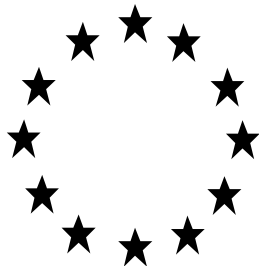
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



FUMICIDE DM

Product type PT18

Deltamethrin as included in the Union list of approved active substances

Case Number in R4BP: BC-SS001500-35

Evaluating Competent Authority: Austria

02/03/2022 (Final)

Public Version

Table of Contents

1 CONCLUSION

Austria was the Competent Authority responsible for evaluation of the biocidal product FUMICIDE DM.

The ready-to-use product FUMICIDE DM is a FU Smoke generator which contains 2.4%(w/w) of the active substance deltamethrin. The following substances of concern were identified: basic copper carbonate and synthetic amorphous silicon dioxide (nano), ammonium nitrate.

The assessment considered:

- The conclusions and recommendations of the Assessment Report for the approval of the active substance deltamethrin including the "elements to be taken into account by Member States when authorising products"
- The specific provisions from Inclusion Directive for the active substance deltamethrin (Inclusion Dir. No 2011/81/EU).

Approval of the active substance:
The active substance deltamethrin is included in the Union list of approved active substances and the specific provisions laid down there are fulfilled:

- When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, where relevant for the particular product, those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment.
- Products shall not be authorised for indoor treatments resulting in sewage treatment plant emissions of the scale for which the Union level risk assessment showed unacceptable risks, unless data are submitted demonstrating that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures.

The field of use is as follows: Indoor use

Target organsims:
Target insects in Domestic premises:
German cockroach (*Blattella germanica*), Oriental cockroach (*Blatta orientalis*), aedes mosquitoe *(Aedes albopictus)*, house dust mites (*Dermatophagoides pteronyssinus*), house spider *(Tegenaria domestica)*, cat flea (*Ctenocephalides felis*), bed bug (*Cimex lectularius*), house fly (*Musca domestica*), hornets (*Vespa crabro*), woodlice (*Armadillidium vulgare*);

Target insects in breeding premises:
Poultry red mite (*Dermanyssus gallinae*), dermestre hide beetle (*Dermestes maculatus*), lesser mealworm (*Alphitobius diaperinus*), German cockroach (*Blattella germanica*), Oriental cockroach *(Blatta orientalis);*

Categories of user: Professionals;

Identity and analytical methods were described in sufficient detail to meet the information requirements as laid down in annex II of regulation (EU) no. 528/2012. The physical-chemical properties and respective characteristics of the biocidal product have been evaluated and are deemed acceptable for the appropriate use, storage and transport of the biocidal product.

Based on the authorised use including the general directions of use and any possibly defined risk mitigation measures and provided that there will be no misuse, the following can be concluded:

- Data on the biocidal product have demonstrated sufficient efficacy against the specific target organisms within the authorised uses, according to the respective application rates, application time and frequency.
- The biocidal product has no immediate or delayed unacceptable effects itself, or as a result of its residues, on the health of humans, including that of vulnerable groups or animals, directly or through drinking water, food, feed, air, or through other indirect effects.
- Also for the environment, it could be demonstrated that the authorised uses are safe for all exposed environmental compartments and the assessment of secondary poisoning has shown that no adverse effects for birds and mammals are to be expected.

The product contains no active substances which are candidates for substitution.

It can be concluded that the conditions of article 19 1) to 4) of regulation (EU) no. 528/2012 are fulfilled and that the product may be authorised.

The biocidal product will be authorised for a period of 10 years in accordance with Article 17(4) of Regulation (EU) No 528/2012.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier	**Country (if relevant)**
FUMICIDE DM	AUSTRIA

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	SHARDA EUROPE BVBA
	Address	Jozef Mertensstraat 142, 1702 Dilbeek, Belgium
Authorisation number	AT-0002046-0000	
Date of the authorisation	See authorisation letter.	
Expiry date of the authorisation	See authorisation letter.	

2.1.1.3 Manufacturer of the product

Name of manufacturer	LCB food safety S.A.S.
Address of manufacturer	P.A.E. ACTIPARC, Rue des acacias, 01190 – Boz France
Location of manufacturing sites	P.A.E. ACTIPARC, Rue des acacias, 01190 – Boz France

2.1.1.4 Manufacturer of the active substance

Active substance	deltamethrin
Name of manufacturer	Sharda Cropchem Ltd.
Address of manufacturer	Dominic Holm, 29th Road, Bandra (w), Mumbai-400050-INDIA
Location of manufacturing sites	Dominic Holm, 29th Road, Bandra (w), Mumbai-400050-INDIA

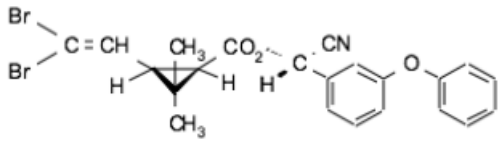
2.1.2 Product composition and formulation

The full qualitative and quantitative composition of the product according to Annex III Title 1 is 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	deltamethrin
IUPAC or EC name	(S)-α-cyano-3-phenoxybenzyl (1R,3R)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropane carboxylate
EC number	258-256-6
CAS number	52918-63-5
Index number in Annex VI of CLP	607-319-00-X
Minimum purity / content	>98.5%
Structural formula	

2.1.2.2 Candidate(s) for substitution

The active substance deltamethrin is not a candidate for substitution.

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

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (% w/w)**
Deltamethrin	(S)-α-cyano-3-phenoxybenzyl (1R,3R)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropane carboxylate	Active substance	52918-63-5	258-256-6	2.4
Ammonium nitrate	Ammonium nitrate	Oxidiser	6484-52-2	229-347-8	40.0
Basic copper carbonate	Copper(II) carbonate-copper(II) hydroxide (1:1)	Non-active substance Catalyst	12069-69-1	235-113-6	1.0
Synthetic amorphous silicon dioxide	Silicon dioxide (amorphous) (nano)	Adsorbent	112926-00-8	231-545-4	14.0

The full composition of the product as well as detailed description of the smoke generator is provided in the confidential annex.

2.1.2.4 Information on technical equivalence

Is the source of deltamethrin the same as the one evaluated in connection with the approval for listing of the active substance on the Union list of approved active substances under Regulation (EU) No 528/2012?

Yes ☐
No ☒

The source has been subject to an assessment of technical equivalence and has been found to be technically equivalent (TE-APP asset number: EU-0003361-0000).

2.1.2.5 Information on the substance(s) of concern

In the biocidal product basic copper carbonate and synthetic amorphous silicon dioxide (nano) were identified as substances of concern (SoCs) for the environment and for human health.
Additionally, ammonium nitrate was identified in the biocidal product as SoC in relation to physical and chemical hazards.
Please see Annex 3.6 for further information.

2.1.2.6 Type of formulation

FU Smoke generator

2.1.3 Hazard and precautionary statements

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

Classification	Self React. Type D, H242 Oxid. Solid 3, H272 Aquatic Acute 1, H400 Aquatic Chronic 1, H410		
Labelling	**Pictograms**		
	GHS02	GHS03	GHS09
			
Signal words	Danger		
Hazard statements	H242: Heating may cause a fire. H272: May intensify fire; oxidizer. H400: Very toxic to aquatic life. H410: Very toxic to aquatic life with long lasting effects.		
Precautionary statements	P102: Keep out of reach of children. P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P220: Keep away from clothing and other combustible materials. P234: Keep only in original packaging. P273: Avoid release to the environment. P391: Collect spillage. P403+P235: Store in a well-ventilated place. Keep cool. P411: Store at temperatures not exceeding 30°C/86°F. P501: Dispose of contents/container in accordance to local/national regulations.		
Note	n.a.		

2.1.4 Authorised use(s)

2.1.4.1 Use description Use 1

Use # 1 – Insecticide, acaricide and product to control other arthropods – professional - air space treatment - indoor – domestic premises

Product Type	PT 18: Insecticides, acaricides and products to control other arthropods (pest control)
Where relevant, an exact description of the authorised use	Insecticides, acaricides and products to control other arthropods
Target organism (including development stage)	Scientific name: *Blattella germanica* Common name: German cockroach Development stage: Adults Scientific name: *Blatta orientalis* Common name: Oriental cockroach Development stage: Adults Scientific name: *Aedes albopictus* Common name: Aedes mosquitoes Development stage: Adults Scientific name: *Dermatophagoides pteronyssinus* Common name: House dust mites Development stage: Adults Scientific name: *Tegenaria domestica* Common name: House spider Development stage: Adults Scientific name: *Ctenocephalides felis* Common name: Cat flea Development stage: Adults and nymphs Scientific name: *Cimex lectularius* Common name: Bed bug Development stage: Adults Scientific name: *Musca domestica* Common name: House fly Development stage: Adults Scientific name: *Vespa crabro* Common name: hornets Development stage: Adults Scientific name: *Armadillidium vulgare* Common name: Woodlice Development stage: Adults
Field of use	Indoor – in rooms within domestic premises which are non-living areas (e.g. cellars; curative treatment only)
Application method(s)	Air space treatment by aerosols

Application rate(s) and frequency	**Application rates:** → 0.15 g b.p./m³ (3.6 mg a.s./m^3) – hornets (*Vespa crabro)* → 0.2 g b.p./m³ (4.8 mg a.s./m^3) – cat flea (*Ctenocephalides felis)* – bed bugs (*Cimex lectularius)* – house dust mites (*Dermatophagoides pteronyssinus)* – house spider (*Tegenaria domestica)* – aedes mosquitoes (*Aedes albopictus*) – woodlice (*Armadillidium vulgare*) → 0.5 g b.p./m^3 (12 mg a.s./m^3) – German cockroach *(Blattella germanica)* – Oriental cockroach *(Blatta orientalis)* – house flies *(Musca domestica*) **Number and timing of applications:** Perform maximal 2 applications/year with a minimum interval of 2 weeks between the treatments – cat flea (*Ctenocephalides felis),* (contact time 4h; adults and nymphs) – bed bugs (*Cimex lectularius),* (contact time 4h) – house dust mites (*Dermatophagoides pteronyssinus),* (contact time 4h) – house spider (*Tegenaria domestica),* (contact time 4h) – aedes mosquitoes *(Aedes albopictus)*, (contact time 4h) – hornets (*Vespa crabro),* (contact time 4h) – German cockroach *(Blattella germanica),* (contact time 1h) – Oriental cockroach *(Blatta orientalis),* (contact time 4h) – house flies *(Musca domestica),* (contact time 4h) – woodlice *(Armadillidium vulgare)*, (contact time 4h)
Category of users	Professional
Pack sizes and packaging material	Packaging material: Can/tin made of iron, coated with an internal varnish layer, consisting of an epoxy-phenolic resin; with an easy open cap with seal crimping. Packaging sizes: 20 g, 50 g, 100 g, 250 g, 500 g, 1000 g;

2.1.4.2 Use-specific instructions for use

- Only use the product in rooms which are non-living areas (e.g. cellars).
- Do not use the product directly on carpeting or linoleum.
- Keep any readily inflammable or combustible material (e.g. cloth, curtain, or other) outside a distance of 1.5 m from the can.
- After treatment, do not re-enter the room until a safety time of 60 hours has passed in case of treated premises where adequate ventilation is not possible. Otherwise, use the prescribed respiratory protective equipment (RPE) in order to enter the room and open windows and outside-doors for a minimum ventilation duration of 4 hours.
- If treated rooms are accessed with higher frequency or where people stay for longer durations of time, dry-cleaning is mandatory after treatment.

2.1.4.3 Use-specific risk mitigation measures

- The product is only for indoor use in non-living areas and to be strictly applied in dry-cleaned rooms (e.g. cellars).
- N-132, modified: Do not apply in rooms in which food or feed is stored, prepared or eaten.
- Remove items that could come in contact with food (e.g. dishes, tables), before starting the treatment.
- N-214, modified: All objects in the area to be treated must be protected from contamination by covering or removal.
- Covers shall be disposed of and shall not be cleaned with water after use. Dry cleaning methods (broom, vacuum cleaner) may be applied, if needed.
- Toodlers/children must not enter non-cleaned, treated areas.
- N-141: Do not use where release to drains (sewer) and/or surface water cannot be prevented.
- N-142, modified: Do not use where the biocidal product or its ashes can be discharged to municipal sewage treatment plant.
- N-38, modified: Dry-clean (broom or vacuum cleaner) treated area and dispose of residues (product and ashes) to hazardous solid waste in order to prevent releases to water.
- N-37, modified: Do not discharge the biocidal product, nor its residual ashes into the sewage system or the environment.

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

—

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

Covers may not be reused and shall be disposed of in accordance with local/national/international requirements.

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

---

2.1.4.7 Use description Use 2

Table 2. Use # 2 – Insecticide, acaricide and product to control other arthropods – professional – air space treatment - indoor – breeding premises

Product Type	PT 18: Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Insecticides, acaricides and products to control other arthropods
Target organism (including development stage)	Scientific name: *Dermanyssus gallinae* Common name: Poultry red mite Development stage: Adults Scientific name*: Dermestes maculatus* Common name: Dermestre hide beetle Development stage: Adults Scientific name: *Alphitobius diaperinus* Common name: Lesser mealworm Development stage: Adults Scientific name: *Blattella germanica* Common name: German cockroach Development stage: Adults Scientific name: *Blatta orientalis* Common name: Oriental cockroach Development stage: Adults
Field of use	Indoor – breeding premises only: Laying farms, chicken growing farms, fattening pigs and sows (curative treatment only)
Application method(s)	Air space treatment by aerosols
Application rate(s) and frequency	**Application rates:** → 1 g b.p./m^3 (24 mg a.s./m^3) – poultry red mites (*Dermanyssus gallinae)* – dermestre hide beetle (*Dermestes maculatus)* → 0.5 g b.p./m^3 (12 mg a.s./m^3) – German cockroach *(Blattella germanica)* – Oriental cockroach *(Blatta orientalis)* – lesser mealworm (*Alphitobius diaperinus)* **Number and timing of applications:** → 1 application per year

	– poultry red mites (*Dermanyssus gallinae)* (contact time 4h) → 7 applications/year with a 6-7 weeks interval between the treatments – dermestre hide beetle (*Dermestes maculatus),* (contact time 4h) – German cockroach *(Blattella germanica),* (contact time 1h) – Oriental cockroach *(Blatta orientalis)*, (contact time 4h), – lesser mealworm (*Alphitobius diaperinus),* (contact time 4h)
Category(ies) of users	Professional
Pack sizes and packaging material	Packaging material: Can/tin made of iron, coated with an internal varnish layer, consisting of an epoxy-phenolic resin; with an easy open cap with seal crimping. Packaging sizes: 20 g, 50 g, 100 g, 250 g, 500 g, 1000 g;

2.1.4.8 Use-specific instructions for use

• The product is suitable for curative treatment.

• Use the product at the end of a production cycle after animals left the stable. Leave manure and litter on the floor and start the aerosol treatment. Remove contaminated manure and litter after treatment when access to the stable is allowed. Then distribute fresh litter (cf. to general use instructions).

• Alternatively, at the end of a production cycle after animals left the stable, remove manure and litter before the start of the aerosol treatment. Access the stable when allowed (cf. to general use instructions), remove any dead insects from the floor and distribute fresh litter on the treated floor.

• If the room to be treated is in an EXAT-area (explosive atmosphere-area), evaluate the room's EXAT character and if necessary, temporarily suspend the EXAT character of the room by appropriate measure(s) during treatment.

• Keep any readily inflammable or combustible material (e.g. straw or other) outside a distance of 1.50 m from the can.

• N-6, modified: Do not use in animal housings (breeding premises) where exposure to a STP or direct emission to surface water cannot be prevented.

• N-88, modified: Do not use the b.p. where effluent/waste liquid from animal housing (breeding premises) and/or manure storage areas can be discharged to municipal sewage treatment plant or surface water.

• After treatment, provide adequate ventilation to renew the air for a minimum safety time of 4 hours. If you enter the room in order to switch on industrial ventilation, use the prescribed respiratory protective equipment (RPE).Alternatively, open windows and outside-doors for a safety time of 4 hours. In case ventilation is not carried out, do not re-enter the premises until a safety time of 60 hours has passed.

• N-37, modified: Do not discharge the biocidal product, nor its residual ashes into the sewage system or the environment.

• Use only for poultry (laying farms, chicken growing farms) or for fattening pigs and sows (breeding farms). Do not use for other livestock.

2.1.4.9 Use-specific risk mitigation measures

• N-47: Assure animals are not present in areas during air space treatment by aerosol.

• N-45 (modified): Remove all feed and drinking water prior to treatment.

• N-122: Cover all surfaces and facilities likely to be in contact with feed and drinking water.

• For chicks breeding: For use in animal housings where chicks are housed on litter and chickpaper.

• For pig breeding: For use in animal housings where lying areas of suckling piglets are covered with mats, strew or any other suitable material.

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

---

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

---

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

---

2.1.5 General directions for use

2.1.5.1 Instructions for use

- N-248: Always read the label or leaflet before use and follow all the instructions provided.
- N-159, modified: It has to be assured that humans and animals are not staying in the areas to be treated while the air space treatment by aerosol takes place.
- Inform the neighbourhood about the treatment, if smoke is expected to be visible from the outside.
- If necessary, particularly in a sensitive industrial or urban area, inform the fire department about the date and time of the treatment.
- Do not use in extremely dusty rooms (opaque dust cloud).
- Do not use in small defined enclosures, such as e.g. wall voids, pipes, chimneys.
- Close all windows, doors and other openings before starting the treatment.
- Disconnect the smoke detectors and stop the ventilation during treatment.
- Mark all accesses with a warning notice to inform treatment is in progress.
- Uncompact the powder by reverting the can several times before opening.
- Place the can on a heat- and fire-resistant surface on the floor (e.g. earthenware).
- Distribute the required number of cans according to the room volume to be treated. Note: The application rates refer to the amount of biocidal product (respectively a.s.) BEFORE burning it.
- Remove any combustible material at least 1.5 m away from the can.
- Remove the cover from the can and light the wick with a torch lighter.
- Always start off with the can the furthest away from the exit.
- Leave the area and close the door before the smoke spreads.
- Comply with a treatment time from 1 to 4 hours depending the pest to be treated.
- Do not enter the area while the treatment is on-going. In emergency cases, use respiratory protective equipment for accessing the area. Respect the recommended safety time before re-entry of the area (this applies to humans and animals).
- Make sure that the used cans are cold before handling and disposing them of.
- N-280, modified: Adopt integrated pest management methods such as alternation between treatment strategies during the treatment regime (biological, chemical and cultural), taking into account local specificities (climatic conditions, target species, conditions of use, etc.).
- Alternate products containing active substances with a different mode of action, (to remove resistant individuals from the population).
- Take into account the life cycle and characteristics of target insects to adapt treatments. In particular, target the most susceptible stage of the pest, timing of applications and areas to be treated.
- Do not apply the product in areas where resistance to the active substance (s) contained in this product is supected or established.
- Check the efficacy of the product on site: if needed, causes of reduced efficacy must be investigated to ensure that there is no resistance or to identify potential resistance.
- N-249: Inform the authorisation holder if the treatment is ineffective.

• N-278, modified: If the infestation persists, contact a professional pest control operator.

2.1.5.2 Risk mitigation measures

• Do not breathe fume.
- N-333: Contains deltamethrin, may be dangerous/toxic to pets (e.g. cats, bees, fish and other aquatic organisms).
- N-335: Keep cats away from treated surfaces. Due to their particular sensitivity to Deltamethrin, the product can cause severe adverse reactions in cats.
- If the room has to be entered to switch on the ventilation system after treatment: Use of respiratory protective equipment (RPE) providing a minimum protection factor of 10 is mandatory. RPE is required (RPE and filter type (code letter, colour) to be specified by the authorisation holder within the product information).
- Product must be transported under temperature controlled conditions. Take UN No. 3236 into account.

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

Particulars of likely direct or indirect effects:

N-318: Pyrethroids (deltamethrin) may cause paresthesia (burining and prickling of the skin without irritation). If symptoms persist: Get medical advise.

Symptoms and acute health effects:
Fumes may cause irritations. Deltamethrin may have effects on the nervous system resulting in facial sensation such as redness, itching, burning or paresthesia. These sensations are reversible and disappear as soon as exposure stops.
Massive and repeated exposure by inhalation may lead to emphysema.

Immediate medical attention required:
Symptomatic treatment.
The administration of atropine or of adrenaline derivatives is not indicated with deltamethrin. In case of contact with skin or eyes, avoid direct sunlight. Antidotes: Not available

First aid instructions:

POWDER:
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 swallowed:
If symptoms occur call a POISON CENTRE or a doctor.

FUMES:
If inhaled:
Wear Protective Equipment and move the person away from the fumes and provide fresh air. Control of breathing. If symptoms occur call a POISON CENTER or a doctor.

Immediate treatment:
If a person is unconscious, seek the help of a first aid responder for placing the person into the recovery position and monitoring their breathing.

In case of burning by contact with a dose not completely cooled:
In case of a superficial burn (redness), cool the wound under indirect running water for 15 minutes.In case of serious burns (blistering, peeling skin, large affected areas), seek medical advice.

Personal precaution, protective equipment and emergency procedures in case of accidental release of powder:

- Avoid/remove all ignition sources and hot points.
- Aerate or ventilate to prevent the formation of a dust cloud.
- Use gloves and a dust mask or half mask (nose / mouth) with a type P (dust) filter, protective glasses and protective clothing.

Emergency measures to protect the environment:
• Do not allow the product to discharge into the soil, watercourses, sinks or drains.
• If the product contaminates lakes, rivers, sewers or soil, inform the appropriate authorities in accordance with local regulations.
• Collect the product by sucking up and eliminate it in compliance with the local regulations in force.

2.1.5.4 Instructions for safe disposal of the product and its packaging

• Dispose of contents/container to a special waste collection point in accordance with local/national/international requirements.

• Product residues, residual ashes and used cans must be collected and disposed of in accordance with the national waste disposal legislation and any regional and/or local authority requirements.

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

Storage instructions:

• Store in a temperate and ventilated room equipped with collecting tank of fire water.

• Storage temperature: Do not store above 30°C[1]. Product must be stored under temperature controlled conditions. Emergency temperature = 45°C

• Store away from ignition sources.

• Store in a cool, dry and frost-protected place.

• Store away from direct sunlight.

• N-301: Do not store near food, drink and feed.

• Keep away from combustible materials.

• Store in the origin container.

Shelf life: 2 years

[1] Fumicide DM is stable at 40°C during 8 weeks and is stable at 54°C during 14 days (cf. accelerated storage studies).

2.1.6 Other information

NOTE [**not** to be contained on the label]:

Note regarding the curative treatment: No residual efficacy has been demonstrated for each use.

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-pro-fessional)	Compatibility of the product with the proposed packaging materials (Yes/No)
Can/tin	20 g	Iron	Easy open cap with seal crimping	Professional	Yes
Can/tin	50 g	Iron	Easy open cap with seal crimping	Professional	Yes
Can/tin	100 g	Iron	Easy open cap with seal crimping	Professional	Yes
Can/tin	250 g	Iron	Easy open cap with seal crimping	Professional	Yes
Can/tin	500 g	Iron	Easy open cap with seal crimping	Professional	Yes
Can/tin	1000 g	Iron	Easy open cap with seal crimping	Professional	Yes

* The packaging has an internal varnish layer, consisting of an epoxy-phenolic resin.

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

A list of studies for the biocidal product can be found in annex 3.1.

2.1.8.2 Access to documentation

A letter of access for the active substance deltamethrin has been attached to section 13 of the IUCLID-Dossier "FUMICIDE DM".

2.2 Assessment of the biocidal product

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

Use # 1 – Insecticide, acaricide and other arthropods – professional – air space treatment – indoor

Product Type	EU BPR Product type 18: Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Insecticide, acaricide and product to control other arthropods.
Target organism (including development stage)	***Target insects in Domestic premises*** Scientific name: *Lycoriella auripila* common name: Mushroom-infesting fly development stage: adults Scientific name: *Blattellidae: Blattella germanica* common name: German Cockroach development stage: adults Scientific name: *Pyraloidea: Plodia interpunctella* common name: Indian Meal Moth development stage: adults and nymphs Scientific name: *Culicidae: Aedes albopictus* common name: Aedes Mosquitoe development stage: adults Scientific name: *Pyroglyphidae: Dermatophagoides pteronyssinus* common name: House dust mites development stage: adults Scientific name: *Tegenaria domestica* common name: House spider development stage: adults Scientific name: *Pulicidae: Ctenocephalides felis* common name: Cat Flea development stage: adults and nymphs Scientific name: *Cimicidae: Cimex lectularius* common name: Bedbug development stage: adults Scientific name: *Muscidae: Musca domestica* common name: House fly development stage: adults Scientific name: *Vespa cabro* common name: Wasps development stage: adults Scientific name: *Bostrichidae: Rhyzopertha dominica* common name: Lesse Grain Borer development stage: adults

	<u>Target insects in breeding premises</u> ***Bloodsucking pests (laying farms)*** Scientific name: *Dermanyssidae: Dermanyssus gallinae* common name:Poultry red mite development stage: adults ***Insects not affecting livestock (chicken growing farms, fattening pigs ans sows)*** Scientific name: *Tribolium confusum* common name: Confused Flour Beetle development stage: adults Scientific name*: Dermestidae: Dermestes maculatus* common name: Dermestre Hide Beetle development stage: adults Scientific name: *Alphitobius diaperinus* common name: Lesser mealworm development stage: adults Scientific name: *Blattellidae: Blattella germanica* common name: German Cockroach development stage: adults
Field of use	indoor use
Application method(s)	**Method of application:** Air space treatment **Detailed description of the method:** The product is released into the atmosphere by a local thermokinetic effect. An exothermic chemical reaction results in an aerosol release of the active substance. The reaction and diffusion are from the original container. The initiation reaction requires the intervention of an applicator using an ignition device. Broadcasting starts with a time delay after initiation, allowing the applicator leaving a room and it is complete after 5 to 30 minutes respectively for the spaces 50 to 5000 m3. The application itself does not require the use of equipment. The treatment does not require the presence of the applicator. The product dose included in the container is specific for a given volume and a given pest.
Application rate(s) and frequency	**<u>APPLICATION RATES:</u>** **<u>Target insects in Domestic premises</u>** → 0.2 g/m³ (4.8 mg a.s./m^3) - Curative treatment against: – cat flea, – bedbugs,

	– house dust mites, – house spider, – Aedes mosquitoe, – mushroom-infesting fly. → 0.15 g/m³ (3.6 mg a.s./m³) - Curative treatment against: – wasps/hornets. → 0.5 g/m³ (12 mg a.s./m³) - Curative treatment against: – *German cockroaches*, – house flies, – lesser grain borer and – Indian meal moth. **<u>Target insects in Breeding premises</u>** ***Bloodsucking pests (laying farms)*** → 1 g/m³ (24 mg a.s./m³) - Curative treatment against: – poultry red mites. ***Insects not afecting livestock (chicken growing farms, fattening pigs and sows)*** → 1 g/m³ (24 mg a.s./m³) - Curative treatment against: – dermestre hide beetle. → 0.5 g/m³ (12 mg a.s./m³) - Curative treatment against: – *German cockroaches*, – confused flour beetle and – lesser mealworm. **Number and timing of application:** **<u>Target insects in Domestic premises</u>** → 2 applications/year with 2 weeks of interval - Curative treatment against: – cat flea (contact time 4h), – bedbugs (contact time 4h), – house dust mites (*Dermatophagoides pteronyssinus)* (contact time 4h) – house spider (contact time 4h) – Aedes mosquitoe (contact time 4h) – mushroom-infesting fly (contact time 4h) – wasps/hornets (contact time 4h), – *German cockroaches* (contact time 1h) – house flies (contact time 4h), – lesser grain borer (contact time 1h) and – Indian meal moth (contact time 1h) **<u>Target insects in Breeding premises</u>** ***Bloodsucking pests (laying farms)*** → 1 application per year - Curative treatment against:

	– poultry red mites. ***Insects not afecting livestock (chicken growing farms, fattening pigs and sows)*** → 7 applications/year with 6-7 weeks interval - Curative treatment against: – dermestre hide beetle, – *German cockroaches,* – confused flour beetle and – lesser mealworm.
Category(ies) of users	Professional
Pack sizes and packaging material	Pack size is: ≥118.92 — ≤3309.37 cm³, and the packaging material is metal: metal Further description of the packaging: Packages contains 20, 50, 100, 250, 500 and 1000 g of product. Type of closure is type easy open cap with seal crimping Safety features: Easy Open Cap

Use # 2 – Insecticide, acaricide and other arthropods – non professional – air space treatment – indoor.

Product Type	EU BPR Product type 18: Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Insecticide, acaricide and product to control other arthropods.
Target organism (including development stage)	**<u>Target insects in Domestic premises</u>** Scientific name: *Lycoriella auripila* common name: Mushroom-infesting fly development stage: adults Scientific name: *Blattellidae: Blattella germanica* common name: German Cockroach development stage: adults Scientific name: *Pyraloidea: Plodia interpunctella* common name: Indian Meal Moth development stage: adults and nymphs Scientific name: *Culicidae: Aedes albopictus* common name: Aedes Mosquitoe development stage: adults Scientific name: *Pyroglyphidae: Dermatophagoides pteronyssinus* common name: House dust mites development stage: adults Scientific name: *Tegenaria domestica* common name: House spider development stage: adults

	Scientific name: *Pulicidae: Ctenocephalides felis* common name: Cat Flea development stage: adults and nymphs Scientific name: *Cimicidae: Cimex lectularius* common name: Bedbug development stage: adults Scientific name: Muscidae: Musca domestica common name: House fly development stage: adults Scientific name: *Vespa cabro* common name: Wasps development stage: adults Scientific name: *Bostrichidae: Rhyzopertha dominica* common name: Lesser Grain Borer development stage: adults **<u>Target insects in Breeding premises</u>** ***Insects not afecting livestock (chicken growing farms, fattening pigs and sows)*** Scientific name: *Tribolium confusum* common name: Confused Flour Beetle development stage: adults Scientific name: *Alphitobius diaperinus* common name: Lesser Mealworm development stage: adults Scientific name: *Blattellidae: Blattella germanica* common name: German Cockroach development stage: adults
Field of use	indoor use
Application method(s)	**Method of application:** Air space treatment **Detailed description of the method:** The product is released into the atmosphere by a local thermokinetic effect. An exothermic chemical reaction results in an aerosol release of the active substance. The reaction and diffusion are from the original container. The initiation reaction requires the intervention of an applicator using an ignition device. Broadcasting starts with a time delay after initiation, allowing the applicator leaving a room and it is complete after 5 to 30 minutes respectively for the spaces 50 to 5000 m3. The application itself does not require the use of equipment. The

	treatment does not require the presence of the applicator. The product dose included in the container is specific for a given volume and a given pest.
Application rate(s) and frequency	**Application rates:** **<u>Target insects in Domestic premises</u>** → 0.2 g/m³ (4.8 mg a.s./m^3) - Curative treatment against: – cat flea, – bedbugs, – house dust mites, – house spider, – Aedes mosquitoe, – mushroom-infesting fly → 0.15 g/m³ (3.6 mg a.s./m^3) - Curative treatment against: – wasps/hornets. → 0.5 g/m^3 (12 mg a.s./m^3) - Curative treatment against: – *German cockroaches ,* – house flies, – lesser grain borer and – Indian meal moth **<u>Target insects in Breeding premises</u>** ***Insects not afecting livestock (chicken growing farms, fattening pigs and sows)*** → 0.5 g/m^3 (12 mg a.s./m^3) - Curative treatment against: – *German cockroaches* – confused flour beetle and – lesser mealworm. **Number and timing of application:** **<u>Target insects in Domestic premises</u>** → 2 applications/year with 2 weeks of interval - Curative treatment against: – cat flea (contact time 4h), – bedbugs (contact time 4h), – house dust mites (contact time 4h) – house spider (contact time 4h) – Aedes mosquitoe (contact time 4h) – mushroom-infesting fly (contact time 4h) – wasps/hornets (contact time 4h), – *German cockroaches* (contact time 1h) – house flies (contact time 4h), – lesser grain borer (contact time 1h) and – Indian meal moth (contact time 1h) **<u>Target insects in Breeding premises</u>** ***Insects not afecting livestock (chicken growing farms,***

	fattening pigs and sows) → 7 applications/year with 6-7 weeks interval - Curative treatment against: – *German cockroaches* (contact time 1h) – confused flour beetle and – lesser mealworm.
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	Pack size is: ≥118.92 — ≤3309.37 cm³, and the packaging material is metal: metal Further description of the packaging: Packages contains 20, 50, 100, 250, 500 and 1000 g of product. Type of closure is type easy open cap with seal crimping Safety features: Easy Open Cap

2.2.2 Physical, chemical and technical properties

Note: The product indentified as ULTRAD DM tested in several studies has the same composition as the biocidal product (Fumicide DM).

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20°C and 101.3 kPa	PE-11-aspect visuel-v1 (LCB's Internal Method)	≥2.4% deltamethrin, Batch No.: Ext 16-119-2	fluid free-flowing solid powder, without lumps	[redacted] 2010
Colour at 20°C and 101.3 kPa	PE-11-aspect visuel-v1 (LCB's Internal Method)	≥2.4% deltamethrin, Batch No.: Ext 16-119-2	Light green	[redacted] 2010
Odour at 20°C and 101.3 kPa	PE-11-aspect visuel-v1 (LCB's Internal Method)	≥2.4% deltamethrin, Batch No.: Ext 16-119-2	Odourless	[redacted] 2010
Acidity / alkalinity	LCB's Internal Method, compatible with the CIPAC Method MT 75.3	≥2.4% deltamethrin, Batch No.: 181457	The average pH of DM2.4 solution at 1% in ultrapure water at 22°C is 5.4.	[redacted] 2018
	CIPAC Method MT 75.3	≥2.4% deltamethrin, Batch No.: 190786	The average pH of DM2.4 solution at 1% in CIPAC standard water D at 21.6°C is 6.08.	[redacted] 2019
Relative density / bulk density	Internal method PE-02-densité non tassée-v1; Internal method PE-03-densité tassée-v1	≥2.4% deltamethrin, Batch No.: 12676	The bulk density of the product ULTRAD DM is 0.48 g/mL. The specification will be 0.48±0.06 g/mL. The tap density of the preparation ULTRAD DM is 0.72 g/mL. The specification will be 0.72±0.07 g/mL.	[redacted] 2013
	CIPAC Method MT 186	≥2.4% deltamethrin, Batch No.: 190786	The mean bulk density of the product ULTRAD DM is 0.477±0.004 g/mL. The mean tap density of the preparation ULTRAD DM is 0.69±0.001 g/mL.	[redacted] 2019

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results		Reference
	In compliance with EC A.3. method (2008) and OECD Guideline No. 109 (2012)	≥2.4% deltamethrin, Batch No.: 190786	Stereopycnometer method: The mean relative density of DM 2.4 is 1.885 ± 0.004 at 20.2°C.		
Storage stability test – **accelerated storage**	CIPAC MT 46.3 (Storage stability) Determination of the active substance: modified CIPAC method 333/DP/M2/3. HPLC-PDA detection (validated).	≥2.4% deltamethrin, Batch No.: EXT.16.154.2	The product FUMICIDE DM is stable under accelerated conditions at 40ºC during 8 weeks.		[redacted] 2011a
			Initial AS concentration before storage [g/kg]:	AS concentration after storage [g/kg]:	
			23.0 ± 0.2	22.2 ± 0.2	
	CIPAC MT 46.3 (Storage stability) Determination of the active substance: modified CIPAC method 333/DP/M2/3. HPLC-PDA detection (validated).	≥2.4% deltamethrin, Batch No.: EXT.16.126.2	FUMICIDE DM is stable under accelerated storage conditions at 54ºC during 14 days		[redacted] 2011b
			Initial AS concentration before storage [g/kg]:	AS concentration after storage [g/kg]:	
			23.3 ± 0.2	22.6 ± 0.2	
Storage stability test – **long term storage at ambient temperature**	Croplife International monograph N°17 Determination of the active substance: modified CIPAC method 333/DP/M2/3. HPLC-PDA detection	≥2.4% deltamethrin Batch No.: 12676	The test item (20 g/Ref [redacted] 2015a; 1000 g/ [redacted] 2015b) was stored in the finished (commercial) package, away from moisture and direct sunlight. FUMICIDE DM is stable stable after 2 years of storage		[redacted] 2015a, [redacted] 2015b

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	(validated).		at ambient temperature (19.9 ± 3.8°C). Appearance/Initial date: Cream (RAL 9001) powder without characteristic odour After 24 months: No changes No alteration of the container, no change in appearance, and no significant loss of weight was noticed. A shelf-life of 2 years at ambient temperature can therefore be assigned. Justification for not including SoCs in the stability/shelf life study: Ammonium nitrate (CAS: 6484-52-2): the conditions of synthesis of ammonium nitrate in the product are not fulfilled since it would require the presence of nitrate in the form of nitric acid and the presence of ammonia. Moreover, the reaction occurs at a temperature around 150°C. Actually, no component present in the biocidal product contains nitrogen. Consequently, the	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results		Reference
			formation of ammonium nitrate in the biocidal product during storage can be excluded. Basic copper carbonate (CAS: 12069-69-1): no co-formulant present in the product contains copper. Copper is not mentioned in the specification sheet of the co-formulants, even as a residual impurity. Moreover, the formation of copper(II) hydroxide would require the presence of available water in the product (the product is in the form of a powder). Consequently, the formation of basic copper carbonate in the biocidal product during storage can be excluded.		
			Initial AS concentration before storage [g/kg]:	AS concentration after 2 years of storage [g/kg]:	
			23.09 ± 0.51	23.16 ± 0.24	
			Weight of the bottle + test item	Weight of the bottle + test item after 2	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results		Reference
			before storage [g]	years of storage [g]	
			1336.1	1337.3	
Storage stability test – **low temperature stability test for liquids**	The product is a solid formulation. This study is not required.				
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Not relevant: opaque package				
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	CIPAC MT 46.3 (Storage stability)	≥2.4% deltamethrin	Product is stable under high temperatures storage conditions (40 and 50ºC). Hygrometry is not pertinent for stability study of a product contained inside a tin hermetically closed. The recording of hygrometry is not specified in "Croplife International monograph Nº 17"		[redacted] 2011a, [redacted] 2011b [redacted] 2015a, [redacted] 2015b
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	No degradation of packaging material is observed.				
Wettability	The data are required for solid preparations which are to be dispersed in				

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	water. In this case the product is a smoke generator powder for ready to use, so this study is not required.			
Suspensibility, spontaneity and dispersion stability	These studies are required for wettable powders, aqueous suspension concentrates, water dispersible granules, water dispersible powders and formulations forming suspensions on dilutions with water. FUMICIDE DM is a smoke generator powder for ready to use, so this study is not required.			
Wet sieve analysis and dry sieve test	The wet sieve test is required for wettable powders, suspension concentrates, water dispersible granules, aqueous capsule suspensions, dispersible concentrates, suspo-emulsions, water soluble granules and water soluble powders. The dry sieve test is required for dustable powders and granular formulations. FUMICIDE DM is a smoke generator powder for ready to use, so this study is not required.			
Emulsifiability, re-emulsifiability and emulsion stability	This study is required for formulations which form emulsions. FUMICIDE DM is a smoke generator powder for ready to use, so this study is not required.			
Disintegration time	This study is required for ST (water soluble tablets) and WT (water dispersible tablets) formulations. FUMICIDE DM is a smoke generator powder for ready to use, so this study is not required.			
Particle size distribution, content of dust/fines, attrition, friability	Internal method PE-50-granulometrie poudre The method PE 50 corresponds to the CIPAC MT 170 method with the following modifications: • Diameter of holes of sieves are different, more adapted to our powders • Sieves are weighed before and after sieving instead of powder	≥2.4% deltamethrin, Batch: EXT.16.119.2	>500µm: 0.57% 500-315µm: 2.77% 315-200µm: 9.30% 125-100µm: 7.70% 100-50µm: 22.00% <50µm: 44.96%	[redacted] 2011a

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	collected on glazed paper • Sample mass is systematically 30 g, used in the method validation, being considered as representative A first sieving time of 30 min then sieve is turned, for an optimal repartition of the powder on the sieve, then a second sieving time during 15 min, instead of a sole sieving time of 5 min. This is the result of our experience, allowing to obtain repeatable results, proving this procedure is optimal.	≥2.4% deltamethrin, Batch numbers: 12676-13191-13215	Particle size distribution: >100 µm: 35% 50-100 µm: 20% <50 µm: 45%	[redacted] 2013
Persistent foaming	This study is required when the product is applied in water for use. FUMICIDE DM is a smoke generator powder for ready to use, so this study is not required.			
Flowability/Pourability/Dustability	The flowability test is required for granular formulations and the pourability test is required suspension concentrates, capsule suspensions and suspoemulsions. FUMICIDE DM is a smoke generator powder for ready to use, so this study is not required.			
Burning rate — smoke generators	Internal method LCB Rapport nº 170-DM-CH-110301	≥2.4% deltamethrin Batch no of the 50 g samples: EXT.16.122.2; Batch no of the 1000 g samples: RB1.132.2	After 2 min 35 sec, the amount of residues remaining in the 50 g can is 43.5% of the initial product. Mean maximum combustion temperature was 400ºC.	[redacted] 2011b, [redacted] 2014

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results		Reference
			After a smoke emission time of 8 min 45 sec, the amount of residues remaining in the 1000 g can is 40.5% of the initial product. Mean maximum combustion temperature was 534ºC.		
Composition of smoke — smoke generators	FILAB Internal method	≥2.4% deltamethrin, Batch: AIB 1 Sample: Ext 24-46-1, Sample quantity: 10g	The composition of the generated fume and the residual ash has been investigated. For detailed description of the results please see section 3.6.2 (confidential annex)		[redacted] 2016
			Content of deltamethrin in the biocidal product	2.4 %(w/w)	
			Active deltamethrin found in fumes	0.36 %(w/w)	
			Deltamethrin found in the solid residue	0.041 %(w/w)	
Spraying pattern — aerosols	The test is required for aerosols formulations. FUMICIDE DM is a smoke generator powder for ready to use, so this study is not required.				
Physical compatibility	Not applicable. The product is not intended to be used with other products.				
Chemical compatibility	Not applicable. The product is not intended to be used with other products.				
Degree of	This test is required for water soluble bag and for all tablets. FUMICIDE				

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
dissolution and dilution stability	DM is a smoke generator powder for ready to use, so this study is not required.			
Surface tension	Not applicable. FUMICIDE DM is a powder.			
Viscosity	Not applicable. FUMICIDE DM is a powder.			

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

FUMICIDE DM is an insecticide and acaricidal mixture in the form of a smoke generating powder. It´s used for disinfestation of empty premises in public and breeding areas. (PT 18). It is a pale green odourless powder with a bulk and tap density of 0.48 g/cm^3 and 0.72 g/cm^3 respectively. The pH value of DM2.4 solution at 1% in deionized water at 21°C is 5.90. Particle size is below 50 µm for the 45% of the particles and above 100 µm for the 35%. Other chemical characteristics of the product as a smoke generation is the burning rate (43.5% residues remaining in the can after 2 min 45 seconds). The analyses of the combustion residue have determined that it is composed of:

☐ A very low residual deltamethrin
☐ Residual Cyclohexanone
☐ Organic compounds resulting from the degradation of the material or from chemical reaction of the starting materials at high temperature
☐ Copper from the copper carbonate present in the raw sample
☐ Aluminium resulting from initially present Kaolin
☐ Potassium from the impregnated roving for igniting the smoke
☐ Nitrates from ammonium nitrate present in the raw sample
☐ Bromides from the degradation of deltamethrin
☐ Fluorides, chloride, phosphate and sulfate

Regarding the storage stability of product it can be conclude that FUMICIDE DM is stable under accelerated conditions at 40ºC during 8 months, stable under accelerated storage conditions at 54ºC during 14 days, stable after 2 years of storage at ambient temperature and stable under high temperatures storage conditions (40 and 50ºC).

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	UN Test series 2	≥2.4% deltamethrin, ULTRAD DM (batch No. EXT.16.122.2)	Based on the (negative) results obtained during UN test series 2a, 2b and 2c, we conclude that the powder smoke ULTRAD DM: is not a substance of Class 1, under the transport regulations for hazardous materials, is not an explosive substance under the CLP Regulation.	[redacted] 2010
	EU Method A.14 (Explosive properties)	≥2.4% deltamethrin ULTRAD DM (batch No. EXT16.93.2	The test item was not considered to have explosive properties under experimental conditions (mechanical- an heat sensitivity tests).	[redacted] 2010
Flammable gases	The data are required for flammable gases. FUMICIDE DM is a smoke generator powder for ready to use, so this study is not required.			
Flammable aerosols	The data are required for flammable gases. FUMICIDE DM is a smoke generator powder for ready to use, so this study is not required.			
Oxidising gases	This study is required for oxidising gases. FUMICIDE DM is a smoke generator powder for ready to use, so this study is not required.			
Gases under pressure	This test is required for gases under pressure are gases which are contained in a receptacle at a pressure of 200 kPa (gauge) or more, or which are liquefied or liquefied and refrigerated. FUMICIDE DM is a smoke generator powder for ready to use, so this study is not required.			
Flammable liquids	The data are required for flammable liquids. FUMICIDE DM is a smoke generator powder for ready to use, so this study is not required.			
Flammable solids	Carriage of dangerous goods - Manual of	≥2.4% deltamethrin, ULTRAD DM (Batch No.	Preliminary test: The test item blackened at the contact of the	[redacted] 2011

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	tests and criteria - United nations (2003) (UN Method N.1)	Lot XT.16.141.1)	flame's burner. No inflammation was observed but a combustion propagated over 200 mm in 18 minutes 47 seconds (assay 1) and 19 minutes 59 seconds (assay 2). Taking into account the results obtained (no ignition and no burning propagation in less than 4 min) during the preliminary test, no main test was performed. The test item was not assigned to the packing group 4.1.	
Self-reactive substances and mixtures	According with UN recommend ations related with the transport of dangerous goods. UN ST/SG/AC.1 0.1/Rev. 17; UN test series 2: UN test 2a C series: UN test C1 and C2 E series: UN test E1 and E2 F series: UN test F.2	≥2.4% deltamethrin, ULTRAD DM Sample EXT.17.94.1 - lot EXT17.93.2	ULTRAD DM is a self-reactive substance Type D, based on the results that it detonates partially in the chamber conditions (UN test 2a), it does not deflagrate (C series) and reaction to heating under defined confinement is weak (E series). Mean decomposition temperature: 1466 J/g (average of three tests). SADT = 50°C for 50 kg package. It is therefore necessary to determine the type of hazard	[redacted] 2012

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			presented by the product ULTRAD DM, as classification criteria (>300J/g, SADT<75°C/50 kg) for self-reactive substances and mixtures are fulfilled for ULTRAD DM. ULTRAD DM is included in class 4.1 as self-reactive substance type D, as defined in the regulation of the Transportation of Dangerous Goods. The product ULTRAD DM, packaged in a package of 25 kg, has a SADT of 55°C, and can only be transported under controlled temperature conditions.	
Pyrophoric liquids	The data are required for pyrophoric liquids. FUMICIDE DM is a smoke generator powder for ready to use, so this study is not required.			
Pyrophoric solids	Method N.2 of the Manual of Assays and Criteria of UNO for the transport of dangerous goods	≥2.4% deltamethrin, batch No. AIB 1	The composition FUMICIDE DM does not have any pyrophoric properties (no ignition observed when dropping from around 1m high, on a non-combustible surface). Therefore the product should not be considered as a pyrophoric solid matter and does not fall within the	[redacted] 2015

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			danger class 4.2.	
Self-heating substances and mixtures	ONU, Manual of Tests and Criteria N.4	≥2.4% deltamethrin, ULTRAD DM – Ref. 11AO365	Under the CLP Regulation: The test product is not classified as "self-heating", except it is packaged in volume >3 m^3 (it would be "self-heating" of category 2). Under the regulation of the transport of dangerous goods: The test product is not classified in Class 4.2 (self-heating), unless transported volume >3 m^3 (it would be in Class 4.2, packing group III).	[redacted] 2011a
Substances and mixtures which in contact with water emit flammable gases	This study is required for substances and mixtures which in contact with water emit flammable gases. FUMICIDE DM is a smoke generator powder for ready to use, so this study is not required.			
Oxidising liquids	This study is required for oxidising liquids. FUMICIDE DM is a smoke generator powder for ready to use, so this study is not required.			
Oxidising solids	EU Method A.17 (Oxidising Properties (Solids))	≥2.4% deltamethrin, batch No. Lot EXT.16.141.1	The test item was not considered to have oxidizing properties under given experimental conditions: The maximum burning rate of the test item:cellulose mixture=1:9 was 3.45 mm/s. The maximum burning rate of the reference item:cellulose mixture=6:4 was 3.64 mm/s.	[redacted] 2011a

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Hence, the maximum burning rate of the test item / cellulose mixture was lower than the maximum burning rate with reference item /cellulose mixture.	
	Carriage of dangerous goods – Manual of tests and criteria - United nations (2003) (UN-Method O.1)	≥2.4% deltamethrin, batch No. Lot EXT.16.141.1	The mean reaction time with the test item / cellulose mixture in proportions 4:1 was lower than the mean reaction time with the reference item / cellulose mixture in proportions 3:7 (60 s vs. 95 s respectively). The mean reaction time with the test item / cellulose mixture in proportions 1:1 was higher than the mean time of reaction with the reference item / cellulose mixture in proportions 3:7 (199 s vs. 95 s respectively). Therefore, the test item was assigned to oxidsing solids, category 3.	[redacted] 2011b
Organic peroxides	This study is not required, FUMICIDE DM is not an organic peroxide formulation.			
Corrosive to metals	This study is required for substances or a mixtures which by chemical action will materially damage, or even destroy, metals. FUMICIDE DM is a smoke generator powder for ready to use by a heating element activation (ex: ignition of wick) and it is not corrosive. The formulation is stored in metal tins and the stability test show that the product is stable. In addition, according to the classification criteria only substances and mixtures for which the application of the UN Test C.1			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	(described in part III, Section 37.4.1.1 of the UN-MTC) is relevant and needs to be considered. Application of classification criteria in the UN-MTC, Section 37.4 excludes solids, thus this study is not required.			
Auto-ignition temperatures of products (liquids and gases)	This test is not required, FUMICIDE DM is a powder.			
Relative self-ignition temperature for solids	EU Method A.16 (Relative Self-Ignition Temperature for Solids)	≥2.4% deltamethrin, batch No. Lot EXT.16.141.1	The mean self ignition temperature of the test item was observed at 180°C (corrected value).	[redacted] 2011c
Dust explosion hazard	EN 14034-1 EN 14034-2 EN 13821 EN 50281-2-1	≥2.4% deltamethrin, batch No. EXT.10.122.2	Explosion constant KSt = 42 bar.m/s Maximum explosion pressure Pmax = 6.3 bar. Minimum ignition temperature MIT = 400 °C Minimum ignition energy MIE > 1000 mJ Explosion class St1 (weak explosion violence). It can generate an explosive atmosphere when it is put in suspension in air. However, dust explosions are very unlikely, as the product/powder is not intended to be removed from the packaging (can/tin) before or during use/application.	[redacted] 2011b

Note: Based on the transport classification, ammonium nitrate has to be classified for the hazard 'Oxidising solid-Category 3' according to CLP Regulation (EC) No 1272/2008.

