AF of 10		derived from surfacewater by using an AF of 10		equation (50) chapter 2.3.8.4, Guidance BPR IV ENV B(2015)		equation (50) chapter 2.3.8.4, Guidance BPR IV ENV B(2015)	
Dairy cows	6.04E-03	6.74E-37	6.04E-07	0.13	1.51E-08	0.00	1.00E-03	**1.03**	2.51E-05	0.03
Beef cattle	5.39E-03	6.01E-37	5.39E-07	0.11	1.35E-08	0.00	8.95E-04	0.92	2.24E-05	0.02
Veal calves	4.41E-02	4.92E-36	4.41E-06	0.92	1.10E-07	0.02	7.32E-03	**7.48**	1.83E-04	0.19
Sows, in individual pens	1.04E-02	1.16E-36	1.04E-06	0.22	2.61E-08	0.01	1.73E-03	**1.77**	4.34E-05	0.04
Sows in groups	1.32E-02	1.48E-36	1.32E-06	0.28	3.31E-08	0.01	2.20E-03	**2.25**	5.50E-05	0.06
Fattening pigs	8.63E-03	9.62E-37	8.63E-07	0.18	2.16E-08	0.00	1.43E-03	**1.46**	3.58E-05	0.04
Laying hens in battery cages without treatment	9.28E-03	1.03E-36	9.28E-07	0.19	2.32E-08	0.00	1.54E-03	**1.58**	3.85E-05	0.04
Laying hens in battery cages with aeration (belt drying)	1.04E-02	1.16E-36	1.04E-06	0.22	2.59E-08	0.01	1.72E-03	**1.76**	4.30E-05	0.04
Laying hens in batters cages with forced drying (deep pit, high rise)	1.66E-02	1.85E-36	1.66E-06	0.35	4.14E-08	0.01	2.75E-03	**2.81**	6.88E-05	0.07
Laying hens in compact battery cages	3.45E-03	3.85E-37	3.45E-07	0.07	8.63E-09	0.00	5.73E-04	0.59	1.43E-05	0.01
Laying hens in free range with litter floor (partly litter floor, partly slatted)	2.63E-02	2.94E-36	2.63E-06	0.55	6.59E-08	0.01	4.37E-03	**4.47**	1.09E-04	0.11
Broilers in free range with litter floor	7.47E-03	1.25E-36	7.47E-07	0.16	2.80E-08	0.01	1.24E-03	**1.27**	4.65E-05	0.05
Laying hens in free range with grating floor (aviary system)	1.95E-02	2.17E-36	1.95E-06	0.41	4.88E-08	0.01	3.24E-03	**3.31**	8.09E-05	0.08
Parent broilers in free range with grating floor	6.54E-03	1.09E-36	6.54E-07	0.14	2.45E-08	0.01	1.09E-03	**1.11**	4.08E-05	0.04
Parent broilers in rearing with grating floor	1.42E-02	2.37E-36	1.42E-06	0.30	5.32E-08	0.01	2.36E-03	**2.41**	8.84E-05	0.09
Turkeys in free range with litter floor	2.18E-02	2.43E-36	2.18E-06	0.45	5.44E-08	0.01	3.61E-03	**3.70**	9.04E-05	0.09
Geese in free range with litter floor	1.63E-02	1.82E-36	1.63E-06	0.34	4.09E-08	0.01	2.71E-03	**2.77**	6.78E-05	0.07
Ducks in free range with litter floor	2.30E-02	2.56E-36	2.30E-06	0.48	5.75E-08	0.01	3.82E-03	**3.90**	9.55E-05	0.10
Reference	formula 26		formula 27				equation (50) chapter 2.3.8.4, Guidance BPR IV ENV B(2015)		equation (50) chapter 2.3.8.4, Guidance BPR IV ENV B(2015)	

