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

DRAFT RISK ASSESSMENT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the applicant)

Fendona 6 SC

Product type 18

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

Asset Number in R4BP: GR-0015160-0000

NA-MAC Case Number in R4BP: BC-TH052041-49

Evaluating Competent Authority: Greece

Date: June 2019

Table of Contents

TABLE OF CONTENTS **2**

1 **CONCLUSION** **5**

2 **ASSESSMENT REPORT** **8**

2.1 SUMMARY OF THE PRODUCT ASSESSMENT 8
2.1.1 Administrative information *8*
2.1.1.1 Identifier of the product 8
2.1.1.2 Authorisation holder 8
2.1.1.3 Manufacturer(s) of the product 8
2.1.1.4 Manufacturer(s) of the active substance(s) 8
2.1.2 Product composition and formulation *10*
2.1.2.1 Identity of the active substance 10
2.1.2.2 Candidate(s) for substitution 10
2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product 11
2.1.2.4 Qualitative and quantitative information on the composition of the biocidal product family 11
2.1.2.5 Information on technical equivalence 11
2.1.2.6 Information on the substance(s) of concern 11
2.1.2.7 Type of formulation 11
2.1.3 Hazard and precautionary statements *12*
2.1.4 Authorised use(s) *13*
2.1.4.1 Use-specific instructions for use 14
2.1.4.2 Use-specific risk mitigation measures 15
2.1.4.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 16
2.1.4.4 Where specific to the use, the instructions for safe disposal of the product and its packaging 17
2.1.4.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage 17
2.1.5 General directions for use *18*
2.1.5.1 Instructions for use 18
2.1.5.2 Risk mitigation measures 18
2.1.5.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 18
2.1.5.4 Instructions for safe disposal of the product and its packaging 18
2.1.5.5 Conditions of storage and shelf-life of the product under normal conditions of storage 18
2.1.6 Other information *19*
2.1.6.1 Authorised use(s) 20
2.1.6.2 General directions for use 22
2.1.7 Packaging of the biocidal product *26*
2.1.8 Documentation *26*
2.1.8.1 Data submitted in relation to product application 26
2.1.8.2 Access to documentation 27
2.2 ASSESSMENT OF THE BIOCIDAL PRODUCT 28
2.2.1 Intended use(s) as applied for by the applicant *28*
2.2.2 Physical, chemical and technical properties *31*
2.2.3 Physical hazards and respective characteristics *41*
2.2.4 Methods for detection and identification *44*
2.2.5 Efficacy against target organisms *47*
2.2.5.1 Function and field of use 47
2.2.5.2 Organisms to be controlled and products, organisms or objects to be protected 47

2.2.5.3 Effects on target organisms, including unacceptable suffering 47
2.2.5.4 Mode of action, including time delay 48
2.2.5.5 Efficacy data 49
2.2.5.6 Occurrence of resistance and resistance management 76
2.2.5.7 Known limitations 77
2.2.5.8 Evaluation of the label claims 78
2.2.5.9 Relevant information if the product is intended to be authorised for use with other biocidal product(s) 97
2.2.6 Risk assessment for human health 98
2.2.6.1 Assessment of effects on Human Health 98
2.2.6.2 Exposure assessment 113
2.2.6.3 Risk characterisation for human health 153
2.2.7 Risk assessment for animal health 163
2.2.8 Risk assessment for the environment 169
2.2.8.1 Effects assessment on the environment 169
2.2.8.2 Exposure assessment 178
2.2.8.3 Risk characterisation 237
2.2.9 Measures to protect man, animals and the environment 246
2.2.10 Assessment of a combination of biocidal products 246
2.2.11 Comparative assessment 246

***3* ANNEXES 247**

3.1 LIST OF STUDIES FOR THE BIOCIDAL PRODUCT 247
3.2 OUTPUT TABLES FROM EXPOSURE ASSESSMENT TOOLS 256
3.3 NEW INFORMATION ON THE ACTIVE SUBSTANCE 267
3.4 RESIDUE BEHAVIOUR 267
3.5 SUMMARIES OF THE EFFICACY STUDIES (B.5.10.1-XX) 267
3.6 CONFIDENTIAL ANNEX 267
3.7 STUDY SUMMARIES OF CHRIONOMUS RIPARIUS SPIKED SEDIMENT STUDIES WITH FENDONA 6 SC AND FENDONA 1.5 SC 267

Note

This PAR for the major change application of the product authorisation is based on the PAR of the first authorisation. Each section contains the initial assessment, and new information relating to the major change application is included at the end of each relevant point and highlighted in grey.