Conclusion on the physical hazards and respective characteristics of the product

Regarding the explosive properties, based on the results obtained during the tests according to series ONU 2, we conclude that the product FUMICIDE DM is not a substance of Class 1, and under the transport regulations for hazardous materials, it is not an explosive substance according to CLP Regulation. The product was not considered to have explosive properties under experimental conditions.

Regarding the flammability properties, the product was not assigned to the packing group 4.1 according to Carriage of dangerous goods - Manual of tests and criteria - United nations (2003) (UN Method N.1).

The formulation FUMICIDE DM is a self-reactive substance. It is therefore necessary to determine the type of hazard presented by the product FUMICIDE DM. FUMICIDE DM is a self-reactive solid type D, according to the regulations of the Transportation of Dangerous Goods. We conclude that the product FUMICIDE DM is the class 4.1 as self-reactive substance type D, as defined in the regulation of the transport of hazardous materials.
The product FUMICIDE DM, packaged in a package of 25 kg, has a SADT of 55°C, and can only be transported under temperature controlled conditions.

The composition FUMICIDE DM does not have any pyrophoric properties. Therefore the product should not be considered as a pyrophoric solid matter and does not fall within the danger class 4.2. (According to Method N.2 of the Manual of Assays and Criteria of UNO for the transport of dangerous goods)

Under the CLP Regulation the test product is not classified as "self-heating", except it is packaged in volume >3 m^3 (it would be "self-heating" of category 2).
Under the regulation of the transport of dangerous goods the test product is not classified in Class 4.2 (self-heating), unless transported volume >3 m^3 (it would be in Class 4.2, packing group III).

FUMICIDE DM was not considered to have oxidizing properties under our experimental conditions (EU Method A.17 (Oxidising Properties (Solids)) and according to Carriage of dangerous goods – Manual of tests and criteria - United Nations (2003) (UN-Method O.1) the product was assigned to oxidizing solids, category 3.

According to EU Method A.16 (Relative Self-Ignition Temperature for Solids) the product FUMICIDE DM has a mean self-ignition temperature of 180ºC (corrected value).

Relating to dust explosion hazard the product can generate an explosive atmosphere when it is put in suspension in air so is classified in the category of Explosion class St1.

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		
deltamethrin	HPLC-DAD[1]	7 calibration points, 6.1 – 12.03 mg/L, number of fortification s: 5 (for two spiking levels); [20 g/kg-25 g/kg] / 5 measurements for each sample (2 samples)	y = 28758x, R2 = 0.99979	Yes (no interfering peaks in the area of interest)	Spiking Level: 20 g/kg: 99.4 – 102.7 Spiking Level: 25 g/kg: 99.1-102.7	Spiking Level: 20 g/kg: 101.1 Spiking Level: 25 g/kg: 100.8 Mean: 100.9	Spiking Level: 20 g/kg: 1.57 Spiking Level: 25 g/kg: 1.31 Mean: 1.44	LOQ: 6.1 mg/L. this corresponds to 15 g/kg	[redacted] 2011a [redacted] 2011c
Ammonium nitrate	VIS spectrometry (415 nm)	6 calibration points, validated range: 0.15 – 0.26 g/L; number of measurements for each level: 3	y (absorbance) = 3.702x + 0.0161, R2 = 0.9978	Yes (The specificity of the method is evaluated by the absence of response at the specific wavelength 415 nm. When injecting solvent and blank formulation, no response shows up at 415 nm.	98.2-100.9	100.0	1.04	As LOQ the lowest concentration of the standard range was taken into account: 0.15 g/L	[redacted] 2014
Copper	VIS	5	C =	Yes	94-	98	2.99	As LOQ the	[redacted]

	spectrometry (454 nm)	calibration points, validated range: 0.48 – 1.50 mg/L, spiking levels 3; number of measurements for each level: 2	5.7496x Absorbance + 0.0511, R2 = 0.9998	(Absorbance of the blank formulation is less than 3% of the absorbance of the test sample).	101			lowest concentration of the standard range was taken into account: 0.48 mg/L	[redacted] 2022
Copper	ICP-AES	5 calibration points, validated range: 1.55 – 4.75 mg/L, spiking levels: 3; number of measurements for each level: 3	y = 0.9277x + 0.0533, R2 = 0.9908	Yes (no interference or matrix effects were observed). This was confirmed by spiking experiments.	Spiking level: 2000 mg/kg: 103-105 Spiking level: 4000 mg/kg: 102-107 Spiking level: 10000 mg/kg: 99-105	Spiking level: 2000 mg/kg: 103.6 Spiking level: 4000 mg/kg: 105 Spiking level: 10000 mg/kg: 102.3	Spiking level: 2000 mg/kg: 1.15 Spiking level: 4000 mg/kg: 2.65 Spiking level: 10000 mg/kg: 3.06	Considering the dilution factor for sample preparation (dilution by 2000), the following LOD/LOQ values were obtained: LOD: 200 mg Cu/kg sample LOQ: 800 mg/kg	[redacted] 2022
Please refer to the active substance CAR for further methods									

[1] The sample is dissolved in a mixture of iso-octane and dioxane. The deltamethrin content in the biocidal product is determined by high performance liquid chromatography (HPLC) on an absorption type CN column using external standardisation and detection at 230 nm (photo diode array detector).

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		
deltamethrin on litter and manure (supportive information)	LC-MS/MS	[0.010-1.0 mg/kg] / 3 measurements]	R^2 >0.99	Yes MRM transitions: 523 → 281 m/z, 523 →505.7 m/z, 523 → 506 m/z	70.3-101.9	82.9	Not determined	LOQ (mg/kg): 0.01 LOD (mg/kg): 0.005	[redacted] 2013a
deltamethrin on two types of filter (GF/B whatman and cellulose)	GC-ECD	[100-1000 ng/filter] / 10 + 2 (control) determinations per each type of filter	Y=3.7343E-7x + 9.82; R^2 = 0.9963	Yes	[104.3-117.8]	117.9 % for cellulose and 108.8 % for GF/B whatman	3.7% for celullose and 7.5% for GF/B whatman	LOQ: 100 ng/filter; LOD: 12.5 ng7filter	[redacted] 2013
Please refer to the active substance CAR for further methods									

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		
Deltamethrin residues in Soil	GC-MS/MS	[50 – 500 µg/kg] / 5 measurements at Low level and 5 measurements at High level	Matrix matched calibration is linear: quantifier transition: 252.9 → 93 m/z: Y=230 x-1275, correlation coefficient r=0.99948	Method is highly specific: Blank soil response = 1% of LOQ response(guideline: BLK/LOQ < 30%). Qualifier ion transition: 181 → 152.1 m/z Quantifier ion transition: 252.9 → 93 m/z	Low level (51 µg/kg]: [92.0 - 104.6] High level (509.6 µg/kg): [83.0 - 107.7]	Low level (51 µg/kg]: 97.0 High level (509.6 µg/kg): 98.3	Low level (51 µg/kg]: 6% High level (509.6 µg/kg): 10%	LOQ: 51.0 µg/kg LOD: 5.1 µg/L corresponding to 10.2 µg/kg.	[redacted] 2021a
Please refer to the active substance CAR for further methods									

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		
Please refer to the active substance CAR for further methods									

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		
deltamethrin on drinking water (supportive information)	LC-MS/MS	[0.05-0.50 µg/L] / 2	Not determined	Yes	[76-80]	78	Not determined	LOQ (µg/L): 0.05 LOD (µg/L): 0.025	[redacted] 2013b
deltamethrin on drinking water	HPLC-MS/MS	[0.10-1.00 µg/L] /5 times at about 0.10 µg/L (L.O.Q.) and 5 times at 1.00 µg/L (10 x L.O.Q.), as nominal concentration	Linear Quantifier ion, 280.9 m /z: y=610x+50; coefficient of determination, r2 > 0.99; within the range of 0.03 – 1.99 µg/L; qualifier ion, 505.9 m/z: y=236x+28; coefficient of determination, r2 > 0.99	Yes	Product ion: 280.9 [101.8-88.5] Product ion: 505.9 [81.8-95.7]	95.1 88.8	9.55 12.60	Limit of quantitation (LOQ): 0.10 µg/L Limit of detection (LOD): 0.030 µg/L	[redacted] 2021
Please refer to the active substance CAR for further methods									

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

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		
deltamethrin on feed *(Supportive information)*	LC-MS/MS	[0.1 mg/kg] / 1	Not determined	Yes	118.2	118.2	Not determined	LOQ (mg/kg): 0.01 LOD (mg/kg): 0.005	[redacted]
Deltamethrin Residues in Animal feed	GC-MS/MS	[10 – 100 µg/L] / 5 measurements at Low level and 5 measurements at High level	Quantifier transition m/z 252.9 → m/z 93 Range 1.0 – 101.9 µg/L, r = 0.99619 Corresponding to range 2.0 – 203.8 µg/kg*, r = 0.99619 Y=69x+519 Qualifier transition m/z 181 → m/z 152.1 Range 1.0 – 101.9 µg/L, r = 0.99713 Corresponding to range 2.0 – 203.8 µg/kg*, r = 0.99713 Y=64x+372	Yes. Result: 17% the ratio between blank animal feed samples intensity and LOQ intensity (% Ratio BLK/LOQ) not exceed 30% suggested by the guideline.	Low level (10.2 µg/kg): [94.6 - 120.1] High level (101.9 µg/kg): [105.8-125.5]	Low level (10.2 µg/kg): 110.6 High level (101.9 µg/kg): 112.7	Low level (10.2 µg/kg): 9% High level (101.9 µg/kg): 7%	LOQ: 10.2 µg / kg LOD: final injected solution of 1.0 µg/L, corresponding to 2.0 µg/kg in animal feed samples.	[redacted] 2021b
Please refer to the active substance CAR for further methods									

Conclusion on the methods for detection and identification of the product
The analytical methods used for the detection and identification of the product are considered valid in terms of accuracy, repeteability, linearity and specificity.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

The biocidal product is an insecticide containing 2.4% deltamethrin.
The product is claimed to eliminate a broad range of pests and is envisaged for indoor use.

- The applicant applied for use by professional and non-professional users in domestic premises (e.g. residential homes in e.g. cellars) and in breeding premises: (e.g. pig farms; broiler growing farms; laying hen farms)
- The applicant applied for use in workplace environment by professional users e.g.:
    - Farmers
    - Industrial personal (operator or employee of an industry)
    - Specialized service (pest control)
    - Breeder or breeding technician (breeding sheds: pig farms; broiler growing farms; laying hen farms)

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

The product is designed to control German cockroach *(Blattella germanica)*, Oriental cockroach *(Blatta orientalis)*, aedes mosquitoes *(Aedes albopictus)*, house dust mites *(Dermatophagoides pteronyssinus)*, house spider (T*egenaria domestica*), cat flea *(Ctenocephalides felis)*, bed bug *(Cimex lectularius)*, house fly *(Musca domestica)*, hornets *(Vespa crabro)*, woodlice (*Armadillidium vulgare*), poultry red mite (*Dermanyssus gallinae*), dermestre hide beetle *(Dermestes maculatus)* and lesser mealworm *(Alphitobius diaperinus)*.
The product is intended to protect domestic and breeding premises (industrial premises) from the respective target organisms.

2.2.5.3 Effects on target organisms, including unacceptable suffering

The product is an insecticide which kills insects almost instantly by neurotoxic knockdown, blocking the transmission of nerve impulses.

2.2.5.4 Mode of action, including time delay

The active substance deltamethrin, belonging to the pyrethroid chemical family acts by contact and ingestion. The molecule kills almost instantly by neurotoxic knockdown, blocking the transmission of nerve impulses.
Deltamethrin is diffused in the air and is harmful to target pest by contact and ingestion.

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 and acaricide	Indoor use including domestic premises, industrial premises and breeding premises	ULTRAD DM (FUMICIDE DM deltamethrin 2.4%)	*Musca domestica* (house fly), *Blattella germanica* (German cockroach), , *Dermestes maculatus* (dermeste hide beetle), *Dermanyssus gallinae* (poultry red mite),	Method C.E.B. nº 135 bis	Simulated use assay, performed in an empty storage building of 138 m² (691 m³). The curative effect of the product was investigated. Dose: 12, 18 and 24 mg a.s./m^3 Exposure time: 1 or 4h 20-24°C, 80% HR and light 400 lux. In one fumigated room 4 cages (batches) of insects were exposed to the treatment. Number of insects per batch: House fly: 25 German cockroach: 25 Dermeste hide beetle: 10 Poultry red mite: 95±2	Untreated control mortality <10%. DOSE 24 mg a.s./m^3: All insects are dead at the end of exposure (1 or 4 hours) except *Dermestes maculatus* which needs after 4 hours of exposure 7 days to reach 100% mortality. DOSE 18 mg a.s./m^3: All insects are dead at the end of exposure (1 or 4 hours) except *Dermestes maculatus* which needs after 4 hours of exposure 7 days to reach 95% mortality. DOSE 12 mg a.s./m^3: All insects are dead at the end of exposure (1 or 4 hours) except *Dermestes maculatus* which do not reach 100% mortality at the end of the test period of 7 days.	[redacted] 2010a
Insecticide and acaricide	Indoor use including domestic premises, industrial premises and	ULTRAD DM (FUMICIDE DM deltamethrin 2.4%)	*Aedes albopictus* (aedes mosquitoes), *Dermatophagoides pteronyssinus* (house dust mites), *Tegenaria domestica* (house	Method C.E.B. nº 135 bis	Simulated-use assay in a test chamber 24 m² (60 m³) containing cardbord,polysterene blocks and harbourages for the test insects.	The death rate in the untreated control is low enough to validate the trial (<10%). After 1 hour after exposure all species except *Tegenaria domestica*	[redacted] 2010b

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**
	breeding premises		spider), *Ctenocephalides felis* (cat flea), *Cimex lectularius* (bed bug) *Armadillidium vulgare* (woodlice)		Dose: 4.8 mg a.s./m^3 Exposure time: 4h 20+/-1°C, 70+/-5% HR and light 1200 lux. According to the standard (C.E.B. 135 bis) the treatment (2 cages in one fumigated room) is replicated one time (i.e. there were 2 treatments per experimental factor). Overall 4 batches of insects were exposed to the treatment. Number of insects per batch: Mosquitoes: 25 House dust mites: 200 ±10 House spider: 5 Cat flea: 25 (adults) and 20 (nymphs) Bedbug: 25 Woodlice: 25	reached 100% mortalitiy. After 4 hours after exposure to the product all species reached 100% mortality. The 24 hours assessment confirms that it was a lethal effect (no recoveries).	
Insecticide and acaricide	Indoor use including domestic premises, industrial premises and breeding premises	ULTRAD DM (FUMICIDE DM deltamethrin 2.4%)	*Alphitobius diaperinus* (lesser mealworm)	Method C.E.B. nº 135 bis	Simulated-use assay in a test chamber 24 m^2 (60m^3) containing cardbord,polysterene blocks and harbourages. Dose: 12 mg a.s./m^3 Exposure time: 1-4h 20+/-1°C, 70+/-5% HR and light 1200 lux.	The death rate in the untreated control is low enough to validate the trail (<10%). DOSE 12 mg a.s./m3: 100% mortality occurred during the first hour after exposure. The 24 hours assessment confirms that it was a lethal	[redacted] 2011a

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**
					According to the standard (C.E.B. 135 bis) the treatment (2 cages in one fumigated room) is replicated one time (i.e. there were 2 treatments per experimental factor). Overall 4 batches of insects were exposed to the treatment. Number of insects: 50 per batch	effect (no recoveries).	
Insecticide and acaricide	Indoor use including domestic premises, industrial premises and breeding premises	ULTRAD DM (FUMICIDE DM deltamethrin 1.8%)	*Vespa crabro* (hornet)	Method C.E.B. nº 135 bis	Laboratory assay in an empty storage building 165 m² (660 m³) Dose: 3.6 mg a.s./m^3 Exposure time: 4h 20 +/-1°C, 70+/-5% HR and light 1200 lux. 4 Replications per species per application dosage. According to the standard (C.E.B. 135 bis) the treatment (2 cages in one fumigated room) is replicated one time (i.e. there were 2 treatments per experimental factor). Overall 4 batches of insects were exposed to the treatment. Number of insects: 10	The death rate in the untreated control is low enough to validate the trail (<10%). DOSE 3.6 mg a.s./m^3: 100% mortality occurred during the first hour after exposure. The 24 hours assessment confirms that it was a lethal effect (no recoveries).	[redacted] 2011b

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**
					per batch		
Insecticide and acaricide	Indoor use (breeding premises)	ULTRAD DM (FUMICIDE DM deltamethrin 2.4%)	*Dermanyssus gallinae* (puoltry red mite)	Method C.E.B. nº 135 and 135bis	Simulated-use assay in a test chamber 24 m² (60 m³) containing cardbord,polysterene blocks, harbourages and test tiles.Test species were placed on treated surfaces (test tiles) 1, 4, 8, 16, 24, 32, 36, 48 weeks after exposure of tiles in test chamber to the product. Mortality was assessed after 4, 24, 48 hours and 7 days of test species to treated tiles. Dose: 24 mg a.s./m^3 Exposure of tiles per treatment 4 hours 1, 2 and 3 treatments were assessed. In Case of multiple treatment 24 h waiting period between treatments. 20+/-1°C, 70+/-5% HR and light 1200 lux. According to C.E.B. 135 bis the treatment (2 cages in one fumigated room) is replicated one time (i.e. there were 2 treatments per	The death rate in the untreated control is low enough to validate the trial (<10%). The product FUMICIDE DM showed residual efficacy against poultry red mites. 1 treatment (24 mg a.s./m³) showed 100% mortality of species after 24h exposure to treated surface tiles until 8 weeks after initial treatment. 2 and 3 treatments (48/72 mg a.s./m³) showed 100% mortality of species after 24 hours exposure to treated surface tiles until 48 weeks after treatment.	[redacted] 2011c

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**
					experimental factor). Overall 4 batches of insects were exposed to the treatment.. Number of insects: 50 ±1 per batch		
Insecticide and acaricide	Indoor use live stock breeding premises	FUMICIDE DM (deltamethrin 2.4%)	*Musca domestica* (house fly),	French Standard Method C.E.B. nº 107	Field trial in 4 buildings (150 to 200 m^3). Fly population (only *Musca domestica* is counted) was assessed prior to treatement by traps in the premise. Additionally *Musca domestica* was tested in cages (4 cages; 2 on ground and 2 hung in 1.80 m) in the premise. Dose: 4.8 mg a.s./m^3 Exposure time: 4 h Fly population was assessed after 24h, 7 days, 14 days and 30 days. Trial was conducted from November to December in 2010 in closed buildings.	In the conditions of this trial, the smoke generator FUMICIDE DM at a dose of 4.8 mg a.s./m^3 lead to 100% mortality after 24 hours for Musca domestica both in cages. The fly population (only Musca domestica assessed) was reduced at a rate of 91% 24 hours after treatment, 98.3% after 7 days, 98.7 after 14 days and 99.5 after 30 days (end of trial). Efficacy was assessed by comparing pre-treatment conditions with treated conditions. Control premises showed no significant fly population reduction during the trial.	[redacted] 2010c
Insecticide and acaricide	Indoor use	FUMICIDE DM 2.4	*Blatta orientalis* (Oriental cockroach)	Method C.E.B. 135bis	Simulated-use assay Dose: 0.5 g product/m^3, i.e. 12 mg a.s./m^3 Exposure time: 4h	The product FUMICIDE DM 2.4, applied as a space treatment at a rate of 30 g in 60 m^3, has proved a fast and definitive insecticide	[redacted] 2019

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**
					Number of insects: 10 adults	efficacy against the oriental cockroaches *Blatta orientalis*, adults	
Insecticide and acaricide	Indoor use	FUMICIDE DM 2.4	*Blatta orientalis* (Oriental cockroach)	Method C.E.B. 135bis	Simulated-use assay Dose: 0.5 g product/m^3, i.e. 12 mg a.s./m^3 Exposure time: 4h Number of insects: 25 per batch	Results shows a very good efficacy of the product with almost 100% of mortality only 10h after the start of the treatment for *Blatta orientalis*.	[redacted] 2019
Insecticide and acaricide	Indoor use	FUMICIDE DM 2.4	*Blatta orientalis* (Oriental cockroach)	Method C.E.B.n°249	Field efficacy test Test system: Application was done in the preferred insect's locations (and unreachable to humans and pets) as: under the fridge, under the kitchen sinks and behind kitchen skirting's, under the oven and the water-heater, on all dark places that can be an harborage for cockroaches. Dose: 0.5 g product/m^3, i.e. 12 mg a.s./m^3 Exposure time: 4h Assessments: 1 day and 1, 2 and 3 weeks after treatment.	The product FUMICIDE DM 2.4, applied as a space treatment at a rate of 0.5 g/m^3, has proved a fast and almost complete insecticide efficacy against the oriental cockroaches Blatta orientalis. The efficacy is lasting 3 weeks after treatment.	[redacted] 2019b

Conclusion on the efficacy of the product

Efficacy studies (2 Laboratory trials, 5 simulated-use trials and 2 Field trial) have been conducted to prove the curative efficacy of FUMICIDE DM against the claimed range of target organisms. The product was shown to be efficious for the claimed indoor use in domestic and breeding (industrial) premises. All studies were performed according to the French standard methods C.E.B.n° 135 or C.E.B.n° 107. Concerning the replicates the standard methods were not always considered definitely. One replicate (2 cages of insects in one fumigated room per replicate, overall 4 cages) was performed per test according to the mentioned standard documents with the exception of study 1368c/0310R ([redacted] 2010a) in which no replicates were performed but 4 batches of insects were tested simultaneously (4 cages with insects in one fumigated room). Detailed results are summarized under chapter 2.2.5.5 efficacy data. The studies are suitable as proof of the efficacy for indoor use since 100% mortality was shown for a sufficient amount of individual target insects. No residual efficacy has been demonstrated for each use, only curative treatment is claimed and sufficiently proved.

For the following target pests up to two applications per year are envisaged: cat flea (*Ctenocephalides felis*), bed bugs (*Cimex lectularius*), house dust mites (*Dermatophagoides pteronyssinus*), house spider (*Tegeneraria domestica*), aedes mosquitoes (*Aedes albopictus*), hornets (*Vespa crabro*), German cockroach (*Blattella germanica*), the Oriental cockroach (*Blatta orientalis*), house fly (*Musca domestica*), and woodlice *(Armadillidum vulgare)*
In case of the claimed efficacy against hornets (*Vespa crabro*) in the study 1368h3h/0310 ([redacted] 2011) the used product formulation deviated by containing 1.8% of active substance instead of 2.4%. This is due to a technical reason. To reach the efficous dose of 3.6 mg a.s./ m³ using the formulation with 2.4% a.s. 7.5 g of product would be needed per dose. The smoke generating reaction starts when the formulation content in the dose is at least 10 g. Thus to allow the reaction the formulation was adjusted to 1.8% of a.s. which results in 10 g of formulation per dose.For the following target organisms 7 applications per year are envisaged to cover the whole year in regard of curative treatment for reinfestation of treated premises (breeding premises, chicken growing farms, fattening pigs and sows): Dermestre hide beetle *(Dermestes maculatus),* German cockroach *(Blattella germanica),* and lesser mealworm *(Alphitobius diaperinus).*
In case of dermestre hide beetle *(Dermestes maculatus)* treatment does not lead to 100% moratlity at the end of the exposure time (4 hours). However, the test organisms are heavily impaired which results in steadily increasing mortality after exposure. After 24 hours 50%, 48 hours 85% and 100% are reached after 7 days post exposure and thus was accepted by the eCA.

The submitted efficacy tests support all intended target organisms. For all target organisms at least a laboratory test, performed in a test room, has been submitted fulfilling the requirements of the respective guidance (Technical notes for guidance on Product Evaluation, 2008). The current guidance in force requires at least laboratory screening and simulated use or field trials for all claimed target organisms. Due to the currently acceptable general claim for crawling insects the simulated use trial and field trials against both required cockroach species allow extrapolation to the other tested target organisms for which studies are also available. The comparable efficacy of the product for oriental cockroaches and german cockroaches allows a read across.
Thus, the eCA accepts the simulated use trials for both cockroach species and the field trial for the oriental cockroach and the tests submitted for the other target organisms.
Since the assessment of the efficacy studies for all intended target organisms was executed with regard to the TNsG on Product Evaluation (2009), special attention will be given at the renewal to review the complete efficacy data according to the current efficacy

guidance (Vol. II, Parts B+C) for this dossier.
Preventive treatment was claimed by the applicant for Poultry red mites *(Dermanyssus gallinae)* with a contact time of 24h and three applications with a 24h interval in between. Following the definition of preventive activity as stated in the guidance in force at the time of submission (Technical notes for guidance on Product Evaluation, 2008) preventive is linked to the prevention of crossing of a treated area for the target organisms (e.g. barrier treatment for termites). The product is not intended for preventive treatment but rather as residual treatment to allow ongoing efficacy of the product for an extended amount of time. As residual treatment a simulated use trial was submitted. In this trial tiles were collected and after a period of waiting reintroduced into the testing chamber. The treated tiles displayed residual efficacy for 48 weeks. However, the tests have not been performed using litter as is intended to be used in the stable environment. Thus, it remains unclear if the residual efficacy of empty tiles may be readily extrapolated onto litter covered tiles. The eCA does not accept the use.

Justification for the recommended time intervals between applications

Based on the efficacy data provided, only a curative treatment is validated without a claim of residual efficacy. The indicated number of treatments per year is based on the following recommendations given by the applicant.
For domestic premises: 1 application per year consisting in 2 treatments with a 2-week interval between the treatments for solving a high infestation level in domestic areas or premises where the application of liquid products is not possible. Such treatment should be considered as the last solution when no other solution was successful and therefore should be exceptional. So 2 applications should be the maximal frequency for a same place.
For breeding premises: 7 applications per year with a 6-7 week interval between applications is the recommended application frequency in broiler growing farms for treating high infestation level. The growing cyclus is generally 6-7 weeks; the treatment is performed during the sanitation period between growing cyclus.

The eCA accepts the justifications.

2.2.5.6 Occurrence of resistance and resistance management

Resistance to pyrethroids has been documented in many countries for a range of organisms (e.g. mosquitoes, http://www.pesticideresistance.org). Any insect population may contain naturally tolerant individuals to insecticides. If insecticides are used repeatedly and not in the recommended dosage the resistant individuals may eventually dominate the pest insect population. In order to avoid development of resitance by mosquitoes it is recommended to rotate the use of pyrethroid-based products with other insecticidal products of different chemical families and also change the target development stage if possible (larvae - adults).

Management strategies:

Because resistance is well known to be a potential problem, strategies to avoid resistance development are normal practice. For example, the use of alternating sequences, mixtures and avoidance of frequent repeated use are standard. General advice is provided by IRAC. The principles of strategies for preventing and managing the development of resistance are similar for transfluthrin as they are for other synthetic pyrethroids;
To delay the development of resistance it is necessary to apply the following instructions for use:

- N-248: Always read the label or leaflet before use and follow all the instructions provided.
- N-280, modified: Adopt integrated pest management methods such as alternation between treatment strategies during the treatment regime (biological, chemical and cultural), taking into account local specificities (climatic conditions, target species, conditions of use, etc.).
- N-249: The users should report to the authorization holder if the treatment is ineffective
- N-278, modified: If the infestation persists, contact a professional pest control operators.

2.2.5.7 Known limitations

Not known.

2.2.5.8 Evaluation of the label claims

The authorised label claims for the product are:

- For Professional users:
  - Curative treatment (No residual efficacy has been demonstrated)
  - Exposure time and concentration of the product is depending on the respective target pest
  - Indoor application in domestic premises to control:
    German cockroach, adults *(Blattella germanica)*, Oriental cockroach, adults *(Blatta orientalis)*, , aedes mosquitoes, adults *(aedes albopictus)*, house dust mites, adults *(Dermatophagoides pteronyssinus)*, house spider, adults *(Tegenaria domestica)*, cat flea, adults and nymphs *(Ctenocephalides felis)*, bed bug, adults *(Cimex lectularius)*, house fly, adults *(Musca domestica)*, hornets, adults *(Vespa crabro)*, and woodlice *(Armadillidium vulgare);*
  - Indoor application in breeding premises to control blood sucking pests:
    Poultry red mite, adults *(Dermanyssus gallinae)*;
  - Indoor application in breeding premises to control target pests not affecting livestock: dermestre hide beetle, adults *(Dermestes maculatus)*, lesser mealworm, adults *(Alphitobius diaperinus)*, German cockroach, adults *(Blattella germanica)* and Oriental cockroach, adults *(Blatta orientalis)*;

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

Copper(II) carbonate-copper(II) hydroxide (1:1) and silicon dioxide (amorphous) (nano) were identified as substances of concern for the human health in the biocidal product. A quantitative risk assessment for Copper(II) carbonate-copper(II) hydroxide (1:1) is not carried out since dermal decomposition takes place and no exposure is expected. For silicon dioxide (amorphous) (nano) the applicant provided a study ([redacted] 2019) which demonstrates that the deduced AECs are not exceeded by SiO_2 particles emitted in b.p. fumes (see Conf. Annex for the SoC assessments).

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

No data are available for the product. Product classification is carried out based on the mixture calculation method under CLP.

Data waiving	
Information requirement	IIIB 8.1 Skin corrosion and irritation
Justification	In order to avoid further testing on vertebrates no studies on the skin irritation of the product were conducted as there are valid data available an each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in the Regulation (EC) 2072/2008 (CLP) and no synergistic effects between any of the components are expected.

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Classification not required.
Justification for the value/conclusion	The active substance deltamethrin is not classified for skin irritation or corrosion. None of the co-formulants are classified for skin irritation/corrosion or are present in concentrations relevant for classification according to CLP Regulation.
Classification of the product according to CLP and DSD	-

Eye irritation

Two GLP and OECD guideline conform studies (OECD 405, 438) have been carried out with FUMICIDE DM. The results are summarised in the table below.

Summary table of animal studies on serious eye damage and eye irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance ,Dose levels, Duration of exposure**	**Results** *Average score (24, 48, 72h)/ observations and time point of onset, reversibility*	**Remarks** *(e.g. major deviations)*	**Reference**
Acute eye irritation/corrosion OECD TG 405 (Acute Eye Irritation/Corrosion) GLP compliant, Klimisch 1	New Zealand white rabbits, male, n=3	FUMICIDE DM; ULTRAD DM, 0.1 g Duration of exposure: 1 second Conjunctival sac of one eye, lid were gently hold together for about 1 second; Examinations were performed 1, 24, 48 and 72 hrs	The ocular reactions observed during the study have been slight to moderate and totally reversible. The mean score for animal Nr. 1, Nr. 2 and Nr. 3 for conjunctivivae chemosis, is 0,0,0.7, for conjunctivae redness 0.3, 0.3, 1.7, for iris lesion 0, 0, 0.7, for cornea opacity 0, 0.3, 1.0. at the conjunctivae level: a slight to moderate redness noted 1 hour after the test item instillation and totally reversible between days 2 and 7 associated with a slight chemosis noted 1 hour after the test item instillation and totally reversible between days 1 and 3. - at the conjunctivae level: a slight to moderate redness noted 1 hour	Deviations to the study plan:____Environ-mental parameters A relative humidity lower than 30% was registered on 17, 18 & 19 February 2016. The minimum value measured was 22%. This deviation is considered as without impact on the conclusion of the study.	[redacted] 2016

Summary table of animal studies on serious eye damage and eye irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance ,Dose levels, Duration of exposure**	**Results** *Average score (24, 48, 72h)/ observations and time point of onset, reversibility*	**Remarks** *(e.g. major deviations)*	**Reference**
		following treatment	after the test item instillation and totally reversible between days 2 and 7 associated with a slight chemosis noted 1 hour after the test item instillation and totally reversible between days 1 and 3. - at the iris level: an injection, noted 24 hours after the test item instillation in one animal and totally reversible on day 3. - at the corneal level: a slight opacity, noted 24 hours after the test item instillation in two animals and totally reversible between days 2 and 7. A white coloration of palpebral conjunctivae was noted in one animal between day 1 and 2 and in a second animal at the reading time one hour.		
Isolated Chicken Eye Test Method (ICE) OECD TG 438	Chicken eye (Total: 8 eyes)	FUMICIDE DM; ULTRAD DM 30 mg of the test item was	The ocular reactions observed in eyes treated with the test item were: - maximal mean score of **corneal opacity**: 0.3 (ICE class I); -mean score of **fluorescein retention:** 2.7 (ICE class IV);	None	[redacted] 2016

Summary table of animal studies on serious eye damage and eye irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance ,Dose levels, Duration of exposure**	**Results** *Average score (24, 48, 72h)/ observations and time point of onset, reversibility*	**Remarks** *(e.g. major deviations)*	**Reference**
(Isolated chicken eye test method for identifying I) chemicals inducing serious eye damage and II) chemicals not requiring classification for eye irritation or serious eye damage) GLP compliant, Klimisch 1		applied for 10 seconds	- maximal mean corneal swelling: +7% at 240 minutes post dose (ICE class II). The combination of the three endpoints for the test item FUMICIDE DM was **1 x IV, 1 x II, 1 x I.** Positive and negative control were included and considered appropriate. The results obtained under these experimental conditions do not enable to predict the classification (Cat. 1 or no classification) of the test item FUMICIDE DM.		

Comparison with classification criteria:

The outcome of the isolated chicken eye test do not allow to predict wheter a classification into Category 1 or no classification is warranted. No prediction can be made based on the outcome.

According to Regualtion (EC) No. 1272/2008 a substance should be classified for irreversible eye effects (Category 1) if it produces in at least one animal effects on the cornea, iris or conjunctiva that are not expected to reverse or have not fully reversed within an observation period of normally 21 days and/or it produces at least in two of three tested animals a positive response of corneal opacity ≥3 and/or iritis >1.5.

Under CLP, a substance should be classified for reversible eye effects (Category 2) if, in at least two of three tested animals, a positive response is observed of corneal opacity ≥1 and/or iritis ≥1 and/or conjunctival redness ≥2 and/or conjunctival oedema ≥2; calculated as mean score following grading at 24, 48 and 72 hours and which are fully reversible.

The outcome of the OECD TG 405 study does not indicate a classification according to Regulation (EC) No. 1272/2008.

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	No classification required.
Justification for the value/conclusion	Taking into account the results obtained in the tests based on OECD TG 405 and the OECD TG 438 no classification is required. In the acute eye irritation/corrosion test only light to moderate ocular reactions have been observed, which are totally reversible. The classification criteria according to Regulation 1272/2008 are not met. The isolated chicken eye test method does not allow to predict wheter the FUMICIDE DM needs to be classified into Cat. 1A or not. In accordance with the Regulation (EC) No. 1072/2008, the results obtained under these experimental conditions demonstrate that no classification is needed.
Classification of the product according to CLP and DSD	Not irritating

Respiratory tract irritation

No data are available for the product. Product classification is addressed based on the mixture calculation method under CLP Regulation.

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	No indication of respiratory tract irritation: No classification required.
Justification for the conclusion	None of the components used in the mixture are classified for respiratory irritation. Therefore classification is not required for the product.
Classification of the product according to CLP and DSD	-

Data waiving	
Information requirement	Respiratory tract irritation
Justification	Specific testing for respiratory irritation is not required.

Skin sensitization

No data are available for the product. Product classification is addressed based on the mixture calculation method under CLP Regulation.

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	No indication of skin sensitisation: No classification required.
Justification for the value/conclusion	The active substance deltamethrin is not classified for skin sensitisation. None of the co-formulants are classified for skin sensitisation, thus the final product is not classified for skin sensitisation.
Classification of the product according to CLP and DSD	-

Data waiving	
Information requirement	Skin sensitisation
Justification	In order to avoid further testing on vertebrates no studies on the skin sensitisation properties of the product were conducted. A study is scientifically unjustified.

Respiratory sensitization (ADS)

No data are available for the product. Product classification is addressed based on the mixture calculation method under CLP Regulation.

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	No indication of respiratory sensitisation: no classification required
Justification for the value/conclusion	Deltamethrin is not regarded as a respiratory sensitizer. None of the coformulants are considered as respiratory sensitizer too. Therefore, the product FUMICIDE DM is not classified for respiratory sensitivity and no further studies are needed with the formulated product.
Classification of the product according to CLP and DSD	-

Data waiving	
Information requirement	Respiratory sensitization
Justification	Specific testing for respiratory sensitisation is not required and is not possible in the absence of any recognised and validated test method. Classification of the product is addressed using available data for the individual ingredients of the formulation.

Acute toxicity

Three acute toxicity studies according to OECD TG 425 (acute oral toxicity), OECD TG 403 (acute inhalative toxicity) and OECD TG 402 (dermal toxicity) have been submitted by the applicant.

Acute toxicity by oral route

Summary table of animal studies on acute oral toxicity						
Method Guideline GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance Dose levelsType of administration** *(gavage, in diet, other)*	**Signs of toxicity**	**Value LD50**	**Remarks** *(e.g. major deviations)*	**Reference**
OECD Guideline 425 (Acute Oral Toxicity: Up-and-Down Procedure) GLP compliance Reliability: 1	Species: rat Strain: wistar Sex: female No:4	Test substance: FUMICIDE DM Doses: Animal 1 (1-0): 550 mg/kg Animal 2 (2-0): 2000 mg/kg Animal 3 (3-0): 2000 mg/kg Animal 4 (4-0): 2000 mg/kg Type of administration: gavage	Mortality: The mortality data are summarized as follows: Dose level 550 mg/kg: - Number of animals survived: 1 - Number of animals died: 0 - Number total of animals: 1 Dose level 2000 mg/kg: - Number of animals survived: 3 - Number of animals died: 0 - Number total of animals: 3 Clinical signs: No signs of systemic toxicity were noted during the observation period. Bodyweight: Animals showed expected gains in body weight over the observation period - except for one animal treated at a dose level of 2000 mg/kg which showed expected gain in bodyweight during the first week but no gain in body weight during the second week. Gross pathology: No abnormalities were noted at necropsy.	LD50 ≥ 2000 mg/kg	no major deviations from OECD TG 425	[redacted] 2013

Value used in the Risk Assessment – Acute oral toxicity	
Value	No indication of acute oral toxicity: no classification required.
Justification for the selected value	An acute oral toxicity study with FUMICIDE DM has been carried out according to OECD TG 425 and in compliance with GLP. No major deviations from the guideline are present and the study has a reliability score of 1. *A classification for the oral route is required where the LD_{50} is ≤2000 mg/kg bw. The LD_{50} for FUMICIDE DM is >2000 mg/kg bw. Thus no classification for oral acute toxicity is required.*
Classification of the product according to CLP and DSD	-

Acute toxicity by inhalation

Summary table of animal studies on acute inhalation toxicity						
Method, Guideline, GLP status , Reliability	**Species, Strain, Sex, No/group**	**Test substance, form** *(gas, vapour, dust, mist)* **and particle size (MMAD) Actual and nominal concentration, Type of administration** *(nose only / whole body/ head only)*	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**LC50**	**Remarks** *(e.g. major deviations)*	**Reference**
OECD Guideline 403 (Acute Inhalation Toxicity) GLP compliance Reliability: 1	Species: rat Strain: RccHanTM : WIST strain Sex: male/female No:5 male/5 female	Test substance form: dust Nominal concentration: Between 4.93 mg/L and 5.54 mg/L (mean achieved concentration =5.17 mg/L) Type of administration: nose only	No deaths occurred in a group of ten rats exposed to a mean achieved atmosphere concentration of 5.17 mg/L for four hours. 4 hr LC50 of 2.4% FUMICIDE DM in wistar rat was greater than 5.17 m g/L. Sings of toxicity included respiratory rate, hunched posture, pilo-erection and wet fur. Lobored respiration and red/brown staining around the nose was also noted.	LC_{50} >5.17 mg/L	Animals were acclimatised to the restraint tubes for 2 hours at the day of exposure. These deviations have no impact on study validity.	[redacted] 2013

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	No indication of acute inhalation toxicity: no classification required
Justification for the selected value	An acute inhalative toxicity study with FUMICIDE DM has been carried out according to OECD TG 403 and in compliance with GLP. No major deviations from the guideline are present and the study has a reliability score of 1. *A classification for the inhalative route is required where the LC_{50} value is ≤5 mg/L (dusts and mists). The LC_{50} for FUMICIDE DM is >5.17 mg/L. Thus no classification for inhalative acute toxicity is required.*
Classification of the product according to CLP and DSD	-

Acute toxicity by dermal route

Summary table of animal studies on acute dermal toxicity						
Method, Guideline, GLP status, Reliability	**Species, strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Surface area**	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**LD50**	**Remarks** *(e.g. major deviations)*	**Reference**
OECD Guideline 402 (Acute Dermal Toxicity), Semi-occluded GLP compliance/ Reliability: 1	Species: rat Strain: wistar Sex: male/female No:5 male/5 female	Test substance: FUMICIDE DM Vehicle: Test item is moistened with distilled water Dose levels: 2000 mg / kg bw Surface area: back and flanks of each animal	Mortality: No deaths. Clinical signs: No signs of systemic toxicity. Gross pathology: No abnormalities were noted at necropsy.	LD50 >2000 mg/kg body weight.	No deviations were observed.	[redacted] 2013

Value used in the Risk Assessment – Acute dermal toxicity	
Value	No indication of acute dermal toxicity: no classification required
Justification for the selected value	An acute dermal toxicity study with FUMICIDE DM has been carried out according to OECD TG 402 and in compliance with GLP. No major deviations from the guideline are present and the study has a reliability score of 1. *A classification for the dermal route is required where the LD50 value is ≤2000 mg/kg bw. The LD_{50} for FUMICIDE DM is >2000 mg/kg bw. Thus no classification for dermal acute toxicity is required.*
Classification of the product according to CLP and DSD	-

Information on dermal absorption

There is no experimental data available on the dermal absorption of the biocidal product FUMICIDE DM (powder) and residual deposits of the generated fume: FUMICIDE DM (fume). Human dermal exposure takes place only to FUMICIDE DM after air space treatment by aerosol (FUMICIDE DM (fume)). According to EFSA Guidance (EFSA, 2017) a procedure has been established demonstrating in which cases the data on the active substance to formulated product can be used (flow chart 6, page 31). According to EFSA guidance new data or a justification is needed. In the following a justification is provided why data from Deltametrins AR have been considered for the dermal absorption value.

Justification for dermal absorption value

Considering the physical state of the biocide formulation after the air space treatment a 2% dermal absorption value is considered for risk characterization (Sweden, 2011).
This value was set for an elmusifiable concentration formulation (considered the worst case) between different tested formulations (e.g., oil in water (EW), suspension concentrate (SC), water-dispersible granules (WG)) in Deltamethrin's AR (Sweden, 2011).

A revision of the dermal absorption value taken the EFSA guidance into account (EFSA, 2017) was proposed by DE during commenting phase and is followed by the eCA.

Dermal absorption of Decis EC 25 was derived by performing a triple pack study. The three studies (rat and human in vitro and rat in vivo) were evaluated according to EFSA 2017. The following values were derived in the studies. The rounded dermal absorption value is 7% (for details see confidential annex for MS only).
For solid formulations, such as FUMICIDE DM (powder and fume); a lower dermal absorption is expected since certain solvents favour the absorption of deltamethrin. In the OECD TG Notes on dermal absorption series on testing and assessment No. 156 (OECD, 2011) it is stated that on a case by case basis it can be argued that solids do not have a higher dermal absorption than organic. For Decis EC 25 organic solvents have been used whereas for FUMICIDE DM (powder) no solvent is used at al. A comparison of the formulations tested (DECIS EC 25) and the FUMICIDE DM (powder) is provided in the confidential annex (for MS only).

FUMICIDE DM (powder) does not contain any other substance that would result in skin irritation or sensitization classification of the formulation.

Furthermore, the acute dermal toxicity study performed with FUMICIDE DM disclose same LD50 (>2000 mg/kg bw) than based on active substances CAR. Following deltamethrin's CAR, deltamethrin is not classified as sensitizer nor irritating. Deltamethrin's concentration in FUMICIDE DM (powder) is 2.4%, which is in the same order of magnitude than for the tested EC formulation.

Nevertheless, it needs to be taken into account that human exposure takes place to DM FUMICIDE (fume). Therefore, the comparision should be interpreted with caution. It has been demonstrated that after the air space treatment by aerosol only 15% of the a.s. remains. The concentration of the a.s. in the FUMICIDE DM (fume) is 3.6 mg/g product corresponds according to the study design of the study of [redacted] (2016) to 3.6 mg/m^3. Dermal exposure is not considered to be a major pathway for this kind of biocidal product (smoke generator).

Taking all this information above into account and considering chapter 7.2.3 (solid vs liquid formulations) from the OECD Guidance Notes on dermal absorption (OECD, 2011), it may be assumed that skin penetration of solid biocide formulation after aerosol treatment (FUMICIDE DM (fume)), will be less than for organic solvent-based formulation (assessed in Deltamethrin's CAR), therefore a dermal absorption value of 7% as worst case is considered as appropriate.

Therefore a 2% dermal absorption value is considered as an appropriate estimate.

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Deltamethrin
Value(s)*	7%
Justification for the selected value(s)	Based on Deltamethrin AR (Sweden, 2011) and additional information (EFSA, 2017, OECD, 2011)

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

One substance of concern Copper(II)carbonate - copper(II) hydroxide (1:1) has been identified.
A further substance Cyclohexanone (CAS: 108-94-1) was subject to SoC identification. For cyclohexanone a IOEL has been set and is 40.8 mg/m3 (= 10 ppm) for long-term exposure Limit (LTEL) values and 81.6 mg/m3 (= 20 ppm) for Short-term Exposure Limit (STEL). Furthermore, it has a skin designation. Therfore, the substance is a candidate to SoC analysis (CG-45_e-c Harmonized aprr._SoC and workplace exp. limits.pdf).
However, due to hazard, potency and exposure consideration, it is not considered further as SoC.

After combustion some substance of relevance for human health consideration have been identified in the FUMICIDE DM (fume). Please refer to the detailed composition of non-active substance in the powder and in the fume in the confidential Annex (Chapter 3.6).

Available toxicological data relating to a mixture

--

2.2.6.2 Exposure assessment

Identification of main paths of human exposure towards active substance 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.	No	Yes	Yes
Dermal	N.a.	Yes	Yes	N.a.	No	Yes	Yes
Oral	N.a.	No	No	N.a.	No	Yes	Yes

N.a. not available

The biocidal product FUMICIDE DM is an insecticidal product in the form of smoke generator powder used against flying and crawling insects. FUMICIDE DM is used by professional and non-professional users in indoor volume treatments of domestic and breeding premises. No humans and animals are present during treatment.

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
[1]	Re-entry to connect the ventilation system	The product may be used in premises where an efficient ventilation system exists (natural or artificial ventilation) and which must be activated manually in the treated premises after product's treatment (or opened in the case of natural ventilation, e.g. windows). Human exposure may occur when the operator reenters the treated premise before safety time for a short time in order to start the ventilation system. In other cases a sufficiently efficient ventilation system might not exist or the sytem control may be outside the treated premise (as in general in breeding premises). In this case, entering the premises is not considered to be likely.	Professional, non-professional
[2]	Disposal product and cleaning treated areas	Cleaning surfaces and disposal packaging should take place after 4 or 60 hours safety time This scenario is considered for adults such as for professional and non-professional users who clean treated premises.	Professional, non-professional
[3]	Stay in treated premises	Secondary exposure to general public after treatment. This secondary exposure may occur by dermal route to adults and childer and by dermal and oral route to infants reentering treated zones.	General public
[4]	Laundering contaminated work clothes	Secondary exposure of people laundering contaminated work clothes at home.	General public

Professional exposure

FUMICIDE DM (powder) is a smoke generator formulation. Human exposure is considered to be relevant after the application phase. This is due to the fact that the application phase is done by remote control in closed premises without human or animal presence. The product is initiated through a retarded wick which allows the operator to leave the premise under treatment with enough time to avoid exposure to the product. No mixing and loading stages are required as the product is a ready-to-use formulation.