- **for the emission pathway via STP**

type of housing	Fraction to STP		ELOCAL_WWTP						
	Fwastewater	Qai_prescri	Amount of a.i. reaching STP	EFFLUENT SPT	Clocal_inf	PECstp	RCR STP	Fstp_water (fraction of emission directed to water by STP)	Fstp_sludge (fraction of emission directed to sludge by STP)
	(-)	kg	kg.d-1	[l.d-1]	[mg.l-1]	[mg.l-1]		[-]	[-]
Dairy cows	0.00	5.85E-02	-	2E+06	-	-	-	0.09754	0.2916
Beef cattle	0.00	1.85E-02	-	2E+06	-	-	-	0.09754	0.2916
Veal calves	0.00	8.00E-03	-	2E+06	-	-	-	0.09754	0.2916
Sows, in individual pens	0.00	2.80E-02	-	2E+06	-	-	-	0.09754	0.2916
Sows in groups	0.00	3.55E-02	-	2E+06	-	-	-	0.09754	0.2916
Fattening pigs	0.00	3.00E-02	-	2E+06	-	-	-	0.09754	0.2916
Laying hens in battery cages without treatment	0.00	3.75E-02	-	2E+06	-	-	-	0.09754	0.2916
Laying hens in battery cages with aeration (belt drying)	0.20	3.75E-02	7.50E-03	2E+06	0.004	0.004	3.75E-05	0.09754	0.2916
Laying hens in batters cages with forced drying (deep pit, high rise)	0.00	3.75E-02	-	2E+06	-	-	-	0.09754	0.2916
Laying hens in compact battery cages	0.00	3.75E-02	-	2E+06	-	-	-	0.09754	0.2916
Laying hens in free range with litter floor (partly litter floor, partly slatted)	0.20	7.15E-02	1.43E-02	2E+06	0.007	0.007	7.15E-05	0.09754	0.2916
Broilers in free range with litter floor	0.20	5.55E-02	1.11E-02	2E+06	0.006	0.006	5.55E-05	0.09754	0.2916
Laying hens in free range with grating floor (aviary system)	0.00	6.35E-02	-	2E+06	-	-	-	0.09754	0.2916
Parent broilers in free range with grating floor	0.00	1.95E-02	-	2E+06	-	-	-	0.09754	0.2916
Parent broilers in rearing with grating floor	0.00	2.50E-02	-	2E+06	-	-	-	0.09754	0.2916
Turkeys in free range with litter floor	0.20	1.67E-01	3.33E-02	2E+06	0.017	0.017	1.67E-04	0.09754	0.2916
Geese in free range with litter floor	0.20	1.25E-01	2.50E-02	2E+06	0.013	0.013	1.25E-04	0.09754	0.2916
Ducks in free range with litter floor	0.20	1.00E-01	2.00E-02	2E+06	0.010	0.010	1.00E-04	0.09754	0.2916
Reference			formula 34 (ENV/JM/MONO(2006)4		equation 32, chapter 2.3.7.1, Guidance BPR IV ENV B (2015)	equation 38, Guidance BPR IV ENV B (2015)		Obtained from Simple treat	

type of housing	Clocal_eff	PECsw	RCR SW	PECsed	RCR Sed	Csludge	$Csludge_{soil10}$	PEClocalsoil	RCR Soil	PEClocalgroundwater
	[mg.l-1]	[mg.l-1]		mg.kgdt		[mg.kg-1]	[mg.kg-1]	[mg.kg-1]		[µg.L-1]
Dairy cows	-	-	-	-	-	-	-	-	-	-
Beef cattle	-	-	-	-	-	-	-	-	-	-
Veal calves	-	-	-	-	-	-	-	-	-	-
Sows, in individual pens	-	-	-	-	-	-	-	-	-	-
Sows in groups	-	-	-	-	-	-	-	-	-	-
Fattening pigs	-	-	-	-	-	-	-	-	-	-
Laying hens in battery cages without treatment	-	-	-	-	-	-	-	-	-	-
Laying hens in battery cages with aeration (belt drying)	3.66E-04	3.28E-05	6.84	5.45E-02	55.72	3.64E-03	3.64E-02	3.64E-02	4.12E-02	2.70E-02
Laying hens in batters cages with forced drying (deep pit, high rise)	-	-	-	-	-	-	-	-	-	-
Laying hens in compact battery cages	-	-	-	-	-	-	-	-	-	-
Laying hens in free range with litter floor (partly litter floor, partly slatted)	6.97E-04	6.26E-05	13.04	1.04E-01	106.24	6.95E-03	6.94E-02	6.94E-02	7.86E-02	5.15E-02
Broilers in free range with litter floor	5.41E-04	4.86E-05	10.12	8.07E-02	82.47	5.39E-03	5.38E-02	5.38E-02	6.10E-02	0.04
Laying hens in free range with grating floor (aviary system)	-	-	-	-	-	-	-	-	-	-
Parent broilers in free range with grating floor	-	-	-	-	-	-	-	-	-	-
Parent broilers in rearing with grating floor	-	-	-	-	-	-	-	-	-	-
Turkeys in free range with litter floor	1.62E-03	1.46E-04	30.36	2.42E-01	247.40	1.62E-02	1.62E-01	1.62E-01	1.83E-01	1.20E-01
Geese in free range with litter floor	1.22E-03	1.09E-04	22.79	1.82E-01	185.73	1.21E-02	1.21E-01	1.21E-01	1.37E-01	9.00E-02
Ducks in free range with litter floor	9.75E-04	8.75E-05	18.23	1.45E-01	148.59	9.72E-03	9.70E-02	9.70E-02	1.10E-01	7.20E-02
Reference	equation 33, chapter 2.3.7.1, Guidance BPR IV ENV B (2015)	equation 45 Guidance BPR IV ENV B (2015) PECsw = Clocal_water		equation 50 Guidance BPR IV ENV B (2015)		equation 39 Guidance BPR IV ENV B (2015)		equation 55 and 66 Guidance BPR IV ENV B (2015)		equation 56 Guidance BPR IV ENV B (2015)