Major change application

Use #1, Urban Pest Control (UPC), is now included, which was not approved in the initial Mutual Recognition in Parallel (MRP) authorisation. The following data and information, together with the previously submitted data for the original MRP dossier, are provided to support the authorisation of this use:

i) New efficacy data to support efficacy of Fendona 6 SC indoors in Urban Pest Control (Intended use #1) by professionals at 15 mg a.s./m^2 against the following target pests:

- Crawling insects: German cockroaches (*Blattela germanica*), ants (*Lasius niger*) and bedbugs (*Cimex lectularius*)
- Flying insects, including houseflies (*Musca domestica*), mosquitoes (*Culex* spp) and wasps (*Vespula* spp)

ii) An updated environmental risk assessment, using the EU-agreed endpoint for $PNEC_{sed}$.

iii) The introduction of the RMMs (large buildings only) and a fsim of 0.204% (1-2 applications per year), permitting safe use for sediment dwelling organisms.

1 CONCLUSION

FENDONA 6 SC is a Suspension Concentrate (SC) containing 60 g/L alpha-cypermethrin. Its physicochemical properties are considered acceptable. Acceptable analytical methods have also been submitted.
An acceptable risk to humans, following primary and secondary exposure to the active substance alpha-cypermethrin, has been identified for all uses assessed.

According to the environmental risk assessment, there is an unacceptable risk for sediment dwelling organisms in the urban pest control scenario (scenario 1) when FENDONA 6 SC is applied and thus **USE 1 is NOT authorised**. For USE 2, an acceptable risk for non-target organisms is demonstrated provided that label instructions are followed and FENDONA 6 SC is ONLY applied in animal subcategories 7, 9, 10, 13, 14, 15 (for explanation of animal subcatefories number see relevant table in page 183). Strictly not to be used in stables/animal housings connected to a sewage treatment plant.

In terms of efficacy, several studies (laboratory, simulated use and field studies) were submitted for Fendona 6 SC, using also studies conducted with Fendona 1.5 SC based on a bridging approach, which are sufficient to prove efficacy of Fendona 6 SC in urban pest control (Intended use 1 as applied for by the applicant) by professionals at 15 mg a.s./m^2 and in animal houses/shelters (intended use 2 as applied for by the applicant) by professionals and non-professionals at 15 and 30 mg a.s./m^2 as follows:
In urban pest control (Intended use 1) the product was proved to be effective against German cockroaches (*Blattella germanica*), ants (*Lasius niger*) and bedbugs *(Cimex lectularius)*, as a coarse spray to cracks & crevices, and/or onto targeted spots or areas where insects may crawl and hide; and against mosquitoes (*Culex spp.*) and wasps *(Vespula spp)*, as a coarse spray onto targeted spots or areas where insects may settle, noting that:

- "Activity against German cockroaches is achieved only with fresh deposits.".
- "Mortality of German cockroaches is achieved 1 week after exposure of the insects to the treated surfaces".
- "Residual activity against ants (*Lasius niger*) is up to 1 month".
- "Activity against mosquitos (*Culex spp.)* is achieved only with fresh deposits on non-porous surfaces (not on porous surfaces)".
- "Mortality of mosquitos (*Culex spp.)* is achieved 48 hours after exposure of the insects to the treated surfaces".
- "Residual activity against wasps (*Vespula* spp.) is achieved only on non-porous surfaces (not on porous surfaces) for up to 3 months".
- "Noticeable knockdown effect on wasps is expected within 6 hours after contact of the insects with non-porous treated surfaces and mortality is achieved at 24 hours".
- "Residual activity against bedbugs is up to 3 months".
- "Mortality of bedbugs is achieved 1 week after exposure of the insects to the treated surfaces".
- "At least 1 re-application is required against bedbugs.".

In animal houses/shelters (intended use 2) the product was proved to be effective against German cockroaches (*Blattella germanica*), ants (*Lasius niger*), mosquitoes *(Culex spp.)* and wasps *(Vespula spp),* and is applied throughout the infested area as a coarse spray for surface treatment. Special attention should be paid to cracks, crevices and any place where insects may hide and on surfaces over which they may crawl or settle. The product is effective against the target organisms noting that:

- "Activity against German cockroaches is achieved only with fresh deposits.".
- "Mortality of German cockroaches is achieved 1 week after exposure of the insects to the treated surfaces".