Nevertheless, exposure may occur right after the application, if the operator is required to re-enter into the treated premise for some minutes for starting the ventilation process (e.g. opening of windows). In other cases the ventilation system control may be outside the treated premise and can be switched on without the necessity to enter and without any potential of being exposed (e.g. in breeding premises in common).

After treatment and potential start of a ventilation process, a safety time is required in order to allow the clearance of air and deposition of product residues on surfaces. Following the use instructions, the rooms shall be ventilated for a minimum time of 4 hours after the treatment of domestic premises and breeding premises before re-entry if efficient ventilation is possible.

In treated premises where sufficient ventilation is not possible (assumption of no ventilation at all as reasonable worst case), a safety time of 60 hours (before re-entering the premise) is required to assure acceptable residual substance concentrations in air during the operator's tasks of disposal of cans or cleaning of the treated premise. The derivation of these values for safety time are explained below.

After passing the safety time, re-entry is allowed and product cans are removed and disposed as hazard waste. Disposal of used cans may lead to dermal exposure when removing the cans with residues of product deposited on the can's surface after the treatment.

Inhalation exposure:

Maximum product doses applied and reasonable worst case-concentration in air after application(no safety time)

According to a study submitted by the applicant ([redacted] (2016)), the quantitative analysis of collected deltamethrin in emitted fumes from 10 g of the product FUMICIDE DM is 36 mg deltamethrin/10 g product (average value of 3 samples). The maximum value of these 3 samples is used for further calculations: 38.5 mg deltamethrin/10 g product. This concentration is considered to be the maximum concentration of deltamethrin that might be found in air during and right after treatment or deposited on the treated surfaces after treatment, if no cleaning has been done.

Based on the following product doses and the release of 38.5 mg deltamethrin/10 g product, the following reasonable worst case concentrations in air during and right after treatment are calculated for risk assessment:

Product doses
- 0.5 g of FUMICIDE DM/m^3 for domestic areas (maximum dose) and
- 1 g of FUMICIDE DM/m^3 for breeding premises (maximum dose).

10 g product cover a volume of 20 m^3 for domestic premises and 10 m^3 for breeding areas. Hence, the maximum expected concentrations in air during or right after treatment in the different premises are:

- Domestic (dose of 0.5 g Product/m^3): 38.5 mg deltamethrin / 20 m^3 = 1.925 mg deltamethrin/m^3
- Breeding (dose of 1 g Product/m^3): 38.5 mg deltamethrin / 10 m^3 = 3.85 mg deltamethrin/m^3

A summary description of [redacted] (2016) is provided in the confidential annex section.

Concentrations in air after safety times and derivation of safety times

1 vol/hr and 2 vol/hr have been assumed as ventilation rates for domestic and breeding premises respectively, if ventilation is possible. As no agreed default values are available, these conservative values are applied. The safety time of 4 hours is a proposal of the applicant. Taking these ventilations rates and 4 hours safety time into account, the total systemic exposure levels for users taking all tasks into account are safe justifying the applicability of the input applied.

In the case that no efficient ventilation is possible (air exchange considered to be zero), a safe deltamethrin's concentration in air was measured after 60 hours safety time referring to deltamethrin's concentration obtained from a trial test ([redacted] 2017). This study demonstrated that the concentration of deltamethrin for a dose of 0.5 g product/m^3 applied in a sealed premise is 0.0145 mg/m^3 in air and 4.12 mg/m^2 on surfaces after 60 hrs. A summary description of [redacted] (2017) is provided in the confidential annex section.

Hence, at this time (after 60 hours) someone can enter into the room without being exposed to a non-acceptable level of deltamethrin present in air.

The following active substance concentrations in air after 4 hour treatment (C_1) and after 4hours/60hours safety time (C_2) have been derived for scenarios 1 and 2.

The formula considers the impact of air exchange by ventilation and requires uniform distribution of the fume for best consistency. Settlement of fume particles (speed increased by agglomeration of particles) reduces fume concentration in air in addition to air exchange by ventilation leading to a concentration gradient in the treated room with time. Regarding these two key processes cleaning the air, the formula is considered to provide conservative estimates in this context, as the impact of particle sedimentation is disregarded and the derived concentration to be overestimations. For subscenario[2-dom], the formula is not applied, as air exchange is assumed to be zero and a measured value after 60 hours safety time is applied instead. The substance concentration in air is considered to be reduced in the absence of any ventilation by sedimentation only in this case.

- Domestic premise: ventilation system present: 1 vol/hr, 4hrs safety time

[1-dom]: C_1= 1.925 mg/m^3 (after treatment)

[1-dom]: C_2 = 1.925 $[mg.m^{-3}] \times e^{-1[vol/hr] \times 4[hr]}$ = 0.0352 mg $_{Deltam}$./m^3 (after 4 hrs safety time)

- Domestic premise: ventilation system not present: 0 vol/hr, 60hr safety time

[2-dom]: C_1= 1.925 mg/m^3 (after treatment, not relevant as premise is not entered)

[2-dom]: C_2 = 0.0145 mg $_{deltamethrin}$/m^3 (*) (after 60 hrs safety time)

- Breeding premise: ventilation system present: 2 vol/hr, 4hsr safety time

[1-bre]: C_1= 3.85 mg/m^3 (after treatment)

[1-bre]: C_2 = 3.85 $[mg.m^{-3}] \times e^{-2[volhr] \times 4[hr]}$ = 0.00129 mg $_{Deltam}$./m^3 (after 4hrs safety time)

Dermal exposure

Referring to a study carried out by [redacted] (2016c), 7.4 mg deltamethrin per m^2 (mean value) have been found as residue on floor in a test chamber after 15 hours exposure and 30 minutes ventilation using the biocidal product at a dose of 1g/m^3. This value is applied for breeding premises (1-bre) corresponding to 1 g of FUMICIDE DM/m^3 product dose applied. Half of the value: 3.7 mg deltamethrin per m^2 is assumed for the floors of domestic premises with ventilation (1-dom) corresponding to 0.5 g FUMICIDE DM/m^3 applied.

Regarding domestic premises without ventilation (2-dom) 4.12 mg deltamethrin per m^2 are used for risk assessment. The study performed by [redacted] (2017) demonstrated that this concentration of deltamethrin for a dose of 0.5 g$_{product}$/m^3 applied in a sealed premise without ventilation is found on surfaces 60 hrs after treatment.
Summary descriptions of [redacted] (2016c) and [redacted] (2017) are provided in the confidential annex section.

A value of 7% (dermal absorption value) is considered in this risk assessment for estimating exposure to active substance residuals on treated surfaces.

* Deltamethrin's concentration obtained from the trial test ([redacted], 2017)

Scenario [1]: Reentry in treated premise - Primary exposure

Description of Scenario [1] – Reentry in treated premise (Primary exposure)		
As it was already described, the operator may be primary exposed when he re-enters the treated premises to connect the ventilation system after treatment. This is considered to be the reasonable worst case scenario, when a user enters in the treated premise before activating the ventilation sytem. The assumed durations per day are 5 minutes for domestic and 10 minutes for breeding premises respectively. Inhalation is expected to be the main path of exposure (ES: 1-dom, 1-bre). Dermal exposure is expected to be covered by the disposal and cleaning activities (exposure scenario 2). In other cases a (sufficiently) efficient ventilation system might not exist in domestic premises (ES 1: 2-dom)or the system control may be outside the treated premise (as in general in breeding premises). In these case, entering the premises for this purpose is not required. The present exposure scenario is assessed for domestic and breeding premises. Please see below the considered assumptions for each scenario:		
	Parameters	**Value**
Tier 1	Exposure time in the treated premise when connect the ventilation system: Domestic premise (1-dom) Domestic premise (2-dom) Breeding premise (1-bre)	 5 min Not assumed 10 min
	Active substance concentration in air at this point of time (C_1): C_1 - Domestic premise (1-dom) C_1 - Domestic premise (2-dom) C_1 - Breeding premise (1-bre)	 1.925 mg/m^3* 1.925 mg/m^3 (not relevant[1])* 3.85 mg/m^{3*}
	Frequency of use [*FQ*]	1 event/day
	Body weight [*BW*]	60 kg[(2)]
	Fraction released to air [*Fair*]	100%
	Inhalation rate [*IR*]	1.25 m^3/hour[(2)]
Tier 2	Mask (APF 10) is considered as RPE	Fraction 1/10 Penetration 10%

[1] Not relevant, as premise is not entered, as there is no ventilation system to activate
[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 (2017)
*Refer to introduction of the human exposure section

Calculations for Scenario [1]: Reentry in treated premise - Primary exposure

Summary table: systemic exposure from professional uses					
Exposure scenario	**Tier**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
ES 1: 1-dom	Tier 1	$3.34x10^{-3}$ mg/kg bw/d	-	-	$3.34x10^{-3}$ mg/kg bw/d
ES 1: 1-dom	Tier 2	$3.34x10^{-4}$ mg/kg bw/d	-	-	$3.34x10^{-4}$ mg/kg bw/d
ES 1: 2-dom	Not applicable, as premise has no ventilation system to activate				
ES 1: 1-bre	Tier 1	$1.34x10^{-2}$ mg/kg bw/d	-	-	$1.34x10^{-2}$ mg/kg bw/d
ES 1: 1-bre	Tier 2	$1.34x10^{-3}$ mg/kg bw/d	-	-	$1.34x10^{-3}$ mg/kg bw/d

Scenario [2]: Disposal product's can and cleaning - Primary exposure

Description of Scenario [2] - Disposal product's can and cleaning (Prim. Exp.)		
As it was mentioned above, the operator may be primary exposed when removing the product's can from the treated premises and during the cleaning activity. The frequency of treatment is expected to be 1 event per day. 1 hour of duration for domestic premises and 2 hours for breeding premises are considered. Dermal and inhalation uptake are considered to be the two potential routes exposure. A safety time for re-entry 4 hrs is considered for domestic or breeding premises (C2 (1-dom, 1-bre)) or 60 hrs for domestic premises (C2 (2-dom)), if no ventilation is present. Two situations leading to inhalation exposure are considered in this scenario, one due to the residue in the air treatment and a second one due to the process of cleaning the floor by broom/vacuum cleaner. Further details can be seen in the Annex 3.2.1 of the present dossier. Values considered in the present assessment are shown below:		
	Parameters	**Value**
Tier 1	Active substance concentration in air (C_2) after safety time C_2 - Domestic premise (1-dom) C_2 - Domestic premise (2-dom) C_2 - Breeding premise (1-bre)	 0.0352 mg_{Delta}/m^{3*} 0.0145 mg_{Delta}/m^{3*} 0.00129 mg_{Delta}/m^{3*}
	Active substance concentration on treated surfaces after safety time Domestic premise (1-dom) Domestic premise (2-dom) Breeding premise (1 -bre)	 3.7 mg_{Delta}/m^{2*} 4.12 mg_{Delta}/m^{2*} 7.4 mg_{Delta}/m^{2*}
	Frequency of use [*FQ*]	1 event/day
	Exposure time Domestic premise (1-dom) Domestic premise (2-dom) Breeding premise (1-bre)	 1 hour 1 hour 2 hours
	Skin surface area in contact with treated surface	820 cm^2 (1)
	Fraction released to air during cleaning	1%[3]
	Dislodgeable fraction for dermal exposure	100%
	Inhalation absorption	100%
	Dermal absorption	7%
	Inhalation rate	1.25 m^3/hour[1]
	Body weight	60 kg[1]
Tier 2	With PPE and RPE (gloves and mask)	Fraction 1/10 Penetration 10%[2]

[1] 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 (2017)
[2] HEEG No. 9, Default protection factors for protective clothing for gloves
[3] cf. to COMMISSION REGULATION (EU) No 666/2013 of 8 July 2013 implementing Directive 2009/125/EC of the European Parliament and of the Council with regard to ecodesign requirements for vacuum cleaners, Annex I, 1 b): "dust re-emission shall be no more than 1.00 %"
*Refer to introduction of the human exposure section

Calculations for Scenario [2]: Disposal product's can and cleaning (Primary exposure) – after safety time

Summary table: systemic exposure from professional uses					
Exposure scenario	**Tier**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
ES 2: 1-dom	Tier 1	1.03×10^{-3} mg/kg bw/d	3.54×10^{-4} mg/kg bw/d	-	1.38×10^{-3} mg/kg bw/d
ES 2: 1-dom	Tier 2	1.03×10^{-4} mg/kg bw/d	3.54×10^{-5} mg/kg bw/d	-	1.38×10^{-4} mg/kg bw/d
ES 2: 2-dom	Tier 1	6.28×10^{-4} mg/kg bw/d	3.94×10^{-4} mg/kg bw/d	-	1.02×10^{-3} mg/kg bw/d
ES 2: 2-dom	Tier 2	6.28×10^{-5} mg/kg bw/d	3.94×10^{-5} mg/kg bw/d	-	1.02×10^{-4} mg/kg bw/d
ES 2: 1-bre	Tier 1	6.39×10^{-4} mg/kg bw/d	7.08×10^{-4} mg/kg bw/d	-	1.35×10^{-3} mg/kg bw/d
ES 2: 1-bre	Tier 2	6.39×10^{-5} mg/kg bw/d	7.08×10^{-5} mg/kg bw/d	-	1.35×10^{-4} mg/kg bw/d

Combined scenarios: Professional exposure (ES 1 + ES 2)

	Summary table: combined systemic exposure from professional uses				
Scenarios combined	**Tier**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
ES 1 + ES 2: 1-dom	Tier 1	4.37×10^{-3} mg/kg bw/d	3.54×10^{-4} mg/kg bw/d	-	4.72×10^{-3} mg/kg bw/d
ES 1 + ES 2: 1-dom	Tier 2	4.37×10^{-4} mg/kg bw/d	3.54×10^{-5} mg/kg bw/d	-	4.72×10^{-4} mg/kg bw/d
ES 1 + ES 2: 2-dom	Tier 1	6.28×10^{-4} mg/kg bw/d	3.94×10^{-4} mg/kg bw/d	-	1.02×10^{-3} mg/kg bw/d
ES 1 + ES 2: 2-dom	Tier 2	6.28×10^{-5} mg/kg bw/d	3.94×10^{-5} mg/kg bw/d	-	1.02×10^{-4} mg/kg bw/d
ES 1 + ES 2: 1-bre	Tier 1	1.40×10^{-2} mg/kg bw/d	7.08×10^{-4} mg/kg bw/d	-	1.47×10^{-2} mg/kg bw/d
ES 1 + ES 2: 1-bre	Tier 2	1.40×10^{-3} mg/kg bw/d	7.08×10^{-5} mg/kg bw/d	-	1.47×10^{-2} mg/kg bw/d

Non-professional exposure

Instructions of use for non-professional users are the same as those for professional operators at domestic premises except for the use of PPE.

The product is a ready to use smoke generating formulation and hence no previous step of mixing/loading is necessary. During application, the operator shall light the wick and immediately leave the room where the treatment is performed. The retarded mechanism of the wick allows the operator to leave the room without being exposed to the product. The operator is completely segregated from the biocidal source during release of the product and therefore inhalation and dermal exposures to the product during application are not likely during the application phase.

Inhalation and dermal exposure to the product during re-entry is likely in the worst case that the connection of ventilation system is located inside the treated domestic premise and for cleaning tasks after safety time.

Scenario [1]: Re-entry in treated premise - Primary exposure

Description of Scenario [1] – Re-entry in treated premise- Primary exposure
Please refer to the corresponding exposure scenarios for professionals. The exposure scenarios are considered to be the same except for the anticipated non-use of PPE or RPE. Therefore, the Tier 1-exposure of the professional's scenario are considered to apply for non-professionals.

Summary table: systemic exposure from professional uses					
Exposure scenario	**Tier**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
ES 1: 1-dom	Tier 1	$3.34x10^{-3}$ mg/kg bw/d	-	-	$3.34x10^{-3}$ mg/kg bw/d
ES 1: 2-dom	Not applicable, as premise has no ventilation system to activate				
ES 1: 1-bre	Tier 1	$1.34x10^{-2}$ mg/kg bw/d	-	-	$1.34x10^{-2}$ mg/kg bw/d

Scenario [2]: Disposal product's can and cleaning - Primary exposure

Description of Scenario [2] - Disposal product's can and cleaning- Primary exposure
Please refer to the corresponding exposure scenarios for professionals. The exposure scenarios are considered to be the same except for the anticipated non-use of PPE or RPE: Therefore, the Tier 1-exposure of the professional's scenario are considered to apply for this situation.

Calculations for Scenario [2]: Disposal product's can and cleaning - Primary exposure

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
ES 2- 1-dom	Tier 1	$1.03x10^{-3}$ mg/kg bw/d	$1.01x10^{-4}$ mg/kg bw/d	-	$1.13x10^{-3}$ mg/kg bw/d
ES 2: 2-dom	Tier 1	$6.28x10^{-4}$ mg/kg bw/d	$1.13x10^{-4}$ mg/kg bw/d	-	$7.40x10^{-4}$ mg/kg bw/d
ES 2: 1-bre	Tier 1	$6.39x10^{-4}$ mg/kg bw/d	$2.02x10^{-4}$ mg/kg bw/d	-	$8.41x10^{-4}$ mg/kg bw/d

Combined scenarios:Non-professional exposure (ES 1 + ES 2)

Summary table: combined systemic exposure from non-professional uses					
Scenarios combined	**Tier**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
ES 1 + ES 2: 1-dom	Tier 1	$4.37x10^{-3}$ mg/kg bw/d	$1.01x10^{-4}$ mg/kg bw/d	-	$4.47x10^{-3}$ mg/kg bw/d
ES 1 + ES 2: 2-dom	Tier 1	$6.28x10^{-4}$ mg/kg bw/d	$1.13x10^{-4}$ mg/kg bw/d	-	$7.40x10^{-4}$ mg/kg bw/d
ES 1 + ES 2: 1-bre	Tier 1	$1.40x10^{-2}$ mg/kg bw/d	$2.02x10^{-4}$ mg/kg bw/d	-	$1.42x10^{-2}$ mg/kg bw/d

Exposure of the general public

Scenario [3]: Exposure to general public after surface treatment application indoors

Exposure of the general public is possible considering dermal contact with contaminated surfaces and inhalatory uptake, if residual amounts of fume are still present in air after safety time.
Regarding breeding premises, exposure of the general public is unlikely, as the general public is not expected to stay at all or not for a long time at these premises.
Considering domestic premises, the potential and level of exposure of the general public is expected to be higher. In the domestic premises where the product is intended to be applied (e.g. cellars), no cleaning methods are normally applied in order to prolong the effect of the product. Treated surfaces should be cleaned, if there is a relevant potential for human exposure e.g. for areas where people stay for longer durations of time or access them with higher frequency.

Referring to the two situations for domestic premises (non-ventilated and ventilated rooms), the higher air concentration derived is used for this scenario (0.0353 mg/m^3). As long presence in areas like cellars are considered to be unlikely, 2 hours are assumed to be a conservative assumption.Exposure may occur by inhalation and dermal route to adults and by all three routes to children and infants.

Description of Scenario [3] – Secondary Exposure to general public after surface treatment application indoors			
Secondary exposure may occur accidentally by dermal route to adults and by dermal and oral (hand-to-mouth transfer).			
	Parameters		Value
Tier 1	For inhalation uptake	Active substance concentration in air (C_2) after safety time and during presence C_2 - Domestic premise (1-dom)	0.0353 mg_{Delta}/m^{3*}
		Exposure duration	2 h/day
		Inhalation absorption	100%
		Inhalation rate	1.26 m^3/h for toddler[1] 1.25 m^3/h for adult[1]
		Exposure duration	2 hr/day
		Indoor transfer coefficient	0.2 m^2/h for toddler[2] 0.78 m^2/hr for adult[2]
		Active substance concentration on treated surface Domestic premises (2 dom)	4.12 mg_{Delta}/m^{2*}
		Dislodgeable fraction (Disl)	50%[3]
		Demal absorption	7%
		Oral absorption	75%
	For oral uptake	Oral uptake is assessed according to the guidance RIVM-320005002 (2006), where it is indicated that the ingestion rate can be calculated based on the assumption that from the total dermal exposure 10% is taken in orally due to hand-mouth contact	
	Body weight		10 kg for toddler[1] 60 kg for adult[1]

[1] 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 (2017)
[2] Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure: New default values for indoor Transfer Coefficient (2016)
[3] Annex VI of TNsG HUMAN EXPOSURE TO BIOCIDAL PRODUCTS (June 2007). 50%: value for powders on vinyl, most conservative value for potential floor materials, stainless steel (70% for dry hands) is not expected as material for floors.
*Refer to introduction of the human exposure section

Calculations for Scenario [3]: Secondary Exposure to general public after surface treatment application indoors

Summary table: systemic exposure					
Exposure scenario	**Description Tier 1**	**Estimated inhalation uptake**	**Estimated dermal uptake***	**Estimated oral uptake**	**Estimated total uptake**
ES 3: 2-dom	Adults reentering treated non-cleaned premises	1.47×10^{-3} mg/kg bw/d	3.75×10^{-3} mg/kg bw/d	-	5.22×10^{-3} mg/kg bw/d
ES 3: 2-dom	Toddler rubbing non-cleaned floor after treatment and transfer to mouth	8.88×10^{-3} mg/kg bw/d	5.19×10^{-2} mg/kg bw/d	6.18×10^{-3} mg/kg bw/d	1.23×10^{-2} mg/kg bw/d

Scenario [4] (Exposure to persons laundering contaminated work clothing)

In general this approach assumes that the laundering is undertaken in a domestic, automatic washing machine. Therefore, exposure will be by the dermal route, via the hands, from handling the contaminated clothing prior to and during introduction of the clothing into the washing machine. It is considered that laundering is undertaken after a five day work week.

Description of Scenario [4] – Secondary Exposure to persons laundering contaminated work clothing
Home laundering of contaminated work clothes like coveralls is a potential scenario. This task might be done by the operator or someone else. The level of contamination of coveralls via deposition of active substance from air is expected to be low, as the time spent in treated premises for starting the ventilation system (scenario 1) is short and the concentration in air has reduced significantly after safety time as most particles in air have settled or been removed via ventilation (scenario 2). Regarding direct contact with treated surfaces during cleaning activities as potential source for coverall contamination (scenario 2), the level of potential exposure is expected to be highest for hands. Wherease exposure and contamination of other body parts covered by clothing might be more limited in comparison to hand's exposure. Based on these considerations, the scenario of persons laundering contaminated work clothing is expected to be covered by scenario 3 for general public (Tier 1), which considers direct contact with non-cleaned, treated surfaces and no use of any PPE.

Combined scenarios

No combined scenarios are foreseeable for general public.

Dietary and livestock exposure

The product FUMICIDE DM is a smoke generator formulation (FU) based on deltamethrin (2.4% w/w) intended to be used for control of insects in empty domestic premises (e.g. cellars)and breeding premises (piggery and poultry) by professional and non-professional users.

The Biocidal Products Regulation (BPR) requires that whenever food contamination results from the use of a biocidal product, a dietary risk assessment should be performed.
Due to the application pattern of FUMICIDE DM, indirect food contamination cannot be excluded as residues of the product might remain deposited on surfaces where food may be stored or placed. Food becomes contaminated when put on a surface that contains residues either because surface cleaning did not take place or surface cleaning was not fully effective. Direct contamination of food is not intended to take place during application of the product as all food items should be removed before or well-covered during treatment.
In domestic premises, treatments might lead to unmeant contamination of kitchen or food storage rooms, although FUMICIDE DM is not intended to be directly applied on surfaces that can be in contact with food.
Regarding breeding premises like for poultry exposure to foodstuffs might be through eggs or consumption of exposed meat. These scenarios are covered by the livestock scenarios.

Scenario number	**Description of scenario**	**Subject of exposure**
1.Dietary scenario	Human may be exposed to the product residues if they come into contact with food	Food
2.Livestock scenario	Human may be exposed to the product residues if they come into contact with chicken	Chicken
3.Livestock scenario	Human may be exposed to the product residues if they come into contact with pig	Pig
4.Transference to food	Same scenario as [1]	Chicken, Pig

No ADI or ARfD has been derived during the revision of the active substance deltamethrin as a biocidal actice substance, however, for PPP generally an ADI and ARfD of 0.01 mg a.s./kg was agreed for deltamethrin.

Human dietary risk assessment

FUMICIDE DM might be applied several times per year. Nevertheless, contaminated surfaces might remain contaminated for longer time-periods or more food might have been contaminated leading to potential consumption of contaminated food on several days per year.

Regarding the following dietary exposure assessment, Guidance on BPR: Volume III Parts B+C Version 4.0 December 2017: chapter 5.6.3 Insecticides in residential homes has been taken into account. The given model is considered to be applicable for this case as well.

Assumptions given in guidance document: comments regarding the applicability for theuse of FUMICIDE DM

- a.s. is diffused into air and 100% of a.s. is deposited on horizontal surfaces only (Comment: measured value for domestic floor area is used). Accumulation of biocide residues over several days is not considered. Biocide residues are assumed to be distributed evenly throughout the airspace. No room ventilation is considered. If refinement options are available and are scientifically justified, they can be proposed; (Comment: Accumulation is not assumed, as only a few number of treatments per year are expected and contaminated surfaces are expected to be cleaned several times during the events).

- Biocidal product is used daily; (Comment: reasonable worst case, assuming that treated surfaces remain contaminated for longer periods of time)

- 100% of surface biocide residues are transferred to food in contact with the surface. Product specific data on mass transfer efficiency may be considered if available; (Comment: 100% applied, as no data for refinement are available)

- Exposure of adult and toddler age groups

- Default value for contaminated surface area in contact with food (that represents daily dietary exposure of consumer): 0.53 m^2 ; the dietary intake fraction: acute = 1.0/day and chronic = 0.5/day; the default value for chronic exposure reflects the fact that vaporisers are not typically used continuously for 24 hours per day (Comment: 0.5/day and 1.0/day are applied)

Regarding the two premises, domestic and breeding, exposure of food (meat, eggs) in breeding premises is considered to be covered by the performed lifestock exposure assessment (see next chapter). Regarding domestic premises, food might get contaminated assuming contact with non-cleanend or not sufficiently cleaned surfaces.

Scenario [1]- Dietary scenario considering food contaminated in domestic premises

Description of Scenario [1]: Food contaminated via treated surfaces in domestic premises		
According to Guidance on BPR: Volume III Parts B+C Version 4.0 December 2017 (page 315), the following equation is recommended for estimating consumer dietary exposure: $Exp_{cons} = R_{surface} * A_{food\ contact} * TF * D/ bw$		
	Parameters[1]	Value
Tier 1	Consumer exposure [Exp_{cons}]	$Exp_{cons\ (adult)}$ = 3.7 mg a.s./m^2 * 0.53 m^2 * 1 * 1/d / 60 kg bw = 0.032 mg a.s./kg bw/d $Exp_{cons\ (adult)}$ = 3.7 mg a.s./m^2 * 0.53 m^2 * 1 * 0.5/d / 60 kg bw = 0.016 mg a.s./kg bw/d $Exp_{cons\ (toddler)}$ = 3.7 mg a.s./m^2 * 0.53 m^2 * 1 * 1/d / 10 Kg bw = 0.196 mg a.s./kg bw$Exp_{cons\ (toddler)}$ = 3.7 mg a.s./m^2 * 0.53 m^2 * 1 * 0.5/d / 10 Kg bw = 0.098 mg a.s./kg bw
	Biocide residues on surface [$R_{surface}$]	3.7 mg a.s./m^2 (*)
	Area in contact with food [$A_{food\ contact}$]	0.53 m^2
	Transferred to food [TF]	100% of surface residues are transferred to food in contact with the surface.
	Dietary intake fraction [D]	1/d for acute exposure 0.5/d for chronic exposure
	Body weight (kg) [bw]	60 kg for adult 10 kg for toddler (**)

(*) Application dose of 0.5 g product/m^3 in rooms with natural ventilation (dom-1)was asumed as a worse case for domestic premises. Refer to introduction of the human exposure section for the source of this value

(**) Toddlers represent the most sensitive consumer group.

Consumption of contaminated food is considered to happen on several days and also acute exposure is considered, therefore the relevant comparison value for intake dose is the ADI and ARfD. No ARfD/ADI was derived for deltamethrin as biocide. For Plant Protection Products a value of 0.01 mg/kg bw was derived and has been used in this assessment for the sake of comparison. Therefore, the intake of deltamethrin by the relevant populations assessed after treatment of commercial/industrial premises with FUMICIDE DM is:

Acute exposure

Adults: (0.032 mg a.s./Kg bw) / (0.01 mg a.s./Kg bw) = 3.2

Toddler: (0.196 mg a.s./Kg bw) / (0.01 mg a.s./Kg bw) = 19.6

Chronic exposure

Adults: (0.016 mg a.s./Kg bw) / (0.01 mg a.s./Kg bw) =1.6

Toddler: (0.098 mg a.s./Kg bw) / (0.01 mg a.s./Kg bw) = 9.8

The calculated intake by adults and toddlers indicate an unacceptable risk, if food contaminated via treated and non-cleaned surfaces is consumed.

Refinement options (Tier 2)

Therefore, based on the identified non-acceptable risk, the following mitigation measures are required in order to avoid the contact of food with contaminated objects and surfaces:

- N-132, modified: Do not apply in rooms in which food or feed is stored, prepared or eaten.
- Remove items that could come in contact with food (e.g. dishes, tables), before starting the treatment.

Estimating Livestock Exposure to Active Substances used in Biocidal Products

Regarding situations leading to exposure of livestock animals (poultry and pigs in this case), the following scenarios are identified in principle.

- Animals could be *exposed directly during treatment (inhalation, dermal, oral),*
- Contact with contaminated surfaces (dermal, oral)
- Consumption of contaminated feed (oral)
- Consumption of insects killed as result of the treatment (oral)
- Gaseous release of residues (inhalation)

Regarding the following estimates and assumptions, Guidance on BPR: Volume III Parts B+C Version 4.0 December 2017: chapter 6 is considered.

The Federal Institute for Risk Assessment (BfR) developed a tool to facilitate the estimation of livestock exposure to biocidal active substances as described in this guidance document (BfR calculator for estimating external exposure of livestock animals to biocidal active substances: https://www.bfr.bund.de/en/exposure_estimation_for_biocides-239939.html). This tool offers the calculation of exposure levels for screening and realistic worst case scenarios. The exposure levels for the screening scenario will be discussed as Tier-1 and the levls for the realistic worst case scenarios as Tier 2-predicitions. The tool will be used to identify the required risk mitigation measures in a tiered approach.

Referring to the following calculations, inhalation of gaseous releases is not taken into account due to the low vapour pressure of the active substance (1.24×10^{-8} Pa at 25ºC). Consumption of contaminated feed is not considered as feed must be removed or covered following the label's instructions.

Scenario [2]and [3]: Tier 1: Treatment of Animal Housing – Exposure of poultry and pigs

Description of Scenario [2]: Exposure of poultry and pigs		
In the following calculations, default values of the Guidance on BPR: Volume III Parts B+C Version 4.0 December 2017: chapter 6 are used. The Federal Institute for Risk Assessment (BfR) has developed a tool to facilitate the estimation of the livestock exposure to biocidal active substances as described in this guidance document (BfR calculator for estimating external exposure of livestock animals to biocidal active substances: https://www.bfr.bund.de/en/exposure_estimation_for_biocides-239939.html). The following input has been applied. The excel-file containing the calculations, details on the formulas and further defaults is attached to Annex 3.2.1.		
Tier 1 (Screening, scenario)	Parameters	Value
	Type of product application	air space treatment by aerosols
	Maximimal application rate of a.s.	7.4 mg/m^2
	Screening scenario	Surface treatment of animal housing (floor only)*

*According to field study [redacted] 2013, main fraction of a.s. residues are found on floor

Calculations for estimating livestock exposure for Scenario [2] - Tier 1: poultry

Exposure of poultry	
Tier: Animal species	**Total exposure [mg/kg bw/d]**
Tier 1: Broilers: free range, litter floor	0.2416
Tier 1: Broilers: parent broilers, free range (grating floor)	0.2425
Tier 1: Broilers: parent broilers in rearing, free range (grating floor)	0.2418
Tier 1: Laying hen: battery	0.1391
Tier 1: Laying hen: free range (litter floor)	0.5569
Tier 1: Laying hen: ree range (grating floor)	0.2473

Calculations for estimating livestock exposure for Scenario [3]-Tier 1: pigs

Exposure of pigs	
Tier: Animal species	**Total exposure [mg/kg bw/d]**
Tier 1: Fattening pig	0.1110
Tier 1: Breeding pig: individual housing	0.1207
Tier 1: Breeding pig: group housing	0.1531

Discussion of results and conclusion:

Although use of the biocidal product is space treatment, surface treatment of animal housing (floor only) has been selected in the BfR-calculator tool, as the main fraction of a.s. residues are found on floor according to field study of [redacted] (2013). The following formula is applied in this case.

Exposure=AR*Af/Noanim/bw
AR: Application rate (mg/m^2)
Af: floor area per stable (m^2) (default, TNsG Table 2)
Noanim: No. of animals per stable (default, TNsG Table 2)
bw: body weight (kg) (default, TNsG Table 1)

It considers that the total amount of residual a.s. is exposed in equal parts to all animals and predicts external exposure levels. This approach is considered to be representative for the assumption that animals are present in the premise during treatment. The air space treatment by aerosols leads to direct deposition of a.s. on the animals (inhalation, dermal, oral). Deposits on the floor might be taken up in addition.

As the trigger value of 0.004 mg a.s./kg bw/d is exceeded, indicating the possible presence of residues in food products from these animals, animals shall be removed from the premises to be treated during treatment.

Scenario [2]: Tier 2: Treatment of Animal Housing – Exposure of poultry

For Tier 2 the realistic worst case scenarios of the calculation tool were considered.
Regarding the treatment of poultry housings, the following standard scenarios are offered by the calculation tool:

- Oral- Uptake of feed contaminated in trough
- Oral- Direct treatment of feeding trough surface
- Oral- Ingestion of dead insects

Oral- Uptake of feed contaminated in trough and *oral- Direct treatment of feeding trough surface* are avoided by removing or covering feed and covering trough surfaces before treatment..

The scenario *Oral-Ingestion of dead insects* is not expected to be relevant, as aerosol treatment is performed after the production cycle (removal of manure and litter afterwards) or manure/litter-free surfaces are covered with fresh litter after treatment. Access to killed insects/flies is expected to be limited and to be of minor relevance as predicted in comparison to the assumptions of the standard scenario (e.g. 10 dead flies per day per animal). More information are provided below in the corresponding section of this scenario.

The offered scenarios for considering exposure via treatment: *Dermal- Dermal exposure through spray treatment* and *Inhalative- Inhalation after air space treatment* are not assumed to be applicable. The formula of Dermal- Dermal exposure through spray treatment considers wall area of the stable as an parameter and an emission factor for spray application (fraction emitted to floor during surface treatment; default: 0.11). As according to field study [redacted] (2013), the main fraction of a.s. residues are found on floor (emission factor: 1) and the level of exposure of animals is not considered to be proportionate directly to the wall area, levels derived from this scenario are not expected to be valid in this case. Therefore, the Tier-1 predicitions are preferred in this situation.

Scenario [2]: Tier 2: Treatment of Animal Housing – Exposure of poultry

Description of Scenario [2]- Tier 2: Exposure of poultry		
In the following calculations, default values of the Guidance on BPR: Volume III Parts B+C Version 4.0 December 2017: chapter 6 are used. The Federal Institute for Risk Assessment (BfR) has developed a tool to facilitate the estimation of the livestock exposure to biocidal active substances as described in this guidance document (BfR calculator for estimating external exposure of livestock animals to biocidal active substances: https://www.bfr.bund.de/en/exposure_estimation_for_biocides-239939.html). The following input has been applied. The excel-file containing the calculations, details on the formulas and further defaults is attached to Annex 3.2.1.		
Tier 2 (Realistic worst-case estimate)	Selected rwc-scenario	1) Oral- Uptake of feed contaminated in trough 2) Oral- Direct treatment of feeding trough surface 3) Oral ingestion of dead insects
	Maximum application rate of a.s for scenarios 1) and 2).	7.4 mg/m^2
	Scenario 3	
	Fly consumption per animal	10
	Consumption of biocidal product by fly	3.5 mg biocidal product
	Concentration of a.s. in b.p.	2.4%
	Maximum application rate for scenario 3) = Consumption of a.s. by fly	0.084 mg active substance

*According to field study [redacted] 2013, main fraction of a.s. residues are found on floor

Calculations for estimating livestock exposure for Scenario [2] - Tier 2: poultry

Exposure of poultry					
Animal Species		Oral - Uptake of feed contaminated in trough [mg/kg bw/d]	Oral - Direct treatment of feeding trough surface [mg/kg bw/d]	Oral - Ingestion of dead insects [mg/kg bw/d]	Total exposure [mg/kg bw/d]
Broilers				(0.4941)[1]	0
Broilers	free range, litter floor				
Broilers	parent broilers, free range (grating floor)				
Broilers	parent broilers in rearing, free range (grating floor)				
Laying hen		0.0043		(0.4421)[1]	0.0043
Laying hen	battery		(0.0389)[2]		0
Laying hen	free range (litter floor)				
Laying hen	free range (grating floor)				
Turkey				(0.1200)[1]	0

[1] The use instructions of this biocidal product are as such that exposure to dead insects is excluded. Therefore, this value is not applied in the following calculations.
[2] The RMMs of this biocidal product exclude direct treatment of surfaces and facilities likely to be in contact with feed and drinking water. Therefore, this value is not applied in the following calculations.

Discussion of results and conclusion:
Referring to the former table, the values provided by the tool are presented.

Oral- Ingestion of dead insects:
As aerosol treatment is performed after the production cycle (removal of manure and litter afterwards) or manure/litter-free surfaces are covered with fresh litter after treatment, consumption of killed flies or other insects is not expected to be relevant, as they are removed or not accessible. Therefore, this scenario is not taken into account.
In addition, the accurateness of the predicted value is uncertain. Referring to the corresponding assumptions used by the tool, it is expected that 3.5 mg biocidal product containing 2.4% active substance are consumed by a fly. In reality, the fly is exposed to the fume of the biocidal product and not to the biocidal product as such. In addition, the composition of the fume differs from the b.p. The scenario is considered to be over-conservative.

Nevertheless, consumption of killed flies needs to be avoided.

Following use specific instructions are made:

- Alternatively, at the end of a production cycle after animals left the stable, remove manure and litter before the start of the aerosol treatment. Access the stable when allowed (cf. to general use instructions), **remove any dead insects from the floor** and distribute fresh litter on the treated floor.

Oral- exposure via trough
Referring to the calculated levels, the trigger value of 0.004 mg a.s./kg bw/d is exceeded for each scenario. Therefore, food in troughs need to be removed and troughs to be covered or cleaned for avoiding these sources of exposure.

Scenario [3]: Tier 2: Treatment of Animal Housing – Exposure of pigs

For Tier 2, the realistic worst case scenarios of the tool were considered.
Regarding the treatment of pig housings, the following scenarios offered by the tool are assumed to be relevant in this case.

- Oral - Animals licking surfaces
- Oral- Uptake of feed contaminated in trough
- Oral- Direct treatment of feeding trough surface
- Dermal- Rubbing against surfaces

Oral- Uptake of feed contaminated in trough and *Oral- Direct treatment of feeding trough surface* are avoided by removing or covering feed and covering trough surfaces before treatment.
The offered scenarios for considering exposure via treatment: *Dermal- Dermal exposure through spray treatment* and *Inhalative- Inhalation after air space treatment* are not assumed to be applicable. The formula of Dermal- Dermal exposure through spray treatment considers wall area of the stable as an parameter and an emission factor for spray application (fraction emitted to floor during surface treatment; default: 0.11). As according to field study [redacted] 2013, the main fraction of a.s. residues are found on floor (emission factor: 1) and the level of exposure of animals is not considered to be proportionate directly to the wall area, levels derived from this scenario are not expected to be valid in this case. Therefore, the Tier-1 predicitions are preferred in this situation.

Scenario [3]: Tier 2: Treatment of Animal Housing – Exposure of pigs

Description of Scenario [3]: Exposure of pigs		
In the following calculations, default values of the Guidance on BPR: Volume III Parts B+C Version 4.0 December 2017: chapter 6 are used. The Federal Institute for Risk Assessment (BfR) has developed a tool to facilitate the estimation of the livestock exposure to biocidal active substances as described in this guidance document (BfR calculator for estimating external exposure of livestock animals to biocidal active substances: https://www.bfr.bund.de/en/exposure_estimation_for_biocides-239939.html). The following input has been applied. The excel-file containing the calculations, details on the formulas and further defaults is attached to Annex 3.2.1.		
	Parameters	Value
Tier 1 (Screening, scenario)	Type of product application	air space treatment by aerosols
	Maximimal application rate of a.s.	7.4 mg/m^2
	Screening scenario	Surface treatment of animal housing (floor only)*
Tier 2 (Realistic worst-case estimate)	Selected rwc-scenarios	Oral- Animals licking surfaces Dermal- Rubbing against surfaces
	Maximimal application rate of a.s.	7.4 mg/m^2

*According to field study [redacted] 2013, main fraction of a.s. residues are found on floor

Calculations for estimating livestock exposure for Scenario [3] - Tier 2: pigs

Animal Species		Oral - Animals licking surfaces [mg/kg bw/d]	Oral - Uptake of feed contaminated in trough [mg/kg bw/d]	Oral - Direct treatment of feeding trough surface [mg/kg bw/d]	Dermal - Rubbing against surfaces [mg/kg bw/d]	Total exposure [mg/kg bw/d]
Fattening pig		0.0059	(0.0033)[1]	(0.0888)[1]	0.0333	0.0392
Breeding pig		0.0023			0.0239	0.0262
Breeding pig	individual housing		(0.0119)[1]	(0.1776)[1]		0
Breeding pig	group housing		(0.0141)[1]	(0.0797)[1]		0

[1] The RMMs of this biocidal product exclude direct treatment of surfaces and facilities likely to be in contact with feed and drinking water. Therefore, this value is not applied in the following calculations.

Discussion of results and conclusion:

Whereas the calculated exposure levels of some individual scenarios are below the trigger value of 0.004 mg a.s./kg bw/d, values of other scenarios are significantly higher than the reference value. Assuming these scenarios in combination, the trigger value is exceeded for each animal species. It is highlighted that in contrast to the calulcations for risk assessment for animal health (section 2.2.7), refinements like a lower dermal absorption of pig skin than the default 100% are not considered for these calculations.

Based on the calculated values, food in troughs needs to be removed and troughs to be covered or cleaned. Access of animals to contaminated areas needs to be prevented. Surfaces accessible to animals need to be clean. As air space treatment by aerosol is performed after the production cycle (removal of biocide with manure and litter afterwards) or manure/litter-free surfaced are covered with fresh litter after treatment, animals are expected to be exposed to clean surfaces in common limiting sufficiently the contact with a.s..

Additional information: Discussion of field study ([redacted] 2013) provided by applicant as Tier 3 for livestock-risk assessment

The assessment of the applicant is provided in Annex 3.2.1. A FUMICIDE DM treatment event was monitored in a broiler shed. After treatment, 1 day old-chickens were introduced and reared for 34 days in breeding premise with a capacity of 33000 chickens. The applicants derived an total uptake of 7.56×10^{-4} mg a.s./kg bw/d by the chickens based on the deltamethrin concentration found in drinking water and the assumption that food contains 0.01 mg a.s./kg (reference value for food). As this value is below the trigger value of 0.004 mg/kg bw/day, the applicant concluded no potential presence of residues in food products from these animals.

The conclusion that the expected exposure level is below the trigger value of 0.004 mg/kg bw/d based on the previous considerations is not shared, as the same study reveals that 41.7% (equal to 5.72 g a.s) of the substance found in fresh litter at the beginning of the rearing period is "lost" after the rearing period. Considering that the lost amount has been transferred to the animals (external and internal exposure) and the number of animals in shed (33.000 chickens), an exposure level of 0.17 mg/chicken (=5.72 x 1000 /33.000) is calculated. This value is equal to 0.10 mg/kg bw, consider the default body weight for broilers (1.7 kg bw).

Assuming the same level of contamination for each day, this is equal to 0.0051 mg/chicken/d (= 0.003 mg/kg bw/d, 1.7 kg bw default for broilers) leading to a value below 0.004 mg/kg bw/d. Regarding the formulas of the BFR-calculator, these calculations do not take into account, that the substance might be taken up on several days after treatment. Applying the same conservatism, it is not considered to be valid to divide the exposure level by the number of days without further justifications demonstrating this reasonable assumption.
On the other hand, it is not fully clear, if the total amount of substance leading to contamination has been larger than 5.72 g a.s. considering excretion of a.s. already taken up and found again in manure.

Final conclusion:

The following mitigation measures (label restrictions) are taken into account for the following calculations:

• N-45 (modified): Remove all food, feed and drinking water prior to treatment.
• N-47: Assure animals are not present in areas during air space treatment by aerosol.
• N-122: Cover all surfaces and facilities likely to be in contact with feed and drinking water.

Scenario 4:Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)

For further details please refer to scenario [2] and [3].

Worst case consumer exposure (WCCE) assessment

Referring to the exposure levels derived for the individual scenarios for poultry and pigs, the trigger value of 0.004 mg/kg bw/day was exceeded for several scenarios, therefore a WCCE approach is conducted, taken into consideration residues of the substance that occur as a result of authorised use.

For the WCCE approach eggs from laying hen (total exposure: 0.0043 mg/kg bw) and meat commodities form (total exposure without refinement 0.0392 mg/kg bw) are considered. Please be aware that for fattening pig a refinement of the internal total expsure was carried out considering a revised dermal absorption value (21% instead of default of 100%) and a modified transfer factor was used (see 2.2.7.3. Risk characterisation for animal health) resulting in a total exposure of 0.0072 mg/kg/bw/d. This refined total exposure value was for margin of exposure calculations.

In the present WCCE, however, the worst case value of 0.0392 mg/kg bw was considered.

The WCCE approach takes into consideration the use instruction and the RMMs set. In regard to the toxikokinetic behaviour of Deltamethrin in animals, following information is available:

Deltamethrin is fatsoluble and it is distributed to all tissues, higher values have been found in fat . Metabolism studies in livestocks (cows, poultries) have been carried out in the frame of Directive 91/414/EEC. In EFSA (2015) it ist stated, that metabolism studies in ruminants indicate that Deltamethrin was the major compound in all tissues accounting for up to 90% of the total radioactive residue in fat. Metabolites Br2CA and PB acid were present at the same level as parent in liver and kidney (23 and 33% of the total radioactive residue, respectively). No studies with pigs are available, however the metabolism studies in cow could be extrapolated to pigs (EFSA, 2015).

In poultry tissues and eggs, deltamethrin was the main compound found (19-65% of the total radioactive residue), except in kidney where, apart for deltamethrin (25-28% total radioactive residue), metabolites c-Br2CA and c/t-COOH-c-Br2CA (together 22% total radioactive residue), and c-CH2OH-c-Br2CA and t-COOH-c-CH2OH-c-Br2CA-lactone (together 15-22% total radioactive residue) were also identified (EFSA, 2015).

Within the active substance approval of Deltamethrin (Sweden, 2011) oral absorption of 75% (Sweden, 2011) is considered. Results from a toxicokinetic study in rat (oral route) reveals that deltamethrin was distributed to most tissues. Residues in tissues and carcases were low (less than 2% of the total dose administered, 7 days postdose after single or repeated oral administration to rats). The highest residues were found in fat. In a further toxicokinetic study in rat (intravenous route) the residue of deltamethrin in adipose tissue in rats eliminated with a half-life of >24 hrs. Overall, the results offered no indication of possible accumulation in brain, spinal cord or nerve tissues (Sweden, 2011). Deltamethrin

was rapidly excreted in both urine and faeces after oral or intravenous administration to rats. In rats, administered single or repeated oral doses of deltamethrin at 0.55 or 5.5 mg/kg bw, 31% to 56% of the radioactivity was eliminated with the urine and 36% to 59% in faeces, 7 days postdose. The material balances for groups ranged from 84% to 96%, indicating no bioaccumulation. The majority of the radioactivity was eliminated within 24 hrs after dosing (19-47% with the urine, 32-55% in faeces) (Sweden, 2011).

The WCEE was performed assuming residues in eggs and in meat (including consumption of fat, liver and kidney):

Screening calculation residues in eggs: No data are available that would allow quantifying the transfer of the active substance, therefore 100% of the external exposure calculation of laying hens was used for the calculation. I_{eggs} is from the EMA food basket (0.1 kg/day).

Consumption of eggs

WCCE = amount of transfer into eggs*I_{eggs}/bw human

WCCE: 0.0043 mg/kg bw/d*0.1 kg/d /60 kg = 7.2×10^{-6} mg/kg bw/d

Consumption of meat

Screening calculation residues in meat (including consumption of fat, liver and kidney): No data are available that would allow quantifying the transfer of the active substance, therefore 100% of the external exposure calculation of fattening pigs was used for the calculation as worst case in comparison to the consumption of poultry. I_{meat} is from the EMA food basket (0.5 kg/day including the consumption of meat as such (0.3 kg/d), fat (0.05 kg/d), liver (0.1 kg/d) and kidney (0.05 kg/d).