Simple Treat 4.0 outputs:

Simple Treat_MASSOCIDE AD

3.3 New information on the active substance

Not available

3.4 Residue behaviour

Not available

3.5 Summaries of the efficacy studies (B.5.10.1-xx)[3]

See summary table of efficacy tests. section 2.2.5.5.

3.6 Confidential annex

Please, see confidential PAR.

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

3.7 Other

3.7.1 Granulometric data for raw materials

3.7.1.1 Carrier

Calcium carbonate used , is obtained from natural sources (mineral extraction) from a carbonate disposed located very close of MASSO´s manufacturer plant. It is a micronized material , not nano.

Reverté
CARBONATOS DE CALCIO

ESPECIFICACIÓN DE PRODUCTO

BL50

REF. ESPECIFICACION: DTE/LAB/10.21 FECHA EDICION: 06-00 REV.2

PRODUCTO: CARBONATO CALCIO MICRONIZADO

PARAMETROS DE LA ESPECIFICACIÓN

GRANULOMETRIA	VALOR	METODO ANALÍTICO
Diámetro medio estadístico D(43)	9.0 ± 2.0 µm	MASTERSIZER S
Rechazo al tamíz de 45 µm	< 0.01 %	ISO 787R/7 (81)
Rechazo al tamíz de 200 µm	< 0 %	ISO 787R/7 (81)

BLANCURA	SECO	DOP	METODO ANALÍTICO
L	96.0 ± 1.0	74.0 ± 3.0	SPECTRAFLASH SF450
a	-0.35 ± 0.2	-0.9 ± 1.6	SPECTRAFLASH SF450
b	4.5 ± 0.8	12 ± 3.0	SPECTRAFLASH SF450

DATOS TÉCNICOS (1)

TEST	VALOR	METODO ANALÍTICO
HUMEDAD	<0.1%	ISO 787R/2(81)
ABSORCIÓN DE ACEITE	18g/100g $CaCO_3$	ISO 787R/5 (81)
ABSORCIÓN DE DOP	30g/100g $CaCO_3$	ISO 787R/5 (81)
PH (SOL. ACUOSA 10%)	9	ISO 787R/9 (81)
DENSIDAD APARENTE	1Kg/l	ISO 787R/11 (81)
ÁREA SUPERFICIAL	1.4 m^2/g	GEMINI (B.E.T)