- "An application rate 15 mg/m^2 is set for high hygiene shelter places against cockroaches, otherwise an application rate 30 mg/m^2 should be used".
- "Residual activity against ants (*Lasius niger*) is up to 1 month".
- "Activity against mosquitos (*Culex spp.)* is achieved only with fresh deposits on non-porous surfaces (not on porous surfaces) at the low dose and on porous and non-porous surfaces at the high dose".
- "Mortality of mosquitos (*Culex spp.)* is achieved 48 hours after exposure of the insects to the treated surfaces".
- "Residual activity against wasps (*Vespula* spp.) is achieved only on non-porous surfaces (not on porous surfaces) for up to 3 months".
- "Noticeable knockdown effect on wasps is expected within 6 hours after contact of the insects with non-porous treated surfaces and mortality is achieved at 24 hours".

Major change application conclusions

The applicant submitted a major change application in order to include the Intended Use 1 (Urban pest control) as shown in the highlighted table in 2.2.1 (Major change application – Intended uses as applied for by applicant).

In addition to the several efficacy studies (laboratory, simulated use and field studies) originally submitted for the MRP Fendona 6 SC dossier, using also studies conducted with Fendona 1.5 SC based on a bridging approach, one new study (Gibson 2019b) against mosquitoes and houseflies has been submitted by the applicant and included in the PAR to support efficacy of Fendona 6 SC indoors in urban pest control (Intended use 1) by professionals at 15 mg a.s./m^2 against the following claimed target pests:

- Crawling insects: German cockroaches (*Blattela germanica*), ants (*Lasius niger*) and bedbugs (*Cimex lectularius*)
- Flying insects, including houseflies (*Musca domestica*), mosquitoes (*Culex* spp) and wasps (*Vespula* spp)

Taking into consideration the efficacy evaluation already performed by the eCA for both intended uses 1 & 2 based on the efficacy studies submitted for MRP Fendona 6SC dossier, the new submitted study by Gibson 2019b, and the conclusions of the teleconference on 5 March 2019 and the outcome of the discussions of 34th CG meeting on 12 March 2019 concerning the Referral to the Coordination Group of a disagreement on Mutual recognition (MR) in accordance with Article 35(2) of the Regulation (EU) No 528/2012 (BPR) for Fendona 6SC, the intended use 1 (urban pest control) of Fendona 6 SC, from the efficacy point of view, is acceptable as applied for a major change by the applicant (2.2.1), noting that:
In urban pest control (Intended use 1) the product is efficacious against German cockroaches (*Blattella germanica*), ants (*Lasius niger*) and bedbugs *(Cimex lectularius)*, as a coarse spray to cracks & crevices, and/or onto targeted spots or areas where insects may crawl and hide; and against flying insects including houseflies (*Musca domestica*), mosquitoes (*Culex spp.*) and wasps *(Vespula spp)*, as a coarse spray onto targeted spots or areas where insects may settle, with the following limitations per target organism:

- "Activity against German cockroaches is achieved only with fresh deposits.".
- "Mortality of German cockroaches is achieved 1 week after exposure of the insects to the treated surfaces".
- "Residual activity against ants (*Lasius niger*) is up to 1 month".
- "Activity against mosquitoes (*Culex* spp*.)* is achieved only with fresh deposits on non-porous surfaces (not on porous surfaces)".
- "Mortality of mosquitoes (*Culex* spp*.)* is achieved between 2 and 4 days after exposure of the insects to the treated surfaces".
- "Noticeable knockdown effect on houseflies is expected within 6 hours after contact with the treated surfaces and mortality is achieved 24-72 hours after exposure".

- "Residual activity against wasps (*Vespula* spp.) is achieved only on non-porous surfaces (not on porous surfaces) for up to 3 months".
- "Noticeable knockdown effect on wasps is expected within 6 hours after contact of the insects with non-porous treated surfaces and mortality is achieved at 24 hours".
- "Noticeable knockdown effect on bedbugs is expected within 24 h after contact with treated surfaces and mortality is achieved 1 week after exposure".
- "For the control of bedbugs at least 1 re-application is required".