WCCE = amount of transfer into meat*I_{meat}/bw human

WCCE : 0.0392 mg/kg bw/d *0.5 kg/d /60 kg = 3.3×10^{-4} mg/kg bw/d

Sum of both calculations:

WCCE: 3.4×10^{-4} mg/kg bw/d

The acceptable daily intake of Deltamethrin is 0.01 mg/kg bw/day and thus only about approximately 3.4% of the ADI are exploited due to consumption of meat and eggs.

Adherence of MRLs

For Deltamethrin (cis-deltamethrin) MRLs have been set (Com. Reg. (EU) 2018/832).

No accumulation in a specific organ is reported in the available studies. Deltamethrin is fatsoluble and most of the Deltamethrin was detected in fat (see toxicokinetic considerations above).

The MRL consideration is especially relevant for fattening pig, the estimated total uptake levels of 0.0072 are lower (about 36%) than the lowest derived MRLs (0.02 mg/kg for muscle, liver, kidney) in swine.

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

Not applicable according to the intended use pattern.

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

Occupational exposure during production and formulation of the biocidal product is not assessed under the requirements of the BPR. It is assumed that the production is performed in conformity with national and European occupational safety and health regulations.
In addition, production or formulation of biocidal products are already covered by REACH legislation, where the registrants (manufacturers/importers) of substances are obliged to consider human hazard and exposure and to provide RMMs/exposure scenarios for ensuring safe use (e.g. via SDS in the supply chain). Moreover, it is assumed that industrial production sites are subject to permit for installation. Therefore, it is not considered relevant to perform an additional exposure assessment under the biocide regime.

Aggregated exposure

Not applicable as the product FUMICIDE DM is not intended to be used under a different biocidal product type such as PT18.

Information of non-biocidal use of the active substance
The active substance deltamethrin is approved pesticide and a veterinary medical product.

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation (obtained from Deltamethrin's CAR).

Reference	Study	NOAEL (LOAEL)	AF	Correction for oral absorption	Value (mg/kg bw/day)
AELshort-term	13-week dog study	1	100	75%	0.0075
AELmedium-term	13-week and 1-year dog studies	1	100	75%	0.0075
AELlong-term	1-year dog study	1	100	75%	0.0075
ARfD(*)	1-year dog study	-	100	-	0.01
ADI(*)	1-year dog study	-	100	-	0.01

(*) No ARfD or ADI has been derived for deltamethrin as biocide. As Plant production product an ADI/ARfD has been derived and is considered.

Maximum residue limits or equivalent for Deltamethrin (cis-deltamethrin)

Residue definitions "Deltamethrin (cis-deltamethrin)"

MRLs or other relevant reference values for Deltamethrin (cis-deltamethrin)	Reference	Relevant commodities	Value (mg/kg)
		Products of animal origin- terrestrial animals: Swine, bovine, sheep, goat, equine	
MRL	Com. Reg. (EU) 2018/832	Muscle	0.03
MRL	Com. Reg. (EU) 2018/832	Fat	0.5
MRL	Com. Reg. (EU) 2018/832	Liver	0.03*
MRL	Com. Reg. (EU) 2018/832	Kidney	0.03*
MRL	Com. Reg. (EU) 2018/832	Edible offals (other than liver and kidney)	0.5*
MRL	Com. Reg. (EU) 2018/832	Others	0.02*
	Com. Reg. (EU) 2018/832	**Poultry**	
MRL	Com. Reg. (EU) 2018/832	Muscle	**0.02***
MRL	Com. Reg. (EU) 2018/832	Fat	0.1*
MRL	Com. Reg. (EU) 2018/832	Liver	0.02*
MRL	Com. Reg. (EU) 2018/832	Kindney	0.02*
MRL	Com. Reg. (EU) 2018/832	Edible offals (other than liver and kidney)	0.02*
MRL	Com. Reg. (EU) 2018/832	Others	0.02*
MRL	Com. Reg. (EU) 2018/832	Egg (chicken)	0.02*

(*)limit of analytical detection

Risk for professional users

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario 1: Re-entry in treated premise – primary exposure						
Scenario [1- Re-entry in treated domestic premise] ES 1: 1-dom	Tier 1 / No RPE	1	0.0075	0.003	40	Yes
Scenario [1- Re-entry in treated domestic premise] ES 1: 1-dom	Tier 2 / RPE	1	0.0075	0.0003	4	Yes
Scenario [1- Re-entry in treated breeding premise] ES 1: 1-bre	Tier 1 / No RPE	1	0.0075	0.0134	178.6	No
Scenario [1- Re-entry in treated breeding premise] ES 1: 1-bre	Tier 2 / RPE	1	0.0075	0.00134	17.9	Yes
Scenario 2: Disposal product´s can and cleaning (primary exposure) – after safety time						
Scenario [2: Disposal product´s can and cleaning in domestic premise] ES 2: 1-dom	Tier 1 / No RPE	1	0.0075	$1.38x10^{-3}$	18.4	Yes
Scenario [2: Disposal product´s can and cleaning in domestic premise] ES 2: 1-dom	Tier 2 / RPE	1	0.0075	$1.38x10^{-4}$	1.8	Yes
Scenario [2: Disposal product´s can and cleaning in domestic premise]	Tier 1 / No RPE	1	0.0075	$1.02x10^{-3}$	13.6	Yes

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
ES 2: 2-dom						
Scenario [2: Disposal product´s can and cleaning in domestic premise] ES 2: 2-dom	Tier 2 / RPE	1	0.0075	$1.02x10^{-4}$	1.36	Yes
Scenario [2: Disposal product´s can and cleaning in breeding premise] ES 2: 1-bre	Tier 1 / No RPE	1	0.0075	$1.35x10^{-3}$	18	Yes
Scenario [2: Disposal product´s can and cleaning in breeding premise] ES 2: 1-bre	Tier 2 / RPE	1	0.0075	$1.35x10^{-4}$	1.8	Yes

No unacceptable risk is expected for **Scenario 1 – Re-entry in treated domestic premise** after 4 hrs application time and without any safety time to re- enter the premise as worst case estimate for domestic premises.
Scenario 1- Re-entry in treated breeding premise, however, is only safe, if RPE (a mask) is used. For the domestic premise 0.5 mg Product /m3 and for the breeding premise 1 g Product/m3 are considered.

For **Scenario 2 - Disposal product´s can and cleaning in domestic and breeding premise** no unacceptable risk is expected. Safety time for re-entry has been considered.

Combined scenarios

Scenarios combined	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenarios [1 + 2] for domestic premises with ventilation [1-dom]	Tier 1	1	0.0075	$4.42x10^{-3}$	58.9	Yes
	Tier 2			$4.42x10^{-4}$	5.89	Yes
Scenarios [1 + 2] for domestic premises without ventilation [2-dom]	Tier 1			$1.02x10^{-3}$	13.6	Yes
	Tier 2			$1.02x10^{-4}$	1.4	Yes
Scenarios [1 + 2] for breeding premises	Tier 1			$1.47x10^{-2}$	196	No
	Tier 2			$1.47x10^{-3}$	19.6	Yes

Local effects
There is no need to consider local effects separately.

Conclusion

Three different combined szenarios are considered:
1-dom: re-entry in domestic pre-mise immediately after FUMICIDE DM application (worst case), disposal of product´s can and cleaning after 4 hrs safety time
2-dom: no re-entry – since no ventilation system present, disposal of product´s can and cleaning after 60 hrs safety time
1-bre: re-entry in breeding premise immediately after FUMICIDE DM application (worst case), disposal of product´s can and cleaning after 4 hrs safety time

For application in domestic premises acceptable risk is estimated for professional users who apply FUMIDE DM and re-entry the premise in case a ventilation system is put in place (1-dom) and clean the premise by dry method (e.g. broom, vacuum cleaner) after a safety time of 4 hrs (1-dom) or 60 hrs (2-dom, no ventilation).

On the other hand, when the operator use the product without any PPE and RPE, unacceptable risk is estimated at breeding premises if the ventilation sytem is switched on inside the premises to be treated. Therefore professional operators need to use PPE and RPE.

Based on these results the following instructions for labelling are required (see also 2.1.5.1):

- N-44, modified: After treatment provide if available adequate ventilation (industrial ventilation or keeping windows and doors open) to renew the air for a minimum of 4 hours. The stay to activate ventilation in the treated area should be minimized.

- In treated premises where ventilation is not possible do not re-enter before a safety time of 60 hours has passed.

Safety measures during treatment:

If the room has to be entered to switch on the ventilation system after treatment: Use of respiratory protective equipment (RPE) providing a minimum protection factor of 10 is mandatory. RPE is required (RPE and filter type (code letter, colour) to be specified by the authorisation holder within the product information).

Risk for non-professional users

Instructions of use for non-professional users are the same as those for professional operators at domestic premises except for the use of PPE. Therefore a higher Tier is not considered for non-professionals.

Systemic effects

Task/ Scenario	**Tier**	**Systemic NOAEL mg/kg bw/d**	**AEL mg/kg bw/d**	**Estimated uptake mg/kg bw/d**	**Estimated uptake/ AEL (%)**	**Acceptable (yes/no)**
Scenario [1- Re-entry in treated domestic premise: 1-dom]	Tier 1	1	0.0075	$3.34x10^{-3}$	40	Yes
Scenario [2- Disposal product's can and cleaning in treated domestic premise: 1-dom]	Tier 1			$1.13x10^{-3}$	15.07	Yes
Scenario [2- Disposal product's can and cleaning in treated domestic premise: 2-dom]	Tier 1			$7.40x10^{-4}$	9.87	Yes
ES 1 (Re-entry in reated premise) 1-bre	Tier 1			1.34x10-2	178.7	No
ES 2 (Disposal product´s can and cleaning): 1-bre	Tier 1			$8.41x10^{-4}$ mg/kg bw/d	11.21	Yes

Combined scenarios

Scenarios combined	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenarios [1 + 2] for domestic premises (1-dom)	Tier 1	1	0.0075	$4.47x10^{-3}$	59.6	Yes
Scenarios [1 + 2] for domestic premises (2-dom)	Tier 1			$7.40x10^{-4}$	9.87	Yes
ES 1 + ES 2: 1-bre	Tier 1			$1.42x10^{-2}$	189	No

Local effects

There is no need to consider local effects separately.

Conclusion

For application in **domestic premises** acceptable risk is estimated for non-professional users who apply FUMIDE DM and re-entry the premise in case a ventilation system is put in place (1-dom) and clean the premise by dry method (e.g. broom, vacuum cleaner) after a safety time of 4 hrs (1-dom) or 60 hrs (2-dom, no ventilation).

For non-professional users **use in breeding premisis is not permitted,** since a human health risk have been estimated in a Tier 1 estimate. Tier 2 (use of PPE) cannot be carried out for non-professional users.

Risk for the general public

Systemic effects

Task/ Scenario	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Adults, re-entering treated premises without ventilation / non cleaned premises Scenario [3-Domestic premise] [2-dom]		0.0075	$5.22x10^{-3}$		Yes
Toddler, rubbing floor after treatment and transfer to mouth in premises without ventilation / non cleaned premises Scenario [3-Domestic premise] [2-dom]			$1.23\ x10^{-2}$		No
Scenario [4- laundering contaminated work clothing]			neglible	-	Yes

Local effects
There is no need to consider local effects separately.

Conclusion
Exposure to general public due to entry into breeding permises is highly unlikely. Thus, only the worst case szenarios for domestic permisis (no ventilation, no cleaned permises) are considered.

An acceptable risk is expected for adults re-entering treated non-cleaned domestic permises.
An unacceptable risk is assumed in a worst-case szenario, if toddler rub non-cleaned floor after treatment and there is a transfer to the mouth. However, it is important to regard that in those domestic premises which are intended to be treated, it not likely that a toddler may be present in such kind of domestic premises. .Therefore following instructions for use should be stated on the label:

- Toodlers/children must not enter non-cleaned, treated areas.

Eposure levels while laundering contaminated clothes areconsidered to be negligible , thus no unacceptable risk is expected.

Risk for consumers via residues in food

No toxicological reference values for acceptable daily intake (ADI) or acute referene dose (ARfD) was derived for deltamethrin as biocide. As Plant Protection Products a value of 0.01 mg/kg bw was derived and has been used in this assessment for the sake of comparison.

The calculated intake by adults and toddlers indicate an unacceptable risk, if food contaminated via treated and non-cleaned surfaces is consumed.

Adults: estimated uptake (0.016 mg a.s./kg bw) / ADI (0.01 mg a.s./kg bw) =1.6
Toddler: estimated (0.098 mg a.s./kg bw) / ADI (0.01 mg a.s./kg bw) = 9.8

Therefore, based on the identified non-acceptable risk, the following mitigation measures are required in order to avoid the contact of food with contaminated objects and surfaces:

• N-132, modified: Do not apply in rooms in which food or feed is stored, prepared or eaten.
• Remove items that could come in contact with food (e.g. dishes, tables), before starting the treatment.

Humans can get also exposed via consumption of livestocks. As the trigger value of 0.004 mg a.s./kg bw/d is exceeded for each scenario, indicating the possible presence of residues in food products from these animals, food in troughs need to be removed and troughs to be covered or cleaned. Considering potential consumption of dead insects, contaminated manure and litter after treatment when access to the stable is allowed needs to be removed or alternatively the manure and litter is removed bevor starting the aerosol treatment for avoiding uptake. Following risk mitigation measures are needed:

• N-47: Assure animals are not present in areas during air space treatment by aerosol.
•N-45 (modified): Remove all food, feed and drinking water prior to treatment.
• N-122: Cover all surfaces and facilities likely to be in contact with feed and drinking water.

Adhering the RMMs and use instructions, it can be concluded, that the worst case consumer exposure (WCCE) are fare below the acceptable daily intake (ADI) (3.4% of the ADI) and that the MRL are not exceeded (see chapter 2.2.6.2). No risks is anticipated, if humans consum meat and eggs of livestocks housed in the treated premisis if RMMs and use instructions are adhered.

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

As it was mentioned in section 3.6 of the present dossier, several substances determined in field studies performed by the product manufacturer LCB on fume, ashes and residues deposited in surfaces after product application have been identified.

No substance of concern are present in FUMICIDE DM (powder) prior to application. In the fume (FUMICIDE DM (fume) beside deltamethrin nine substances were identified. Please refer to the substances identified, their concentration, their CLP classification and -as far as available also- toxicological limit values included in the Confindential Annex for the FUMICIDE DM (fume) (see section 3.6.3.2).

Toxicological limit values are only available for deltamethrin within the biocides CAR and for five of the combustion products within the REACH registration dossiers or other relevant information. For the other substances, although QSARs tool have been used to derive toxicological reference value, they were not available.The data underlying the DNEL derivation in the REACH registration dossier were not reviewed by the eCA in the context of this FUMICIDE biocides assessment; the responsibility for these underlying toxicological data remains with the REACH registrant.

Compared to deltamethrin the five combustion products appear to be clearly less of a toxicological concern. The ratio of the concentration of deltamethrin to its AEL is very high compared to the ratios of the concentrations of the combustion products to their systemic, long term, general public relevant DNELs, i.e. the lowest DNELs presented in the REACH registration dossier. This is the basis for concluding that the exposure and risk assessment for deltamethrin is covering the highest concern and no specific exposure and risk assessment for the combustion products is necessary.

For some of the combustion products no limit values could be identified. However their concentration compared to deltamethrin is lower in fume and ashes.

Consequenlty, considering best available toxicological knowledge, the exposure and risk assessment is carried out only for deltamethrin and this is likely to cover the highest concern of all potential combustion products (for details see chapter 3.6.3.2 FUMICIDE DM (fume)).

2.2.7 Risk assessment for animal health

2.2.7.1 Assessment of effects on animal health

Skin corrosion and irritation

Skin irritation

In order to avoid further testing on vertebrates, no studies on the skin corrosion and irritation properties of the product were conducted as 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) 1272/2008 (CLP) and no synergistic effects between any of the components are expected.

Eye irritation

Two eye irriation studies have been carried out with the biocidal product. According to the rules laid down Regulation (EC) 1272/2008 (CLP) no classification is needed.

Respiratory irritation

None of the components used in the mixture are classified for respiratory irritation. Therefore classification is not required for the product. There is no indication of respiratory tract irritation.

Sensitisation

In order to avoid further testing on vertebrates no studies on the skin sensitisation properties of the product were conducted as there are valid data available an each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in the Regulation (EC) 1272/2008 (CLP) and no synergistic effects between any of the components are expected.

Acute toxicity

The biocidal product FUMICIDE DM is composed of the active substance deltamethrin combined with a number of co-formulants. The proposed classification for FUMICIDE DM is based on the acute toxicity results performed with the formulated product for human health effects. In accordance with the provisions laid down in the Regulation (EC) 1272/2008 (CLP) no classification for acute toxicity is needed.

Dermal absorption

In the absence of a dermal absorption study on FUMICIDE DM (fume) a dermal absorption value of 2% has been considered as a worst case in the current risk assessment for the solid residues of FUMICIDE DM. There is no evidence, that for different livestocks the dermal absorption is different, nevertheless in the risk assessment a worst case of 100% dermal absorption has been considered for livestocks.

Oral absorption

For the oral absorption a value of 75% (human absorption value) is considered.

Toxicological reference values

The biocidal product FUMICIDE DM is composed of the active substance deltamethrin combined with a number of co-formulants (see confidential annex 3.6). Following the Competent Authority Report of deltamethrin, a NOAEL of 1 mg/kg bw/day is established for chronic and acute exposition as the relevant value for human health risk assessment. Therefore, an AEL systemic of 0.0075 mg/kg bw/day is obtained by correction using an oral absorption of 75% and a safety factor of 100 and has been used in the human exposure assessment.

Other

Not relevant.

2.2.7.2 Exposure assessment

Exposure assessment for livestocks (pigs and poultry) is carried out in section Estimating Livestock Exposure to Active Substances, cf. to scenario [2] and [3]. Exposure to other animals is based on the authorized use is not covered. Animals are not treated with the b.p. and are not present in the premisses during treatment.

Referring to the exposure of **poultry** the following standard scenarios are offered by the calculation tool:

- Oral- Uptake of feed contaminated in trough
- Oral- Direct treatment of feeding trough surface
- Oral- Ingestion of dead insects

The use instructions of this biocidal product are as such that exposure to dead insects is excluded. Therefore, this value is not applied in the following calculations.
The RMMs of this biocidal product exclude direct treatment of surfaces and facilities likely to be in contact with feed and drinking water. Therefore, this value is not applied in the following calculations.

Referring to the exposure of **pigs**, the following standard scenarios are considered and calculated in this assessment

- Oral - Animals licking surfaces
- Oral- Uptake of feed contaminated in trough
- Oral- Direct treatment of feeding trough surface
- Dermal- Rubbing against surfaces

The RMMs of this biocidal product exclude direct treatment of surfaces and facilities likely to be in contact with feed and drinking water. Therefore, this value is not applied in the following calculations.

The total exposure levels of individual animal species via these scenarios are identified in the corresponding section of Estimating Livestock Exposure to Active Substances (cf. to Calculations for estimating livestock exposure for Scenario [2] and [3]) and in the following table for estimating risk.

2.2.7.3 Risk characterisation for animal health

Exposure to animals is avoided since animals are not present during aerosol treatment and safety times also apply for animals. However, since the animals are afterwards in the premises the remaining risk has been detrmined.

No AELs are available for animals. Therefore a margin of exposure approach is considered to determine the potential total risk for livestocks (pigs and poultry). The margin of exposure values are presented in the table below.

Margin of exposure of estimated total uptake to derived NOAEL

Animal	Specification	NOAEL long term [mg/kg bw/d]	Estimated total uptake – Tier 2 [mg/kg bw/d]	Margin of exposure (MOE)
Broilers	-	1	0	n.a
Laying hen	-	1	0.0043	233
Laying hen	battery	1	0	n.a.
Turkey	-	1	0	n.a.
Fattening pig	-	1	0.0392	25
Breeding pig	-	1	0.0262	38
Breeding pig	individual housing	1	0	n.a
Breeding pig	group housing	1	0	n.a

The margin of exposure values are very low for fattening and breeding pig (25 for fattening pigs and 38 for breeding pigs). However a very conservative approach has been followed to estimate the uptake from dermal rubbing against surfaces for pigs.

Refinement of the assessment:

Dermal absorption:

A dermal of absorption rate for pig skin of 100% has been considered, which is appropriate taken into account the lack of substance specific data. However, Deltamethrin is supposed to have a low dermal absorption value for humans (see also information on dermal absorption page 77).

Moreover, there is evidence that there are similarities between human and big dermal absorption (Simon GA and Maibach HI, 2000, Jung EC and Maibach HI, 2014) and that the pig is a valid experimental animal model of percutaneous permeation of man, while comparing qualitative and quantitative information. For example, the skin of both man and pig is characterized by a spare hair coat, a thick epidermis that has a well-differentiated undersculpture, a dermis that has a well-differentiated papillary body and a large content of elastic tissue. Dissimilarities are for example in the vascularization (rich in man, poor in the pig) and in type of glands.

The analysis of the 46 studies, which measured permeability of 77 chemicals revealed that for 38 chemicals in 26 studies, percutaneous permeability of porcine skin is close to that of human skin (0.625 < FOD (factor of difference) < 1.6). For 25 chemicals in 15 studies, percutaneous permeability of pigs is higher than that of humans. In this group, nine chemicals were absorbed in porcine skin in a much higher rate than human skin (FOD > 3). For 16 chemicals in six studies, human skin permeability is higher than that of pigs. However, only three chemicals showed higher difference (FOD > 3). In conclusion, 86 % (65 chemicals of 76) fell within the range of **± 1/2 log interval.** (Jung EC and Maibach HI, 2014).

Therefore, we consider a dermal absorption value of 100% to be too high. Considering a variation of ± 1/2 log interval as worst case (see explanation above) for dermal absorption for pig can be considered as 21 % (considering a human absorption of 7%).

Transfer coefficient:

For human skin, transfer coefficients for dislodgeable residues have been set for various surfaces. In case the surface is unspecified, this coefficient is 8 to 18% for dried fluids. The value for powders that are present on surfaces which are not smooth, this value is below 9%. Therefore, 18% is taken as a worst case for this biocidal product, where the floor of the stable may be covered by residues of the fume. However, as there will be litter applied onto the floor, this is a very conservative value.

For pigs, analogy is drawn, as pig skin is comparable to human skin. The follicular structure of pig skin also resembles that of humans. The skin of pig and human is characterised by a spare hair coat, the average of 20 hairs/cm^2 of porcine ear skin is similar to 14–32 hairs/cm^2 in humans and a thick epidermis (Jung EC and Maibach HI, 2014).

In the table below the above described refinements are summarized and the total exposure is calculated. The margin of exposure was calculated in order to characterize the risk.

Species	**Oral exposure [mg/kg bw/d]**	**Dermal exposure [mg/kg bw/d]**	**dermal abs [%]**	**transfer coefficient - dislodgeable fraction (unspecified surfaces) [-]**	**Total exposure [mg/kg bw/d]**	**NOAEL [mg/kg bw/d]**	**MOE**
Fattening pig	0.0059	0.0333	21	0.18	0.0072	1	140
Breeding pig	0.0023	0.02399	21	0.18	0.0032	1	312

In conclusion, we consider that there is no unacceptable risk for livestock animals adhering to the RMMs (see below) and use instructions set. Following risk mitigation measures are considered:

• N-45 (modified): Remove all food, feed and drinking water prior to treatment.

• N-47: Assure animals are not present in areas during air space treatment by aerosol.

• N-122: Cover all surfaces and facilities likely to be in contact with feed and drinking water.

There is also an instruction for use applied for treatment in domestic premises, that animals should not be present in areas during air space threatment by aerosol.

2.2.8 Risk assessment for the environment

The smoke generator formulations are used to treat air volumes and surfaces by deposition of the generated smoke particles. The product is diffused in the whole volume of the premises, reaching the surfaces by deposition of particles.

The environmental exposure of FUMICIDE DM, formulated as an insecticide, acaricide and product to control other arthropods and applied according to the authorized use (see chapter 2.1.4 and 2.1.5) has been assessed in accordance with the recommendations of EUSES 2.1.2 model calculations, the BPR Volume IV Environment – Assessment and Evaluation (Parts B+C, ECHA, 2017a), the "Emission Scenario Document for Insecticides, Acaricides and Products to control other Arthropods (PT18) for household and professional uses" (OECD, 2008) and the "Emission Scenario Document for Stables and Manure Storage Systems" (OECD, 2006).

Copper(II) carbonate-copper(II) hydroxide (1:1) and silicon dioxide (amorphous) (nano) were identified as substances of concern for the environment in the biocidal product. However, a quantitative risk assessment has not been performed, since both co-formulants have proven to be by far less toxic than deltamethrin, although these co-formulants are approved biocidal active substances present in the product at ≥0.1% (see Conf. Annex for the qualitative risk assessments).

2.2.8.1 Effects assessment on the environment

Aquatic compartment
A summary of the effect assessment with relevance to the aquatic compartment for the active substance can be found in the AR on Deltamethrin (Sweden, 2011).

PNEC for aquatic organisms
PNECaquatic was derived from the lowest chronic laboratory NOEC value (3.5 ng/L, from Chironomus) and an assessment factor of 5 (considering that the test organism had been identified as the most sensitive) for the active substance deltamethrin.

PNECaquatic = 0.7 ng/L

PNEC for STP microorganisms
According to AR on Deltamethrin the EC_{50} was established as >0.3 mg/L. Therefore, using this value and an assessment factor of 10, the PNECSTP was set to 30 µg/L.

PNECmicroorganisms (STP) = 30 µg/L

PNEC for sediment-dwelling organisms
Data on the toxicity of deltamethrin to sediment-dwelling organisms are not available in the AR. However, a PNEC for sediment dwellers was estimated, using the equilibrium partitioning method:

PNECsediment = 6.21 µg/kg wwt

Atmosphere
According to the Guidance on the BPR, Volume IV Environment – Assessment and Evaluation (Parts B + C), Version 2.0, (ECHA, 2017a), it is currently not possible to perform a quantitative risk characterisation for the air compartment.
The physical-chemical properties of deltamethrin, such as vapour pressure (<0.1 mPa) and molecular weight (502.2 g/mol), indicate that deltamethrin will not readily volatilise into the atmosphere at ambient temperature and pressure. According to the Atkinson method of calculation, the main route of degradation of deltamethrin in air is via the reaction with hydroxyl radicals. The degradation in air is rapid with a DT_{50} of 16.4 hours (based on 24-hour days). In conclusion, deltamethrin is not expected to have any adverse impact on the atmosphere, birds and non-target insects.

Terrestrial compartment
According to AR of Deltamethrin (Sweden, 2011), the PNECsoil is based on the NOEC from the reproduction test on springtails. Using an assessment factor of 10, the resulting PNECsoil is 0.075 mg/kg wwt standard soil.

$PNEC_{soil}$ = 0.075 mg/kg wwt

Non compartment specific effects relevant to the food chain (secondary poisoning)
The potential impact of substances on top predators is based on the accumulation of hydrophobic chemicals through food chains and should in principle be assessed by comparing the measured or estimated concentration in the tissues and organs of the top predators with the no-effect concentrations for these predators expressed as the internal dose. Data on internal concentrations in wildlife animals are hardly ever available and most no-effect levels are expressed in terms of concentration in the food that the organisms consume (i.e. mg/kg food). Therefore, the actual assessment is based on a comparison of the predicted concentration in the food of the top predator and the predicted no-effect concentration which is based on studies with laboratory animals.
Acute toxicity data on birds is available (LD_{50} 14 days = 500 mg/kg dwt). Therefore, an assessment factor of 3000 has been used to convert acute dose to dietary dose.

$PNEC_{birds}$ = 15 mg/kg food
$PNEC_{small\ mammals}$ = 2.67 mg/kg food

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

For the formulated product no studies have been submitted. The proposed classification relies on the data presented in the AR on Deltamethrin (Sweden, 2011). No other co-formulant contributes to the classification of the product.
According to the 1st ATP to Reg. (EC) No 1272/2008 the harmonised classification and labelling of deltamethrin for its environmental hazards is Aquatic Acute 1, H400 Very toxic to aquatic life, (M=1000 000) and Aquatic Chronic 1, H410 Very toxic to aquatic life with long lasting effects. On basis of the data in the AR on Deltamethrin classification of the active substance results in Aquatic Acute 1, H400 Very toxic to aquatic life, (M=1000 000) and Aquatic Chronic 1, H410 Very toxic to aquatic life with long lasting effects, (M=10 000).
Based on the content of deltamethrin 2.4%(w/w) in the biocidal product the formulation FUMICIDE DM has in any case to be classified with Aquatic Acute 1, H400 Very toxic to aquatic organisms and Aquatic Chronic 1, H410 Very toxic to aquatic life with long lasting effects. Therefore the product has to be labelled with the pictogram GHS09, the signal word "Warning", the hazard statement H410 (H400 may be omitted) and the precautionary statements P273, P391 and P501.

Further Ecotoxicological studies

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

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.

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.

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

No data is available and is not required as the biocidal product is not in the form of bait or granules.

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

Not applicable.

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

Foreseeable routes of entry into the environment are described in detail in section "Fate and distribution in exposed environmental compartments".

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

No data is available. Please refer to the data on the active substance.

Leaching behaviour (ADS)

Not applicable for the intended uses.

Testing for distribution and dissipation in soil (ADS)

No data is available. Please refer to the data on the active substance.

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

No data is available. Please refer to the data on the active substance.

Testing for distribution and dissipation in air (ADS)

No data is available. Please refer to the data on the active substance.

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

No data is available and is not required as the biocidal product is not intended to be sprayed near to surface waters.

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)

No data is available and is not required as the biocidal product is not intended to be used outside.

2.2.8.2 Exposure assessment

Copper(II) carbonate-copper(II) hydroxide (1:1) and silicon dioxide (amorphous) (nano) were identified as substances of concern for the environment in the biocidal product. However, a quantitative risk assessment has not been performed, since both co-formulants have proven to be by far less toxic than deltamethrin, although they are approved biocidal active substances present in the product at ≥0,1% (see Conf. Annex for the qualitative risk assessments).

General information

Assessed PT	PT 18
Assessed scenarios	The smoke generator formulations are used to treat air volumes and surfaces by deposition of the generated smoke particles. The product is diffused in the whole volume of the premises, reaching the surfaces by deposition of particles. The biocidal product is used by non-professionals or professionals in the form of a ready-to-use product. **Scenario [1]**: Disinfestation of domestic premises (use # 1, # 3) **Scenario [2]:** Disinfestation of breeding premises (use # 2, # 4)
ESD(s) used	Emission Scenario Documents (ESD) for Product Type 18: - OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 18: Emission Scenario Document for insecticides, acaricides and products to control other arthropods for household and professional uses (OECD, 2008). - OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 14: Emission Scenario Document for insecticides for stables and manure storage systems (OECD, 2006).
Approach	**Scenario [1]:** (use # 1, # 3) The worst case scenario for this intended use is represented by 0.5 g of FUMICIDE DM/m^3 (12 mg a.s./m^3) assuming 2 applications per year with 2 weeks of interval for domestic premises (private houses and larger buildings). This application rate regards to both non-professional and professional use. **Scenario [2]:** (use # 2, # 4) Cleared stables are treated with by air space treatment through the aid of an aerosol can. This method is only applicable to empty stables e.g. cleared housings and battery cage systems for laying hens after each cycle. The use rate is based on the volume of the housing and depends on the type of pest and the kind of premises. The worst case scenarios regarding professional use is represented by 1 g of FUMICIDE DM/m^3 (24 mg a.s./m^3) assuming 7 applications per year with 6-7 weeks of interval for chicken growing farms and fattening pigs and sows stables (insects not affecting livestock) and 1 g of FUMICIDE DM/m^3 (24 mg a.s./m^3) assuming 1 application per year for laying farms (bloodsucking pests). Regarding non-professional use an applicationrate of 0.5 g FUMICIDE DM/m^3 (12 mg a.s./m^3) for chicken growing farms and fattening pigs and sows stables (insects not

	affecting livestock) is foreseen. This non-professional use is therefore covered by the scenario for professional use regarding chicken growing farms and fattening pigs and sows stables (insects not affecting livestock). Note: bloodsucking pests comprise: poultry red mites (*Dermanyssus gallinae*) Insects not affecting livestock comprise: – dermestre hide beetle (*Dermestes maculatus)* – German cockroach *(Blattella germanica)* – Oriental cockroach *(Blatta orientalis)* – lesser mealworm (*Alphitobius diaperinus)*
Distribution in the environment	**Scenario [1]:** (use # 1, # 3) Cleaning events after treatment result only in emissions to wastewater, if wet cleaning is considered. Using dry cleaning methods like vacuum or broom, cleaning events result only in emissions to solid wastes, therefore in this case no environmental compartment will be affected. **Scenario [2]:** (use # 2, # 4) Soils are indirectly exposed when manure/slurry is applied as a soil fertiliser. Subsequently, the active substance may be transported to porewater/groundwater due to leaching from the top soil layer and enters the aquatic compartment due to runoff into the receiving water body.
Groundwater simulation	No higher tier simulation is required regarding the a.s. deltamethrin. The calculation of the concentration in groundwater was performed according to the approach described in ECHA (2017a) where the concentration in pore water of agricultural soil is used as a first indication for groundwater concentrations. Regarding the metabolite Br_2CA refinded groundwater calculations using FOCUS Pearl 4.4.4 are conducted.
Confidential Annexes	No
Life cycle steps assessed	Scenario [1] & [2]: <u>Production and Formulation</u>: Environmental exposure during production and formulation of the biocidal product is not assessed under the requirements of the BPR. These life cycle steps are already covered by REACH legislation, where the registrants (manufacturers/importers) of substances are obliged to consider environmental hazard and exposure and to provide RMMs/exposure scenarios for ensuring safe use (e.g. via SDS in the supply chain). Moreover, it is assumed that industrial production sites are subject to permit for installation. Therefore, it is not considered relevant to perform an additional exposure assessment under the biocide regime. <u>Use:</u> Yes <u>Service life:</u> No (no service life after application)
Remarks	-

Fate and distribution in exposed environmental compartments

Scenario [1] (domestic premises: private houses and larger buildings) (use # 1, # 3)

According to ESD for PT18 (OECD, 2008) insecticides applied indoor will generally reach the treated surfaces, the walls and the floor (even if not directly targeted) and the indoor air in the building. As a result, insecticides will generally not directly reach the environmental compartments usually considered in emission scenario documents: surface water (including sediments), groundwater, soil and air. Most treated surfaces (either target or not) will be cleaned. The cleaning step will therefore lead to releases either to solid wastes (e.g. through dry cleaning methods like vacuuming) or to wastewater (e.g. through wet cleaning methods). In case of wet cleaning, the sewage treatment plant (STP) is considered as the "receiving compartment" where insecticides will be released.

Scenario [2] (breeding premises) (use # 2, # 4)

Regarding scenario [2] (breeding premises) two different emission pathways are described in the ESD for PT18 (OECD, 2006):

- Release via waste water to a sewage treatment plant or
- Release into slurry/manure and afterwards emission to soil by land application

However, a focused enquiry amongst MS showed that a release to the wastewater stream is not allowed per se (c.f. ECHA 2021, #ENV 170). There can however be special agreements for single farms. It was therefore agreed that this exposure pathway does not need to be assessed. The fraction of active substance that could be released to the wastewater sewer, is therefore added to the discharge fraction in manure and increases this fraction reaching soil due to application to agricultural land.

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Fresh-water sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
via STP Scenario [1] (use # 1, # 3)	+	+	n.r.	n.r.	++	(+)	+	+	no
via slurry/ manure Scenario [2] (use # 2, # 4)	+	+	n.r.	n.r.	n.r.	(+)	++	+	no

++ Compartment directly exposed, + Compartment indirectly exposed, (+) Compartment potentially exposed (but unlikely significant concern due to minimal scale of exposure),; n.r. not relevant.

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	Value	Unit	Remarks
Molecular weight	505.2	g/mol	
Melting point	999.4	°C	
Boiling point	None	°C	
Vapour pressure	1.24E-08	Pa (at 25°C)	
Water solubility	<5	µg/L (at 20°C)	
Log Octanol/water partition coefficient	4.6	log10 (at 25°C)	
Organic carbon/water partition coefficient (Koc)	408250	L/kg	
Henry's Law Constant	1.252E-03	Pa x m^3/mol	
Biodegradability	Not ready iodegradable		
DT_{50} for hydrolysis in surface water	Insignificant degradation	at 25ºC/pH 5	
DT_{50} for photolysis in surface water	48	d	
DT_{50} for degradation in soil	48	d (at 12ºC)	
DT_{50} for degradation in air	16	hr	
DT_{50} for soil photolysis	9	d	
BCF earthworm	483	-	
BCF fish	1400	-	

Metabolite Br_2CA

In the CAR of Deltamethrin (Sweden 2011), a major metabolite Br_2CA is identified in water, sediment and soil compartments. Based on the lower molecular weight of Br_2CA (298 g/mol as compared to deltamethrin at 505.2 g/mol) and reduced (eco)toxicity the level of risk posed by Br_2CA can be considered to be low.
However, emission to groundwater due to manure/slurry application (stable treatment - scenario [2]) is considered because of its low Koc of 25.61 L/kg.

Emission estimation

Scenario [1] – Domestic premises (private houses and larger buildings) (use # 1, # 3)

The biocidal product is intended to be used by professional and non-professional users indoors. In both cases the application doses and the number and timing of applications are the same. Therefore, the worst case assumptions regarding the application dose of 0.5 g/m^3 (12 mg a.s./m^3) and a number of 2 applications per year with 2 weeks of interval cover professional and non-professional use.

The ready-to-use product is released into the atmosphere by a local thermokinetic effect. An exothermic chemical reaction results in an aerosol release of the active substance. The initiation reaction requires the intervention of an applicator using an ignition device. The product is placed on the floor or on other heat- and fire-resistant surfaces. Then the combustion is initiated by lighting a wick with a torch lighter. Broadcasting starts with a time delay after initiation, allowing the applicator leaving the room. The application itself does not require the use of equipment and does not require the presence of the applicator.

After the treatment, the premises must be ventilated for a minimum of 4 hours before re-entry.
The product dose, included in a container (can), is specific for a given volume of treated space and a given pest.

The aim of this application mode is to build an insecticide aerosol. The insecticide particles are suspended in the air and fall on the floor at the day scale.
During application of the biocidal product no direct emission to the environmental compartments is assumed. The emission estimation only concerns the cleaning step after treatment. The cleaning step will therefore lead to releases either to solid wastes (e.g. through dry cleaning methods like vacuuming) or to waste water (e.g. through wet cleaning methods). Sewage treatment plants (STP) are considered as the main "receiving compartment" to which the active substance will be released through wet cleaning events.

Simultaneity of non-professional and professional use

In the ESD for PT18 (OECD, 2008), two main categories of users are specified: professional and non-professional users. In addition, two categories of buildings are specified: private houses and commercial buildings (named "larger buildings" in the ESD which include hospitals, warehouses, cinemas etc). The major default path into environmental compartments for indoor use is by wet cleaning of the treated surfaces. The wastewater reaches a sewage treatment plant (STP), where the emissions from all cleaning events accumulate. According to the TAB (ECHA 2021b, ENV #140), for indoor use 4000 private houses and 300 commercial buildings (larger buildings) which emit into the same STP are used as default.
While commercial buildings are only treated by professional users, private houses can however be treated by the residents (non-professional users) themselves as well as by professionals.
An agreement at BPC WG-I-2018 states that no aggregation of emissions from uses in private houses from non-professional and professional application when the same product is used at the same place and time should be conducted. Though, if the product is intended for use in both domestic premises and larger buildings, these emissions have to be aggregated, regardless of the user category in the domestic premises. Therefore, the total emissions from domestic premises and larger buildings are the basis for the risk assessment.

Amount of active substance settle down on the floor

The applicant submitted a study carried out by [redacted] (2016), which characterizes the composition of the fume generated by combustion of the product and the composition of the remaining ashes. For further information please refer to chapter 2.2.8.3 Composition of generated smoke in the confidential annex. This study shows that **15% of the active substance** is surviving the combustion process and is therefore available for distribution by air space treatment by aerosol. As a worst-case assumption these 15% of a.s. (of the initial application rate) will settle down on floor after treatment and is therefore the basis of the emission calculations. This value is supported by other submitted studies e.g. a field test ([redacted] 2013) that was carried out in a poultry shed where 11.9% of a.s. were detected in litter after treatment.

Scenario [2] – Breeding premises
(use # 1, # 3)

The biocidal product can be applied by professionals and non-professionals. However, non-professionals are only allowed to use the product against insects not affecting livestock (chicken growing farms, fattening pigs and sows stables) with an application dose of 0.5 g/m^3 (12 mg a.s./m^3) and a maximum number of seven treatments per year. Since the application dose dedicated to professional users is higher (1 g product/m³ - 24 mg a.s./m³) than that for non-professional users, the calculations considering professional use cover the non-professional use.

The environmental exposure assessment is based on default values regarding the different animal categories and the respective data on housing sizes, animal numbers and manure/slurry production.

According to the ESD for PT18 (OECD, 2006) and based on the intended use, the biocidal product is used as insecticide of breeding premises. After animals left the premises, before the sanitation period, the treatment is done in the presence of the manure and residues will be removed when manure is removed (curative treatment). The product is released into the atmosphere by a local thermokinetic effect. An exothermic chemical reaction results in an aerosol release of the active substance. The reaction and diffusion are from the original container. The initiation reaction requires the intervention of an applicator using an ignition device. Broadcasting starts with a time delay after initiation, allowing the applicator leaving the room. Emissions to the applicator are considered as negligible as the applicator should not be present during aerosol treatments.

The emission estimation is based on suggested default values as described in the ESD for PT18 (OECD, 2006). Basically, it assumes that after the air space treatment of the premises two emission pathways are considered: emissions to wastewater and emissions to slurry/manure (it is assumed that the product could come into contact with manure/slurry which is subsequently collected, stored and applied to agricultural soils).

18 animal categories are presented in the ESD for PT18 (OECD, 2006) with different default parameters e.g. for the number of animals per stable, area treated to estimate the amount of biocidal product used and the amount and type of manure produced. Furthermore, animal categories are distinguished in relation to their phosphate (P_2O_5), nitrogen (N) and manure production. An overview regarding the different animal categories is presented in the tables below.

Animal categories considered in ESD for PT18 (OECD, 2006)		
Index	**Category**	**Subcategory**
1	Cattle	Dairy cattle (housed during grazing season)
2		Beef cattle (housed during grazing season)
3		Veal calves
4	Pigs	Sows, individual
5		Sows in groups
6		Fattening pigs
7	Poultry	Laying hens in battery without treatment (aeration)
8		Laying hens in battery with treatment (belt drying)
9		Laying hens in battery cages with forced drying (deep pit, high rise)

Animal categories considered in ESD for PT18 (OECD, 2006)		
Index	**Category**	**Subcategory**
10		Laying hens in compact battery cages
11		Laying hens in free ranges with litter floor (partly litter floor, partly slatted)
12		Broilers in free range with litter floor
13		Laying hens in free range with grating floor (aviary system)
14		Parent broilers in free range with grating floor
15		Parent broilers in rearing with grating floor

The default values for the animal categories used in the environmental exposure calculations are reported in the table below: number of animals in housing unit, stable volumes and nitrogen and phosphate production per animal (according to OECD, 2006, page 37 and 42).
In the following table only these animal categories (4 to 18) are presented that are listed in the intended use and for which a risk assessment is calculated.

Default values for stable volumes, number of animals present in EU animal housings and average amounts of phosphate and nitrogen per animal in each subcategory				
Animal and building type	**Number of animals in housing unit**	**Housing volume (m³)**	**Qphosphcat (kg/ animal*d)**	**Qnitrogcat (kg/ animal*d)**
Sows – individual (4)	132	1960	0.05566	0.07106
Sows – group (5)	132	2480	0.05566	0.07106
Pigs – fattening (6)	400	2110	0.02033	0.03043
Battery hens (7)	21000	2810	0.00122	0.00202
Battery hens – belt dry (8)	21000	2810	0.00111	0.00181
Battery hens – deep pit (9)	21000	2810	0.00111	0.00181
Battery hens – compact (10)	21000	2810	0.00111	0.00181
Free range hens – litter (11)	10000	5360	0.00111	0.00171
Free range broilers – litter (12)	20000	4170	0.00066	0.00156
Free range hens – grating (13)	20000	4780	0.00111	0.00171
Free range broilers – grating (14)	7000	1458	0.00188	0.00298
Free range rearing broilers (15)	9000	1880	0.00077	0.00137

Furthermore, these animal categories and their housings are related to the estimates for the fraction of the active substance released to the relevant streams: manure/slurry and/or wastewater (according to OECD, 2006, Table 5.4, page 40).

Emissions of the active substance as liquid waste (slurry) and dry waste (manure) can be pooled as both forms will be applied to land as fertiliser. With regard to wastewater, in principle (according to OECD 2006), this will either be directed to municipal STP via drains or if no such connections exist, it will be added to dry/liquid waste and applied to land. On

this basis and according to the fractions of active substance released to the different streams (c.f ECHA 2021, #ENV 168), animal housing/breeding units have been grouped according to the compartment receiving the generated emissions (slurry, manure or waste water):

According to the ESD for PT18 (OECD 2006), animal housing categories **4, 5, 6, 7, 10, 13, 14** and **15** give rise to a discharge fraction of 0.35 in either manure or slurry which will ultimately reach the soil compartment. None of these categories are considered to give rise to emissions to waste water and STP.

According ESD for PT18 (OECD 2006) animal housing categories **11** and **12** give rise to a discharge fraction in manure, which will ultimately reach the soil compartment via manure deposition on agricultural land. Furthermore, for these housing categories a discharge fraction to wastewater is mentioned, which could either reach the municipal STP or must be added to the discharge fraction in manure and increases this fraction reaching soil in cases where no connection to local drainage system is assumed. According to TAB (ECHA 2021b, #ENV 170) it has been agreed that the exposure pathway to the sewer system does not need to be assessed and therefore, the fraction assumed to be released to wastewater is summed up with the fraction released to manure/slurry.

Considering animal housing category **8**, laying hens in battery cages with aeration (belt drying), gives rise to a discharge fraction to slurry, where in Table 5.4 of the ESD for PT18 (OCED, 2006, page 40) the fraction from waste water is already added to the "belt dried slurry" fraction and will reach the soil compartment.

Release fractions to maure/slurry and waste water due to aerosol application			
Animal category	**Aerosol application**		
	Manure	**Waste Water**	**Slurry**
Sows – individual (4)	0	0	0.35
Sows – group (5), Pigs – fattening (6)	0	0	0.35
Battery hens (7)	0	0	0.35
Battery hens – belt dry (8)	0	0.1	*Corr. 0.25 (OECD, 2006, table 5.4: 0.35)
Battery hens – deep pit (9)	0.35	0	0
Battery hens – compact (10)	0	0	0.35
Free range hens – litter (11)	0.25	0.1	0
Free range broilers – litter (12)	0.25	0.1	0
Free range hens – grating (13)	0	0	0.35
Free range broilers – grating (14)	0	0	0.35
Free range rearing broilers (15)	0	0	0.35

For the application intervals, the ESD for PT18 (OECD, 2006) distinguishes four types of insecticides:

- Insecticides against flies (adulticides)
- Insecticide (adulticide) against other insects and arthropods (bloodsucking pests)
- Insecticides against other insects (not affecting livestock)
- Larvicides for manure storage systems

According to the instructions given by the applicant the target insects in breeding premises are:

- Bloodsucking pests (laying farms) and
- Insects not affecting livestock (chicken growing farms, fattening pigs and sows)

According to the intended use of the biocidal product the following application intervals and application doses are used for the environmental exposure assessment:

Maximal application doses and number of treatments per year			
Target insects	**Animal category**	**Max. application dose (worst case)**	**Treatments per year**
Bloodsucking pests	laying farms	24 mg a.s. /m³	1 application/year
Insects not affecting livestock	chicken growing farms, fattening pigs and sows	24 mg a.s. /m³	7 applications/year with 6-7 weeks interval

Emission to soil via manure/slurry application

According to the ESD of PT18 (OECD, 2006), manure is applied to arable soil (1 application/year) and to grassland (4 applications/year) and the applications are controlled according to EU standards for phosphate and nitrogen emissions. Therefore, potential concentrations of the active substance are estimated for the soil compartment (arable land and grassland) based on phosphate or nitrogen standard application rates.

The amount of biocide present in the manure is related to the nitrogen content and the nitrogen load, which is allowed according to the immission standard. However, in various countries there may be an immission standard for phosphate (P_2O_5) instead. It is even possible that there are standards for both phosphate and nitrogen. Information for different countries on tolerated nitrogen values for use of manure are taken from Defra (2005) and adapted to the decisions made by the member states at Technical Meeting I/08. According to the Technical Agreements for Biocides (ECHA, 2021b, #ENV 60) it is sufficient to provide a risk assessment only based on nitrogen immission standards. Therefore, the phosphate related values are only presented for the sake of completeness. It is assumed that the legal standards on the phosphate and nitrogen load determine the amount of the insecticide in soil at the moment of land application. Following the equations presented in the ESD for PT18 (OECD, 2006) initial concentrations of the active substance deltamethrin in soil after manure/slurry application were calculated. The emission to soil from the application of slurry/manure has been determined based upon the nitrogen immission standard based on 10 consecutive years loading with leaching and degradation in soil. The BPC WG-IV-2017 agreed to calculate the PEC in soil for a period of 10 years as proposed in the guidance.