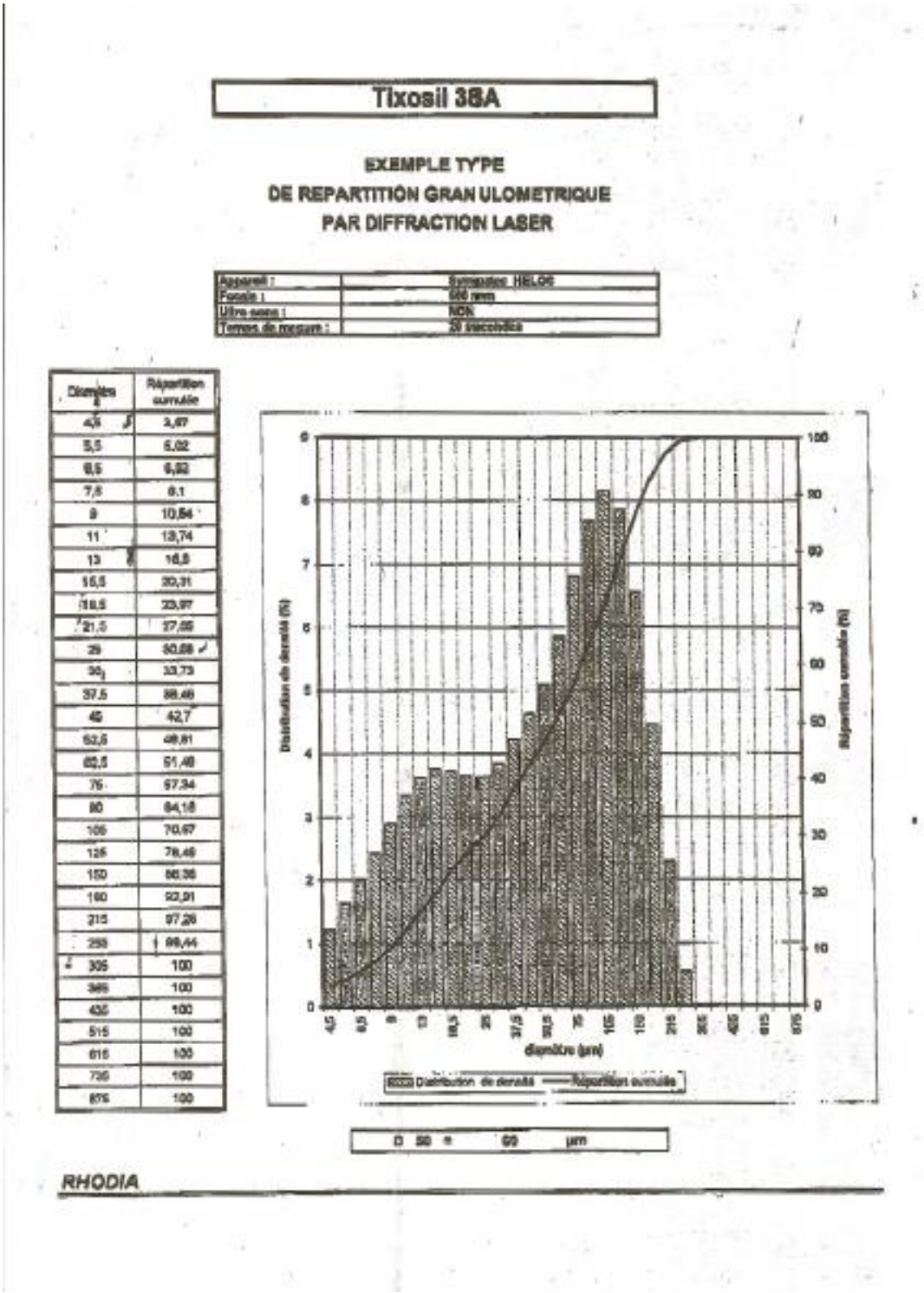
COMPOSICION QUÍMICA (1)

SUSTANCIA	VALOR	METODO ANALÍTICO
$CaCO_3$	98.96%	I.C.P.
$MgCO_3$	0.59%	I.C.P.
Fe_2O_3	0.044%	I.C.P.

(1) Estos resultados corresponden a valores promedio.

3.7.1.2 Absorbent

Tixosil 38 A is an amorphous synthetic silicon dioxide which acts as absorbent /dispersant agent to help in the homogenization process to guarantee the uniform distribution of the Active ingredient within the product. This product is not nano material, with a median particle size of 50 µm



Tixosil 38A

EXEMPLE TYPE
DE REPARTITION GRANULOMETRIQUE
PAR DIFFRACTION LASER

Appareil :	Sympatec HELOS
Fonde :	632 nm
Ultra-sons :	NON
Temps de mesure :	30 secondes

Diamètre	Répartition cumulée
4,5	3,87
5,5	5,02
6,5	6,32
7,5	8,1
9	10,84
11	13,74
13	16,8
15,5	20,31
18,5	23,97
21,5	27,66
25	30,88
30	33,73
37,5	38,46
45	42,7
52,5	46,81
62,5	51,48
75	57,34
90	64,18
105	70,67
125	78,46
150	86,36
180	93,91
215	97,26
255	99,44
305	100
365	100
435	100
515	100
615	100
735	100
875	100

RHODIA

3.7.1.3 Endocrine Disruptor assessment

Monday, 17 August 2020

Endocrine Disruptor Certificate

Whom may concern

According to CLP classification and product's formulation no further substances of concern than the active substance has been identified in MASSOCIDE AD 0.4 formulation.

Following active substance's CAR, Alpha-cypermethrin has not been shown to have toxic effect on endocrine organs and has not been identified as having endocrine disrupting properties, non of the other ingredients are considered to pose any risk or have any potential endocrine system effect they are inorganic carriers with a low bioavailability potential.

Any of the ingredients present in MASSOCIDE AD04 is the ECHA´s **Endocrine disruptor assessment list published on ECHA´s Website .** ECHA's endocrine disruptor (ED) assessment list includes the substances undergoing an ED assessment under REACH or the Biocidal Products Regulation that have been brought for discussion to ECHA's ED Expert Group.

Non of the substances present in MASSOCIDE AD04 have neither similar profile nor chemical structure equivalent to the 93 substances included in the above list , that may lead any potential endocrine disruption properties

COMERCIAL QUMICA MASSO , SA
FDO. Rosana MARIN

Rosana Marin Sanchez

Regulatory Affairs Manager