According to the revised environmental risk assessment, after the major change application amendments, i.e., the introduction of the RMMs (large buildings only) and a Fsim of 0.204% (1-2 applications per year), an acceptable risk for all environmental compartments is now demonstrated (permitting safe use for sediment dwelling organisms) in the urban pest control scenario (scenario 1), when FENDONA 6 SC is applied. Thus **USE 1 is authorised**.

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)
Fendona 6 SC	GREECE (Reference Member State)

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	BASF Hellas S.A.
	Address	2 Paradisou Str, 15125 Maroussi - Athens, Greece
Authorisation number	ΤΠ18-0346	
Date of the authorisation	04-06-2019	
Expiry date of the authorisation	04-06-2029	

2.1.1.3 Manufacturer(s) of the product

Name of manufacturer	BASF Agro B.V. Arnhem (NL) – Freienbach Branch
Address of manufacturer	Huobstrasse 3, 8808 Pfäffikon SZ Former address given in the CAR: BASF Agro B.V., Arnhem (NL) – Wädenswil Branch Moosacherstrasse 2 CH-8804 Wädenswil/Au Switzerland The change is due to a relocation of the headquarter of BASF Agro BV.
Location of manufacturing sites	BASF Agri-Production S.A.S.,Rue Jacquard; Z.I. Lyon Nord; 69727 Genay Cedex; France

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

Active substance	alpha-cypermethrin
Name of manufacturer	BASF Agro B.V. Arnhem (NL) – Freienbach Branch
Address of manufacturer	Huobstrasse 3, 8808 Pfäffikon SZ Switzerland Former address given in the CAR: BASF Agro B.V., Arnhem (NL) – Wädenswil Branch Moosacherstrasse 2 CH-8804 Wädenswil/Au Switzerland The change is due to a relocation of the headquarter of BASF Agro BV.
Location of manufacturing sites	Tagros Chemicals India Ltd. Sipcot Industrial Complex Pachayankuppam Cuddalore-607 005 India and

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

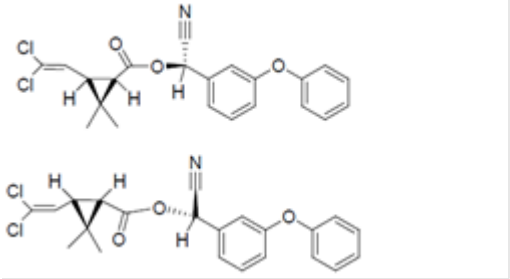
2.1.2 Product composition and formulation

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

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

Yes ☐
No ☐

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	Alpha-cypermethrin
IUPAC or EC name	1:1 mixture (racemate) of the pair of enantiomers (S)-α-cyano-3-phenoxybenzyl-(1R,3R)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate and (R)-α-cyano-3-phenoxybenzyl-(1S,3S)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate
EC number	Not allocated
CAS number	67375-30-8
Index number in Annex VI of CLP	607-422-00-X
Minimum purity / content	≥93 % w/w
Structural formula	

2.1.2.2 Candidate(s) for substitution

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

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

Common name	IUPAC name	Function	CAS number	EC number	Content (w/w %)
Alpha-cypermethrin	1:1 mixture (racemate) of the pair of enantiomers (S)-α-cyano-3-phenoxybenzyl-(1R,3R)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate and (R)-α-cyano-3-phenoxybenzyl-(1S,3S)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate	Active substance	67375-30-8	Not allocated	5.83 (Pure) 6.27 (Tech)
(*)	(*)	Non-active substance	(*)	(*)	(*)

(*) Please refer to the confidential information in section 2.3 of IUCLID.

2.1.2.4 Qualitative and quantitative information on the composition of the biocidal product family

Fendona 6 SC is not a biocidal product family.

2.1.2.5 Information on technical equivalence

Not applicable because the source of active substance is the same as was evaluated for inclusion in the Union list of approved active substances. Please refer to section 2.1.2.

2.1.2.6 Information on the substance(s) of concern

Fendona 6 SC contains 1,2-Propylene glycol.