The calculations in detail are reported in Annex 3 under chapter 3.3.2 Environmental Exposure.

The following tables represent the input data of each animal category for the risk assessment.

Para-meter	**Symbol**	**Laying hens in battery cages without treat-ment**	**Laying hens in battery cages with aeration (belt drying)**	**Laying hens in battery cages with forced drying**	**Laying hens in com-pact batt-ery cages**	**Laying hens in free range with litter floor**	**Laying hens in free range with grating floor (aviary system)**	**Unit**	**S/D/O/R ***
Type of housing for application of the notification	category	7	8	9	10	11	13	-	D (Appendix1 Table 7)
Type of biocide	bioctype	Insecticide (adulticide) against other insects and arthropods (bloodsucking pests)						-	D (Appendix1 Table 7)
Type of application	appway	Aerosol/fogging						-	D (Appendix1 Table 7)
Relevant emission stream	stream **	manure/slurry						-	D (Appendix1 Table 7)
Capacity of one aerosol can (assuming 15% a.s. in fume, respectively)	Qaerosol	3.60 E-03	3.60 E-03	3.60 E-03	3.60 E-03	3.60 E-03	3.60 E-03	g	S
Volume to be treated with one aerosol can	$VOLUME_{aerosolcan}$	1	1	1	1	1	1	m^3	D
Volume of the housing	$VOLUME_{housing}$	2810	2810	2810	2810	5360	4780	m^3	D ESD Table 5.2
Fraction of active	$F_{slurry/manure}$	0.35	0.25	0.35	0.35	0.25	0.35	-	D ESD

ingredient released to maure/ Slurry (Aerosol)									Table 5.4
Number of disinfectant applications in one year	$N_{app-bioc}$	1	1	1	1	1	1	-	D
Interval between two disinfectant applications	$T_{bioc-int}$	365	365	365	365	365	365	-	D
Number of manure applications for Grassland	$N_{lapp-grass}$	4						-	D ESD Table 5.10
Number of manure applications for arable land	$N_{lapp-arab}$	1						-	D ESD Table 5.10
Number of land application for arable land during 10 year of application	Nlapp-arab,101	10						-	D
Land application interval for grassland	T_{gr-int}	53						d	according to ECHA,2014
Manure storage time arable land	Tmanure-int$_{ar2}$	212						d	according to ECHA,2014
Number of animals in housing	N_{anima1}	21000	21000	21000	21000	10000	20000	-	D (Appendi

[1] Recommendation of the BPC Ad hoc Working Group on Environmental Exposure

									x 1: Table 8)
Amount of phosphate per animal	Q_{phosph}	0.00122	0.00111	0.00111	0.00111	0.00111	0.00111	kg/d	D (Appendix 1: Table 11)
Amount of nitrogen per animal	Q_{nitrog}	0.00202	0.00181	0.00181	0.00181	0.00171	0.00171	kg/d	D (Appendix 1: Table 11)
If phosphate emission standards are applied									
Phosphate emission standard for one year on grassland	$QP_2O_{5,grassland}$	110						kg/ha	D (Appendix 1: Table 13)
Phosphate emission standard for one year on arable land	$QP_2O_{5,arable\_land}$	85						kg/ha	D (Appendix 1: Table 13)
If nitrogen emission standards are applied									
Nitrogen emission standard for one year on grassland	$QN_{,grassland}$	170						kg/ha	D (Appendix 1: Table 13)
Nitrogen emission standard for one year on arable land	$QN_{,arable\_land}$	170						kg/ha	D (Appendix 1: Table 13)
Soil default values									
Mixing depth with soil, grassland	$DEPTH_{grassland}$	0.05						m	D ESD Table 5.10

Mixing depth with soil, arable land	$DEPTH_{arable\_land}$	0.20	m	D ESD Table 5.10
Density of wet bulk soil	$RHO_{soilwet}$	1700	kg/m^3	D
*Set, Default, Output, Refined **Release to the environment via application of manure/slurry to soil only.				

Para-meter	Symbol	Sows, in individual pens	Sows in groups	Fattening pigs	Broilers in free range with litter floor	Parent broilers in free range with grating floor	Parent broilers in rearing with grating floor	Unit	S/D/O/R *
Type of housing for application of the notification	category	4	5	6	12	14	15	-	D (Appendix1 Table 7)
Type of biocide	bioctype	Insecticide (adulticide) against other insects and arthropods (bloodsucking pests)						-	D (Appendix1 Table 7)
Type of application	appway	Aerosol/fogging						-	D (Appendix1 Table 7)
Relevant emission stream	stream **	manure/slurry						-	D (Appendix1 Table 7)
Capacity of one aerosol can (assuming 15% a.s. in fume, respectively)	Qaerosol	3.60 E-03	3.60 E-03	3.60 E-03	3.60 E-03	3.60 E-03	3.60 E-03	g	S
Volume to be treated with one aerosol can	$VOLUME_{aerosolcan}$	1	1	1	1	1	1	m^3	D
Volume of the housing	$VOLUME_{housing}$	1960	2480	2110	4170	1458	1880	m^3	D ESD Table 5.2
Fraction of active ingredient released to maure/ Slurry (Aerosol)	$F_{slurry/manure}$ $F_{wastewater}$	0.35 -	0.35 -	0.35 -	0.25 0.10	0.35 -	0.35 -	-	D ESD Table 5.4

Number of disinfectant applications in one year	$N_{app\text{-}bioc}$	7	7	7	7	7	7	-	S
Interval between two disinfectant applications	$T_{bioc\text{-}int}$	42	42	42	42	42	42	-	D
Number of manure applications for Grassland	$N_{lapp\text{-}grass}$	4						-	D ESD Table 5.10
Number of manure applications for arable land	$N_{lapp\text{-}arab}$	1						-	D ESD Table 5.10
Number of land application for arable land during 10 year of application	$N_{lapp\text{-}arab,10}$[2]	10						-	D
Land application interval for grassland	$T_{gr\text{-}int}$	53						d	according to ECHA,2014
Manure storage time arable land	$T_{manure\text{-}intar2}$	212						d	according to ECHA,2014
Number of animals in housing	N_{anima1}	132	132	400	20000	7000	9000	-	D (Appendix 1: Table 8)
Amount of phosphate	Q_{phosph}	0.05566	0.05566	0.02033	0.00066	0.00188	0.00077	kg/d	D (App

2 Recommendation of the BPC Ad hoc Working Group on Environmental Exposure

per animal									endix 1: Table 11)
Amount of nitrogen per animal	Q_{nitrog}	0.07106	0.07106	0.03043	0.00156	0.00298	0.00137	kg/d	D (Appendix 1: Table 11)
If phosphate emission standards are applied									
Phosphate emission standard for one year on grassland	$QP_2O_{5,grassland}$	110						kg/ha	D (Appendix 1: Table 13)
Phosphate emission standard for one year on arable land	$QP_2O_{5,arable\_land}$	85						kg/ha	D (Appendix 1: Table 13)
If nitrogen emission standards are applied									
Nitrogen emission standard for one year on grassland	$QN_{,grassland}$	170						kg/ha	D (Appendix 1: Table 13)
Nitrogen emission standard for one year on arable land	$QN_{,arable\_land}$	170						kg/ha	D (Appendix 1: Table 13)
Soil default values									
Mixing depth with soil, grassland	$DEPTH_{grassland}$	0.05						m	D ESD Table 5.10
Mixing depth with soil, arable land	$DEPTH_{arable\_land}$	0.20						m	D ESD Table 5.10

Density of wet bulk soil	$RHO_{soilwet}$	1700	kg/ m^3	D
*Set, Default, Output, Refined **Release to the environment via application of manure/slurry to soil only.				

Calculated PEC values

Scenario [1] – Domestic premises (private houses and larger buildings) (use # 1, # 3)

The biocidal product is on the market in a ready-to-use form. Therefore, a mixing loading step is not considered for this product. During the application step no emissions to the environment are considered. In the ESD for PT18 (OECD, 2008) emission to the applicator is assumed, from an environmental point of view: either the clothes of the applicator are disposable (emission to solid waste) or have to be washed after treatment (emission to wastewater). Due to the fact, that there is latency between the ignition of the wick and the release of the biocidal product in order to give the applicator the time to leave the room, the emission to the applicator is then equal to 0.

Therefore, PEC calculations only concern the cleaning step after treatment.

The cleaning step considers only the cleaning of the surfaces and will therefore lead to releases either to solid waste (e.g. through dry cleaning methods like vacuuming) or to wastewater (e.g. through wet cleaning methods).

The risk assessment only considers the emission pathway of the biocidal product to wastewater and subsequently to a sewage treatment plant due to cleaning of the contaminated surfaces and goods through wet cleaning methods. The definition of dry cleaning methods is assumed to include vacuuming as well as cleaning with disposable clothes. Wet cleaning refers to any method that uses water. It is assumed that residues removed through wet cleaning may potentially be emitted to the wastewater compartment, whilst residues removed through dry cleaning would potentially be emitted to municipal landfill (OECD, 2008, page 63).

The emissions of the active substance deltamethrin has been calculated for indoor treatment in private houses using a simultaneity factor of 0.20%. A simultaneity factor (F_{sim}) specifies which percentage of these buildings emits to the STP at the same day. This value was obtained as described below, by using the approach presented in the ESD for PT18 (OECD 2008, page 39), but considering the relevant frequency (2 applications per year) of use for the product.

Indoor simultaneity factor F_{sim} = (37.82 x 0.54)/100 = 0.20%

That means eight houses are treated at the same time (4000 houses x 0.002 = 8 houses). At BPC WG-II-2016 it was agreed that the derived Fsim is considered also applicable for professional users (ECHA, 2021b, ENV #145).

Basically, it is assumed that there is a distinction between the treated surface and the wet cleaned area of a house. At the BPC ENV WG-I-2018 it was agreed that for non-professional use the wet cleaned area in a domestic house is equal to 38.5 m².

Furthermore, in contrast to non-professional users it is assumed that treatments by professional users take place in larger buildings with a total house surface of 609 m² and a wet cleaning area of 180 m² (ECHA, 2021b ENV #140). In this case only one room is treated and therefore, the wet cleaning area is equal to the floor area. However, the residues on the floor depend on the volume of the room and it is assumed that the residues found in fume are 15% of the initial amount of the active substance deltamethrin (refer to [redacted] 2016)

Release during cleaning step

In the ESD for PT18 (OECD, 2008, page 25) smoke generators are called "one-shot aerosol cartridge". In the ESD for PT18 (OECD, 2008) it has been considered that treatment and cleaning steps of these smoke generators take place the same day. Basically, emissions due to both steps are added to estimate the final releases into the environment. However, in this case, only the cleaning step is considered for the risk assessment.

According to the ESD for PT18 (OECD, 2008) the fraction emitted to air during cleaning events is considered to be negligible. Therefore, releases to air are not considered to be significant: $E_{cleaning,\ air} = 0$

Please note, for application by aerosol/fogging the fractions released (to slurry, manure, and wastewater) were corrected taking account that 2% of the releases will go to the air (BPC WG-I-2021; ECHA 2021: #ENV 233).
However, regarding the amount of 2% a.s. in the air, it has to be pointed out that regarding the instructions for use, in case ventilation is not carried out, the premises must not be re-entered until a safety time of 60 hours has passed. The ESD for PT18 (OECD 2008, page 72) states that it has been demonstrated that all particles above 1 µm diameter will deposite on the floor within 1 day. Therefore, it can be assumed that all particles settle down during this time.
In the other case, if after treatment anadequate ventilation with a minimum duration of 4 hours is provided, the particles will not stay in the air, either.

Therefore, the cleaning event results in emissions to wastewater due to wet cleaning or in emissions to soild waste due to dry cleaning.

Releases to wastewater and soild wastes during cleaning event depend on the efficiency of the cleaning. The efficiency of the cleaning is taken from the cleaning efficiency factors as proposed in OECD, (2008, page 64), Table 3.3–8. The cleaning efficiency regarding aerosol application is 100%.

According to the ESD for PT18 (OECD, 2008, page 48) the mean volume of a private room is 58 m^3. This is in line with the value in Consexpo software (Human exposure).

The local emission to waste water is calculated according to the ESD for PT18 (OECD, 2008, pages 72, 101)

Non-professional and professional use (private houses and larger buildings)

Variable	Symbol	Unit	Default		S/D/O/P
Input					
			Private houses	Larger buildings	
Treatment rate, amount of active substance per volume	$Q_{a.s.}$	g/m³	0.012	0.012	S
Volume of treated house	$VOLUME_{treated}$	m³	58	2436	D
Number of applications per day, house	$N_{appl,\ building}$	d	1	1	S
Fraction emitted to the floor during application	F_{floor}	-	0.15*	0.15*	P
Cleaning efficiency	F_{CE}	-	Aerosol: 1	Aerosol: 1	P
Fraction emitted to waste water from cleaning treated surface	F_{ww}	-	1	1	P
Indoor simultaneity factor F_{sim} = (37.82 * 0.54)/100 = 0.20%	F_{sim}	-	0.002	0.002	P
Number of houses connected to a STP	N_{houses}	-	4000	-	D
Number of commercial builings (larger builings)	$N_{commercial}$	-	-	300	D
Output					
$E_{floor,\ treated} = (N_{appl,\ building} * F_{floor} * Q_{a.s.} * VOLUME_{treated})/1000$					
Emission to the floor	$Efloor_{,treated}$	kg/d	1.04E-04	4.38E-03	O
$E_{local,water,1\ house} = E_{floor,\ treated} * F_{CE} * F_{ww}$					
Emission to waste water from treated surfaces from 1 house	Etreated,ww	kg/d	1.04E-04	4.38E-03	O
$E_{local,water} = E_{treated,ww} * N_{houses} * F_{sim}$					
Local emission to waste water during episode	Elocal, water	kg/d	8.35E-04	2.63E-03	O

* The applicant submitted a study carried out by [redacted] (2016), which characterizes the composition of the fume generated by combustion of the product and the composition of the remaining ashes. This study shows that 15% of the active substance deltamethrin is surviving the combustion process and is therefore available for distribution by air space treatment. It is assumed that these 15% of the initinal amount of used active substance deltamethrin emit to the floor.

A BPC decision on the RMM for PT18 states that the use of wet wipes as cleaning device (to be disposed off) could be accepted if the cleaning of non-treated areas is done after the treatment. However, this would be applicable only for the use in small defined areas e.g. for targeted spot applications (spot treatments, barrier treatments, application in cracks and crevices). The proposed RMM is not applicable to broadcast treatments like e.g. dusting/fogging and is therefore not applicable for this biocidal product (agreed at BPC ENV WG-IV-2017).

The PEC-calculations are conducted with EUSES 2.1.2. Please note, that "Indoor, sprayapplication – air space treatment (volume)" is choosen for the following calculations.

The above calculated "Local emissions to waste water during episode" are inserted in EUSES 2.1.2.

Summary table on calculated PEC values for deltamethrin - scenario [1] – Domestic premises (private houses and larger builings) use # 1, # 3						
	PEC_{STP}	**$PEC_{surface\ water}$**	**$PEC_{surface\ water\ sed}$ ***	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**
	[mg/L]	[mg/L]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/L]	[mg/m^3]
via STP						
Private houses	4.01E-05	2.49E-06	-	1.40E-02	1.95E-03	n.r.
Larger buildings	1.26E-04	7.83E-06	-	4.42E-02	6.13E-03	n.r.
Total: Private and larger buildings	1.66E-04	1.03E-05	-	5.82E-02	8.08E-03	n.r.

***** The sediment risk assessment is essentially equal to the aquatic risk assessment as both PECsediment and PNECsediment have been calculated with the Equilibrium Partitioning Method (EPM) from the PEClocal,water and the PNECaquatic, respectively (refer to ECHA 2017a, page 139-140). Therefore, no PECsediment values are listed in this table.

Scenario [2] – Breeding premises
(use # 2, # 4)

The ESD for PT18 (OECD 2006, page 44) states default values for the number of biocide applications (Napp-biocmax) and the interval time (Tbioc-int). However, the environmental exposure assessment is based on the target organisms, the values for the insecticide application interval and the number of applications according to the intended use:

- for laying farms (1 application/year with an corresponding application interval of 365 days and
- for chicken growing farms and fattening pigs and sows stables 7 applications/year with 6-7 weeks interval corresponding to an application interval of 42 days is considered.

The fractions of the active substance reaching manure/slurry and/or waste water depends on the animal species, type of manure storage system and specific type of the application of the biocide (aerosol, spraying, sprinkling ect.). The estimates take into account that a biocidal product present on window sills or rafters, for example, will remain there at cleaning (cf. OECD 2006, page 39). That is the reason why adding all fractions (manure/slurry and wastewater) listed in the ESD for PT18 (OECD, 2006) the result is not 100%.

Regarding the stable space the ESD for PT18 (OECD, 2006) states that aerosols or fogging with the aid of mist blower, will generally go to air. After treatment the breeding premises

will have to stay closed for a certain period of time, afterwards it will be ventilated. In the mean time the mist will settle on the floor or adhere to objects or vertical surfaces.

Emission to soil via manure/slurry application

The fraction of the insecticide, i.e. the active substance, reaching the manure depends on the animal species, type of manure storage system and specific type of application of the biocide. Regarding the pathway via manure/slurry application, $PIEC_{soil}$ [3], $PIEC_{groundwater}$ and $PIEC_{surfacewater}$ values were calculated for application to grassland and arable land, each based on phosphate and nitrogen standards. It should be noted that the nitrogen standard is the most relevant in Europe and the focus in the evaluation of deltamethrin is put on the nitrogen standard, e.g. the PEC-values are based on the nitrogen standard only, according to TAB (ECHA, 2021b ENV 51). The nitrogen immission standards are taken from the EC Nitrates Directive (Reg. (EC) No 91/676/EEC) of 170 kg N per ha and year for all soils (arable land and grassland) as defined in TAB (ECHA, 2021b ENV #124).

PEC in soil and groundwater

At BPC ENV WG-IV-2017 the Member States agreed to use k_{leach} to derive k_{total}, which is relevant for the groundwater assessment:
$k_{total} = k_{degradation} + k_{leach}$

Please note, k_{volat} is not taken into account because for both, grassland and arable land, k_{volat} is in the range of 10E-13 and thus the impact of k_{volat} on k_{total} is comparatively low and therefore negligible. K_{total} with and without k_{volat} results in a degradation rate constant of 0.014 d^{-1}.

PECs in groundwater (PIECgw) were calculated according to equations (67) and (68) of ECHA, (2017a) using $PECsoil_{10years}$ values concidering degradation and leaching. This approach has been agreed at BPC ENV WG-IV-2017. As an indication for potential groundwater levels, the concentration in porewater of agricultural soil is taken. According to the CAR of Deltamethrin (Sweden, 2011) the solid-water partition coefficient Ksoil-water is equal to 1.22E+04 m^3/m^3 and the soil density (RHOsoil) is assumed to be 1700 kg/m^3 as default regarding to ECHA (2017a).

Metabolite Br_2CA

The parent compound has a molecular mass of 505.2 g/mol, whilst the metabolite Br_2CA has a molecular mass of 298.0 g/mol. Therefore, the estimate of potential exposure of the metabolite has been adjusted by a factor of 0.59 (i.e. 298.0 / 505.2).

The calculations are executed accordingly to the document "Exposure assessment of metabolites in the terrestrial compartment – indirect exposure via sewage sludge and

3 Please note, that the model calculations for scenarios concerning breeding premises (manure/slurry application) supply the Predicted Initial Environmental Concentration for soil, groundwater and surface water and are therefore stated as PIEC.

manure" (ECHA 2019c). The calculations in detail are represented in the Annex 1.4 of this document.
While deltamethrin is strongly adsorbed to soil with an arithmetic mean Koc value of 408 250 L/kg, its metabolite Br_2CA is more mobile, with arithmetic mean Koc values of 25.6 L/kg.
There is potential for residues of the metabolite Br_2CA in soil to be transported via leaching to groundwater due to its low Koc of 25.61 L/kg. The PECgw values were calculated on the basis of worst case PECsoil values that were calculated on the unrealistically worst-case assumption that 100% of the parent compound is transformed to Br_2CA. The PECgw values range between 2.60E-01 and 1.69 µg/L. The calculations in detail are shown in chapter 3.2 Output tables from exposure assessment tools (Environmental Exposure). These groundwater concentrations exceed the trigger value of 0.1 µg/L of the Directive 98/8/EC. Therefore, a refinement of the groundwater calculations are conducted using FOCUS Pearl 4.4.4.

The refined groundwater calculations were conducted according to TAB (ECHA 2021, #ENV 10) and the document "Exposure assessment of metabolites in the terrestrial compartment – indirect exposure via sewage sludge and manure/slurry".

The concentration in soil is used for the initial groundwater assessment. According to ECHA (2020) the PEC in porewater is calculated from PIECgrs10_degr–N. The worst case value PIECgrs10_degr–N considering "sows in groups (cat. 5)" is 9.64E-04 mg/kg_{wwt}. The worst case value PIECars10_degr–N considering "sows in groups (cat. 5)" is 1.35E-04 mg/kg_{wwt}.
FOCUS Pearl 4.4.4 calculations are based on the TAB entry #ENV 165 (ECHA, 2021):
In case of manure/slurry application scenarios from animal housings it was agreed that both grassland and arable land scenarios should be used in FOCUS groundwater models. In case of manure/slurry application on grassland the crop grass (alfalfa) has to be selected and the scenario considers 4 times manure/slurry application per year on fixed dates 1st of March, 23rd of April, 15th of June and 7th of August (considering 53 days between application) and 5 cm incorporation depth. In case of manure/slurry application on arable land the scenario considers either one-time application per year to maize 20 days before crop event "emergence" (relative application) and 20 cm incorporation depth.

The parameter setting applied to FOCUS Pearl groundwater scenarios are are chosen according to TAB entry #ENV 23 (ECHA, 2021).

The table below represents the input parameter for Br_2CA (c.f. Sweden 2011) used for refined groundwater assessment using FOCUS Pearl 4.4.4:

Parameter	**Value**
Molecular weight	298.0 g/mol
Laboratory degradation in soil at 12°C and Field capacity	DT50 = 5.6 days (geometric mean, n=3) Range: 2.1-32.3 days
Sorption to organic carbon	Koc = 25.61 L/kg
Vapour Pressure	8.2E-04 Pa
Water solubility	60.5 mg/L
Henry's law constant	40.4E-03 $Pa.m^3/mol$
Air water partition coefficient ($K_{air\ water}$)	1.71E-05
Soil water partition coefficient (Kp_{soil})	0.512 L/kg
Soil-water equilibrium partition distribution coefficient ($K_{soil\ -\ water}$)	0.97

The application rates of the metabolite Br_2CA Appl_rate [kg/ha] is calculated as followes:

Grassland:
$Appl\_rate_{grass} = PIECgrs * RHO_{soil\_wet} * DEPTH_{grass} * 10^{-2}$
$Appl\_rate_{grass} = 9.64E\text{-}04$ mg/kgwwt * 1700 kg/m³ * 0.05 m * 10^{-2} = 8.19E-04 kg/ha

Arable land:
$Appl\_rate_{arable} = PIECarable * RHO_{soil\_wet} * DEPTH_{arable} * 10^{-2}$
$Appl\_rate_{arable}$ = 1.35E-04 mg/kgwwt * 1700 kg/m³ * 0.20 m * 10^{-2} = 4.59E-04 kg/ha

Area	**Concentration in groundwater closest to the 80th percentile (grassland)**
CHATEAUDUN	0.000019 µg/L
HAMBURG	0.000019 µg/L
JOKIOINEN	0.000362 µg/L
KREMSMUENSTER	0.000089 µg/L
OKEHAMPTON	0.000071 µg/L
PIACENZA	0.000028 µg/L
PORTO	0.000011 µg/L
SEVILLA	< 10E-06 µg/L
THIVA	< 10E-06 µg/L

Area	**Concentration in groundwater closest to the 80th percentile (arable land)**
CHATEAUDUN	< 10E-06 µg/L
HAMBURG	< 10E-06 µg/L
JOKIOINEN	-
KREMSMUENSTER	< 10E-06 µg/L
OKEHAMPTON	< 10E-06 µg/L
PIACENZA	< 10E-06 µg/L
PORTO	< 10E-06 µg/L
SEVILLA	< 10E-06 µg/L
THIVA	< 10E-06 µg/L

The FOCUS Pearl 4.4.4. output tables are shown in 3.2 Output tables from exposure assessment tools (Environmental Exposure).

PEC in surface water and sediment

In case of application of manure/slurry to arable land or grassland, exposure of the active substance to surface water could potentially occur as a result of run-off from areas (arable lands and grassland) treated with manure, according to the ESD for PT18 (OCED, 2006). The surface water concentration is calculated from the pore water concentration according to the method of Montforts (1999). The concentrations were additionally corrected for sorption onto suspended matter. PECs where therefore calculated according to equation (48) of ECHA, (2015a) by using a partition coefficient in suspended matter (Kp, susp) of 4.08E+04 L/kg and a dilution factor of ten. Therefore, PIEC in surface water ($PIEC_{sw}$) is estimated based on the following adapted equation:

$$PIEC_{sw} = PEC_{local\ soil,porew} / ((1 + K_{p,\ susp} \times SUSP_{water} \times 10^{-6}) \times DILUTION_{run\text{-}off})$$

PECs in sediment have been calculated based on the estimated $PIEC_{sw}$ values according to equation (53) of ECHA, (2017a) using a suspended matter-water partitioning coefficient Ksusp_water of 1.02E+04 m³/m³.

According to ECHA (2020), the groundwater calculations are based on the concentrations of the active substance in arable land and grassland soil based on nitrogen immission standard after the last of one and four manure applications per year, respectively, after ten consecutive years, taking degradation into account. Furthermore, the concentraions in surface water are based on these groundwater concentrations. The TAB entry #237 (ECHA, 2021) states that for the PEC in surface water, after drainage or run-off from soil, the PECgw based on the 30d TWA PEClocalsoils in grassland and arable land shall be used to calculate PECsw. However, the assessment based on the document Addendum to OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 14 (2020) represents the worst case.

The following tables present the concentration of the active substance in soil based on nitrogen immission standards for arable land, assuming one manure application event per year and for grassland, assuming four manure application events per year taking degradation not into account. Furthermore, the concentration of the active substance after ten consecutive years of application, taking degradation into account, are reported. On this basis (concentrations in soil after 10 years of application, taking degradation into account) the concentrations in ground water and surface water due to run-off are calculated and listed in the tables below as well.

Concerning different target organisms and therefore different application doses and numbers of treatment, two different cases of calculations are reported: on one hand laying farms (bloodsucking pest) and chicken growing farms and fattening pigs and sows stables (insects not affecting livestock) on the other hand.

All calculations were done on the basis of the Addendum to OECD series on emission scenario documents, number 14 (ECHA, 2020). Concentration of the active substance in soil based on the nitrogen immission standard for arable land and grass land, based on one manure application event per year (arable land) and four manure application events per year (grassland), ten consecutive years, and considering degradation in soil.

According to ECHA (2014, page 14) for the terrestrial risk assessment $PIEC_{grs10\_degr-N}$ is compared to PNECsoil. Furthermore, for the groundwater risk assessment the concentration in porewater is used for the initial groundwater assessment using the porewater concentration from $PIEC_{grs10\_degr-N}$. For the surface water risk assessment the concentration in surface water used for the initial assessment is calculated by dividing $PIEC_{grs10\_degr-gw-N}$ by a dilution factor of 10.
The calculations in detail including calculations based on arable land and phosphate standard, respectively, are reported in Annex 3 under chapter 3.3.2 Environmental Exposure.

Laying farms (bloodsucking pest): 24 mg a.s./m³; 1 application/year

Based on nitrogen immission standards

Variable/ parameter	Symbol	S /D /O	Unit	Laying hensages without treatment (cat 7)	Laying hens in battery cages with aeration (belt drying) (cat 8)	Laying hens in battery cages with forced drying (cat 9)	Laying hens in compact battery cages (cat 10)	Laying hens in free range with litter floor (cat 11)	Laying hens in free range with grating floor (aviary system) (cat 13)
Soil - grassland									
Considering degradation processes in soil, after 10 consecutive years application									
PIECgrs10_degr-N = PIECgrs4_deg-N * [1+ ∑ ($e^{-kdegsoil}$ * Tgr-int_no_manure)^n] , n=1…9									
Concentration of the active substance in grassland soil based on nitrogen immission standard after the last of four manure applications per year, after ten consecutive years, taking degradation into account	PIECgrs 10_degr -N	O	mg/ kg_{wwt}	1.40 E-04	1.11 E-04	1.56 E-04	1.56 E-04	4.72 E-04	2.95 E-04
Ground water and surface water									
For the concentration in surface water the porewater/groundwater concentration is used.									
PIECgrs-gw-N = PIECgrs10_degr-N * RHOsoilwet / (Ksoil-water * 1000)									
PIECgrs-gw-N		O	mg/L	2.91 E-08	2.32 E-08	3.24 E-08	3.24 E-08	9.82 E-08	6.13 E-08
PIECgrs-water-N = PIECgrs-gw-N / DILUTIONrun-off									
PIECgrs-water-N		O	mg/L	2.91 E-09	2.32 E-09	3.24 E-09	3.24 E-09	9.82 E-09	6.13 E-09

Chicken growing farms and fattening pigs and sows stables (insects not affecting livestock): 24 mg a.s. /m³; 7 applications/year with 6-7 weeks interval

Based on nitrogen immission standards

Variable/ parameter	Symbol	S / D / O	Unit	Sows in individual pens (cat 4)	Sows in groups (cat 5)	Fattening pigs (cat 6)	Broilers in free range with litter floor (cat 12)	Parent broilers in free range with grating floor (cat 14)	Parent broilers in rearing with grating floor (cat 15)
Soil - grassland									
Considering degradation processes in soil, after 10 consecutive years application									
PIECgrs10_degr-N = PIECgrs4_deg-N * [1+ ∑ ($e^{-kdegsoil}$ * Tgr-int_no_manure)^{n}] , n=1…9									
Concentration of the active substance in grassland soil based on nitrogen immission standard after the last of four manure applications per year, after ten consecutive years, taking degradation into account	PIECgrs10_degr-N	O	mg/ kg_{wwt}	4.40 E-04	5.57E-04	3.65E-04	2.01E-04	1.47E-04	3.21E-04
Ground water and surface water									
For the concentration in surface water the porewater/groundwater concentration is used.									
PIECgrs-gw-N = PIECgrs10_degr-N * RHOsoilwet / (Ksoil-water * 1000)									
PIECgrs-gw-N		O	mg/L	9.16 E-08	1.16E-07	7.60E-08	4.19 E-08	3.07 E-08	6.69 E-08
PIECgrs-water-N = PIECgrs-gw-N / DILUTIONrun-off									
PIECgrs-water-N		O	mg/L	9.16 E-09	1.16E-08	7.60E-09	4.19 E-09	3.07 E-09	6.69 E-09

Where the housing is not connected to sewage systems, the wastewater remains on site and will be stored with the slurry prior to mixing with dry waste (manure) for application to agricultural land (soil). At the BPC WG-II-2017 (ECHA 2021, ENV 168) it was agreed residues in wastewater fractions should be added to the residues in slurry/manure. The fractions released to manure/slurry for the animal categories cat.8, 11 and 12 are reported in the following table:

Release fractions to maure/slurry when not connected to sewer system	
Animal category	**Manure/slurry**
Battery hens (8)	0.35
Free range hens (11)	0.35
Free range broilers (12)	0.35

The decision to consider only emissions to maure/slurry due to the fact that connection to a STP it is per se not allowed regarding farms and furthermore, a risk mitigation measure (RMM: N-6) , is in line with an agreement at BPC WG-II-2017. It was therefore agreed that this exposure pathway – emission to wastewater due to cleaning of stables - does not need to be assessed (cf. ECHA, 2021b, ENV#170).

Results if waste water fractions are added to the residues in slurry/manure

The entire emission is released to maure/slurry and is furthermore applied on arable soil.

Variable/ parameter	Symbol	S / D / O	Unit	Laying hens in battery cages with aeration (belt drying) (cat 8)	Laying hens in free range with litter floor (cat 11)	Broilers in free range with litter floor (cat 12)
Soil - grassland						
Considering degradation processes in soil, after 10 consecutive years application						
PIECgrs10_degr-N = PIECgrs4_deg-N * [1+ ∑ ($e^{-kdegsoil}$ * Tgr-int_no_manure)^{n}] , n=1…9						
Concentration of the active substance in grassland soil based on nitrogen immission standard after the last of four manure applications per year, after ten consecutive years, taking degradation into account	PIECgrs10_degr-N	O	mg/kg_{wwt}	1.56E-04	6.60E-04	2.82E-04
Ground water and surface water						
For the concentration in surface water the porewater/groundwater concentration is used.						
PIECgrs-gw-N = PIECgrs10_degr-N * RHOsoilwet / (Ksoil-water * 1000)						
PIECgrs-gw-N		O	mg/L	3.24E-08	1.37E-07	5.86E-08
PIECgrs-water-N = PIECgrs-gw-N / DILUTIONrun-off						
PIECgrs-water-N		O	mg/L	3.24E-09	1.37E-08	5.86E-09

Primary and secondary poisoning

Primary poisoning

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

Secondary poisoning

According to ECHA (2017a) the calculation of a possible risk to man via the food chain (PECoralpredator) should be conducted if an a.s. shows a potential for bio-accumulation, indicated by a n-Octanol/water partition coefficient logK_{ow} value >3, a bioconcentration factor BCF >100 L/kgwwt or if a substance is highly adsorptive. Since deltamethrin has a log K_{ow} of 4.6, the potential for bioaccumulation should be considered.

Secondary poisoning via contaminated EARTHWORMS

Since birds and mammals consume worms with their gut contents and the gut of earthworms can contain substantial amounts of soil, the exposure of the predators may be affected by the amount of substance that is in this soil. Therefore, possible effects are estimated on birds and mammals in the environment via uptake through the food-chain soil → earthworm → worm-eating birds or mammals.
As input parameter the concentration in the receiving soil compartment as a result of sludge application (indirect contamination) is included as well as the BCF in earthworms, the concentration in pore water, the fraction of gut loading in worm and the conversion factor for soil concentration wet-dry/weight soil. For calculating the bioconcentration factor, an octanol/water partition coefficient of log K_{ow} of 4.6 is taken.

The $PEC_{oral,earthworm}$ calculations in detail are reported in Annex 3, chapter 3.3.2 Environmental Exposure.

Emission to soil via manure/slurry application

Secondary poisoning results due to manure/slurry application on arable land.

The $PEC_{oral,earthworm}$ calculations in detail are reported in Annex 3, chapter 3.3.2 Environmental Exposure.

Laying farms (bloodsucking pest): 24 mg a.s./m³; 1 application/year

Variable/ parameter	Symbol	S /D /O	Unit	Laying hensages without treatment (cat 7)	Laying hens in battery cages with aeration (belt drying) (cat 8)	Laying hens in battery cages with forced drying (cat 9)	Laying hens in compact battery cages (cat 10)	Laying hens in free range with litter floor (cat 11)	Laying hens in free range with grating floor (aviary system) (cat 13)
Predicted Environmental Concentration in earthworms	**$PEC_{oral,\ earthworm}$**	**O**	**$mg/kg_{wet\ earthw.}$**	2.68 E-05	2.14 E-05	2.98 E-05	2.98 E-05	9.06 E-05	5.64 E-05

Chicken growing farms and fattening pigs and sows stables (insects not affecting livestock): 24 mg a.s. /m³; 7 applications/year with 6-7 weeks interval

Variable/ parameter	Symbol	S / D / O	Unit	Sows in individual pens (cat 4)	Sows in groups (cat 5)	Fattening pigs (cat 6)	Broilers in free range with litter floor (cat 12)	Parent broilers in free range with grating floor (cat 14)	Parent broilers in rearing with grating floor (cat 15)
Predicted Environ-mental Concentra-tion in earthwor ms	**PEC_{oral}, earthwor m**	**O**	**mg/kg_{we} t earthworm**	8.44 E-05	1.07 E04	7.00 E-05	3.86 E-05	2.82 E-05	4.59 E-05

Results if waste water fractions are added to the residues in slurry/manure

Variable/ parameter	Symbol	S / D / O	Unit	Laying hens in battery cages with aeration (belt drying) (cat 8)	Laying hens in free range with litter floor (cat 11)	Broilers in free range with litter floor (cat 12)
Predicted Environmental Concentration in earthworms	**$PEC_{oral,\ earthworm}$**	**O**	**$mg/kg_{wet\ earth\text{-}worm}$**	2.98E-05	1.27E-04	5.41E-05

Secondary poisoning via contaminated FISH

The assessment of secondary poisoning takes account of the PECaquatic, the direct uptake and resulting concentration in food of aquatic organisms and the mammalian and avian toxicity of the active substance. On this basis, possible effects are estimated on birds and mammals in the environment via uptake through the food-chain water → aquatic organisms → fish → fish-eating mammal or fish-eating bird.
The concentration of contaminant in food (fish) of fish-eating predators ($PEC_{oral,\ predator}$) is calculated based on PEC for surface water ($PEClocal_{water}$), the BCF for fish and the biomagnification factor (BMF):

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

It is assumed that 50% of the food is sourced from the local environment and 50% from the regional environment. According to ECHA, (2017a) the foraging area of fish-eating predators may be very large and therefore using the PEClocal may lead to an overestimation of the risk, especially as biodegradation in surface water is not taken into account. PECregional may have the opposite effect. It has therefore been decided that a scenario where 50% of the diet comes from a local area and 50% of the diet comes from a regional area is the most appropriate for the assessment. As the PECregional is not considered in the biocidal risk assessment, the PECregional value is set to 0. According to ECHA, (2017a) the local PEC in surface water during emission episode is used to calculate PECwater. The formula is amended accordingly for pathway 2 – emissions to soil via manure/slurry application - that is based on the concentration of the active substance in surface water due to run-off of treated soil (PIECars-water-N):

Pathway 1 – emissions to waste water/STP:
$PEC_{oral,\ fish} = 0.5 \times (PEClocal_{water} + PECreg_{water}) \times BCF_{fish} \times BMF$
$PEC_{oral,\ fish} = 0.5 \times PEClocal_{water} \times BCF_{fish} \times BMF$
Pathway 2 – emissions to soil via manure/slurry application:
$PEC_{oral,\ fish} = 0.5 \times PIECgrs\text{-}water\text{-}N \times BCF_{fish} \times BMF$

Biomagnification factor (BMF):
The logKow of deltamethrin equals 4.6 and the BCF_{fish} for the whole body has been determined to be 1400. Therefore, according to table 30 in ECHA (2017a, page 179) a BMF of 1-2 should be used for deltamethrin. As a worst case value, a BMF of 2 has been considered, in accordance with the CAR of deltamethrin (Sweden, 2011).

The $PEC_{oral,fish}$ calculations in detail are reported in Annex 3, chapter 3.3.2 Environmental Exposure.

Emission to soil via manure/slurry application

The caculations on secondary poisoning regarding emissions to soil via maure/slurry application are based on PIECars,N-water, which is multiplied by 0.5 due to the fact that only 50% of the diet comes from a local area.

Laying farms (bloodsucking pest): 24 mg a.s./m³; 1 application/year

Variable/ parameter	Symbol	S / D / O	Unit	Laying hensages without treatment (cat 7)	Laying hens in battery cages with aeration (belt drying) (cat 8)	Laying hens in battery cages with forced drying (cat 9)	Laying hens in compact battery cages (cat 10)	Laying hens in free range with litter floor (cat 11)	Laying hens in free range with grating floor (aviary system) (cat 13)
Predicted Environmental Concentration in fish	**$PEC_{oral,\ predator}$**	**O**	mg/kg wet fish	4.06 E-06	3.24 E-06	4.54 E-06	4.54 E-06	1.37 E-05	8.56 E-06

Chicken growing farms and fattening pigs and sows stables (insects not affecting livestock): 24 mg a.s. /m³; 7 applications/year with 6-7 weeks interval

Variable/ parameter	Symbol	S / D / O	Unit	Sows in individual pens (cat 4)	Sows in groups (cat 5)	Fattening pigs (cat 6)	Broilers in free range with litter floor (cat 12)	Parent broilers in free range with grating floor (cat 14)	Parent broilers in rearing with grating floor (cat 15)
Predicted Environ-mental Concentra-tion in fish	**$PEC_{oral\ , predator}$**	**O**	**mg/kg wet fish**	1.28 E-05	1.62 E-05	1.06 E-05	5.87 E-06	4.30 E-06	9.37 E-06

Results if waste water fractions are added to the residues in slurry/manure

Variable/ parameter	Symbol	S / D / O	Unit	Laying hens in battery cages with aeration (belt drying) (cat 8)	Laying hens in free range with litter floor (cat 11)	Broilers in free range with litter floor (cat 12)
Predicted Environmental Concentration in fish	**$PEC_{oral,\ predator}$ = PECwater* BCF_{fish}*BMF**	**O**	**$mg/kg_{wet\ fish}$**	4.54 E-06	1.92E-05	8.20E-06

2.2.8.3 Risk characterisation

Copper(II) carbonate-copper(II) hydroxide (1:1) and silicon dioxide (amorphous) (nano) were identified as substances of concern for the environment in the biocidal product. However, quantitative risk assessments have not been performed, since both co-formulants have proven to be by far less toxic than deltamethrin, although they are approved biocidal active substance present in the product at ≥0,1% (see Conf. Annex for the qualitative risk assessments).

Atmosphere

According to the AR on Deltamethrin the active substance has a low vapour pressure and is not expected to volatilise to air from plants and soil at significant levels. However, deltamethrin has a tendency to volatilise from water. If present in air, the data on indirect photooxidation indicate a rapid degradation when reacting with hydroxyl radicals. Hence, it is concluded that deltamethrin is unlikely to cause either any adverse effects via inhalation or biological effects away from the site of application. Furthermore, no ecotoxicity data are available based on atmospheric exposures and there is no agreed method available to derive a PEC_{air}. Therefore, a $PEC/PNEC_{air}$ cannot be calculated.

Sewage treatment plant (STP)

Scenario [1]: Emission to wastewater/STP
(use # 1, # 3)

The table below shows the $PEC/PNEC_{STP}$ ratios for the active substance deltamethrin reaching a standard STP, if wet cleaning methods are applied after air space treatment by aerosols of the product.

Summary table on calculated $PEC/PNEC_{STP}$ values (15% deltamethrin in the fume)		
Scenario	**PEC_{STP} [mg/L]**	**$PEC/PNEC_{STP}$**
	$PNEC_{STP}$ = 3.00E-02 mg/L	
Scenario [1] – domestic premises		
Private houses	4.01E-05	1.34E-03
Larger buildings	1.26E-04	4.20E-03
Total: Private houses and larger buildings	1.66E-04	5.53E-03

Conclusion: All calculated PEC/PNEC ratios for the STP for scenario [1], if wet cleaning methods are used, are <1, indicating acceptable risk.

Aquatic compartment

Scenario [1]: Emission via wastewater/STP
(use # 1, # 3)

Surface water

The table summarizes the $PEC/PNEC_{surface\ water}$ ratios of the active substance deltamethrin reaching surface water via STP, if wet cleaning methods were used after product application.

Summary table on calculated $PEC/PNEC_{surface\ water}$ values (15% deltamethrin in fume)		
Scenario via STP	**$PEC_{surface\ water}$ [mg/L]**	**$PEC/PNEC_{surface\ water}$**
	$PNEC_{surface\ water}$ = 7.00E-07 mg/L	
Scenario [1] – domestic premises		
Private houses	2.49E-06	**3.56**
Larger buildings	7.83E-06	**11.19**
Total: Private houses and larger buildings	1.03E-05	**14.71**

Sediment

The sediment risk assessment is essentially equal to the aquatic risk assessment as both, $PEC_{sediment}$ and $PNEC_{sediment}$, have been calculated with the equilibrium partitioning method from the $PEC_{local,water}$ and the $PNEC_{aquatic}$, respectively.

Therefore no sediment risk characterisation has been performed.

Conclusion:

All calculated PEC/PNEC ratios for scenario [1] – emission to surface water and sediment via STP, are >1, if wet cleaning methods are used after product application, indicating unacceptable risk for both compartments.

Therefore, use #3 (domestic premises, non-professional users) is not authorised, as it is considered unrealistic for non-professionals to reduce emissions via STP to surface water and freshwater sediment to acceptable levels by applying the numerous and complex instructions for use and RMMs.

For use #1 (domestic premises, professional users), the following risk mitigation measures are proposed in order to reduce the risk to an acceptable level:

- The product is only for indoor use and to be strictly applied in dry-cleaned rooms (cellars).
- N-214, modified: All objects in the area to be treated must be protected from contamination by covering or removal.
- Covers shall be disposed of and shall not be cleaned with water after use. Dry cleaning methods (broom, vacuum cleaner) may be applied, if needed.
- N-141: Do not use where release to drains (sewer) and/or surface water cannot be prevented.
- N-142: Do not use where the biocidal product or its ashes can be discharged to municipal sewage treatment plant.
- N-38, modified: Dry clean (broom or vacuum cleaner) treated area and dispose of residues (product and ashes) to hazardous solid waste in order to prevent releases to water.
- N-37, modified: Do not discharge the biocidal product, nor its residual ashes into the sewage system or the environment.

Scenario [2]: Emission via run-off from arable soil after manure/slurry application
(use # 2, # 4)

Please note, that the model calculations for scenarios concerning breeding premises (manure/slurry application) supply the Predicted Initial Environmental Concentration for soil, groundwater and surface water and are therefore stated as PIEC.

Surface water

Regarding scenario [2] emissions to surface water after application of contaminated manure/slurry on arable soil occur due to run-off. For the surface water risk assessment the concentration in surface water used for the initial assessment is calculated by dividing $PIECgrs_{10\_degr-gw-N}$ by a dilution factor of 10 (ECHA, 2014, page 14).

$PIECgrs_{10\_degr-water-N}$ = $PIECgrs_{10\_degr-gw-N}$ / 10

Summary table on calculated $PIECgrs_{10\_degr-water-N}$/$PNEC_{surface\ water}$ values (15% deltamethrin in fume)

Scenario via run-off from arable soil (slurry/manure application)	**$PIECgrs_{10\_degr\text{-}water\text{-}N}$ [mg/L]**	**$PIECgrs_{10\_degr\text{-}water\text{-}N}$ /$PNEC_{surface\ water}$**
	$PNEC_{surface\ water}$ = 7.00E-07 mg/L	
Scenario [2] – breeding premises **Laying farms - bloodsucking pest (use # 2, # 4)**		
Laying hens cages without treatment (cat. 7)	2.90E-09	4.14E-03
Laying hens in battery cages with aeration (belt drying) (cat. 8)	2.32E-09	3.32E-03
Laying hens in battery cages with forced drying (cat. 9)	3.24E-09	4.62E-03
Laying hens in compact battery cages (cat. 10)	3.24E-09	4.62E-03
Laying hens in free range with litter floor (cat. 11)	9.82E-09	1.40E-02
Laying hens in free range with grating floor (aviary system) (cat. 13)	6.12E-09	8.74E-03
Scenario [2] – breeding premises **Chicken growing farms, fattening pigs and sows stables - insects not affecting livestock (use # 2, # 4)**		
Sows in individual pens (cat. 4)	9.16E-09	1.31E-02
Sows in groups (cat. 5)	1.16E-08	1.66E-02
Fattening pigs (cat. 6)	7.60E-09	1.09E-02
Broilers in free range with litter floor (cat. 12)	4.19E-09	5.99E-03
Parent broilers in free range with grating floor (cat. 14)	3.07E-09	4.39E-03
Parent broilers in rearing with grating floor (cat. 15)	6.69E-09	9.56E-03

Since farms are not allowed to be connected to sewage systems, the wastewater remains on site and will be stored with the slurry prior to mixing with dry waste (manure) for application on soil. The fraction that is calculated to end up in the wastewater is summed up with the fraction released to manure/slurry. This means, that the fraction released to manure/slurry increases. This special assumption only applies for the following animal

categories 8, 11 and 12. The thereof resulting $PIECgrs_{10\_degr\text{-}water\text{-}N}/PNEC_{surface\ water}$ values are reported in the following table.

Summary table on calculated $PIECgrs_{10\_degr\text{-}water\text{-}N}/PNEC_{surface\ water}$ values (15% deltamethrin in fume)		
Scenario via run off from arable soil (slurry/manure application including waste water fractions)	**$PIECgrs_{10\_degr\text{-}water\text{-}N}$ [mg/L]**	**$PIECgrs_{10\_degr\text{-}water\text{-}N}$ /$PNEC_{surface\ water}$**
	$PNEC_{surfasce\ water}$ = 7.00E-07 mg/L	
Scenario [2] – breeding premises (use # 2, # 4)		
Laying hens in battery cages with aeration (belt drying) (cat. 8)	3.24E-09	4.62E-03
Laying hens in free range with litter floor (cat. 11)	1.37E-08	1.96E-02
Broilers in free range with litter floor (cat. 12)	5.86E-09	8.37E-03

Sediment

The sediment risk assessment is essentially equal to the aquatic risk assessment as both $PEC_{sediment}$ and $PNEC_{sediment}$ have been calculated with the equilibrium partitioning method from the $PEC_{surface\ water}$ and the $PNEC_{surface\ water}$, respectively.

Therefore, no risk characterisation for the sediment compartment has been performed.

Conclusion:

All calculated PIEC/PNEC values for scenario [2] for surface water and sediment are far below 1, indicating acceptable risk.

Terrestrial compartment

Scenario [1]: Emission to soil via wastewater/STP (use # 1, # 3)

The table below summarizes the PEC/PNEC$_{soil}$ ratios for the active substance after sewage sludge application on arable land, if wet cleaning methods are applied after treatment.

Summary table on calculated PEC/PNEC$_{soil}$ values (15% deltamethrin in fume)		
Scenario via sludge application	**PEC$_{soil}$ [mg/kg$_{wwt}$]**	**PEC/PNEC$_{soil}$**
	PNEC$_{soil}$ = 7.50E-02 mg/kg$_{wwt}$	
Scenario [1] – domestic premises (use # 1, # 3)		
Private houses	1.40E-02	1.87E-01
Larger buildings	4.42E-02	5.89E-01
Total: Private houses and larger buildings	5.82E-02	7.76E-01

Conclusion:

PEC/PNEC ratios for the terrestrial compartment for scenario [1] are all <1, indicating acceptable risk, for private houses **and/or** larger buildings.

Scenario [2]: Emission to soil via manure/slurry application (use # 2, # 4)

For the terrestrial risk assessment, PIECgrs10_degr–N is compared to PNECsoil (ECHA, 2014, page 14). The following tables report the calculated PIECgrs10_degr-N/PNECsoil ratios of the active substance deltamethrin (concentrations in fume after combustion), based on nitrogen immission standards for grassland, after ten consecutive years and taking degradation into account.

Summary table on calculated $PIEC_{ars\text{-}water\text{-}N}/PNEC_{soil}$ values (15% deltamethrin in fume)		
Scenario via manure/slurry application	**$PIEC_{grs10\_degr\text{-}N}$ [mg/kg_{wwt}]**	**$PIEC_{grs10\_degr\text{-}N}/PNEC_{soil}$ grassland**
	$PNEC_{soil}$ = 7.50E-02 mg/kg_{wwt}	
Scenario [2] – breeding premises **Laying farms - bloodsucking pest (use # 2, # 4)**		
Laying hensages without treatment (cat. 7)	1.40E-04	1.86E-03
Laying hens in battery cages with aeration (belt drying) (cat. 8)	1.11E-04	1.48E-03
Laying hens in battery cages with forced drying (cat. 9)	1.56E-04	2.08E-03
Laying hens in compact battery cages (cat. 10)	1.56E-04	2.08E-03
Laying hens in free range with litter floor (cat. 11)	4.52E-04	6.30E-03
Laying hens in free range with grating floor (aviary system) (cat. 13)	2.94E-04	3.92E-03
Scenario [2] – breeding premises **Chicken growing farms, fattening pigs and sows stables - insects not affecting livestock (use # 2, # 4)**		
Sows in individual pens (cat. 4)	4.40E-04	5.87E-03
Sows in groups (cat. 5)	5.57E-04	7.43E-03
Fattening pigs (cat. 6)	3.65E-04	4.87E-03
Broilers in free range with litter floor (cat. 12)	2.01E-04	2.68E-03
Parent broilers in free range with grating floor (cat. 14)	1.47E-04	1.96E-03
Parent broilers in rearing with grating floor (cat. 15)	3.21E-04	4.28E-03

Since farms are not allowed to be connected to sewage systems, the wastewater remains on site and will be stored with the slurry prior to mixing with dry waste (manure) for application to soil. The fraction that is envisaged to end up in the wastewater is summed up with the fraction released to manure/slurry. This way, the fraction released to manure/slurry increases. This special assumption applies only to the animal categories 8, 11 and 12.

The thereof resulting PIECgrs$_{10_degr-N}$/PNECsoil values are reported in the following table:

Summary table on calculated PIEC$_{grs10_degr-N}$/PNEC$_{soil}$ values (15% deltamethrin in fume)		
Scenario via manure/slurry application including waste water fractions	**PIEC$_{grs10_degr-N}$ [mg/kg$_{wwt}$]**	**PIEC$_{grs10_degr-N}$ /PNEC$_{soil}$ grassland**
	PNEC$_{soil}$ = 7.50E-02 mg/kg$_{wwt}$	
Scenario [2] – breeding premises (use # 2, # 4)		
Laying hens in battery cages with aeration (belt drying) (cat. 8)	1.56E-04	2.08E-03
Laying hens in free range with litter floor (cat. 11)	6.60E-04	8.80E-03
Broilers in free range with litter floor (cat. 12)	2.82E-04	3.76E-03

Conclusion:

PIECgrs$_{10_degr-N}$/PNECsoil ratios for all calculated scenarios are <1, indicating acceptable risk to soil organisms.

Groundwater

According to ECHA (2015a) the concentration in pore water of soil, calculated on basis of the concentration of deltamethrin in fume after combustion, is taken as an indication for potential groundwater levels.

Scenario [1]: Emission to soil via wastewater/STP (use # 1, # 3)

Summary table on calculated PEC$_{groundwater}$ values (15% deltamethrin in fume)	
Scenario via STP sludge application	**PEC$_{groundwater}$ [µg/L]**
Scenario [1] – domestic premises (use # 1, # 3)	
Private houses	1.95E-03
Larger buildings	6.13E-03
Total: Private houses and larger buildings	8.08E-03

Scenario [2]: Emission to soil via manure/slurry application (use # 2, # 4)

For the groundwater risk assessment the concentration in pore water is used for the initial groundwater assessment. The PEC in pore water is calculated from the initial concentration in grassland soil after the last of four manure applications per year, after 10 years of manure application (PIECgrs10_degr–N: according to ECHA, 2014, page 14).

Deltamethrin

Summary table on calculated $PIEC_{grs\text{-}gw\text{-}N}$ values (15% deltamethrin in fume)	
Scenario via run-off from arable soil (slurry/manure application)	**$PIEC_{grs\text{-}gw\text{-}N}$ [µg/L]**
Scenario [2] – breeding premises **Laying farms - bloodsucking pest (use # 2, # 4)**	
Laying hensages without treatment (cat. 7)	2.90E-05
Laying hens in battery cages with aeration (belt drying) (cat. 8)	2.32E-05
Laying hens in battery cages with forced drying (cat. 9)	3.24E-05
Laying hens in compact battery cages (cat. 10)	3.24E-05
Laying hens in free range with litter floor (cat. 11)	9.82E-05
Laying hens in free range with grating floor (aviary system) (cat. 13)	6.12E-05
Scenario [2] – breeding premises **Chicken growing farms, fattening pigs and sows stables - insects not affecting livestock (use # 2, # 4)**	
Sows in individual pens (cat. 4)	9.16E-05
Sows in groups (cat. 5)	1.16E-04
Fattening pigs (cat. 6)	7.60E-05
Broilers in free range with litter floor (cat. 12)	4.19E-05
Parent broilers in free range with grating floor (cat. 14)	3.07E-05
Parent broilers in rearing with grating floor (cat. 15)	6.69E-05

Since farms are not allowed to be connected to sewage systems, the wastewater remains on site and will be stored with the slurry prior to mixing with dry waste (manure) for application to soil. The fraction that is envisaged to end up in the wastewater is summed up with the fraction released to manure/slurry. Therefore, the fraction released to manure/slurry increases. This special assumption applies only to the animal categories 8, 11 and 12. The thereof resulting $PIECgrs_{\_gw\text{-}N}$ values are reported in the following table:

Summary table on calculated $PIEC_{grs-gw-N}$ values (15% deltamethrin in fume)	
Scenario via run off from arable soil (slurry/manure application including waste water)	**$PIEC_{grs-gw-N}$ [µg/L]**
Scenario [2] – breeding premises waste water fractions added to the residues in slurry/manure (use # 2, # 4)	
Laying hens in battery cages with aeration (belt drying) (cat. 8)	3.24E-05
Laying hens in free range with litter floor (cat. 11)	1.37E-04
Broilers in free range with litter floor (cat. 12)	5.86E-05

Conclusion:

Considering scenario [1] – domestic premises (private houses and larger buildings) and assuming wet cleaning after treatment the calculated PEC_{GW} values based on sewage sludge application, as well as the PECars-gw-N values based on manure/slurry application on arable land (scenario [2] – breeding premises) are well under the threshold value of 0.1 µg/L according to the Drinking Water Directive (Reg. (EC) No 98/83/EC) and the quality standard of 0.1 µg/L for pesticide according to the Groundwater Directive (Reg. (EC) No 2006/118/EC). The risk to groundwater is therefore demed acceptable.

Metabolite Br_2CA

The PECgw values were calculated on the basis of worst case PECsoil values that were calculated on the unrealistically worst-case assumption that 100% of the parent compound is transformed to Br_2CA. The PECgw values range between 2.60E-01 and 1.69 µg/L. It should be noted that this is a worst-case assumption, neglecting transformation and dilution. However, these groundwater concentrations exceed the trigger value of 0.1 µg/L of the Directive 98/8/EC. Therefore, refinded groundwater calculations were conducted using FOCUS Pearl 4.4.4. Both scenarios, grassland and arable land, show concentrations in groundwater <0.1 µg/L and therefore, no unacceptable risks are assumed for groundwater.

Primary and secondary poisoning

Primary poisoning

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

Secondary poisoning

Secondary poisoning for the terrestrial food chain via contaminated EARTHWORMS

The possible effects are estimated on birds and mammals in the environment via uptake through the food-chain soil → earthworm → worm-eating birds or mammals.
The values for the Predicted Environmental Concentarations in earthworms are taken from the EUSES 2.1.2 output report (cf. Annex 3).

Scenario [1]: Emission to soil via wastewater/STP (use # 1, # 3)

Secondary poisoning results due to sewage sludge application on arable land, after application of wet cleaning methods after product application.

Summary table on calculated PEC/PNEC values regarding secondary poisoning via contaminated EARTHWORMS: release via STP			
Scenarios	**$PEC_{oral,\ earthworm}$ [$mg/kg_{wwt\ earthworm}$]**	**$PEC/PNEC_{oral}$ birds**	**$PEC/PNEC_{oral}$ mammals**
		$PNEC_{oral}$ birds: 15 mg/kg food	**$PNEC_{oral}$ mammals: 2.67 mg/kg food**
Scenario [1] – domestic premises			
Private houses	1.14E-03	7.60E-05	4.27E-04
Larger buildings	3.58E-03	2.39E-04	1.34E-03
Total: Private houses and larger buildings	4.98E-03	3.32E-04	1.87E-03

Scenario [2]: Emission to soil via manure/slurry application (use # 2, # 4)

Secondary poisoning results due to contaminated manure/slurry application on arable land.
Please note, regarding scenario [2], emissions of the active substance to wastewater and STP, respectively, only occur in the listed animal categories (8, 11, 12) according to ESD of PT18 (OECD 2006). Therefore, results of emissions if wastewater fractions are added to the residues in slurry/manure were calculated additionally (see tables below).

Summary table on calculated PEC/PNEC values regarding secondary poisoning via contaminated EARTHWORMS: release via manure/slurry application			
Scenarios	**$PEC_{oral,\ earthworm}$ [$mg/kg_{wwt\ earthworm}$]**	**$PEC/PNEC_{oral}$ birds**	**$PEC/PNEC_{oral}$ mammals**
		$PNEC_{oral}$ birds: 15 mg/kg food	**$PNEC_{oral}$ mammals: 2.67 mg/kg food**
Scenario [2] – breeding premises **Laying farms – bloodsucking pests (use # 2, # 4)**			
Laying hensages without treatment (cat. 7)	2.68 E-05	1.79E-06	1.00E-05
Laying hens in battery cages with aeration (belt drying) (cat. 8)	2.14 E-05	1.43E-06	8.02E-06
Laying hens in battery cages with forced drying (cat. 9)	2.98 E-05	1.99E-06	1.12E-05
Laying hens in compact battery cages (cat. 10)	2.98 E-05	1.99E-06	1.12E-05
Laying hens in free range with litter floor (cat. 11)	9.06 E-05	6.04 E-06	3.40 E-05
Laying hens in free range with grating floor (aviary system) (cat. 13)	4.56 E-05	3.04 E-06	1.71E-05
Scenario [2] – breeding premises **Chicken growing farms and fattening pigs and sows stables – insects not affecting livestock (use # 2, # 4)**			
Sows in individual pens (cat. 4)	8.44E-05	5.63E-06	3.16E-05
Sows in groups (cat. 5)	1.07E-04	7.13E-06	4.01E-05
Fattening pigs (cat. 6)	7.00E-05	4.67E-06	2.62E-05
Broilers in free range with litter floor (cat. 12)	3.86E-05	2.57E-06	1.45E-05
Parent broilers in free range with grating floor (cat. 14)	2.82E-05	1.88E-06	1.06E-05
Parent broilers in rearing with grating floor (cat. 15)	4.59E-05	3.06E-06	1.72E-05

Results if wastewater fractions are added to the residues in slurry/manure:

Summary table on calculated PEC/PNEC values regarding secondary poisoning via contaminated EARTHWORMS: release via manure/slurry application			
Scenarios	**$PEC_{oral,\ earthworm}$ [$mg/kg_{wwt\ earthworm}$]**	**$PEC/PNEC_{oral}$ birds**	**$PEC/PNEC_{oral}$ mammals**
		$PNEC_{oral}$ birds: 15 mg/kg food	**$PNEC_{oral}$ mammals: 2.67 mg/kg food**
Scenario [2] – breeding premises waste water fractions added to the residues in slurry/manure (use # 2, # 4)			
Laying hens in battery cages with aeration (belt drying) (cat. 8)	2.98E-05	1.99E-06	1.12E-05
Laying hens in free range with litter floor (cat. 11)	1.27E-04	8.44E-06	5.74E-05
Broilers in free range with litter floor (cat. 12)	5.41E-05	3.61E-06	2.03E-05

Secondary poisoning for the aquatic food chain via contaminated FISH

Possible effects are estimated on birds and mammals in the environment via uptake through the food-chain water → aquatic organisms → fish → fish-eating mammal or fish-eating bird.

Scenario [1]: Emission to soil via wastewater/STP (use # 1, # 3)

Secondary poisoning results due to emission to surface water via STP after application of wet cleaning methods after product application.

Summary table on calculated PEC/PNEC values regarding secondary poisoning via contaminated FISH: release via STP			
Scenarios	**$PEC_{oral, fish}$ [$mg/kg_{wwt\ fish}$]**	**$PEC/PNEC_{oral}$ birds**	**$PEC/PNEC_{oral}$ mammals**
		$PNEC_{oral}$ birds: 15 mg/kg food	**$PNEC_{oral}$ mammals: 2.67 mg/kg food**
Scenario [1] – domestic premises (use # 1, # 3)			
Private houses	3.49E-03	2.33E-04	1.31E-03
Larger buildings	1.10E-02	7.33E-04	4.12E-03
Total: Private houses and larger buildings	1.45E-02	9.66E-04	5.43E-03

Scenario [2]: Emission to soil via manure/slurry application (use # 2, # 4)

Secondary poisoning results due to contaminated manure/slurry application on arable land. Regarding scenario [2], emissions of the active substance to wastewater and STP, respectively, only occur in the listed animal categories according to ESD of PT18 (OECD, 2008).

Summary table on calculated PEC/PNEC values regarding secondary poisoning via contaminated FISH: release via manure/slurry application			
Scenarios	**$PEC_{oral, fish}$ [$mg/kg_{wwt\ fish}$]**	**$PEC/PNEC_{oral}$ birds**	**$PEC/PNEC_{oral}$ mammals**
		$PNEC_{oral}$ birds: 15 mg/kg food	**$PNEC_{oral}$ mammals: 2.67 mg/kg food**
Scenario [2] – breeding premises Laying farms - bloodsucking pest (use # 2, # 4)			
Laying hensages without treatment (cat. 7)	4.06E-06	2.70E-07	1.52E-06
Laying hens in battery cages with aeration (belt drying) (cat.8)	3.24E-06	2.16E-07	1.21E-06

Summary table on calculated PEC/PNEC values regarding secondary poisoning via contaminated FISH: release via manure/slurry application			
Laying hens in battery cages with forced drying (cat. 9)	4.54E-06	3.02E-07	1.70E-06
Laying hens in compact battery cages (cat. 10)	4.54E-06	3.02E-07	1.70E-06
Laying hens in free range with litter floor (cat. 11)	1.37E-05	9.16E-07	5.14E-06
Laying hens in free range with grating floor (aviary system) (cat. 13)	8.56E-06	5.70E-06	3.20E-06
Scenario [2] – breeding premises **Chicken growing farms and fattening pigs and sows stables – insects not affecting livestock (use # 2, # 4)**			
Sows in individual pens (cat. 4)	1.28E-05	8.53E-07	4.80E-06
Sows in groups (cat. 5)	1.62E-05	1.08E-06	6.07E-06
Fattening pigs (cat. 6)	1.06E-05	7.07E-07	3.97E-06
Broilers in free range with litter floor (cat. 12)	5.87E-06	3.91E-07	2.20E-06
Parent broilers in free range with grating floor (cat. 14)	4.30E-06	2.87E-07	1.61E-06
Parent broilers in rearing with grating floor (cat. 15)	9.37E-06	6.25E-07	3.51E-06

Results if waste water fractions are added to the residues in slurry/manure:

Summary table on calculated PEC/PNEC values regarding secondary poisoning via contaminated FISH: release via manure/slurry application			
Scenarios	**$PEC_{oral,\ fish}$ [$mg/kg_{wwt\ fish}$]**	**$PEC/PNEC_{oral}$ birds** **$PNEC_{oral}$ birds: 15 mg/kg food**	**$PEC/PNEC_{oral}$ mammals** **$PNEC_{oral}$ mammals: 2.67 mg/kg food**
Scenario [2] – breeding premises **waste water fractions added to the residues in slurry/manure (use # 2, # 4)**			
Laying hens in battery cages with aeration (belt drying) (cat. 8)	4.54E-06	3.02E-07	1.70E-06
Laying hens in free range with litter floor (cat. 11)	1.92E-05	1.28E-06	7.20E-06
Broilers in free range with litter floor (cat. 12)	8.20E-06	5.47E-07	3.10E-06

Conclusion:

All calculated PEC/PNEC values for secondary poisoning via the terrestrial or aquatic food chain for scenario [1] and [2] are far below 1 indicating acceptable risk. Risk of secondary poisoning is therefore not to be expected.

Mixture toxicity

Screening step

Screening Step 1: Identification of the concerned environmental compartments

For scenario [1] there is significant exposure via wet cleaning methods to STP and from there on to surface water and freshwater sediment, as well as to soil and groundwater via sewage sludge application on arable soil.
For scenario [2] there is significant exposure via application of contaminated slurry/ manure to soil and thereof to groundwater. Additionally there is significant exposure to surface water and freshwater sediment via runoff from soil.

Screening Step 2: Identification of relevant substances

Copper(II) carbonate-copper(II) hydroxide (1:1) and silicon dioxide (amorphous, nano) were identified as substances of concern for the environment in the biocidal product, since these co-formulants are approved biocidal active substances present in the product at ≥0,1% (see Conf. Annex for the qualitative risk assessments). However, due to their intrinsic properties no quantitative risk assessment was performed.
No relevant substances were identified in the fume after combustion of the product.
Therefore, the active substance deltamethrin is the only relevant substance for the environment in the biocidal product.

Screening Step 3: Screen on synergistic interactions

Screening step	
	Significant exposure of environmental compartments? (Y/N) Y
	Number of relevant substances >1? (Y/N) N
	Indication for synergistic effects for the product or its constituents in the literature? (Y/N) N (Applicant statement, 2019)

Conclusion:

The active substance deltamethrin is the only relevant substance in the product. Therefore, no mixture toxicity assessment is needed.

Aggregated exposure (combined for relevant emmission sources)

At the time of preparation of this PAR, no EU agreed guidance was available on how to perform a full aggregated exposure assessment. Therefore, no assessment has been made at this stage. This chapter of the PAR has to be reassessed once an agreed guidance has been made available. This could take place at active substance renewal stage or at product authorisation stage, depending on when such guidance becomes available.

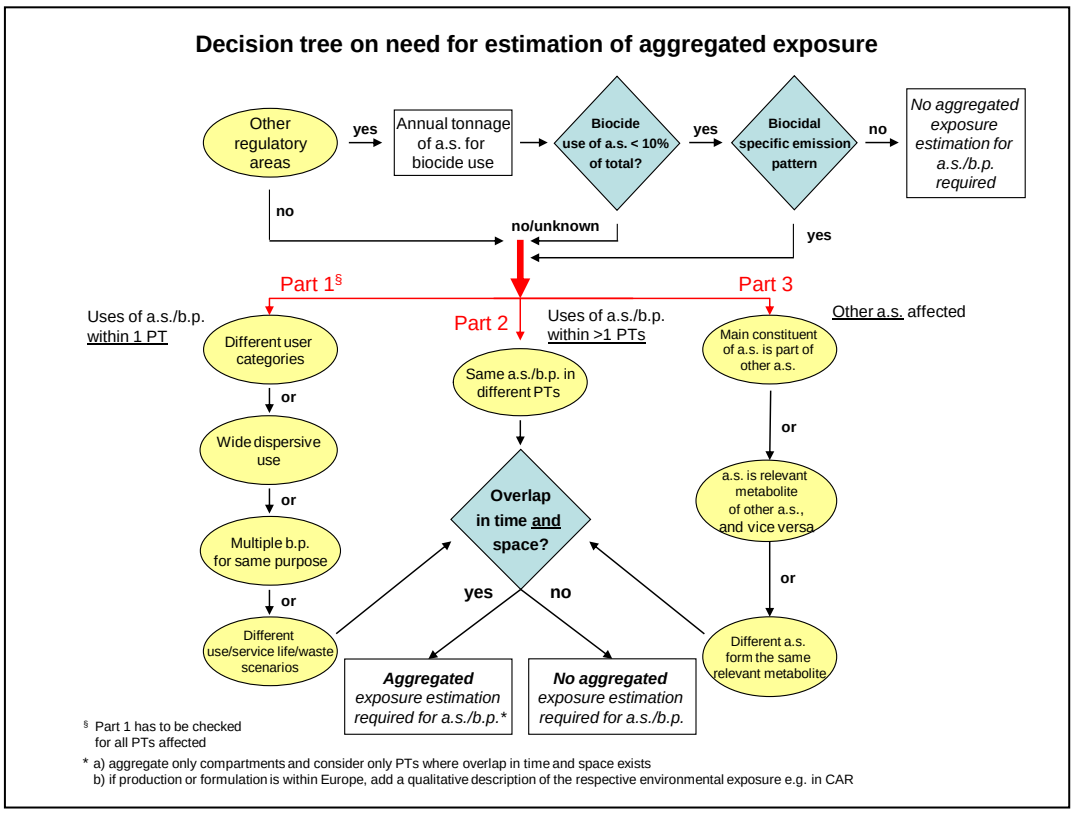


Figure 1: Decision tree on the need for estimation of aggregated exposure

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

Copper(II) carbonate-copper(II) hydroxide (1:1) and silicon dioxide (amorphous, nano) were identified as substances of concern for the environment in the biocidal product, since they are approved biocidal active substances present in the product at ≥0,1% (see Conf. Annex for the qualitative risk assessment). However, due to theire intrinsic properties no quantitative risk assessment was performed.

A complete quantitative risk assessment was performed for the active substance deltamethrin. Risk ratios for deltamethrin in the fume after combustion of the product (15% of the concentration in the product) were calculated for scenario [1] domestic premises, assuming that wet cleaning methods are applied and for scenario [2] breeding premises for exposure via application of contaminated slurry/manure. Additionally a groundwater assessment was performed for the metabolite Br_2CA.

Deltamethrin:

For scenario [1] domesic premises (use #1 and #3) risk ratios were calculated for emissions to STP and thereof for exposure to surface water, sediment, soil and for secondary poisoning.

For STP, soil (private houses **and/or** larger buildings) and secondary poisoning risk ratios <1 were calculated, indicating acceptable risk. Calculated groundwater concentrations were all <0.1 µg/L.

For surface water and freshwater sediment PEC/PNEC values >1 were calculated, indicating unacceptable risk.

Therefore, use #3 (domestic premises, non-professional users) can not be authorised, as it is considered unrealistic for non-professionals to reduce emissions via STP to surface water and freshwater sediment to acceptable levels by applying the numerous and complex instructions for use and RMMs.

In order to reduce the risk to an acceptable level the following risk mitigation measure shall be applied by professional users (use #1):

- The product is only for indoor use and to be strictly applied in dry-cleaned rooms (cellars).
- N-214, modified: All objects in the area to be treated must be protected from contamination by covering or removal.
- Covers shall be disposed of and shall not be cleaned with water after use. Dry cleaning methods (broom, vacuum cleaner) may be applied, if needed.
- N-141: Do not use where release to drains (sewer) and/or surface water cannot be prevented.
- N-142: Do not use where the biocidal product can be discharged to municipal sewage treatment plant.
- N-37, modified: Do not discharge the biocidal product nor its residual ashes into the sewage system or the environment.

- N-38, modified: Dry cleaning (broom or vacuum cleaner) of the treated area and disposal of residues to hazardous solid waste in order to minimize releases to water.

For scenario [2] breeding premises (use #2 and #4) regarding deltamethrin risk ratios were calculated for emissions to soil and thereof for exposure to surface water, freshwater sediment and for secondary poisoning. All these risk ratios were <1, indicating acceptable risk. Calculated groundwater concentrations were <0.1 µg/L.

Metabolite Br_2CA:

Regarding the metabolite Br_2CA risk ratios were calculated for emissions to groundwater. Refined groundwater calculations using FOCUS Pearl 4.4.4. show concentrations in groundwater <0.1 µg/L and therefore, no unacceptable risks are assumed for groundwater.

Conclusion:

Use #1 (domestic premises, professional users) shows acceptable risk for the active substance for all exposed environmental compartments, including groundwater and secondary poisoning, if proposed risk mitigation measures are applied.
Use #2 and use #4 (breeding premises, (non)-professional users) show acceptable risk for the active substance for all exposed environmental compartments, including groundwater and secondary poisoning and acceptable risk for the groundwater regarding the metabolite Br_2CA.
Use #3 (domestic premises, non-professional users) can not be authorised, as it is considered unrealistic for non-professionals to reduce emissions via STP to surface water and freshwater sediment to acceptable levels by applying the numerous and complex instructions for use and RMMs.

2.2.9 Measures to protect man, animals and the environment

Proposed mitigation measures

Reference is made to Chapter 2.1.4

Recommended methods and precautions concerning handling, use, storage, transport or fire:

Safe handling:

Reference is made to Chapter 2.1.4 and 2.1.5.

Safety measures during the treatment:

Reference is made to Chapter 2.1.5.

Storage:

Reference is made to Chapter 2.1.5.

Transport:

- Packed for transport in limited quantity: Inner packaging: ≤500 g
- Total weight: ≤30 kg
- ADR/RID [UN 3226/Self-reactive solid type D/Class 4.1/Environmental hazard: yes]
- IMDG [UN 3226/Self-reactive solid type DClass 4.1/Marine pollutant: no/FS/Ems: F-J, S-G]
- Substances carried in bulk in compliance with Annex II of the MARPOL Convention 73/78 and the IBC Code: Not applicable

Fire:

- Suitable extinguishing media: Water (extinction water must be retained), ABC polyvalent powder
- Unsuitable extinguishing media: Foams with emulsifiers or organic stabilisers, sand.
- Special hazards arising from the mixture:
    - Smoke producing reaction is exothermic
    - Possible release of toxic gases
    - Burning powder may activate the combustion in a fire.
- Advice for fire-fighters:
    - When extinguishing or cooling the canister with water, prevent discharge into the surrounding environment.
    - Self-contained breathing apparatus

Particulars of likely direct or indirect adverse effects:

Reactivity:

- No dangerous reactivity of the product in the original packaging and under normal conditions of use and storage.
- The smoke-generating reaction is exothermic.

Chemical stability:
The product is stable under normal conditions of use and storage.

Possibility of hazardous reactions:
No hazardous reaction under the recommended storage conditions.

Conditions to avoid:
Respect the recommended storage conditions.

Incompatible materials:
No incompatible substances known.

Hazardous decomposition products:
Release of nitrogen oxide, nitrogen dioxide, carbon monoxide and ammonia by the smoke-producing reaction.

Regarding the effects to human health:

Reference is made to Chapter 2.1.5.

Emergency measures in case of an accident:

Reference is made to Chapter 2.1.5.

Emergency measures to protect the environment:

Reference is made to Chapter 2.1.5.

Procedures for product and container waste management and disposal:

Reference is made to Chapter 2.1.5.

2.2.10 Assessment of a combination of biocidal products

Not applicable as the biocidal product is not intended to be authorised for the use with other biocidal products.

2.2.11 Comparative assessment

Not required.

2.2.12 ED assessment

The ED properties of the active substance deltamethrin should be assessed in the context of the renewal of the acive substance approval. Therefore, no further evaluation was carried out for the active substance.

ED properties for the co-formulants of FUMICIDE DM (powder) and also for the combustion products FUMICIDE DM (fume) were evaluated in accordance to the strategy described in CG-34-2019-02 and CA-March21-Doc.4.3, which includes the screening of various databases and information sources for ED concern identification.

The eCA concludes that one co-formulant has indications of ED properties. Also some combustion products formed during the air space treatment have ED concerns. For further details please refer to the confidential Annex.

Based on available information, and considering the legal deadline for biocidal product authorization, it is not possible to conclude whether the biocidal product is considered to have ED properties. The assessment of one (or more) co-formulant must be further assessed in the frame of REACH (or BPR or PPPR if the co-formulant is an active substance with no decision yet on ED). Once the conclusion regarding ED properties of this co-formulant is available, the applicant must inform eCA/rMS. If needed, the conditions of authorization shall be revised.

3 ANNEXES

3.1 List of studies for the biocidal product

Section No	Author	Year	Title	Testing company	Report No	GLP study (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
3.1	[redacted]	2013	CHARACTERISTICS OF INSECTICIDE DM2,4 POWDER COMPOSITION	LCB Food Safety S.A.S	164-DM-CH-100930 v3	No	Yes	LCB Food Safety S.A.S
3.2	[redacted]	2018	pH determination – CIPAC MT75.3	LCB Food Safety S.A.S	N1-0724-DM2.4-pH determination (CIPAC MT75.3)	No	Yes	LCB Food Safety S.A.S
3.2, 3.3	[redacted]	2019	Physico-chemical tests on DM2.4	DEFITRACES	19-912019-001	Yes	Yes	LCB Food Safety S.A.S
3.4.1.1, 5.1	[redacted]	2011 a	Study of the stability of Deltamethrin in ULTRAD DM 2.4% w/w formulation after storage at 40ºC for 8 weeks	ANADIAG Laboratories	R B1014	Yes	Yes	LCB Food Safety S.A.S
3.4.1.1	[redacted]	2011 b	Determination of physical and chemical properties of DELTAMETHRIN 2.4% w/w. Validation of the method for the quantification of deltamethrin in ULTRAD DM 2.4% w/w formulation and study of the stability	ANADIAG Laboratories	R B0218	Yes	Yes	LCB Food Safety S.A.S

Section No	Author	Year	Title	Testing company	Report No	GLP study (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
			after storage					
3.4.1.2	[redacted]	2015 a	Shelf life at ambient temperature of one batch (20g) of in DM 2.4 formulation (Deltamethrin 2.4% w/w)	ANADIAG Laboratories	R B-3026	Yes	Yes	LCB Food Safety S.A.S
3.4.1.2	[redacted]	2015 b	Shelf life at ambient temperature of one batch (1000g) of in DM 2.4 formulation (Deltamethrin 2.4% w/w)	ANADIAG Laboratories	R B3033	Yes	Yes	LCB Food Safety S.A.S
3.5.6	[redacted]	2011 a	Etude Granulometrique de la poudre ULTRAD DM	LCB Food Safety S.A.S	Ref. 168-DM-CH-110307	No	Yes	LCB Food Safety S.A.S
3.5.6	[redacted]	2013	Sieve analysis of DM2.4 powder composition	LCB Food Safety S.A.S	168-DM-CH-130118-v3	No	Yes	LCB food safety
3.5.6	[redacted]	2019	Caracterisation granulometrique sur silice (SiO_2 laser particle size distribution rapport)	FILAB Laboratoire De Chimie	N1-0732 (FILAB report A1800945/1)	No	Yes	FILAB Laboratoire De Chimie
3.5.9	[redacted]	2011 b	Caracteristiques de combustion de la poudre ULTRAD DM. Essais RB.1.116.1-RB.1.116.2	LCB Food Safety S.A.S+	Ref. 170-DM-CH-110301	No	Yes	LCB Food Safety S.A.S
3.5.9, 3.5.10	[redacted]	2014	Smoke- Generating Reaction Characteristics of DM 2,4 Powder Composition Assays Ref. Rb.1.116.1 – Rb.1.116.2 – Rb.1.140.1	LCB Food Safety S.A.S	170-DM-CH-110301-v3	No	Yes	LCB food safety

Section No	Author	Year	Title	Testing company	Report No	GLP study (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
3.5.11	[redacted]	2016	Contribution to the characterization of fumes from the smoke generator DM2.4 with Deltamethrin	FILAB. Laboratoires d'analyses industrielles	N1-0432 (FILAB report 37290-03)	No	Yes	LCB Food Safety S.A.S
3.5.13	[redacted]	2016 a	FUMICIDE DM. DM2.4. Monitoring concentration of gases CO, NH3, HCN, NO2 during emission, contact time and ventilation	LCB	N1-0479-DM2.4	No	Yes	LCB food safety
3.5.13	[redacted]	2016 b	FUMICIDE DM. DM2.4. Monitoring concentration of gases CO, NH3, HCN, NO2 during emission, contact time without ventilation	LCB	N1-0482-DM2.4	No	Yes	LCB food safety
3.5.13	[redacted]	2016 c	FUMICIDE DM Study on residues set on the floor after application of a DM2.4 product containing 2.4% of Deltamethrin	LCB food safety	N1-0436-DM2.4	No	Yes	LCB Food Safety S.A.S
3.5.13	[redacted]	2017	Study on Deltamethrin in air and set on the ground during application of DM2.4 product containing 2.4% of Deltamethrin. Application rates tested: 1 g DM2.4/m3 and 0.5 DM2.4/m3	LCB food safety	N1-0517-CH-170202-DM2.4-EXT24-122	No	Yes	LCB Food Safety S.A.S
4.1	[redacted]	2010	Essais ONU de la Série 2	INERIS	DRA-10-	No	Yes	LCB Food

Section No	Author	Year	Title	Testing company	Report No	GLP study (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
			sur la poudre fumigène ULTRAD DM		117078-13679A			Safety S.A.S
4.1	[redacted]	2010	Explosive properties of solids on ULTRAD DM	DEFRITRACES	10-912019-004	Yes	Yes	LCB Food Safety S.A.S
4.7 (Cf.4.2)	[redacted]	2011	Test of flammability for easily flammable solid items (Test N.1) on ULTRAD DM	DEFRITRACES	10-912019-005	Yes	Yes	LCB Food Safety S.A.S
4.8 (Cf. 4.14.1)	[redacted]	2012	Classement au transport du produit ULTRAD DM (classe 4.1 – matière auto-réactive)	INERIS	DCE-12-123416-06674A_PVi-R1-99/2	No	Yes	LCB Food Safety S.A.S
4.10 (Cf. 4.17)	[redacted]	2015	Assay N. 2: Assay method for pyrophoric solid matters	LCB Food Safety S.A.S	N1-0418	No	Yes	LCB Food Safety S.A.S
4.11 (Cf. 4.17.1)	[redacted]	2011 a	UN Test N.4 carried out with a sample of UTRAD DM	INERIS	DRA-11-121832-05010A	No	Yes	LCB Food Safety S.A.S
4.14.1 (Cf. 4.4)	[redacted]	2011 a	Oxidizing properties of ULTRAD DM	DEFITRACES	10-912019-006	Yes	Yes	LCB Food Safety S.A.S
4.14.2 (Cf. 4.4)	[redacted]	2011 b	Oxidizing properties (carriage of dangerous goods) on ULTRAD DM	DEFITRACES	11-912019-002	Yes	Yes	LCB Food Safety S.A.S
4.17.2 (Cf 4.17.1)	[redacted]	2011 c	Self-Ignition temperature of solids on ULTRAD DM	DEFITRACES	Ref. 11-912019-001	Yes	Yes	LCB Food Safety S.A.S

Section No	Author	Year	Title	Testing company	Report No	GLP study (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
4.17.3 (Cf. 4.2)	[redacted]	2011 b	Essais d´inflammabilite et d´explosivite sur le produit ULTRAD DM	DEFRITRACES	DRA-11-116531-02148A	No	Yes	LCB Food Safety S.A.S
5.1 (Cf. 5)	[redacted]	2011 c	Determination of Physical and Chemical Properties of Deltamethrin 2.4% w/w. Validation of the method for the quantification of deltamethrin in ULTRAD DM 2.4% w/w formulation and study of the stability after storage	ANADIAG Laboratories	R B0218	Yes	Yes	LCB Food Safety S.A.S
5.1 (Cf. 5)	[redacted]	2022	Method validation for the determination of copper concentration by Inductively Coupled Plasma Atomic Emission Spectroscopy (ICP-AES) in a fumigant sample.	Intertek LaCoMeD	2022-LCM-0196EN	No	Yes	LCB Food Safety (Kersia Group)
5.1 (Cf. 5)	[redacted]	2022	Basic copper carbonate analysis in DM2.4 powder by spectrophotometry	LCB Food Safety (Kersia Group)	PE / 135	No	Yes	LCB Food Safety (Kersia Group)
5.1 (Cf. 5)	[redacted]	2014	Method validation for determination of Ammonium Nitrate in DM 2.4 formulation	ANADIAG Laboratoires	B3293	Yes	Yes	LCB Food Safety S.A.S
5.2 (Cf. 5)	[redacted]	2013 a	Use of the insecticide product DM2.4 for aerial insecticide treatment in sheds: Analytical	ANADIAG Laboratoires	R 225 3 0317	Yes	Yes	LCB Food Safety S.A.S

Section No	Author	Year	Title	Testing company	Report No	GLP study (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
			investigations on the transfer of deltamethrin on surfaces and into litter, drinking water and feed in a poultry breeding shed (Annex 5)					
5.2 (Cf. 5)	[redacted]	2013	Use of the insecticide product DM2.4 for aerial insecticide treatment in sheds: Analytical investigations on the transfer of deltamethrin on surfaces and into litter, drinking water and feed in a poultry breeding shed. (Annex 4)	ANADIAG Laboratories	B3088	Yes	Yes	LCB Food Safety S.A.S
5.2.1 (Cf. 5)	[redacted]	2021 a	Validation of the Analytical Method for the Determination of Deltamethrin Residues in Soil	ChemService S.r.l. Controlli e Ricerche	CH – 0552/2021	Yes	Yes	LCB Food Safety S.A.S
5.2.3 (Cf. 5)	[redacted]	2021	Validation of the Analytical Method for the Determinationof Deltamethrin in Drinking Water	ChemService S.r.l. Controlli e Ricerche	CH – 0549/2021	Yes	Yes	LCB Food Safety S.A.S
5.2.3 (Cf. 5)	[redacted]	2013 b	Use of the insecticide product DM2.4 for aerial insecticide treatment in sheds: Analytical investigations on the transfer of deltamethrin on	ANADIAG Laboratoires	Ref. R 225 3 0372/ R 225 3 0388	Yes	Yes	LCB Food Safety S.A.S

Section No	Author	Year	Title	Testing company	Report No	GLP study (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
			surfaces and into litter, drinking water and feed in a poultry breeding shed. (Annex 6)					
5.3 (Cf. 5)	[redacted]	2021 b	Validation of the Analytical Method for the Determination of Deltamethrin Residues in Animal feed	ChemService S.r.l. Controlli e Ricerche	CH – 0538/2021	Yes	Yes	LCB Food Safety S.A.S
6	[redacted]	2010 a	Laboratory assessment of the biological efficacy of a smoke generator intended to control several pests	T.E.C. Laboratory	Ref. 1368c/031 0R	No	Yes	LCB Food Safety S.A.S
6	[redacted]	2010 b	Bioassay in semi-practical conditions of the insecticide efficacy of a smoke generator intended to control insects pests	T.E.C. Laboratory	Ref. 1368d/021 0R	No	Yes	LCB Food Safety S.A.S
6	[redacted]	2011 a	Bioassay in semi-practical conditions of the insecticide efficacy of a smoke generator intended to control insect pests (Lesser mealworm (*Alphitobius diaperinus*))	T.E.C. Laboratory	Ref. 1368f1/03 10R	No	Yes	LCB Food Safety S.A.S
6	[redacted]	2011 b	Bioassay in semi-practical conditions of the insecticide efficacy of a smoke generator intended to control hornets	T.E.C. Laboratory	Ref. 1368j3h/03 10R	No	Yes	LCB Food Safety S.A.S
6	[redacted]	2011 c	Bioassay in semi-practical conditions of the insecticide efficacy of a smoke generator intended	T.E.C. Laboratory	Ref. 1368f3/03 10R	No	Yes	LCB Food Safety S.A.S

Section No	Author	Year	Title	Testing company	Report No	GLP study (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
			to control the chicken red mites					
6	[redacted]	2010c	Field testing of the efficacy of an insecticide speciality to control house flies in livestock premises: *Musca domestica* + *Lycoriella auripila* (the mushroom fly)	T.E.C. Laboratory	Ref. 1368e2/0310R	No	Yes	LCB Food Safety S.A.S
6	[redacted]	2019a	Simulated-use trial of the efficacy of an insecticide applied as a space treatment and intended to control Oriental cockroaches	T.E.C. Laboratory	2512/2019	No	Yes	LCB Food Safety S.A.S
6	[redacted]	2019	Study on the efficacy of the FUMICIDE DM applied in simulated-use trial on Oriental cockroach (*Blatta orientalis*)	IZINOVATION	19KERBoLab001	No	Yes	LCB Food Safety S.A.S
6	[redacted]	2019b	FIELD TRIAL OF THE EFFICACY OF AN INSECTICIDE APPLIED AS A SPACE TREATMENT AND INTENDED TO CONTROL ORIENTAL COCKROACHES	T.E.C. Laboratory	2512a/2019	No	Yes	LCB Food Safety S.A.S
8.1	[redacted]	2016	DM2,4 ASSESSMENT OF ACUTE EYE IRRITATION	Phycher Bio Développement	Ref. 10-0CDE-PH-16/0044	Yes	Yes	LCB Food Safety S.A.S
8.1	[redacted]	2016	Isolated Chicken Eye Test Method for Identifying (i) Chemicals Inducing Serious Eye Damage and	Phycher Bio Développement	Ref. ICE-PH-16/0044e	Yes	Yes	LCB Food Safety S.A.S

Section No	Author	Year	Title	Testing company	Report No	GLP study (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
			(ii) Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage					
8.5.1	[redacted]	2013	2.4% Deltamethrin powder: Acute Oral Toxicity in the Rat – Up and Down Procedure	Harlan Laboratories Ltd.	Ref. 41300027	Yes	Yes	LCB Food Safety S.A.S
8.5.2	[redacted]	2013	2.4% Deltamethrin powder Acute Inhalation Toxicity (Nose Only) Study in the Rat	Harlan Laboratories Ltd.	Ref. 41300029	Yes	Yes	LCB Food Safety S.A.S
8.5.3	[redacted]	2013	2.4% Deltamethrin powder: Acute Dermal Toxicity (Limit Test) in the Rat	Harlan Laboratories Ltd.	Ref. 41300028	Yes	Yes	LCB Food Safety S.A.S
8.7.1	[redacted]	2019	SAMPLES OF NANO SILICA RELEASED INTO THE AIR DURING FUMIGATION OPERATIONS	PARTICLEVER	F-ME301	No	Yes	LCB food safety S.A.S.
9	[redacted]	2019	Declaration of not synergic effects between components	LCB food safety S.A.S.	Applicant statement	n.a.	Yes	LCB food safety S.A.S.

3.2 Output tables from exposure assessment tools

Human and Animal Exposure

Scenario [1] - Reentering in treated premise (Primary exposure)

Professional exposure

- ***<u>Inhalation exposure</u> estimates (Dinh)***

Exposure might occur if clearance time is not respected or when the operator needs to enter in the treated premise to connect the ventilation system. Therefore, this route of inhalation exposure has been considered in this assessment.

Inhalation uptake is estimated based on ECHA-R15 guide, where the inhalation uptake (Dinh) is calculated by the following equation:

$$Dinh = \frac{(RC\ a.s.)x\ (FQ)x\ (F)x\ (ET)x\ (IR)}{(BW)}\ x\ 1000 = \text{[mg/kg bw/day]}$$

***Domestic area (1-dom)-(Tier 1)*:**

$$Dinh_{\ Tier\ 1\_(1\text{-}dom)} = \frac{(1.925 mg/m^3)x\ (1\ event/day)x\ \left(\frac{5}{60}\left(\frac{min}{hr}\right)\right)x\ (1.25\ m^3/h)}{(60\ kg)} = 0.0033 \text{ mg/kg bw/day}$$

***Breeding area (1-bre)-(Tier 1)*:**

$$Dinh_{\ Tier\ 1\_(1\text{-}bre)} = \frac{(3.8 mg/m^3)x(1\ event/day)x\ \left(\frac{10}{60}\left(\frac{min}{hr}\right)\right)x\ (1.25\ m^3/h)}{(60\ kg)} = 0.013 \text{ mg/kg bw/day}$$

Professional users are expected to use PPE/RPE under these circumstaces in order to avoid any risk for health. Hence under the assumption that the operator must use RPE (factor 10), the following exposure is foreseeable for tier 2:

***Domestic area (1-dom) - (Tier 2)*:**

$Dinh_{\ TIER2} = Dinh_{TIER1\ -dom} * 10\% = 0.0003$ mg/kg bw/day

***Breeding area (1-bre) - (Tier 2)*:**

$Dinh_{\ TIER2} = Dinh_{TIER1\text{-}bree} * 10\% = 0.0013$ mg/kg bw/day

Scenario [2] - Disposal product's can and cleaning (Primary exposure)

In order to estimate a realistic inhalation exposure, the above exposure estimates have been recalculated based on the residual concentration of deltamethrin present in the air estimated in a field test in the different premises after the safety time of 4 hours for domestic and breeding premises. A calculation based on the formula issued from the French Observatory for indoor air quality has been developed:

$$C2 = C1 * e^{-n\Delta t}$$ Where:

C1 deltamethrin concentration at T1 (t=0) [mg/m^3]

C2 deltamethrin concentration at T2 (t=safety time) [mg/m^3]

N Air renewal rate, where:

1 vol/hr for domestic premise (1-dom)

2 vol/hr for breeding premises (1-bree).

Δt Duration of the ventilation (safety time) [hours]. According to product's label,4 hrs is set for domestic premises (1-dom) and breeding premises (1-bre).

Hence, the deltamethrin's concentration that should be considered in the operator risk assessment after safety time for each premise is as follows:

C2 domestic premises (1-dom) = $1.925\ [\frac{mg}{m^3}] \times e^{-1[\frac{vol}{hr}]\times 4[hr]}$ = 0.0353 mg deltamethrin/m^3

C2 domestic premises (2-dom) = 0.0145 mg deltamethrin/m^3

This concentration was measured after 60 hrs and is used is for domestic premises where no ventilation process is available. This value was obtained form the trial test: n° N1-0517-CH-170202- DM2.4-EXT24-122 – "Study on Deltamethrin in air and set on the ground during application of DM2.4 product containing 2.4% of deltamethrin".

C2 breeding premises (1-bree) = $3.85\ [\frac{mg}{m^3}] \times e^{-2[\frac{vol}{hr}]\times 4[hr]}$ = 0.00129 mg deltamethrin/m^3

Professional exposure

- ***<u>Inhalation exposure</u> estimates (Dinh)***

Taking in account the residual concentration, Exposure inhalation dose (Dinh) for the operator is estimated for each premise (Inhalation absorption is 100% (=1) and not indicated in the following formulas):

- ***Dinh 1-Domestic premise (1-dom)*:**

$$Dinh1_{\ Tier\ 1\_(1\text{-}dom)} = \frac{0.0353\left(\frac{mg}{m^3}\right) x\ 1\left(\frac{h-event}{day}\right) x\ 1.25\left(\frac{m^3}{h}\right) x)}{60\ [kg]} = 7x10^{-4}\ \text{mg/kg bw/day}$$

- ***Dinh 1-Domestic premise (2-dom)*:**

$$Dinh1_{\ Tier\ 1\_\ (2\text{-}dom)} = \frac{0.0145\left(\frac{mg}{m^3}\right) x\ 1\left(\frac{h-event}{day}\right) x\ 1.25\left(\frac{m^3}{h}\right)}{60\ [kg]} = 3x10^{-4}\ \text{mg/kg bw/day}$$

- ***Dinh 1-Breeding premise (1-bre)*:**

$$Dinh1_{\ Tier\ 1\_\ (1\text{-}bre)} = \frac{0.00129\left(\frac{mg}{m^3}\right) x\ 2\left(\frac{h-event}{day}\right) x\ 1.25\left(\frac{m^3}{h}\right)}{60\ [kg]} = 5x10^{-5}\ \text{mg/kg bw/day}$$

As in the scenario before, professional users should use RPE in order to avoid any risk for health. Hence under the assumption that the operator must use a mask (factor 10), the following exposure is foreseeable for a tier 2:

- ***Dinh 1-Domestic area (1-dom) - (Tier 2)*:**

  Dinh 1 $_{TIER2}$ = Dinh$_{TIER1\ (1\text{-}dom)}$ * 10% = $7x10^{-5}$ mg/kg bw/day

- ***Dinh 1-Domestic area (2-dom) - (Tier 2)*:**

  Dinh 1 $_{TIER2}$ = Dinh$_{TIER1\ (2\text{-}dom)}$ * 10% = $3x10^{-5}$ mg/kg bw/day

- ***Dinh 1-Breeding area (1-bre) - (Tier 2)*:**

  Dinh 1 $_{TIER2}$ = Dinh$_{TIER1\ (1\text{-}bre)}$ * 10% = $5x10^{-6}$ mg/kg bw/day

In addition, Inhalation exposure is potential during the use of broom sweeping or vacuum cleaner due to the fact that although the residual product is solid, powder may be released from their surfaces by mechanical handling.