Common name	IUPAC name	Function	CAS number	EC number	Content (w/w%)
1,2-Propylene glycol (1,2-Propylene glycol)	1,2-Propanediol	antifreeze	57-55-6	200-338-0	14.0

2.1.2.7 Type of formulation

SC Suspension concentrate

2.1.3 Hazard and precautionary statements

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

Classification	
Hazard category	Aquatic Acute – Cat. 1 Aquatic Chronic – Cat. 1
Labelling	
Pictogram	
Signal words	Warning
Hazard statements	H400 Very toxic to aquatic life H410 Very toxic to aquatic life with long lasting effects
Precautionary statements	P273 Avoid release to the environment P391 Collect spillage P501 Dispose of contents/container in accordance with local/regional/national/international regulation.
Note	EUH208: Contains 1,2-Benzisothiazolin-3-one. May produce an allergic reaction

2.1.4 Authorised use(s)

Table 1. Use # 2 – Rural Hygiene (Animal Houses/Shelters)

<table>
<tr><td>Product Type</td><td>PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)</td></tr>
<tr><td>Where relevant, an exact description of the authorised use</td><td>Insecticide</td></tr>
<tr><td>Target organism (including development stage)</td><td>German cockroaches (Blattella germanica), nymphs and adults; and ants (Lasius niger), adults.
Mosquitoes (Culex spp.), adults; and wasps (Vespula spp), adults.</td></tr>
<tr><td>Field of use</td><td>Indoors in the following animal house sub-categories: Laying hen, battery cages without treatment, Laying hen, battery cages with forced drying, Laying hen, compact battery cages, Laying hen, free range with grating floor, Parent broiler >18 weeks, free range with grating floor, Parent broiler in rearing, free range with grating floor.

The product is a liquid concentrate and it is applied as coarse spray for surface treatment. Special attention should be paid to cracks, crevices and any place where insects may hide and on surfaces over which they may crawl or settle.</td></tr>
<tr><td>Application method(s)</td><td>It is applied using any conventional manual or power sprayer equipped to produce a coarse spray at low pressure. For amateur use application is performed either via hand-held or via trigger sprayer. The appropriate volume of the product is added to the required volume of clean water and agitated. If a delay occurs between treatments, re-agitation is needed before re-use.

The product should be applied throughout the infested area as a coarse spray for surface treatment. Special attention should be paid to cracks, crevices and any place where insects may hide and on surfaces over which they may crawl or settle.</td></tr>
<tr><td>Application rate(s) and frequency</td><td>
<table>
<tr><th>6 SC (mL) LOW DOSE RATE</th><th>6 SC (mL) HIGH DOSE RATE</th><th>Water volume for dilution (L)</th><th>Surface area treated (m2)</th></tr>
<tr><td>25</td><td>50</td><td>5</td><td>100</td></tr>
<tr><td>12.5</td><td>25</td><td>2.5</td><td>50</td></tr>
<tr><td>5</td><td>10</td><td>1</td><td>20</td></tr>
<tr><td>2.5</td><td>5</td><td>0.5</td><td>10</td></tr>
<tr><td>1.25</td><td>2.5</td><td>0.25</td><td>5</td></tr>
</table>
e.g., for treating 20 m^2 surface area at the low dose rate:
5 ml product is diluted in 1 liter water (1:200; spray concentration: 0.5% v/v).
For the high dose rate: 10 ml product is diluted in 1 liter water (1:100; spray concentration: 1% v/v).</td></tr>
</table>

	An application rate 15 mg a.i /m^2 is set for high hygiene shelter places against cockroaches, otherwise an application rate 30 mg a.i /m^2 should be used. Residual Activity: The residual life of the deposit will vary depending upon the cleanliness and nature of the surface to which it is applied, and the extent to which the residue remains undisturbed. The product exhibits sustained residual activity, up to 1 month, where residues remain undisturbed, against ants (*Lasius niger*). Activity against German cockroaches is achieved only with fresh deposits. Activity against mosquitos (*Culex spp.)* is achieved only with fresh deposits on non-porous surfaces (not on porous surfaces) at the low dose and on porous and non-porous surfaces at the high dose. Residual activity against wasps (*Vespula* spp.) is achieved only on non-porous surfaces (not on porous surfaces) for up to 3 months. Frequency:**4 applications per year** Laying hen, battery cages without treatment, Laying hen, battery cages with forced drying, Laying hen, compact battery cages, Laying hen, free range with grating floor, Parent broiler >18 weeks, free range with grating floor, Parent broiler in rearing, free range with grating floor
Category(ies) of users	Non-professional and professional
Pack sizes and packaging material	Bottle or Bettix container or Jerry can, HDPE, Non-professional pack size: 0.05, 0.1 litres Professional pack sizes: 0.5, 1, 5 litres The non-professional product pack contains a dosing device.