It is assumed that the substance is released for 1 %[4] as airborne particles and for a worst case situation it is performed indoors in a standard room of 58 m^3 (22 m^2).

The concentration in the inhaled air (Cinh) is then:

- ***Dinh 2-Domestic premise (1-dom) – (Tier 1)*:**

$$Dinh2_{\ Tier\ 1\_(1\text{-}dom)} = \frac{3.7\left(\frac{mg}{m^2}\right) x \frac{22}{58}\left(\frac{m2}{m3}\right) x\ 1\%\ x\ 1\left(\frac{h-event}{day}\right) x\ 1.25\left(\frac{m^3}{h}\right)}{60\ [kg]} = 3x10^{-4}\ \text{mg/kg bw/day}$$

It is important to bear in mind, that same residual concentration on surface is assumed for both domestic premises with and without ventilation systems.

- ***Dinh 2-Domestic premise (2-dom) – (Tier 1)*:**

$$Dinh2_{\ Tier\ 1\_(1\text{-}dom)} = \frac{4.12\left(\frac{mg}{m^2}\right) x \frac{22}{58}\left(\frac{m2}{m3}\right) x\ 1\%\ x\ 1\left(\frac{h-event}{day}\right) x\ 1.25\left(\frac{m^3}{h}\right)}{60\ [kg]} = 3.x10^{-4}\ \text{mg/kg bw/day}$$

It is important to bear in mind, that same residual concentration on surface is assumed for both domestic premises with and without ventilation systems.

- ***Dinh 2-Breeding premise (1-bree) – (Tier 1)*:**

[4] cf. to COMMISSION REGULATION (EU) No 666/2013 of 8 July 2013 implementing Directive 2009/125/EC of the European Parliament and of the Council with regard to ecodesign requirements for vacuum cleaners, Annex I, 1 b): "dust re-emission shall be no more than 1.00 %"

$$Dinh2_{\ Tier\ 1\_(1\text{-}bre)} = \frac{7.4\left(\frac{mg}{m^2}\right) x \frac{690}{1823}\left(\frac{m2}{m3}\right) x\ 1\%\ x\ 1\left(\frac{h-event}{day}\right) x\ 1.25\left(\frac{m^3}{h}\right)}{60\ [kg]} = 6x10^{-4}\ mg/kg\ bw/day$$

For tier 2 (considering PPE and RPE):

- ***Dinh 2-Domestic area (1-dom) - (Tier 2)*:**

Dinh 2 $_{TIER2\_(1\text{-}Dom)}$ = Dinh$_{TIER1\ (1\text{-}dom)}$ * 10% = $3x10^{-5}$ mg/kg

- ***Dinh 2-Domestic premise (2-dom) – (Tier 2)*:**

Dinh 2 $_{TIER2\_(2\text{-}Dom)}$ = Dinh$_{TIER1\ (2\text{-}dom)}$ * 10% = $3x10^{-5}$ mg/kg

- ***Dinh 2-Breeding premise (1-bree) - (Tier 2)*:**

$Dinh2_{\ Tier\ 1\_(1\text{-}bree)}$ = Dinh$_{TIER1\ (1\text{-}bre)}$ * 10% = $6x10^{-5}$ mg/kg bw/day

- ***<u>Dermal exposure</u> estimates (Dderm)***

Dermal exposure is calculated under the assumption that the only dermal surface able to come in contact with the product's residues are the the hands (820 cm^2). Hence, the following equation is derived:

$$Dderm = \frac{A.s\left[\frac{mg}{m^2}\right] \times AREAexp\ [m^2] \times 1\left[\frac{events}{day}\right] \times Derm\text{-}Abs\ [\%]}{BW\ [kg]}$$

Where:

A.s.: is the active substance concentration on treated surfaces after application. For each compartment, the amounts are taken from the study report nºN1-0436-DM2.4, where deltamethrin's concentration on the floor is estimated after product application at highest dose 1 $g_{product}/m^3$.

BW: Body weight

Derm-Abs: Dermal absorption percentage, taken from the active substance's CAR.

Hence, for each scenario:

- ***Domestic area (1-dom) - (Tier 1):***

$$Dderm_{\ Tier1\ (1\text{-}dom)} = \frac{3.7\left[\frac{mg}{m^2}\right] \times 0.082\ [m^2] \times 1\left[\frac{events}{day}\right] \times 7\%}{60\ [kg]} = 3x10^{-4}\ mg/kg\ bw/day$$

- ***Domestic area (2-dom) - (Tier 1):***

$$Dderm_{\ Tier1\ (2\text{-}dom)} = \frac{4.12\left[\frac{mg}{m^2}\right] \times 0.082\ [m^2] \times 1\left[\frac{events}{day}\right] \times 7\%}{60\ [kg]} = 3x10^{-4}\ mg/kg\ bw/day$$

- ***Breeding area (1-bre) - (Tier 1)*:**

$$\text{Dderm}_{\text{Tier1 (1-bre)}} = \frac{7.4\left[\frac{mg}{m^2}\right] \times 0.082\,[m^2] \times 1\left[\frac{events}{day}\right] \times 7\%}{60\,[kg]} = 6\text{x}10^{-4} \text{ mg/kg bw/day}$$

The following exposure is foreseeable for a Tier 2 considering use of gloves:

- ***Domestic area (1-dom) - (Tier 2)*:**

  $\text{Dderm}_{\text{TIER2}} = \text{Derm}_{\text{TIER1 (1-dom)}} * 10\% = 3\text{x}10^{-5}$ mg/kg bw/day

- ***Domestic area (2-dom) - (Tier 2)*:**

  $\text{Dderm}_{\text{TIER2}} = \text{Derm}_{\text{TIER1 (2-dom)}} * 10\% = 3\text{x}10^{-5}$ mg/kg bw/day

- ***Breeding area (1-bree) - (Tier 2)*:**

  $\text{Dderm}_{\text{TIER2}} = \text{Derm}_{\text{TIER1 (1-bree)}} * 10\% = 6\text{x}10^{-5}$ mg/kg bw/day

Non-professional exposure

- ***<u>Inhalation exposure</u> estimates (Dinh)***

Instructions of use for non-professional operators are the same as those for professional operators except for the use of PPE or RPE. Therefore, the Tier 1-exposure levels for professinals apply for non-professional and are used for risk assessment.

- ***<u>Dermal exposure</u> estimates (Dderm)***

The Tier 1-exposure estimates for professionals are also considered to be applicable for non-professionals as use of PPE or RPE is not assumed.

Secondary exposure (general public)

Same scenario which was considered for non-professional can be considered for bystanders as general public in a secondary exposure. Therefore, the same findings can be assumed for this human group.

Scenario [3]: Secondary exposure

Inhalation exposure of adult			
Input	A.s. concentration in air	0.0353	mg/m^3
Input	Frequency	1	1/d
Input	Duration	2	h
Input	Inhalation rate	1.25	m^3/h
Input	Inhalation absorption	100	%
Input	Body weight	60	kg
Calculation	Exp= 0.0353 x 1 x 2 x 1.25 x 100/100 / 60		
Result	Inhalation exposure	**$1.47x10^{-3}$**	mg/kg bw/d

Dermal exposure of adult			
Input	A.s. concentration on floor	4.12	mg/m^2
Input	Frequency	1	1/d
Input	Duration	2	h
Input	Indoor transfer coefficient	0.78	m^2/h
Input	Dislodgeable fraction	50	%
Input	Dermal absorption	7	%
Input	Body weight	60	kg
Calculation	Exp= 4.12 x 1 x 2 x 0.78 x 50/100 x //100/ 60		
Result	DERMAL exposure	**$3.75x10^{-3}$**	mg/kg bw/d

Inhalation exposure of toddler			
Input	A.s. concentration in air	0.0145	mg/m^3
Input	Frequence	1	1/d
Input	Duration	2	h
Input	Inhalation rate	1.26	m^3/h
Input	Inhalation absorption	100	%
Input	Body weight	10	kg
Calculation	Exp= 0.0145 x 1 x 2 x 1.26 x 100/100 / 10		
Result	Inhalation exposure	**$8.88x10^{-3}$**	mg/kg bw/d

Dermal and oral exposure of toddler			
Amount of a.s. on toddlers skin			
Input	A.s. concentration on floor	4.12	mg/m^2
Input	Frequency	1	1/d
Input	Duration	2	h
Input	Indoor transfer coefficient	0.2	m^2/h
Input	Dislodgeable fraction	50	%
Calculation	Amount= 4.12 x 1 x 2 x 0.2 x 50/100		
Result	Amount on skin	**$8.24x10^{-1}$**	mg/d
Dermal exposure			
Input	90% are dermally absorped	90	%
Input	Dermal absorption	7	%
Input	Bodyweight	10	kg
Calculation	Exp= $8.24x10^{-1}$ x 90/100 x 7/100 / 10		
Result	Dermal exposure	**$5.19x10^{-2}$**	mg/kg bw/d
Oral exposure			
Input	10% are orally absorped	10	%
Input	Oral absorption	75	%
Input	Bodyweight	10	kg
Calculation	Exp= $8.24x10^{-1}$ x 10/100 x 75/100 / 10		
Result	Oral exposure	**$6.18x10^{-3}$**	mg/kg bw/d

Lifestock exposure: Exposure of poultry and pigs (Tier 1 and Tier 2)


Livestock Exposure-Deltamethrin- poultry


Livestock Exposure-Deltamethrin- pigs.xls

Livestock exposure: **Field trial: [redacted] 2013**

Assessment of applicant

In order to refine the results of the risk assessment, a field trial has been performed in a poultry breeding premise ([redacted] 2013).

In order to investigate the transfer of deltamethrin on surfaces in a poultry shed and into litter, drinking water and feed (not allowed following label restrictions), a treatment event was monitored in a broiler shed using the product FUMICIDE DM. For this study, after the insecticide treatment, the 1 day old-chicken were introduced and reared for 34 days in a breeding shed with a capacity of 33000 chickens. The size of the shed was 100 m×15 m, the volume was 5100 m^3.

Results showed that the maximal rate of deltamethrin found in litter 15 hours after treatment is 1.96 mg/kg. So the maximal quantity in the whole litter (7 tons) is estimated to be 13.72 g, i.e. 11.9% of the initial 115.5 g of deltamethrin included in the 5100 g of the product DM2.4 used to treat the shed.

The maximal rate of deltamethrin found in litter (manure) after the rearing period is 0.16 mg/kg. So the maximal quantity in the whole manure (50 tons) is estimated to be 8 g, i.e. 6.9% of the initial 115.5 g of deltamethrin included in the 5100 g of the product DM2.4 used to treat the shed. So we have to consider the loss, during the rearing period, of 41.7% of the deltamethrin present in the litter just after the treatment.

On the other hand, filters give undervaluated results with 3 mg/m^2 on the floor, i.e. 3 mg/m^2×1500 m^2 = 4.5 g deltamethrin on the floor, to be compared with 13.72 g deltamethrin found in litter.

According to deltamethrin found on filters on walls and under ceiling (<0.1 mg/m^2), the whole quantity of deltamethrin fixed on walls (565 m^2) and ceiling (1560 m^2) can be considered as negligible, below 200 mg.

During the rearing period, the level of deltamethrin found in drinking water was 1.55 µg/L. The flock of 33000 chicken drinks 7000 L water per day, i.e. 0.212 L per chicken/day, which leads to a ingestion of 1.78×10^{-4} mg a.s./kg bw/d.

During the rearing period, the flock of 33000 chicken eat 120 tons, i.e. 0.107 kg feed per chicken/day. Considering a concentration of deltamethrin in the feed of 0.01 mg/kg, a chicken would ingest 5.78×10^{-4} mg s.a./kg bw/day.

So, as a worst case, a chicken would ingest (1.78×10^{-4} + 5.78×10^{-4}) mg/kg bw/d = 7.56×10^{-4} mg a.s./kg bw/d.

This value is well-below the trigger value of 0.004 mg/Kg bw/day set for unacceptable risk to livestock animals. Therefore, the risk for chickens after application of FUMICIDE DM according with recommended application rates is acceptable.

Environmental Exposure

EUSES 2.1.2 output table

Intermediate and output calculations regarding scenario [2] - Breeding premises

Target insects in breeding premises: bloodsucking pest (laying hens): 24 mg a.s. /m³; 1 application/year

Variable/ parameter	**Symbol**	**Unit**	**Laying hens in battery cages without treatment (cat 7)**	**Laying hens in battery cages with aeration (belt drying) (cat 8)**	**Laying hens in battery cages with forced drying (deep pit, high rise) (cat 9)**	**Laying hens in compact battery cages (cat 10)**	**Laying hens in free range with litter floor (partly litter floor, partly slatted) (cat 11)**	**Laying hens in free range with grating floor (aviary system) (cat 13)**
If Tbioc-int ≥ Tmanure-int$_{ar2}$, then Napp-bio$_{manure_ar2}$ = 1 If Tbioc-int < Tmanure-int$_{ar2}$, then Napp-bio$_{manure_ar2}$ = ROUND [(Tmanure-int$_{ar2}$/Tbioc-int),(1)] If Napp-bio$_{manure_ar2}$ >Napp-bioc, then Napp-bio$_{manure_ar2}$ = Napp-bioc								
Number of biocide applications during manure storage period for application on arable land	Napp-bio$_{manure_ar2}$	[-]	1	1	1	1	1	1
If Tbioc-int ≥ Tgr-int, then Napp-manure$_{gr}$ = 1 If Tbioc-int < Tgr-int, then Napp-manure$_{gr}$ = ROUND [(Tgr-int/Tbioc-int),(1)] If Napp-manure$_{gr}$ >Napp-prescr, then Napp-manure$_{gr}$ = Napp-prescr								
Maximum number of biocide applications during manure storage period for application on grassland	Napp-manure$_{gr}$	[-]	1	1	1	1	1	1
Qai-prescr = 10-3 x Qaerosol x Volumnehousing/Volumeaerosolcan								
Amount of active substance to be used in housing for one application	Qas-prescr	kg	1.01 E-02	1.01 E-02	1.01 E-02	1.01 E-02	1.93 E-02	1.72E-02
Qas-manure/slurry = Fmanure/slurry * Qas-prescr								
Amount of active substance in manure/slurry after one application	Qas-manure/ slurry	kg	3.54E-03	2.53 E-03	3.54 E-03	3.54 E-03	4.82 E-03	6.02E-03
Qas-wastewater = Fwastewater * Qas-prescr								
Amount of active substance in wastewater after one application	Qas-wastewater	kg	---	1.01E-03	---	---	1.93E-03	---
Qas-grass = Qas-manure/slurry * Napp-manure$_{gr}$								

Variable/ parameter	Symbol	Unit	Laying hens in battery cages without treatment (cat 7)	Laying hens in battery cages with aeration (belt drying) (cat 8)	Laying hens in battery cages with forced drying (deep pit, high rise) (cat 9)	Laying hens in compact battery cages (cat 10)	Laying hens in free range with litter floor (partly litter floor, partly slatted) (cat 11)	Laying hens in free range with grating floor (aviary system) (cat 13)
Amount of active substance in manure or slurry after the relevant number of biocide applications for the manure application to grassland	Qas-grass	kg	3.54E-03	2.53 E-03	3.54 E-03	3.54 E-03	4.82E-03	6.02 E-03
Qas-arab = Qas-manure/slurry * Napp-bio$_{manure_ar2}$								
Amount of active substance in manure or slurry after the relevant number of biocide applications for the manure application to arable land	Qas-arab	kg	3.54 E-03	2.53 E-03	3.54 E-03	3.54 E-03	4.82E-03	6.02 E-03
Qphosp-grass = N * Qphosph * Tgr-int								
Amount of phosphate produced during the relevant period for every relevant (sub)category of animal/housing and application to grassland	Qphosph-grass	kg/ yr	1357.86	1235.43	1235.43	1235.43	588.3	1176.6
Qphosp-arab = N * Qphosph * Tar$_2$-int								
Amount of phosphate produced during the relevant period for every relevant (sub)category of animal/housing and application to arable land	Qphosph-arab	kg/ yr	9351.3	8508.15	8508.15	8508.15	4051.5	8103
Qnitrog-grass = N * Qnitrog * Tgr-int								
Amount of nitrogen produced during the relevant period for every relevant (sub)category of animal/housing and application to grassland	Qnitrog-grass	kg/ yr	2248.26	2014.53	2014.53	2014.53	906.3	1812.6
Qnitrog-arab = N * Qnitrog * Tar$_2$-int								
Amount of nitrogen produced during the relevant period for every relevant (sub)category of animal/housing and application to arable land	Qnitrog-arab	kg/ yr	15483.3	13873.65	13873.65	13873.65	6241.5	12483

Variable/ parameter	Symbol	Unit	Laying hens in battery cages without treatment (cat 7)	Laying hens in battery cages with aeration (belt drying) (cat 8)	Laying hens in battery cages with forced drying (deep pit, high rise) (cat 9)	Laying hens in compact battery cages (cat 10)	Laying hens in free range with litter floor (partly litter floor, partly slatted) (cat 11)	Laying hens in free range with grating floor (aviary system) (cat 13)
Output								
Soil - arable land								
If the phosphate immission standard is applicable								
PIECars-P_2O_5 = 100 * Qai-arab * $Q_{P2O5.arable\text{-}land}$ / (Qphosph-arab * Nlapp-arab * $DEPTH_{arab\text{-}land}$ * $RHOsoil_{wet}$)								
Concentration of the active ingredient in soil based on phosphate immission standard for arable land one manure application event per year degradation not taken into account	PIECars-P_2O_5	mg/kg wwt	9.47E-06	7.43 E-06	1.04 E-05	1.04 E-05	2.98E-05	1.86E-05
If the nitrogen immission standard is applicable								
PIECars-N = 100 * Qai-arab * $Q_{N.arable\text{-}land}$ / (Qnitrog-arab * Nlapp-arab * $DEPTH_{arab\text{-}land}$ * $RHOsoil_{wet}$)								
Concentration of the active ingredient in soil based on nitrogen immission standard for arable land one manure application event per year degradation not taken into account	PIECars-N	mg/kg wwt	1.14E-05	9.11 E-06	1.28 E-05	1.28 E-05	3.86E-05	2.41 E-05
Considering degradation processes in soil, after 1 year application								
If the phosphate immission standard is applicable								
$PIECars_{1\_degr}$-P_2O_5 = PIECars-P_2O_5 * {[1-($e^{-kdegsoil * Tar2\text{-}int}$)$^{Nlapp\text{-}arab}$] / [1-$e^{-kdegsoil * Tar2\text{-}int}$]}								
Concentration of the active ingredient in soil based on phosphate immission standard for arable land after one manure application event taking degradation into account	$PIECars_{1\_degr}$-P_2O_5	mg/kg wwt	9.47 E-06	7.43 E-06	1.04 E-05	1.04 E-05	2.98E-05	1.86 E-05
If the nitrogen immission standard is applicable								
$PIECars_{1\_degr}$-N = PIECars-N * {[1-($e^{-kdegsoil * Tar2\text{-}int}$)$^{Nlapp\text{-}arab}$] / [1-$e^{-kdegsoil * Tar2\text{-}int}$]}								
Concentration of the active ingredient in soil based on nitrogen immission standard for arable land after one	$PIECars_{1\_degr}$-N	mg/kg wwt	1.14 E-05	9.11E-06	1.28E-05	1.28 E-05	3.86E-05	2.41 E-05

Variable/ parameter	Symbol	Unit	Laying hens in battery cages without treatment (cat 7)	Laying hens in battery cages with aeration (belt drying) (cat 8)	Laying hens in battery cages with forced drying (deep pit, high rise) (cat 9)	Laying hens in compact battery cages (cat 10)	Laying hens in free range with litter floor (partly litter floor, partly slatted) (cat 11)	Laying hens in free range with grating floor (aviary system) (cat 13)
manure application event taking degradation into account								
Considering degradation processes in soil, after 10 consecutive years application								
If the phosphate immission standard is applicable								
$PIECars_{10\_degr}$-P_2O_5 = PIECars-P_2O_5 * $\{[1-(e^{-kdegsoil * Tar2\text{-}int})^{Nlapp\text{-}arab.10}]/[1-e^{-kdegsoil * Tar2\text{-}int}]\}$								
Concentration of the active ingredient in soil based on phosphate immission standard for arable land and one manure application event per year after ten consecutive years taking degradation into account	$PIECars_{10\_degr}$-P_2O_5	mg/kg wwt	9.51E-06	7.47 E-06	1.05 E-05	1.05 E-05	2.99 E-05	1.87E-05
If the nitrogen immission standard is applicable								
$PIECars_{10\_degr}$-N = PIECars-N * $\{[1-(e^{-kdegsoil * Tar2\text{-}int})^{Nlapp\text{-}arab.10}] / [1-e^{-kdegsoil * Tar2\text{-}int}]\}$								
Concentration of the active ingredient in soil based on nitrogen immission standard for arable land and one manure application event per year after ten consecutive years taking degradation into account	$PIECars_{10\_degr}$-N	mg/kg wwt	1.15E-05	9.16 E-06	1.28 E-05	1.28 E-05	3.88E-05	2.42 E-05
Soil - grassland								
If the phosphate immission standard is applicable								
$PIECgrs_4$-P_2O_5 = 100 * Qai-grass * $Q_{P2O5.\ grassland}$ / (Qphosph-grass * $DEPTH_{grassland}$ * $RHOsoil_{wet}$)								
Concentration of the active ingredient in soil based on phosphate immission standard for grassland land four manure application events degradation not taken into account	$PIECgrs_4$-P_2O_5	mg/kg wwt	3.37E-04	2.65 E-04	3.71 E-04	3.71 E-04	1.06 E-03	6.62E-04
If the nitrogen immission standard is applicable								

Variable/ parameter	Symbol	Unit	Laying hens in battery cages without treatment (cat 7)	Laying hens in battery cages with aeration (belt drying) (cat 8)	Laying hens in battery cages with forced drying (deep pit, high rise) (cat 9)	Laying hens in compact battery cages (cat 10)	Laying hens in free range with litter floor (partly litter floor, partly slatted) (cat 11)	Laying hens in free range with grating floor (aviary system) (cat 13)
$PIECgrs_4$-N = 100 * Qai-grass * $Q_{N.grassland}$ / (Qnitrog-grass * $DEPTH_{grassland}$ *$RHOsoil_{wet}$)								
Concentration of the active ingredient in soil based on nitrogen immission standard for grassland land four manure application events degradation not taken into account	$PIECgrs_4$-N	mg/kg $_{wwt}$	3.15E-04	2.51 E-04	3.52E-04	3.52 E-04	1.06 E-03	6.65 E-04
Considering degradation processes in soil, after 1 year application								
If the phosphate immission standard is applicable								
$PIECgrs_{4\_degr}$-P_2O_5 = ($PIECgrs_4$-P_2O_5 / Nlapp-grass) * {[1-($e^{-kdegsoil * Tgr\text{-}int}$)$^{Nlapp\text{-}grass}$] / [1-$e^{-kdegsoil * Tgr\text{-}int}$]}								
Concentration of the active ingredient in soil based on phosphate immission standard for grassland land four manure application events taking degradation into account	$PIECgrs_{4\_degr}$-P_2O_5	mg/kg$_{wwt}$	1.50 E-04	1.18 E-04	1.65 E-04	1.65 E-04	4.73 E-04	2.95E-04
If the nitrogen immission standard is applicable								
$PIECgrs_{4\_degr}$-N = ($PIECgrs_4$-N / Nlapp-grass) * {[1-($e^{-kdegsoil * Tgr\text{-}int}$)$^{Nlapp\text{-}grass}$] / [1-$e^{-kdegsoil * Tgr\text{-}int}$]}								
Concentration of the active ingredient in soil based on nitrogen immission standard for grassland land four manure application events taking degradation into account	$PIECgrs_{4\_degr}$-N	mg/kg$_{wwt}$	1.40 E-04	1.12 E-04	1.57 E-04	1.57 E-04	4.74 E-04	2.96E-04
Considering degradation processes in soil, after 10 consecutive years application								
If the phosphate immission standard is applicable								
$PIECgrs_{10\_degr}$-P_2O_5 = $PIECgrs_{4\_deg}$-P_2O_5 * [1+ $\sum$ ($e^{-kdegsoil * Tgr\text{-}int\_no\_manure}$)^n] . n=1…9								
Concentration of the active ingredient in grassland soil based on phosphate immission standard after the last of four manure applications per year after ten consecutive years taking	$PIECgrs_{10\_degr}$-P_2O_5	mg/kg$_{wwt}$	1.50 E-04	1.17 E-04	1.64 E-04	1.64 E-04	4.70E-04	2.94 E-04

Variable/ parameter	Symbol	Unit	Laying hens in battery cages without treatment (cat 7)	Laying hens in battery cages with aeration (belt drying) (cat 8)	Laying hens in battery cages with forced drying (deep pit, high rise) (cat 9)	Laying hens in compact battery cages (cat 10)	Laying hens in free range with litter floor (partly litter floor, partly slatted) (cat 11)	Laying hens in free range with grating floor (aviary system) (cat 13)
degradation into account								
PEC/PNEC$_{soil}$			1.99 E-03	1.57 E-03	2.19 E-03	2.19 E-03	6.27E-03	3.92 E-03
If the nitrogen immission standard is applicable								
PIECgrs$_{10_degr}$-N = PIECgrs$_{4_deg}$-N * [1+ Σ ($e^{-kdegsoil * Tgr-int\_no\_manure}$)^{n}] . n=1…9								
Concentration of the active substance in grassland soil based on nitrogen immission standard after the last of four manure applications per year after ten consecutive years taking degradation into account	PIECgrs$_{10_degr}$-N	mg/ kg$_{wwt}$	**1.40 E-04**	**1.11 E-04**	**1.56 E-04**	**1.56 E-04**	**4.72 E-04**	**2.95 E-04**
PEC/PNEC$_{soil}$			1.86 E-03	1.48 E-03	2.08 E-03	2.08 E-03	6.29 E-03	3.93E-03
Ground water and surface water								
Based on nitrogen immission standards								
Grassland								
PIECgrs-gw-N = PIECgrs10_degr-N * RHOsoil$_{wet}$ / (K$_{soil-water}$ * 1000)								
grass land	PIECgrs-gw-N	ground water	mg/L	**2.91 E-08**	**2.32 E-08**	**3.24 E-08**	**3.24 E-08**	**9.82 E-08**	**6.13 E-08**
PIECgrs-water-N = PIECgrs-gw-N / DILUTION$_{run-off}$								
grass land	PIECgrs-water-N	surface water	mg/L	**2.91 E-09**	**2.32 E-09**	**3.24 E-09**	**3.24 E-09**	**9.82 E-09**	**6.13E-09**
PEC/PNEC$_{water}$				4.15 E-03	3.31 E-03	4.63 E-03	4.63 E-03	1.40 E-02	8.76E-03
Arable land								
PIECars-gw-N = PIECars10_degr-N * RHOsoil$_{wet}$ / (K$_{soil-water}$ * 1000)								
arable land	PIECars-gw-N	ground water	mg/L	2.39 E-09	1.91 E-09	2.67E-09	2.67 E-09	8.08 E-09	5.05 E-09

Variable/ parameter		Symbol	Unit	Laying hens in battery cages without treatment (cat 7)	Laying hens in battery cages with aeration (belt drying) (cat 8)	Laying hens in battery cages with forced drying (deep pit, high rise) (cat 9)	Laying hens in compact battery cages (cat 10)	Laying hens in free range with litter floor (partly litter floor, partly slatted) (cat 11)	Laying hens in free range with grating floor (aviary system) (cat 13)
PIECars-water-N = PIECars-gw-N / $DILUTION_{run-off}$									
arable land	PIECars-water-N	surface water	mg/L	2.39 E-10	1.91E-10	2.67E-10	2.67 E-10	8.08E-10	5.05E-10
PEC/$PNEC_{water}$				3.42E-04	2.72E-04	3.81E-04	3.81E-04	1.15E-03	7.21E-04
Based on phosphate immission standards									
PIECgrs-gw-P2O5 = PIECgrs10_degr-P2O5 * $RHOsoil_{wet}$ / ($K_{soil-water}$ * 1000)									
grass land	PIECgrs-gw-P2O5	ground water	mg/L	3.11 E-08	2.44 E-08	3.42 E-08	3.42 E-08	9.79 E-08	6.11 E-08
PIECgrs-water-P2O5 = PIECgrs-gw-P2O5 / $DILUTION_{run-off}$									
grass land	PIECgrs-water-P2O5	surface water	mg/L	3.11 E-09	2.44 E-09	3.42 E-09	3.42 E-09	9.79 E-09	6.11 E-09
PEC/$PNEC_{water}$				4.45 E-03	3.49 E-03	4.89 E-03	4.89 E-03	1.40E-02	8.73 E-03
PIECars-gw-P2O5 = PIECars10_degr-P2O5 * $RHOsoil_{wet}$ / ($K_{soil-water}$ * 1000)									
arable land	PIECars-gw-P2O5	ground water	mg/L	1.98 E-09	1.55E-09	2.18 E-09	2.18 E-09	6.23 E-09	3.89 E-09
PIECars-water-P2O5 = PIECars-gw-P2O5 / $DILUTION_{run-off}$									
arable land	PIECars-water-P2O5	surface water	mg/L	1.98 E-09	1.55E-09	2.18E-09	2.18 E-09	6.23 E-09	3.89E-09
PEC/$PNEC_{water}$				2.83 E-04	2.22 E-04	3.1 E-04	3.11 E-04	8.89 E-04	5.55 E-04
STP									
Qas-wastewater = Fwastewater * Qas-prescr									
Amount of active substance reaching the standard STP		Qas-waste water	kg/d	**---**	**1.01E-03**	**---**	**---**	**1.93E-03**	**---**

Target insects in breeding premises: Insects not affecting livestock (chicken growing farms. fattening pigs and sows): 24 mg a.s. /m³; 7 applications/year with 6-7 weeks interval.

Categories 4, 5, 6, 12, 14, 15

Variable/parameter	Symbol	Unit	Sows, in individual pens (cat 4)	Sows in groups (cat 5)	Fattening pigs (cat 6)	Broilers in free range with litter floor (cat 12)	Parent broilers in free range with grating floor (cat 14)	Parent broilers in rearing with grating floor (cat 15)
If Tbioc-int ≥ $Tmanure\text{-}int_{ar2}$, then $Napp\text{-}bio_{manure\_ar2}$ = 1 If Tbioc-int < $Tmanure\text{-}int_{ar2}$, then $Napp\text{-}bio_{manure\_ar2}$ = ROUND [($Tmanure\text{-}int_{ar2}$/Tbioc-int),(1)] If $Napp\text{-}bio_{manure\_ar2}$ > Napp-bioc, then $Napp\text{-}bio_{manure\_ar2}$ = Napp-bioc								
Number of biocide applications during manure storage period for application on arable land	$Napp\text{-}bio_{manure\_ar2}$	[-]	4.1	4.1	4.1	4.1	4.1	4.1
If Tbioc-int ≥ Tgr-int, then $Napp\text{-}manure_{gr}$ = 1 If Tbioc-int < Tgr-int, then $Napp\text{-}manure_{gr}$ = ROUND [(Tgr-int/Tbioc-int),(1)] If $Napp\text{-}manure_{gr}$ > Napp-prescr, then $Napp\text{-}manure_{gr}$ = Napp-prescr								
Maximum number of biocide applications during manure storage period for application on grassland	$Napp\text{-}manure_{gr}$	[-]	1	1	1	1	1	1
Qai-prescr = 10^{-3} x Qaerosol x Volumnehousing/Volumeaerosolcan								
Amount of active substance to be used in housing for one application	Qas-prescr	kg	7.06 E-03	8.93 E-03	7.60 E-03	1.50E-02	5.25 E-03	6.77E-03
Qas-manure/slurry = Fmanure/slurry * Qas-prescr								
Amount of active substance in manure/slurry after one application	Qas-manure/ slurry	kg	2.47E-03	3.12 E-03	2.66 E-03	3.75 E-03	1.84 E-03	2.37E-03
Qas-wastewater = Fwastewater * Qas-prescr								
Amount of active substance in wastewater after one application	Qas-wastewater	kg	---	---	---	1.50 E-03	---	---
Qas-grass = Qas-manure/slurry * $Napp\text{-}manure_{gr}$								
Amount of active substance in manure or slurry after the relevant number of biocide applications for the manure application to grassland	Qas-grass	kg	2.47E-03	3.12 E-03	2.66 E-03	3.75 E-03	1.84E-03	2.37 E-03
Qas-arab = Qas-manure/slurry * $Napp\text{-}bio_{manure\_ar2}$								
Amount of active substance in manure or slurry after the relevant number of biocide	Qas-arab	kg	1.01E-02	1.28 E-02	1.09 E-02	1.54 E-02	7.53E-03	9.71 E-03

Variable/parameter	Symbol	Unit	Sows, in individual pens (cat 4)	Sows in groups (cat 5)	Fattening pigs (cat 6)	Broilers in free range with litter floor (cat 12)	Parent broilers in free range with grating floor (cat 14)	Parent broilers in rearing with grating floor (cat 15)
applications for the manure application to arable land								
Qphosp-grass = N * Qphosph * Tgr-int								
Amount of phosphate produced during the relevant period for every relevant (sub)category of animal/housing and application to grassland	Qphosph-grass	kg/ yr	389.397 36	389.397 36	430.9 96	699.6	697.48	367.29
Qphosp-arab = N * Qphosph * Tar_2-int								
Amount of phosphate produced during the relevant period for every relevant (sub)category of animal/housing and application to arable land	Qphosph-arab	kg/ yr	2681.69 88	2681.69 88	2968. 18	4818	4803.4	2529.45
Qnitrog-grass = N * Qnitrog * Tgr-int								
Amount of nitrogen produced during the relevant period for every relevant (sub)category of animal/housing and application to grassland	Qnitrog-grass	kg/ yr	497.135 76	497.135 76	645.1 16	1653.6	1105.58	653.49
Qnitrog-arab = N * Qnitrog * Tar_2-int								
Amount of nitrogen produced during the relevant period for every relevant (sub)category of animal/housing and application to arable land	Qnitrog-arab	kg/yr	3423.67 08	3423.67 08	4442. 78	11388	7613.9	4500.45
Output								
Soil - arable land								
If the phosphate immission standard is applicable								
PIECars-P_2O_5 = 100 * Qai-arab * $Q_{P2O5.arable\text{-}land}$ / (Qphosph-arab * Nlapp-arab * $DEPTH_{arab\text{-}land}$ * $RHOsoil_{wet}$)								
Concentration of the active ingredient in soil based on phosphate immission standard for arable land one manure application event per year degradation	PIECars-P_2O_5	mg/kg $_{wwt}$	9.44E-05	1.19 E-04	9.18 E-05	7.98E-05	3.92 E-05	9.60 E-05

Variable/parameter	Symbol	Unit	Sows, in individual pens (cat 4)	Sows in groups (cat 5)	Fattening pigs (cat 6)	Broilers in free range with litter floor (cat 12)	Parent broilers in free range with grating floor (cat 14)	Parent broilers in rearing with grating floor (cat 15)
not taken into account								
If the nitrogen immission standard is applicable								
PIECars-N = 100 * Qai-arab * $Q_{N.arable\text{-}land}$ / (Qnitrog-arab * Nlapp-arab * $DEPTH_{arab\text{-}land}$ * $RHOsoil_{wet}$)								
Concentration of the active ingredient in soil based on nitrogen immission standard for arable land one manure application event per year degradation not taken into account	PIECars-N	mg/kg $_{wwt}$	1.48E-04	1.87 E-04	1.23 E-04	6.76E-05	4.95 E-05	1.08 E-04
Considering degradation processes in soil, after 1 year application								
If the phosphate immission standard is applicable								
$PIECars_{1\_degr}$-P_2O_5 = PIECars-P_2O_5 * {[1-($e^{-kdegsoil * Tar2\text{-}int}$)$^{Nlapp\text{-}arab}$] / [1-$e^{-kdegsoil * Tar2\text{-}int}$]}								
Concentration of the active ingredient in soil based on phosphate immission standard for arable land after one manure application event taking degradation into account	$PIECars_{1\_degr}$-P_2O_5	mg/kg $_{wwt}$	9.44E-05	1.19 E-04	9.18 E-05	7.98 E-05	3.92 E-05	9.60 E-05
If the nitrogen immission standard is applicable								
$PIECars_{1\_degr}$-N = PIECars-N * {[1-($e^{-kdegsoil * Tar2\text{-}int}$)$^{Nlapp\text{-}arab}$] / [1-$e^{-kdegsoil * Tar2\text{-}int}$]}								
Concentration of the active ingredient in soil based on nitrogen immission standard for arable land after one manure application event taking degradation into account	$PIECars_{1\_degr}$-N	mg/kg $_{wwt}$	1.48E-04	1.87 E-04	1.23E-04	6.76 E-05	4.95 E-05	1.08 E-04
Considering degradation processes in soil, after 10 consecutive years application								
If the phosphate immission standard is applicable								
$PIECars_{10\_degr}$-P_2O_5 = PIECars-P_2O_5 * {[1-($e^{-kdegsoil * Tar2\text{-}int}$)$^{Nlapp\text{-}arab.10}$]/[1-$e^{-kdegsoil * Tar2\text{-}int}$]}								

Variable/parameter	Symbol	Unit	Sows, in individual pens (cat 4)	Sows in groups (cat 5)	Fattening pigs (cat 6)	Broilers in free range with litter floor (cat 12)	Parent broilers in free range with grating floor (cat 14)	Parent broilers in rearing with grating floor (cat 15)
Concentration of the active ingredient in soil based on phosphate immission standard for arable land and one manure application event per year after ten consecutive years taking degradation into account	$PIECars_{10\_degr}$-P_2O_5	mg/kg $_{wwt}$	9.49E-05	1.20 E-04	9.23E-05	8.03 E-05	3.94 E-05	9.65 E-05
If the nitrogen immission standard is applicable								
$PIECars_{10\_degr}$-N = PIECars-N * $\{[1-(e^{-kdegsoil * Tar2\text{-}int})^{Nlapp\text{-}arab.10}] / [1-e^{-kdegsoil * Tar2\text{-}int}]\}$								
Concentration of the active ingredient in soil based on nitrogen immission standard for arable land and one manure application event per year after ten consecutive years taking degradation into account	$PIECars_{10\_degr}$-N	mg/kg $_{wwt}$	**1.49E-04**	**1.88 E-04**	**1.23E-04**	**6.79 E-05**	**4.97 E-05**	**1.08 E-04**
Soil - grassland								
If the phosphate immission standard is applicable								
$PIECgrs_4$-P_2O_5 = 100 * Qai-grass * $Q_{P2O5.\ grassland}$ / (Qphosph-grass * $DEPTH_{grassland}$ * $RHOsoil_{wet}$)								
Concentration of the active ingredient in soil based on phosphate immission standard for grassland land four manure application events degradation not taken into account	$PIECgrs_4$-P_2O_5	mg/kg $_{wwt}$	8.21E-04	1.04 E-03	7.98 E-04	6.94 E-04	3.41 E-04	8.35E-04
If the nitrogen immission standard is applicable								
$PIECgrs_4$-N = 100 * Qai-grass * $Q_{N.grassland}$ / (Qnitrog-grass * $DEPTH_{grassland}$ *$RHOsoil_{wet}$)								
Concentration of the active ingredient in soil based on nitrogen immission standard for grassland land four manure application events degradation not taken into account	$PIECgrs_4$-N	mg/kg $_{wwt}$	9.94 E-04	1.26 E-03	8.24 E-04	4.54E-04	3.32 E-04	7.25 E-04
Considering degradation processes in soil, after 1 year application								
If the phosphate immission standard is applicable								

Variable/parameter	Symbol	Unit	Sows, in individual pens (cat 4)	Sows in groups (cat 5)	Fattening pigs (cat 6)	Broilers in free range with litter floor (cat 12)	Parent broilers in free range with grating floor (cat 14)	Parent broilers in rearing with grating floor (cat 15)
$PIECgrs_{4\_degr}$-P_2O_5 = ($PIECgrs_4$-P_2O_5 / Nlapp-grass) * {[1-($e^{-kdegsoil * Tgr-int}$)$^{Nlapp-grass}$] / [1-$e^{-kdegsoil * Tgr-int}$]}								
Concentration of the active ingredient in soil based on phosphate immission standard for grassland land four manure application events taking degradation into account	$PIECgrs_{4\_degr}$-P_2O_5	mg/kg_{wwt}	3.66E-04	4.63 E-04	3.56E-04	3.09 E-04	1.52 E-04	3.72 E-04
If the nitrogen immission standard is applicable								
$PIECgrs_{4\_degr}$-N = ($PIECgrs_4$-N / Nlapp-grass) * {[1-($e^{-kdegsoil * Tgr-int}$)$^{Nlapp-grass}$] / [1-$e^{-kdegsoil * Tgr-int}$]}								
Concentration of the active substance in soil based on nitrogen immission standard for grassland land four manure application events taking degradation into account	$PIECgrs_{4\_degr}$-N	mg/kg_{wwt}	4.43 E-04	5.60 E-04	3.67 E-04	2.02 E-04	1.48 E-04	3.23E-04
Considering degradation processes in soil, after 10 consecutive years application								
If the phosphate immission standard is applicable								
$PIECgrs_{10\_degr}$-P_2O_5 = $PIECgrs_{4\_deg}$-P_2O_5 * [1+ ∑ ($e^{-kdegsoil * Tgr-int\_no\_manure}$)^n], n=1…9								
Concentration of the active substance in grassland soil based on phosphate immission standard after the last of four manure applications per year after ten consecutive years taking degradation into account	$PIECgrs_{10\_degr}$-P_2O_5	mg/kg_{wwt}	3.64 E-04	4.60 E-04	3.54 E-04	3.08E-04	1.51 E-04	3.70E-04
$PEC/PNEC_{soil}$			4.85 E-03	6.14 E-03	4.72 E-03	4.10E-03	2.01 E-03	4.93E-03
If the nitrogen immission standard is applicable								
$PIECgrs_{10\_degr}$-N = $PIECgrs_{4\_deg}$-N * [1+ ∑ ($e^{-kdegsoil * Tgr-int\_no\_manure}$)^n], n=1…9								
Concentration of the active substance in grassland soil based on nitrogen immission standard after the last of four manure applications per year after ten consecutive years. taking degradation into account	$PIECgrs_{10\_degr}$-N	mg/kg_{wwt}	**4.40 E-04**	**5.57 E-04**	**3.65 E-04**	**2.01 E-04**	**1.47 E-04**	**3.21E-04**

Variable/parameter	Symbol	Unit	Sows, in individual pens (cat 4)	Sows in groups (cat 5)	Fattening pigs (cat 6)	Broilers in free range with litter floor (cat 12)	Parent broilers in free range with grating floor (cat 14)	Parent broilers in rearing with grating floor (cat 15)
PEC/PNEC$_{soil}$			5.87 E-03	7.43 E-03	4.87 E-03	2.68 E-03	1.96 E-03	4.28E-03
Ground water and surface water								
Based on nitrogen immission standards								
PIECgrs-gw-N = PIECgrs10_degr-N * RHOsoil$_{wet}$ / (K$_{soil-water}$ * 1000)								
grass land	PIECgrs-gw-N	ground water	mg/L	**9.16 E-08**	**1.16 E-07**	**7.60E -08**	**4.19 E-08**	**3.07 E-08**	**6.69 E-08**
PIECgrs-water-N = PIECgrs-gw-N / DILUTION$_{run-off}$								
grass land	PIECgrs-water-N	surface water	mg/L	**9.16 E-09**	**1.16 E-08**	**7.60E -09**	**4.19 E-09**	**3.07 E-09**	**6.69 E-09**
PEC/PNEC$_{water}$				1.31 E-02	1.66 E-02	1.09E -02	5.98 E-03	4.38 E-03	9.55 E-03
PIECars-gw-N = PIECars10_degr-N * RHOsoil$_{wet}$ / (K$_{soil-water}$ * 1000)								
arable land	PIECars-gw-N	ground water	mg/L	**3.09 E-08**	**3.91 E-08**	**2.57E -08**	**1.41 E-08**	**1.03 E-08**	**2.26 E-08**
PIECars-water-N = PIECars-gw-N / DILUTION$_{run-off}$								
arable land	PIECars-water-N	surface water	mg/L	**3.09 E-09**	**3.91 E-09**	**2.57E -09**	**1.41 E-09**	**1.03 E-09**	**2.26 E-09**
PEC/PNEC$_{water}$				4.42 E-03	5.59 E-03	3.67E -03	2.02 E-03	1.48 E-03	3.22 E-03
Based on phosphate immission standards								
PIECgrs-gw-P2O5 = PIECgrs10_degr-P2O5 * RHOsoil$_{wet}$ / (K$_{soil-water}$ * 1000)								
grass land	PIECgrs-gw-P2O5	ground water	mg/L	7.57 E-08	9.58 E-08	7.36E -08	6.40 E-08	3.14 E-08	7.70 E-08
PIECgrs-water-P2O5 = PIECgrs-gw-P2O5 / DILUTION$_{run-off}$								
grass land	PIECgrs-water-P2O5	surface water	mg/L	7.57 E-09	9.58 E-09	7.36 E-09	6.40 E-09	3.14 E-09	7.70E-09
PEC/PNEC$_{water}$				1.08 E-02	1.37 E-02	1.05 E-02	9.15 E-03	4.49 E-03	1.10E-02
PIECars-gw-P2O5 = PIECars10_degr-P2O5 * RHOsoil$_{wet}$ / (K$_{soil-water}$ * 1000)								

Variable/parameter		Symbol	Unit	Sows, in individual pens (cat 4)	Sows in groups (cat 5)	Fattening pigs (cat 6)	Broilers in free range with litter floor (cat 12)	Parent broilers in free range with grating floor (cat 14)	Parent broilers in rearing with grating floor (cat 15)
arable land	PIECars-gw-P2O5	ground water	mg/L	1.97 E-08	2.50 E-08	1.92 E-08	1.67 E-08	8.20 E-09	2.01E-08
PIECars-water-P2O5 = PIECars-gw-P2O5 / $DILUTION_{run-off}$									
arable land	PIECars-water-P2O5	surface water	mg/L	1.97 E-09	2.50 E-09	1.92 E-09	1.67 E-09	8.20 E-10	2.01E-09
$PEC/PNEC_{water}$				2.82 E-03	3.57 E-03	2.74 E-03	2.39 E-03	1.17 E-03	2.87E-03
STP									
Qas-wastewater = Fwastewater * Qas-prescr									
Amount of active substance reaching the standard STP		Qas-waste water	kg/d	---	---	---	**1.50 E-03**	---	---

Results if waste water fractions are added to the residues in slurry/manure

According to the ESD for PT18 (OECD, 2006), several categories (animal housings) have splitted release pathways: on one hand an emission to maure/slurry and on the other hand an emission to wastewater. However, it was agreed at WG-II-2017 that the exposure pathway wastewater does not need to be assessed. Therefore, the fractions released to maure/slurry and the fraction release to wastewater are summed up to only one fraction of release to the maure/slurry (e.g. no emission to wastewater), where no connection to local drainage system is assumed. This is in accordance with ECHA (2021b, ENV #170).

Variable/parameter	Symbol	Unit	Laying hens in battery cages with aeration (belt drying) (cat 8)	Laying hens in free range with litter floor (cat 11)	Broilers in free range with litter floor (cat 12)
If Tbioc-int ≥ Tmanure-int$_{ar2}$. then Napp-bio$_{manure_ar2}$ = 1 If Tbioc-int < Tmanure-int$_{ar2}$, then Napp-bio$_{manure_ar2}$ = ROUND [(Tmanure-int$_{ar2}$/Tbioc-int),(1)] If Napp-bio$_{manure_ar2}$ > Napp-bioc, then Napp-bio$_{manure_ar2}$ = Napp-bioc					
Number of biocide applications during manure storage period for application on arable land	Napp-bio$_{manure_ar2}$	[-]	1	1	4.1
If Tbioc-int ≥ Tgr-int, then Napp-manure$_{gr}$ = 1 If Tbioc-int < Tgr-int, then Napp-manure$_{gr}$ = ROUND [(Tgr-int/Tbioc-int),(1)] If Napp-manure$_{gr}$ > Napp-prescr, then Napp-manure$_{gr}$ = Napp-prescr					
Maximum number of biocide applications during manure storage period for application on grassland	Napp-manure$_{gr}$	[-]	1	1	1
Qai-prescr = 10^{-3} x Qaerosol x Volumnehousing/Volumeaerosolcan					
Amount of active substance to be used in housing for one application	Qas-prescr	kg	1.01E-02	1.93E-02	1.50E-02
Qas-manure/slurry = Fmanure/slurry * Qas-prescr					
Amount of active substance in manure/slurry after one application	Qas-manure/ slurry	kg	3.54E-03	6.76E-03	5.25E-03
Qas-grass = Qas-manure/slurry * Napp-manure$_{gr}$					
Amount of active substance in manure or slurry after the relevant number of biocide applications for the manure application to grassland	Qas-grass	kg	3.54E-03	6.76E-03	5.25E-03
Qas-arab = Qas-manure/slurry * Napp-bio$_{manure_ar2}$					
Amount of active substance in manure or slurry after the relevant number of biocide applications for the manure application to arable land	Qas-arab	kg	3.54E-03	6.76E-03	2.15E-02

Variable/parameter	Symbol	Unit	Laying hens in battery cages with aeration (belt drying) (cat 8)	Laying hens in free range with litter floor (cat 11)	Broilers in free range with litter floor (cat 12)
Qphosp-grass = N * Qphosph * Tgr-int					
Amount of phosphate produced during the relevant period for every relevant (sub)category of animal/housing and application to grassland	Qphosph-grass	kg/yr	1235.43	588.3	699.6
Qphosp-arab = N * Qphosph * Tar_2-int					
Amount of phosphate produced during the relevant period for every relevant (sub)category of animal/housing and application to arable land	Qphosph-arab	kg/yr	8508.15	4051.5	4818
Qnitrog-grass = N * Qnitrog * Tgr-int					
Amount of nitrogen produced during the relevant period for every relevant (sub)category of animal/housing and application to grassland	Qnitrog-grass	kg/yr	2014.53	906.3	1653.6
Qnitrog-arab = N * Qnitrog * Tar_2-int					
Amount of nitrogen produced during the relevant period for every relevant (sub)category of animal/housing and application to arable land	Qnitrog-arab	kg/yr	13873.65	6241.5	11388
Output					
Soil - arable land					
If the phosphate immission standard is applicable					
PIECars-P_2O_5 = 100 * Qai-arab * $Q_{P2O5.arable\text{-}land}$ / (Qphosph-arab * Nlapp-arab * $DEPTH_{arab\text{-}land}$ * $RHOsoil_{wet}$)					
Concentration of the biocide (active ingredient) in soil based on phosphate immission standard for arable land. one manure application event per year. degradation not taken into account	PIECars-P_2O_5	mg/kg wwt	1.04E-05	4.16E-05	1.12E-04
If the nitrogen immission standard is applicable					

Variable/parameter	Symbol	Unit	Laying hens in battery cages with aeration (belt drying) (cat 8)	Laying hens in free range with litter floor (cat 11)	Broilers in free range with litter floor (cat 12)
PIECars-N = 100 * Qai-arab * $Q_{N.arable-land}$ / (Qnitrog-arab * Nlapp-arab * $DEPTH_{arab-land}$ * $RHOsoil_{wet}$)					
Concentration of the biocide (active ingredient) in soil based on nitrogen immission standard for arable land. one manure application event per year. degradation not taken into account	PIECars-N	mg/kg wwt	1.28E-05	5.42E-05	9.46E-05
Considering degradation processes in soil, after 1 year application					
If the phosphate immission standard is applicable					
$PIECars_{1\_degr}$-P_2O_5 = PIECars-P_2O_5 * {[1-($e^{-kdegsoil * Tar2-int}$)$^{Nlapp-arab}$] / [1-$e^{-kdegsoil * Tar2-int}$]}					
Concentration of the biocide (active ingredient) in soil based on phosphate immission standard for arable land. after one manure application event. taking degradation into account	$PIECars_{1\_degr}$-P_2O_5	mg/kg wwt	1.04E-05	4.16E-05	1.12E-04
If the nitrogen immission standard is applicable					
$PIECars_{1\_degr}$-N = PIECars-N * {[1-($e^{-kdegsoil * Tar2-int}$)$^{Nlapp-arab}$] / [1-$e^{-kdegsoil * Tar2-int}$]}					
Concentration of the biocide (active ingredient) in soil based on nitrogen immission standard for arable land. after one manure application event. taking degradation into account	$PIECars_{1\_degr}$-N	mg/kg wwt	1.28E-05	5.42E-05	9.46E-05
Considering degradation processes in soil, after 10 consecutive years application					
If the phosphate immission standard is applicable					
$PIECars_{10\_degr}$-P_2O_5 = PIECars-P_2O_5 * {[1-($e^{-kdegsoil * Tar2-int}$)$^{Nlapp-arab.10}$]/[1-$e^{-kdegsoil * Tar2-int}$]}					
Concentration of the biocide (active ingredient) in soil based on phosphate immission standard for arable land and one manure application event per year. after ten consecutive years. taking	$PIECars_{10\_degr}$-P_2O_5	mg/kg wwt	1.05E-05	4.18E-05	1.12E-04

Variable/parameter	Symbol	Unit	Laying hens in battery cages with aeration (belt drying) (cat 8)	Laying hens in free range with litter floor (cat 11)	Broilers in free range with litter floor (cat 12)
degradation into account					
If the nitrogen immission standard is applicable					
$PIECars_{10\_degr}$-N = PIECars-N * {[1-($e^{-kdegsoil * Tar2\text{-}int}$)$^{Nlapp\text{-}arab.10}$] / [1-$e^{-kdegsoil * Tar2\text{-}int}$]}					
Concentration of the biocide (active ingredient) in soil based on nitrogen immission standard for arable land and one manure application event per year. after ten consecutive years. taking degradation into account	$PIECars_{10\_degr}$-N	mg/kg wwt	**1.28E-05**	**5.44E-05**	**9.51E-05**
Soil – grassland					
If the phosphate immission standard is applicable					
$PIECgrs_4$-P_2O_5 = 100 * Qai-grass * $Q_{P2O5.\ grassland}$ / (Qphosph-grass * $DEPTH_{grassland}$ * $RHOsoil_{wet}$)					
Concentration of the biocide (active ingredient) in soil based on phosphate immission standard for grassland land. four manure application events. degradation not taken into account	$PIECgrs_4$-P_2O_5	mg/kg wwt	3.70E-04	1.55E-03	9.72E-04
If the nitrogen immission standard is applicable					
$PIECgrs_4$-N = 100 * Qai-grass * $Q_{N.grassland}$ / (Qnitrog-grass * $DEPTH_{grassland}$ *$RHOsoil_{wet}$)					
Concentration of the biocide (active ingredient) in soil based on nitrogen immission standard for grassland land. four manure application events. degradation not taken into account	$PIECgrs_4$-N	mg/kg wwt	3.52E-04	1.49E-03	6.35E-04
Considering degradation processes in soil, after 1 year application					
If the phosphate immission standard is applicable					
$PIECgrs_{4\_degr}$-P_2O_5 = ($PIECgrs_4$-P_2O_5 / Nlapp-grass) * {[1-($e^{-kdegsoil * Tgr\text{-}int}$)$^{Nlapp\text{-}grass}$] / [1-$e^{-kdegsoil * Tgr\text{-}int}$]}					

Variable/parameter	Symbol	Unit	Laying hens in battery cages with aeration (belt drying) (cat 8)	Laying hens in free range with litter floor (cat 11)	Broilers in free range with litter floor (cat 12)
Concentration of the biocide (active ingredient) in soil based on phosphate immission standard for grassland land. four manure application events. taking degradation into account	$PIECgrs_{4\_degr}$-P_2O_5	mg/kg_{wwt}	1.65E-04	6.62E-04	4.33E-04
If the nitrogen immission standard is applicable					
$PIECgrs_{4\_degr}$-N = (PIECgrs$_4$-N / Nlapp-grass) * {[1-($e^{-kdegsoil * Tgr-int}$)$^{Nlapp-grass}$] / [1-$e^{-kdegsoil * Tgr-int}$]}					
Concentration of the biocide (active ingredient) in soil based on nitrogen immission standard for grassland land. four manure application events. taking degradation into account	$PIECgrs_{4\_degr}$-N	mg/kg_{wwt}	1.57E-04	6.64E-04	2.83E-04
Considering degradation processes in soil, after 10 consecutive years application					
If the phosphate immission standard is applicable					
$PIECgrs_{10\_degr}$-P_2O_5 = $PIECgrs_{4\_deg}$-P_2O_5 * [1+ ∑ ($e^{-kdegsoil * Tgr-int\_no\_manure}$)^n], n=1…9					
Concentration of the biocide (active ingredient) in grassland soil based on phosphate immission standard after the last of four manure applications per year. after ten consecutive years. taking degradation into account	$PIECgrs_{10\_degr}$-P_2O_5	mg/kg_{wwt}	1.64E-04	6.58E-04	4.31E-04
PEC/$PNEC_{soil}$			1.10E-03	4.39E-03	5.74E-03
If the nitrogen immission standard is applicable					
$PIECgrs_{10\_degr}$-N = $PIECgrs_{4\_deg}$-N * [1+ ∑ ($e^{-kdegsoil * Tgr-int\_no\_manure}$)^n], n=1…9					
Concentration of the biocide (active substance) in grassland soil based on nitrogen immission standard after the last of four manure applications per year. after ten consecutive years. taking degradation into account	$PIECgrs_{10\_degr}$-N	mg/kg_{wwt}	1.56E-04	6.60E-04	2.82E-04

Variable/parameter	Symbol	Unit	Laying hens in battery cages with aeration (belt drying) (cat 8)	Laying hens in free range with litter floor (cat 11)	Broilers in free range with litter floor (cat 12)
PEC/PNEC$_{soil}$			1.04E-03	4.40E-03	3.76E-03
Ground water and surface water					
Based on nitrogen immission standards					
PIECgrs-gw-N = PIECgrs10_degr-N * RHOsoil$_{wet}$ / (K$_{soil-water}$ * 1000)					
grass land	PIECgrs-gw-N	ground water	mg/L	3.24E-08	1.37E-07	5.86E-08
PIECgrs-water-N = PIECgrs-gw-N / DILUTION$_{run-off}$					
grass land	PIECgrs-water-N	surface water	mg/L	3.24E-09	1.37E-08	5.86E-09
PEC/PNEC$_{water}$				2.32E-03	9.82E-03	8.37E-03
PIECars-gw-N = PIECars10_degr-N * RHOsoil$_{wet}$ / (K$_{soil-water}$ * 1000)					
arable land	PIECars-gw-N	ground water	mg/L	**2.66E-09**	**1.13E-08**	**1.98E-08**
PIECars-water-N = PIECars-gw-N / DILUTION$_{run-off}$					
arable land	PIECars-water-N	surface water	mg/L	**2.66E-10**	**1.13E-09**	**1.98E-09**
PEC/PNEC$_{water}$				3.82E-04	1.62E-03	2.83E-03
Based on phosphate immission standards					
PIECgrs-gw-P2O5 = PIECgrs10_degr-P2O5 * RHOsoil$_{wet}$ / (K$_{soil-water}$ * 1000)					
grass land	PIECgrs-gw-P2O5	ground water	mg/L	3.42E-08	1.37E-07	8.96E-08
PIECgrs-water-P2O5 = PIECgrs-gw-P2O5 / DILUTION$_{run-off}$					
grass land	PIECgrs-water-P2O5	surface water	mg/L	3.42E-09	1.37E-08	8.96E-09
PEC/PNEC$_{water}$				4.88E-03	1.96E-02	1.28E-02
PIECars-gw-P2O5 = PIECars10_degr-P2O5 * RHOsoil$_{wet}$ / (K$_{soil-water}$ * 1000)					

Variable/parameter		Symbol	Unit	Laying hens in battery cages with aeration (belt drying) (cat 8)	Laying hens in free range with litter floor (cat 11)	Broilers in free range with litter floor (cat 12)
arable land	PIECars-gw-P2O5	ground water	mg/L	2.18E-09	8.72E-09	2.34E-08
PIECars-water-P2O5 = PIECars-gw-P2O5 / $DILUTION_{run-off}$						
arable land	PIECars-water-P2O5	surface water	mg/L	2.18E-10	8.72E-10	2.34E-09
$PEC/PNEC_{water}$				3.10E-04	1.25E-03	6.68E-03

Secondary poisoning

Secondary poisoning via contaminated EARTHWORMS

Calculated according to ECHA (2017a, page 150), equation 103c:

$$C_{earthworm} = \frac{BCF_{earthworm} \times C_{porewater} + C_{soil} \times F_{gut} \text{ x } CONV_{soil}}{1 + F_{gut} \text{ x } CONV_{soil}}$$

Emission to soil via manure/slurry application

Mammals and birds may consume contaminated worms. As input parameter the concentration in the receiving soil compartment as a result of sludge or manure/slurry application (indirect contamination) is included as well as the BCF in earthworms, the concentration in pore water, the fraction of gut loading in worm and the conversion factor for soil concentration wet-dry/weight soil. For calculating the bioconcentration factor, an octanol/water partition coefficient of log K_{ow} of 4.6 is taken.

Laying farms (bloodsucking pest): 24 mg a.s./m³; 1 application/year

Variable/ parameter	Symbol	S /D /O	Unit	Laying hensages without treatment (cat 7)	Laying hens in battery cages with aeration (belt drying) (cat 8)	Laying hens in battery cages with forced drying (cat 9)	Laying hens in compact battery cages (cat 10)	Laying hens in free range with litter floor (cat 11)	Laying hens in free range with grating floor (aviary system) (cat 13)
Concentration of a.s. in soil for arable land and one manure application event per year, after ten consecutive years, taking degradation into account	PIECars10_degr-N	O	mg/ kg_{wwt}	1.15 E-05	9.16 E-06	1.28 E-05	1.28 E-05	3.88 E-05	2.42 E-05
Predicted Environmental Concentration in pore water	$PECloca l_{soil,porewater}$	O	mg/L	2.40 E-09	1.91 E-09	2.66 E-09	2.66 E-09	8.08 E-09	5.04 E-09
Density of earthworm	$RHO_{earthworm}$	D	[kg_{wwt}/ L]	1					
Bioconcentration factor for earthworm on wet weight basis	BCF = (0.84 + 0.012 K_{ow})/ $RHO_{earthw.}$	P	L/$kg_{wet\ earthworm}$	483					
Fraction of gut loading in worm	F_{gut}	D	kg/kg	0.1					
Conversion factor for soil concentration wet-dry weight soil	$CONV_{soil}$	D	kg_{wwt}/ kg_{dwt}	1.13					
Predicted Environmental Concentaration in earthworms	**$PEC_{oral,\ earthworm}$**	**O**	**mg/ $kg_{wet\ earth-worm}$**	**2.20 E-06**	**1.76 E-06**	**2.46 E-06**	**2.46 E-06**	**7.44 E-06**	**4.64 E-06**

Chicken growing farms and fattening pigs and sows stables (insects not affecting livestock): 24 mg a.s. /m³; 7 applications/year with 6-7 weeks interval

Categories 4,5,6,12,14,15

Variable/ parameter	Symbol	S /D /O	Unit	Sows in individual pens (cat 4)	Sows in groups (cat 5)	Fattening pigs (cat 6)	Broilers in free range with litter floor (cat 12)	Parent broilers in free range with grating floor (cat 14)	Parent broilers in rearing with grating floor (cat 15)
Concentration of a.s. in soil for arable land and one manure application event per year, after ten consecutive years, taking degradation into account	PIECars10_degr-N	O	mg/ kg_{wwt}	1.49 E-04	1.88 E-04	1.23 E-04	6.79 E-05	4.97 E-05	1.08 E-04
Predicted Environmental Concentration in pore water	$PECloca l_{soil,porewater}$	O	mg/L	3.09 E-08	3.91 E-08	2.57 E-08	1.41 E-08	1.03 E-08	2.26 E-08
Bioconcentration factor for earthworm on wet weight basis	BCF	P	L/$kg_{wet\ earthworm}$	483					

Variable/ parameter	Symbol	S /D /O	Unit	Sows in individual pens (cat 4)	Sows in groups (cat 5)	Fattening pigs (cat 6)	Broilers in free range with litter floor (cat 12)	Parent broilers in free range with grating floor (cat 14)	Parent broilers in rearing with grating floor (cat 15)
Fraction of gut loading in worm	F_{gut}	D	kg/kg	0.1					
Conversion factor for soil concentration wet-dry weight soil	$CONV_{soil}$	D	kg_{wwt}/kg_{dwt}	1.13					
Predicted Environmental Concentaration in earthworms	**$PEC_{oral,\ earthworm}$**	**O**	**mg/ $kg_{wet\ earth-worm}$**	**2.85 E-05**	**3.61 E-05**	**2.36 E-05**	**1.30 E-05**	**9.52 E-06**	**2.08 E-05**

Results if waste water fractions are added to the residues in slurry/manure

The entire emission is released to maure/slurry and is furthermore applied on arable soil.

Variable/ parameter	Symbol	S /D /O	Unit	Battery hens – belt dry (cat 8)	Free range hens – litter floor (cat 11)	Free range broilers – litter floor (cat 12)
Concentration of a.s. in soil for arable land and one manure application event per year, after ten consecutive years, taking degradation into account	PIECars10 _degr-N	O	mg/kg wwt	1.28 E-05	5.44 E-05	9.51 E-05
Predicted Environmental Concentration in pore water	$PEClocal_{soil\ ,porewater}$	O	mg/L	2.66 E-09	1.13 E-09	1.98 E-08
Density of earthworm	$RHO_{earthw.}$	D	[kg_{wwt}/ L]	1		
Bioconcentration factor for earthworm on wet weight basis	BCF = (0.84 + 0.012 K_{ow})/ $RHO_{earthw.}$	P	$L/kg_{wet\ earthworm}$	483		
Fraction of gut loading in worm	F_{gut}	D	kg/kg	0.1		
Conversion factor for soil concentration wet-dry weight soil	$CONV_{soil}$	D	kg_{wwt}/kg_{dwt}	1.13		
Predicted Environmental Concentaration in earthworms	**$PEC_{oral,\ earthworm}$**	**O**	**mg/ $kg_{wet\ earthw.}$**	**2.46E-06**	**1.04E-05**	**1.82E-05**

Secondary poisoning via contaminated FISH

The concentration of contaminant in food (fish) of fish-eating predators ($PECoral_{predator}$) is calculated based on PEC for surface water ($PEClocal_{water}$) according to ECHA (2017a, equation 95):

$PECoral_{predator} = PECwater * BCF_{fish} * BMF$

Emission to soil via manure/slurry application

Laying farms (bloodsucking pest): 24 mg a.s./m³; 1 application/year

Variable/ parameter	Symbol	S/D/O	Unit	Laying hensages without treatment (cat 7)	Laying hens in battery cages with aeration (belt drying) (cat 8)	Laying hens in battery cages with forced drying (cat 9)	Laying hens in compact battery cages (cat 10)	Laying hens in free range with litter floor (cat 11)	Laying hens in free range with grating floor (aviary system) (cat 13)
Predicted environmental concentration in surface water due to run-off	PEC_{water} = 0.5* PIECars-water-N	O	mg/L	1.20 E-09	9.54 E-10	1.33 E-09	1.33 E-09	4.04 E-09	2.52 E-09
Bioconcentration factor for fish on wet weight basis	BCF_{fish}	O	$L/kg_{wet\ fish}$	1400					
Biomagnification factor in fish	BMF	S	-	2					
Predicted Environmental Concentaration in fish	**$PEC_{oral,\ predator}$**	O	**mg/kg wet fish**	**3.34 E-06**	**2.66 E-06**	**3.74 E-06**	**3.74 E-06**	**1.13 E-05**	**7.06 E-06**

Chicken growing farms and fattening pigs and sows stables (insects not affecting livestock): 24 mg a.s. /m³; 7 applications/year with 6-7 weeks interval

Variable/ parameter	Symbol	S/D/O	Unit	Sows in individual pens (cat 4)	Sows in groups (cat 5)	Fattening pigs (cat 6)	Broilers in free range with litter floor (cat 12)	Parent broilers in free range with grating floor (cat 14)	Parent broilers in rearing with grating floor (cat 15)
Predicted environmental concentration in surface water due to run-off	PEC_{water} = 0.5* PIECars-water-N	O	mg/L	1.55 E-09	1.96 E-09	1.28 E-09	7.07 E-10	5.17 E-10	1.13 E-09
Bioconcentration factor for fish on wet weight basis	BCF_{fish}	O	$L/kg_{wet\ fish}$	1400					
Biomagnification factor in fish	BMF	S	-	2					
Predicted Environmental Concentaration in fish	**$PEC_{oral,\ predator}$**	**O**	**$mg/kg_{wet\ fish}$**	**4.33 E-06**	**5.48 E-06**	**3.59 E-06**	**1.98 E-06**	**1.45 E-06**	**3.16 E-06**

Results if waste water fractions are added to the residues in slurry/manure

Categories 8, 11, 12

Variable/ parameter	**Symbol**	**S /D /O**	**Unit**	**Laying hens in battery cages with aeration (belt drying) (cat 8)**	**Laying hens in free range with litter floor (cat 11)**	**Broilers in free range with litter floor (cat 12)**
Predicted environmental concentration in surface water due to run-off	PEC_{water} = 0.5* PIECars-water-N	O	mg/L	1.33E-10	5.66E-10	9.90E-10
Bioconcentration factor for fish on wet weight basis	BCF_{fish}	O	$L/kg_{wet\ fish}$	1400		
Biomagnification factor in fish	BMF	S	-	2		
Predicted Environmental Concentaration in fish	**$PEC_{oral,\ predator}$**	**O**	**$mg/kg_{wet\ fish}$**	**3.72E-07**	**1.58E-06**	**2.77E-06**

Scenario [1] – Domestic premises (private houses and larger buildings)

Secondary poisoning via contaminated FISH

Variable / paramter	Symbol	S/D/O	Unit	private houses	larger buildings	total (private houses + larger buidings)
Predicted environmental concentration in surface water due to run-off	PECwater = 0.5* PEClocal water	O	mg/L	1.25E-06	3.93E-06	4.69E-06
Bioconcentration factor for fish on wet weight basis	BCFfish	O	L/kgwet fish	1400	1400	1400
Biomagnification factor in fish	BMF	S	-	2	2	2
Predicted Environmental Concentaration in fish	**$PEC_{oral,\ predator}$**	**O**	**mg/ $kg_{wet\ fish}$**	**3.49E-03**	**1.10E-02**	**1.45E-02**

Groundwater calculations regarding metabolite Br_2CA due to manure/slurry application (scenario [2])

bloodsucking pest (laying farms): 24 mg a.s./m³; 1 application/year

Variable/ parameter	Symbol	S/D/O	Unit	Laying hensages without treatment (cat 7)	Laying hens in battery cages with aeration (belt drying) (cat 8)	Laying hens in battery cages with forced drying (cat 9)	Laying hens in compact battery cages (cat 10)	Laying hens in free range with litter floor (cat 11)	Laying hens in free range with grating floor (aviary system) (cat 13)
Soil - arable land ksoil_metabolite = 0.1238									
PIECars-Ni1,i2,i3,i4_metabolite= (100*Qai-arabi1,i2,i3,i4*QN,arable_land)/(Qnitrog-arabi1,i4 *DEPTHarable_land *RHOsoil) *fij *Massmolar_metabolite/Massmolar_parent	PIECars-Ni1,i2,i3,i4_metabolite	O	mg/kgwwt	6.75 E-06	5.38 E-06	7.53 E-06	7.53 E-06	2.28 E-05	1.42 E-05
Fsoilars_10_metabolite = (1- ⟦(e^(-kdegsoil_metabolite * Tar-int,10))⟧ ^Nlapparab,10)/(1- e^(-kdegsoil_metabolite *Tar-int,10))	Fsoilars_10_metabolite	O	-	1	1	1	1	1	1
PIECars10degr-Ni1,i2,i3,i4_metabolit =PIECars-	PIECars10degr-Ni1,i2,i3,i	O	mg/kgwwt	6.75 E-06	5.38 E-06	7.53 E-06	7.53 E-06	2.28 E-05	1.42 E-05

Variable/ parameter	Symbol	S / D / O	Unit	Laying hensages without treatment (cat 7)	Laying hens in battery cages with aeration (belt drying) (cat 8)	Laying hens in battery cages with forced drying (cat 9)	Laying hens in compact battery cages (cat 10)	Laying hens in free range with litter floor (cat 11)	Laying hens in free range with grating floor (aviary system) (cat 13)
Ni1,i2,i3,i4_metabolite *Fsoilars_10_metabolite	4_metabolite								
Soil – grassland ksoil_metabolite = 0.1238									
PIECgrs-N_(i1,i2,i3,i4_metabolite)= (100*Qai-grass_(i1,i2,i3,i4)*Q_(N,grassland))/(Qnitrog-grass_(i1,i4)*Nlapp-grass *DEPTH_grassland*RHOsoil) *f_ij *Mass_(molar_metabolite)/Mass_(molar_metabolite)	PIECgrs-N_i1,i2,i3,i4_metabolite	O	mg/kgwwt	1.86 E-04	1.48 E-04	2.07 E-04	2.07 E-04	6.28 E-04	3.92 E-04
Fsoilgrs_metabolite = (1-(e^(-kdegsoil_metabolite * Tgr-int))^Nlappgrass)/(1- e^(-kdegsoil_metabolite *Tgr-int))	Fsoilgrs_metabolite	O	-	1	1	1	1	1	1
PIECgrs4_degr-Ni1,i2,i3,i4_metabolite=PIECgrs-Ni1,i2,i3,i4_metabolite *Fsoilgrs_metabolite	PIECgrs4_degr-Ni1,i2,i3,i4_metabolite	O	mg/kgwwt	1.86 E-04	1.48 E-04	2.08 E-04	2.08 E-04	6.29 E-04	3.93 E-04
Fsoilgrs2_metabolite = e^(-kdegsoil_metabolite * Tgr-intnomanure)	Fsoilgrs2_metabolite	O	-	2.39 E-20	2.39 E-20	2.39 E-20	2.39 E-20	2.39 E-20	2.39 E-20
PIECgrs10degr-Ni1,i2,i3,i4_metabolite= PIECgrs4_degr-Ni1,i2,i3,i4_metabolite *(1-Fsoilgrs2_metabolite^10)/(1-Fsoilgrs2_metabolite)	PIECgrs10degr-Ni1,i2,i3,i4_metabolite	O	mg/kgwwt	1.86 E-04	1.48 E-04	2.08 E-04	2.08 E-04	6.29 E-04	3.93 E-04
Groundwater ksoil_water_metabolite = 0.97 (Sweden, 2011)									
PIECgrs_(10_degr)- gw-N_i1,i2,i3,i4 = (PIECgrs_10_degr)-N_(i1,i2,i3,i4)*RHOsoil _wet)/(K_soil-water*1000) **Based on 100% of parent transformation in soil**	PIECgrs_10_degr-gw - N_i1,i2,i3,i4	O	mg/L	3.26 E-04	2.60 E-04	3.64 E-04	3.64 E-04	1.10 E-03	6.88 E-04
	PIECgrs_10_degr-gw - N_i1,i2,i3,i4	O	µg/L	3.26 E-01	2.60 E-01	3.64 E-01	3.64 E-01	1.10	6.88 E-01

Not affected livestock: 24 mg a.s./m³; 7 applications/year, 6-7 weeks intervall

Variable/ parameter	Symbol	S / D / O	Unit	Sows, in individual pens (cat 4)	Sows in groups (cat 5)	Fattening pigs (cat 6)	Broilers in free range with litter floor (cat 12)	Parent broilers in free range with grating floor (cat 14)	Parent broilers in rearing with grating floor (cat 15)
Soil - arable land ksoil_metabolite = 0.1238									
PIECars-Ni1,i2,i3,i4_metabolite= (100*Qai-arabi1,i2,i3,i4*QN,arable_land)/(Qnitrog-arabi1,i4 *DEPTHarable_land *RHOsoil) *fij *Massmolar_metabolite/Massmolar_parent	PIECars-Ni1,i2,i3,i4_metabolite	O	mg/kgwwt	1.06 E-04	1.35 E-04	8.83 E-05	4.86 E-05	3.56 E-05	7.76 E-05
Fsoilars_10_metabolite = (1-〖(e^(-kdegsoil_metabolite * Tar-int,10))〗^Nlapparab,10)/(1- e^(-kdegsoil_metabolite *Tar-int,10))	Fsoilars_10_metabolite	O	-	1	1	1	1	1	1
PIECars10degr-Ni1,i2,i3,i4_metabolit =PIECars-Ni1,i2,i3,i4_metabolite *Fsoilars_10_metabolite	PIECars10degr-Ni1,i2,i3,i4_metabolite	O	mg/kgwwt	1.06 E-04	**1.35 E-04 ***	8.83 E-05	4.86 E-05	3.56 E-05	7.76 E-05
Soil – grassland ksoil_metabolite = 0.1238									
PIECgrs-N_(i1,i2,i3,i4_metabolite)= (100*Qai-grass_(i1,i2,i3,i4)*Q_(N,grassland))/(Qnitrog-grass_(i1,i4)*Nlapp-grass *DEPTH_grassland*RHOsoil) *f_ij *Mass_(molar_metabolite)/Mass_(molar_metabolite)	PIECgrs-N_i1,i2,i3,i4_metabolite	O	mg/kgwwt	7.62 E-04	9.64 E-04	6.32 E-04	3.48 E-04	2.55 E-04	5.56 E-04
Fsoilgrs_metabolite = (1-(e^(-kdegsoil_metabolite * Tgr-int))^Nlappgrass)/(1- e^(-kdegsoil_metabolite *Tgr-int))	Fsoilgrs_metabolite	O	-	1	1	1	1	1	1
PIECgrs4_degr-Ni1,i2,i3,i4_metabolite=PIECgrs-Ni1,i2,i3,i4_metabolite *Fsoilgrs_metabolite	PIECgrs4_degr-Ni1,i2,i3,i4_metabolite	O	mg/kgwwt	7.62 E-04	9.64 E-04	6.32 E-04	3.48 E-04	2.55 E-04	5.56 E-04
Fsoilgrs2_metabolite = e^(-kdegsoil_metabolite * Tgr-intno manure)	Fsoilgrs2_metabolite	O	-	2.39 E-20	2.39 E-20	2.39 E-20	2.39 E-20	2.39 E-20	2.39 E-20
PIECgrs10degr-Ni1,i2,i3,i4_metabolite= PIECgrs4_degr-Ni1,i2,i3,i4_metabolite *(1-Fsoilgrs2_metabolite^10)/(1-	PIECgrs10degr-Ni1,i2,i3,i4_metabolite	O	mg/kgwwt	7.62 E-04	**9.64 E-04 ***	6.32 E-04	3.48 E-04	2.55 E-04	5.56 E-04

Variable/ parameter	Symbol	S / D / O	Unit	Sows, in individual pens (cat 4)	Sows in groups (cat 5)	Fattening pigs (cat 6)	Broilers in free range with litter floor (cat 12)	Parent broilers in free range with grating floor (cat 14)	Parent broilers in rearing with grating floor (cat 15)
Fsoilgrs2_metabolite)									
Groundwater ksoil_water_metabolite = 0.97 (Sweden, 2011)									
PIECgrs_(10_degr)- gw-N_i1,i2,i3,i4 = (PIECgrs_10_degr)-N_(i1,i2,i3,i4)*RHOsoil _wet)/(K_soil-water*1000) **Based on 100% of parent transformation in soil**	PIECgrs_10_degr-gw - N_i1,i2,i3,i4	O	mg/L	1.34 E-03	1.69 E-03	1.11 E-03	6.10 E-04	4.47 E-04	9.75 E-04
	PIECgrs_10_degr-gw - N_i1,i2,i3,i4	O	µg/L	1.34	1.69	1.11	6.10 E-01	4.47 E-01	9.75 E-01

* worst case values – basis for FOCUS Pearl 4.4.4 groundwater calculations

Refined groundwater calculations using FOCUS Pearl 4.4.4

Grassland

Project summary report of project: Br2CA_grass

Date: 10/02/2022

RUN_ID	RESULT_TEXT	SUBSTANCE	BR2CA	LOCATION	APPLICATION_SCHEME	CROP_CALENDAR	SOIL_TYPE	METEO_STATION	IRRIGATION_SCHEME	DEP
47	Concentration closest to the 80th percentile (ug/L)	Br2CA	0.000019	CHATEAUDUN	Br2CA_grass	CHAT-GRASS	CHAT-S_Soil	CHAT-M	FOCUS	
48	Concentration closest to the 80th percentile (ug/L)	Br2CA	0.000019	HAMBURG	Br2CA_grass	HAMB-GRASS	HAMB-S_Soil	HAMB-M	No	
49	Concentration closest to the 80th percentile (ug/L)	Br2CA	0.000362	JOKIOINEN	Br2CA_grass	JOKI-GRASS	JOKI-S_Soil	JOKI-M	No	
50	Concentration closest to the 80th percentile (ug/L)	Br2CA	0.000089	KREMSMUENSTER	Br2CA_grass	KREM-GRASS	KREM-S_Soil	KREM-M	No	
51	Concentration closest to the 80th percentile (ug/L)	Br2CA	0.000071	OKEHAMPTON	Br2CA_grass	OKEH-GRASS	OKEH-S_Soil	OKEH-M	No	
52	Concentration closest to the 80th percentile (ug/L)	Br2CA	0.000028	PIACENZA	Br2CA_grass	PIAC-GRASS	PIAC-S_Soil	PIAC-M	FOCUS	
53	Concentration closest to the 80th percentile (ug/L)	Br2CA	0.000011	PORTO	Br2CA_grass	PORT-GRASS	PORT-S_Soil	PORT-M	FOCUS	
54	Concentration closest to the 80th percentile (ug/L)	Br2CA	0.000000	SEVILLA	Br2CA_grass	SEVI-GRASS	SEVI-S_Soil	SEVI-M	FOCUS	
55	Concentration closest to the 80th percentile (ug/L)	Br2CA	0.000000	THIVA	Br2CA_grass	THIV-GRASS	THIV-S_Soil	THIV-M	FOCUS	

Arable land

Project summary report of project: Br2CA_arable

Date: 10/02/2022

RUN_ID	RESULT_TEXT	SUBSTANCE	BR2CA	LOCATION	APPLICATION_SCHEME	CROP_CALENDAR	SOIL_TYPE	METEO_STATION	IRRIGATION_SCHEME	DE
56	Concentration closest to the 80th percentile (ug/L)	Br2CA	0.000000	CHATEAUDUN	Br2CA_arable	CHAT-MAIZE	CHAT-S_Soil	CHAT-M	FOCUS	
57	Concentration closest to the 80th percentile (ug/L)	Br2CA	0.000000	HAMBURG	Br2CA_arable	HAMB-MAIZE	HAMB-S_Soil	HAMB-M	No	
58	Concentration closest to the 80th percentile (ug/L)	Br2CA	0.000000	KREMSMUENSTER	Br2CA_arable	KREM-MAIZE	KREM-S_Soil	KREM-M	No	
59	Concentration closest to the 80th percentile (ug/L)	Br2CA	0.000000	OKEHAMPTON	Br2CA_arable	OKEH-MAIZE	OKEH-S_Soil	OKEH-M	No	
60	Concentration closest to the 80th percentile (ug/L)	Br2CA	0.000000	PIACENZA	Br2CA_arable	PIAC-MAIZE	PIAC-S_Soil	PIAC-M	FOCUS	
61	Concentration closest to the 80th percentile (ug/L)	Br2CA	0.000000	PORTO	Br2CA_arable	PORT-MAIZE	PORT-S_Soil	PORT-M	FOCUS	
62	Concentration closest to the 80th percentile (ug/L)	Br2CA	0.000000	SEVILLA	Br2CA_arable	SEVI-MAIZE	SEVI-S_Soil	SEVI-M	FOCUS	
63	Concentration closest to the 80th percentile (ug/L)	Br2CA	0.000000	THIVA	Br2CA_arable	THIV-MAIZE	THIV-S_Soil	THIV-M	FOCUS	

3.3 New information on the active substance

No new information is provided on the active substance.

3.4 Residue behaviour

Field studies on the residue behaviour after product combustion have been presented in this dossier.

3.5 Summaries of the efficacy studies (B.5.10.1-xx)[5]

A IUCLID file is available and the summaries are considered sufficient.

3.6 Confidential annex

Please confer to separate document.

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

3.7 Other

3.7.1 Reference list (excluding list of studies. cf. to chapter 3.1)

Almasri M.N. (2007), *Nitrate contamination of groundwater: A conceptual management framework.* Environmental Impact Assessment Review 27. 2007. 220–242. Available at: https://www.sciencedirect.com/science/article/abs/pii/S0195925506001314

Bae JW, Kwon HJ, Kim SH, Ma L, Im H, Kim E, Kim MO and Kwon WS. (2020), Inhalation of ammonium sulfate and ammonium nitrate adversely affect sperm function. Reprod Toxicol. 2020 Aug 29;96:424-431. doi: 10.1016/j.reprotox.2020.08.009. Epub ahead of print. PMID: 32866586.

Bengtsson G. and Bergwall C. (2000), *Fate of ^{15}N labelled nitrate and ammonium in a fertilized forest soil.* Soil Biology and Biochemistry 132 (4). 2000. 545–557. Available at: https://www.sciencedirect.com/science/article/abs/pii/S0038071799001832

Bjerregaard et al. (2018), *Investigation of the potential endocrine effect of nitrate in zebrafish Danio rerio and brown trout Salmo trutta.* Comparative Biochemistry and Physiology 211 part C. 32–40 2000. 545–557. Available at: https://www.sciencedirect.com/science/article/abs/pii/S1532045618300620

CG (2019), *Assessment of endocrine disruption (ED) properties of co-formulants in biocidal products – instructions for applicants CG-34-2019-02 AP 16.5*

Defra (2005), *VetCalc: Exposure Modelling Tool for Veterinary Medicines. Draft User's Manual.* 2005. Defra Research Project VM02133 Veterinary Medicines Directorate. Addlestone. UK.

Denmark (2017), *Substance Evaluation Conclusion as required by REACH Article 48 and Evaluation Report for 6,6'-di-tert-butyl-2,2'-methylenedi-p-cresol, EC No 204-327-1, CAS No 119-47-1.* Available at: https://echa.europa.eu/documents/10162/99eb8c10-8e55-ddd7-7f89-c9d7df6666dc. 2021-10-14

ECB (no date), *Summary fact sheet, PBT Working Group – PBT List No. 117, TC NES Subgroup on identification of PBT and vPvB substances, Results of the evaluation of the PBT/vPvB properties of: 6,6'-Di-tert-butyl-2,2'-methylenedi-p-cresol.* Availabe at: https://echa.europa.eu/documents/10162/4fbb0b56-ebe4-45b8-8ee7-4bf505ff7998. 2019-09-16

ECHA (2014), *Addendum to OECD SERIES ON EMISSION SCENARIO DOCUMENTS. Number 14: Emission Scenario Document for Insecticides for Stables and Manure Storage Systems. ENV/JM/MONO(2006)4. Outcome of the ECHA BPC Ad hoc EE WG consultation "PT 18 - Ad hoc EE WG consultation on the exposure assessment for manure application".* launched at September 29. 2014. Agreed at the Environment Working Group V on November 26. 2015. Available at: https://echa.europa.eu/documents/10162/20733977/env_89_addendum_to_esd_for_pt18_en.pdf 2020-12-02

ECHA (2015), *Biocides Human Health Exposure Methodology*. Available at: https://echa.europa.eu/de/about-us/who-we-are/biocidal-products-committee/working-groups/human-exposure 2019-08-23

ECHA (2017a), *Guidance on the Biocidal Products Regulation. Volume IV Environment - Assessment and Evaluation (Parts B + C).* Version 2.0. ECHA October 2017. Reference: ECHA-17-G-23-EN. Available at: https://echa.europa.eu/documents/10162/23036412/bpr_guidance_ra_vol_iv_part_b-c_en.pdf/e2622aea-0b93-493f-85a3-f9cb42be16ae. 2018-03-22.

ECHA (2017c), *Guidance on the Biocidal Products Regulation. Volume III Human Health – Assessment & Evaluation (Parts B+C)* Version 4.0. December 2017. Available at: https://echa.europa.eu/documents/10162/23036412/biocides_guidance_human_health_ra_iii_part_bc_en.pdf/30d53d7d-9723-7db4-357a-ca68739f5094. 2021-01-20

ECHA (2019a), *Opinion Persuant to Article 77(3)c) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals. M-factor for long-term aquatic hazard for the copper substances listed in Commission Regulation (EU) 2016/1179.* ECHA/RAC/A77-O_0000001412-86-262/F 15 March 2019 Adopted. Available at: https://echa.europa.eu/documents/10162/13579/article77_3_c_opinion_copper_compounds_en.pdf/951ec919-e038-e9e3-90bb-0ba50c536d87. 2020-12-11

ECHA (2019b), *Committee for Risk Assessment RAC Opinion proposing harmonized classification and labelling at EU level of 6,6'-di-tert-butyl-2,2'-methylenedi-p-cresol (DBMC), EC Number: 204-327-1, CAS Number: 119-47-1, CLH-O-0000001412-86-288/F, Adopted 13 June 2019.* Available at: https://echa.europa.eu/documents/10162/f5a13a30-d11a-65b9-6730-592692c151f2. 2021-10-14

ECHA (2019c), ENV 10 v2: Exposure assessment of metabolites in the terrestrial compartment – indirect exposure via sewage sludge and manure/slurry. Available at: https://webgate.ec.europa.eu/s-circabc/faces/jsp/extension/wai/navigation/container.jsp 2022-01-14

ECHA (2020), Proposal for an Addendum to OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 14: Emission Scenario Document for Insecticides for Stables and Manure Storage Systems, ENV/JM/MONO(2006)4.

ECHA (2021a), *Proposal to bridge the endocrine disruptor assessment of biocidal non-active substances with REACH screening and assessment CA-March21-Doc.4.3.* Available at: https://echa.europa.eu/documents/10162/17158508/ca-march21-Doc43_final_bridging_biocides_with+_reach_en.pdf/130151c9-7733-1bbd-b389-6bc642e68e95. 2021-10-14

ECHA (2021b), *Technical Agreement for Biocides (TAB)*. Release date November 2021. Available at: https://echa.europa.eu/documents/10162/20733977/technical_agreements_for_biocides_en.pdf/4280fdc4-dfb0-405e-898e-70f3cdf62ce2. 2018-03-22

EFSA (2017), *Guidance on dermal absorption*. EFSA Journal. doi: 10.2903/j.efsa.2017.4873EFSA Journal 2017; 15(6):4873, 60 pp

EFSA (2015). Review of the existing maximum residue levels for deltamethrin according to Article 12 of Regulation (EC) No 396/200. doi:10.2903/j.efsa.2015.4309

European Commission (2013), *CA-Document CA-Sept13-Doc.6.2.b Rev.1 Authorisation under the Biocidal Products Regulation of products containing more than one existing active substance or belonging to more than one product-type.*

France (2011), *Assessment Report Basic copper carbonate, Product-type 8 (Wood preservatives), September 2011*. Available at: http://dissemination.echa.europa.eu/Biocides/ActiveSubstances/0006-08/0006-08_Assessment_Report.pdf 2018-05-23

France (2014), *Assessment Report Synthetic amorphous silicon dioxide, Product-type 18 (Insecticides), May 2011.* Available at: http://dissemination.echa.europa.eu/Biocides/ActiveSubstances/1378-18/1378-18_Assessment_Report.pdf 2018-05-23

Greenlee AR, Ellis TM, Berg RL. (2004). Low-dose agrochemicals and lawn-care pesticides induce developmental toxicity in murine preimplantation embryos. Environ Health Perspect 112(6):703-709.

Jannat et al. (2014), *Nitrate (NO_3^-) and nitrite (NO_2^-) are endocrine disruptors to downregulate expression of tyrosine hydroxylase and motor behavior through conversion to nitric oxide in early development of zebrafish*. Biochemical and Biophysical Research Communications 2014 Sep 26;452(3):608-13. Available at: https://pubmed.ncbi.nlm.nih.gov/25173937/

Jung EC, Maibach HI (2014) Animal models for percutaneous absorption. Journal of applied toxicology. Volume 35, Issue 1, 1-10

Latvia (2011), *Assessment Report Hydrochloric acid, Product –type 2 (Private area and public health area disinfectant and other biocidal products)* December 2011. Available at: https://echa.europa.eu/documents/10162/f26dc9ec-c221-6748-7665-f90978f09d72 2019-09-16

Masahiko Katoh et al. (2012), *Sorption of Lead in Animal Manure Compost: Contributions of Inorganic and Organic Fractions.* Available at: https://link.springer.com/article/10.1007/s11270-013-1828-2 2021-01-17

Mitran E, Callender T, Orha B, Dragnea P, Botezatu G. (1997). Neurotoxicity associated with occupational exposure to acetone, methyl ethyl ketone, and cyclohexanone. Environ Res 73(1-2):181-188.

Monta-Sanchez D. and Wise J.C. (2021), *The Arthropod Pesticide Resistance Database. Michigan State University.* Available at: http://www.pesticideresistance.org 2021-10-14

Montforts (1999), *Environmental risk assessment for veterinary medicinal products. Part 1. Other than GMO-containing and immunological products*. First update. National Institute of public health and environment. The Netherlands. Bilthoven RIVM report no. 601300001.

OECD (2006), *OECD SERIES ON EMISSION SCENARIO DOCUMENTS. Number 14. Emission Scenario Document for Insecticides for Stables and Manure Storage Systems.* Available at: https://echa.europa.eu/documents/10162/16908203/pt18_insecticides_for_stables_and_manure_en.pdf/cc437f66-35ef-4116-a281-026c4f2fb6d0. 2018-03-22

OECD (2008), *OECD SERIES ON EMISSION SCENARIO DOCUMENTS. Number 18. EMISSION SCENARIO DOCUMENT FOR INSECTICIDES. ACARICIDES AND PRODUCTS TO CONTROL OTHER ARTHROPODS FOR HOUSEHOLD AND PROFESSIONAL USES.* Available at: https://echa.europa.eu/documents/10162/16908203/pt18_oecd_esd_household_professional_uses_en.pdf/bb353df7-5606-41d2-b799-ea15717a8d4b

OECD (2011) OECD GUIDANCE: NOTES ON DERMAL ABSORPTION Series on Testing and Assessment No. 156

Paciência I, Cavaleiro Rufo J, Silva D, Martins C, Mendes F, Farraia M, Delgado L, de Oliveira Fernandes E, Padrão P, Moreira P, Severo M, Barros H, Moreira A. (2019), Allergy. Exposure to indoor endocrine-disrupting chemicals and childhood asthma and obesity. 2019 Jul;74(7):1277-1291. doi: 10.1111/all.13740 . Epub 2019 Mar 5.

Poland (2017), *Substance Evaluation Conclusion as required by REACH Article 48 and Evaluation Report for Cyclohexanone, EC No 203-631-1, CAS No 108-94-1.* Available at: https://echa.europa.eu/documents/10162/d7f40e5b-de43-8d69-b9b8-ab2c2ec18110 . 2021-10-14

Poulsen R, Cedergreen N, Hayes T, and Hansen M. (2018), Nitrate: An Environmental Endocrine Disruptor? A Review of Evidence and Research Needs. Environmental Science and Technology 52 (7). 215–224. Available at: https://pubs.acs.org/doi/10.1021/acs.est.7b06419

RAC (2013). 24thMeeting of the committee of risk assessment; 5 - 8 MARCH 2013. Authorisation, establishing reference DNELs for DEHP; p. 1- 8

Recous et al. (1988), *The fate of labelled ^{15}N urea and ammonium nitrate to a winter wheat crop.* Plant and Soil 112, 215–224. Available at: https://link.springer.com/article/10.1007/BF02139998

Reimann et al. (2012), *Lead and lead isotopes in agricultural soils of Europe – The continental perspective.* Applied Geochemistry 27. Available at: https://www.sciencedirect.com/science/article/abs/pii/S088329271100494X?via%3Dihub 2021-01-17

Simon GA and Maibach HI. The Pig as an experimental Animal Model of Percutaneous Permeation in Man: Qualitative and Quantitative Observations – an overview. Skin Pharmacol Appl Skin Physiol 2000; 13:229-234

Sweden (2011), *Assessment Report Deltamethrin, Product-type 18 (Insecticides), May 2011.* Available at: https://circabc.europa.eu/sd/a/87972aa2-c237-4a44-a13a-e1ec7c7ef625/Deltamethrin%20PT%2018%20final%20AR%20-%20converted-confirmed.pdf . 2018-03-29

The Netherlands, Ctgb (2017), *CA-Document CA-Sept17-Doc.4.2 Categories of co-formulants being active substances (or not),* 19 September 2017. Available at:

http://files.chemicalwatch.com/CA-meeting%20for%20biocidal%20products.pdf. 2021-10-14

LEGAL NORMS

Dir. (EU) No 2011/81: Commission Directive 2011/81/EU of 20 September 2011 amending Directive 98/8/EC of the European Parliament and of the Council to include deltamethrin as an active substance in Annex I thereto. Available at: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32011L0081, 2021-01-12

Reg. (EC) No 91/676: Council Directive 91/676/EEC of 12 December 1991 concerning the protection of waters against pollution caused by nitrates from agricultural sources. Available at: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31991L0676. 2018-04-03

Reg. (EC) No 98/83: Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption. Available at: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31998L0083, 2018-04-12

Reg. (EC) No 2006/118: Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration. Available at: http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:372:0019:0031:EN:PDF, 2018-04-12

Reg. (EC) No 1272/2008: Regulation (EC) no 1272/2008 of the European parliament and of the council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directive 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. Available at: https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A32008R1272, 2018-05-23

Reg. (EU) No 528/2012: Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (BPR). Available at: https://echa.europa.eu/regulations/biocidal-products-regulation/legislation, 2018-06-05