2.1.4.1 Use-specific instructions for use

Read the label before use.

- Estimate the surface area that needs to be treated.
- Prepare the spray solution by adding the appropriate volume of Fendona 6 SC to the required volume of clean water and agitate.
- For non-professional users, the appropriate volume of Fendona 6 SC is measured using the dosing device provided in the product pack.
- For professional users, the appropriate volume of Fendona 6 SC is measured using the Bettix dispensing product container or a standard dosing device.
- When empty, triple rinse the container and use the rinsate to make up the spray solution for application.
- The appropriate volume of Fendona is measured using the dosing device provided according to the table above (see Application rates & frequency).

Apply using any conventional manual or power sprayer equipped to produce a coarse

spray at low pressure. Add the appropriate volume of product to the required volume of clean water and agitate. If a delay occurs between treatments, re-agitate before re-use.

The low and high application rates are used for low and high levels of infestation, respectively.

Following application, insects that have contacted the deposit should show signs of knockdown within 30 – 60 minutes with noticeable impact on population numbers expected within a few days.

Mortality of German cockroaches is achieved 1 week after exposure of the insects to the treated surfaces.

Mortality of mosquitos (*Culex spp.)* is achieved 48 hours after exposure of the insects to the treated surfaces.

Noticeable knockdown effect on wasps is expected within 6 hours after contact of the insects with non-porous treated surfaces and mortality is achieved at 24 hours.

Treated areas should be re-inspected after 2– 3 weeks. Where initial infestation was severe or new infestation is observed, a second application may be required particularly if the first treatment has been disturbed or some harbourages/landing sites were missed in the initial application.

Allow the applied solution to dry before re-entry into the treated areas by either humans or animals.

Strategies for managing the development of resistance:

- Where possible, application treatments should be recommended to be combined with non-chemical measures.
- To avoid the potential for insect resistance to Fendona 6SC, treatments should be alternated with insecticidal products having different modes of action.
- If resistance is confirmed, stop the use of Fendona 6SC immediately and rotate to an insecticide with alternative mode of action. By removing the selection pressure, the less-fit, resistant individuals will be removed over time and susceptibility should return to the population.
- Apply the recommended label dose rate during the proper timing to ensure complete control of the pest species. By allowing the fewest insects to survive, the spread of the resistant insects will be slowed.
- Follow good application techniques in order to maximize the product activity; deficient applications at less than the recommended label rate will allow the surviving insects to build up the population again, increasing the pest pressure against the product, which may trigger resistance problems in the future.
- Establish a baseline and monitor levels of effectiveness on populations in key areas in order to detect any significant changes in susceptibility to active substance. Information from resistance monitoring programs allows early detection of problems and gives information for correct decision making.
- The users should inform if the treatment is ineffective and report straightforward to the authorization holder. The authorization holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management.

2.1.4.2 Use-specific risk mitigation measures

Professional operators: Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).

A protective coverall (at least type 6, EN 13034) shall be worn.

Allow the applied solution to dry before re-entry into the treated areas by either humans or animals.

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

Do not contaminate foodstuffs, eating utensils or food contact surfaces.

Do not apply to areas susceptible to routine wet cleaning.

Only for application in animal housing authorised.

The product should be applied away from animals' and **'DO NOT apply directly to animals'**

Do not use in animal housings where exposure to a STP and/ or direct emission to surface water cannot be prevented.

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

This product contains a mixture of isothiazolinones!

Likely direct or indirect effects

- May induce an allergic reaction.

First aid Instructions:

- In case of skin contact wash the affected area with plenty of water without scrubbing. If skin irritation/sensitization occurs, persist or intensifies seek medical advice.
- In case of eye exposure; check for and remove contact lenses, wash eyes with plenty of water maintaining eye lids open for at least 15 minutes.
- Inhalation, keep the individual calm and at rest in half-sitting position, conserve body temperature and control breathing. If necessary provide artificial respiration.
- In case of ingestion wash mouth with plenty of water, do NOT induce vomiting and do NOT give anything by mouth to an unconscious individual. If you experience severe abdominal pain or feel unwell seek medical advice.
- If necessary take the affected individual to a healthcare center and bring packaging or label whenever possible.

NEVER LEAVE AN AFFECTED INDIVIDUAL UNATTENDED!

Advice for medical and healthcare personnel:

- Provide symptomatic and supportive treatment.

WHEN ASKING FOR MEDICAL ADVICE KEEP PACKAGING OR LABEL AT HAND AND CALL YOUR LOCAL POISON CONTROL CENTER [*INSERT LOCAL NUMBER HERE*].

Other cautions:

Use personal protective clothing.

Do not breathe vapour/spray.

Avoid contact with the skin, eyes and clothing.

If medical advice is needed, have product container or label at hand.

Keep out of the reach of children.

Keep away from food, drink and animal feeding stuffs.

When using do not eat, drink or smoke.

Avoid release to the environment.
Collect spillage.

Avoid prolonged contact of pets, particularly cats, to treated surfaces.

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

Empty containers, unused product and other waste generated during the treatment are considered hazardous waste. Eliminate those wastes in accordance with current regulations.
Do not throw on unpaved floors, in watercourses, in the sink or in the drain

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

2.1.4.5 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

Read the label before use.

Strategies for managing the development of resistance:

- Where possible, application treatments should be recommended to be combined with non-chemical measures.
- To avoid the potential for insect resistance to the product, treatments should be alternated with insecticidal products having different modes of action.
- If resistance is confirmed, stop the use of the product immediately and rotate to an insecticide with alternative mode of action. By removing the selection pressure, the less-fit, resistant individuals will be removed over time and susceptibility should return to the population.
- Apply the recommended label dose rate during the proper timing to ensure complete control of the pest species. By allowing the fewest insects to survive, the spread of the resistant insects will be slowed.
- Follow good application techniques in order to maximize the product activity; deficient applications at less than the recommended label rate will allow the surviving insects to build up the population again, increasing the pest pressure against the product, which may trigger resistance problems in the future.
- Establish a baseline and monitor levels of effectiveness on populations in key areas in order to detect any significant changes in susceptibility to active substance. Information from resistance monitoring programs allows early detection of problems and gives information for correct decision making.
- The users should inform if the treatment is ineffective and report straightforward to the authorization holder. The authorization holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management.

2.1.5.2 Risk mitigation measures

Please refer to chapter 2.1.4.3 and 2.1.4.8.

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

Please refer to chapter 2.1.4.4 and 2.1.4.9.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Please refer to chapter 2.1.4.5 and 2.1.4.10.

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

Ensure thorough ventilation of stores and work areas.
Keep only in the original container.

Keep container tightly closed.
Keep in a safe place.

Shelf-life: The product remains stable for 3 years when stored in its original, unopened container under cool, dry and well-ventilated conditions.

2.1.6 Other information

The product contains: Alpha-cypermethrin. May cause paraesthesia

Application codes:
- main target organisms I3 (3.1.1, 3.3.1, 4.2, 8.1, 10.3, 11, 12.1*, 12.5, 12.6, 13.1).

*error in guidance: same code for moths and mosquitoes
- Developmental stages of target organisms to be controlled: II.1.5
- Mode of action: III1.3, III.2.2, III.4.2
- Field of use: IV.1.3.1-1.3.4
- User category: V.1, V.2
- Method of application: VI.1.1
- Application aim: VII.3

Type of formulation: VIII.3.1.1

Major change application

A new use has been included with this major change application: Use # 1 - Urban Pest Control (Large / Industrial / Commercial Buildings) – Professional.

2.1.6.1 Authorised use(s)

2.1.6.1.1 Use description: Use # 1 – Urban Pest Control (Large / Industrial / Commercial Buildings) – Professional

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Insecticide
Target organism (including development stage)	German cockroaches (*Blattella germanica*), nymphs and adults; ants (*Lasius niger*), adults; bedbugs *(Cimex lectularius)*, nymphs and adults. Flying insects, including houseflies *(Musca domestica)*, adults; mosquitoes (*Culex spp.*), adults; and wasps *(Vespula spp.)*, adults.
Field of use	Indoors, in large buildings / industrial / commercial premises. The product is a liquid concentrate used as a crack & crevice, and /or spot application.
Application method(s)	It is applied using any conventional manual or power sprayer equipped to produce a coarse spray at low pressure. The appropriate volume of the product is added to the required volume of clean water and agitated. If a delay occurs between treatments, re-agitation is needed before re-use. For German cockroaches, ants and bedbugs, the product should be applied throughout the infested area as a coarse spray to cracks & crevices, and/or onto targeted spots or areas where insects may crawl and hide. For flying insects, the product should be only applied to the infested area as a coarse spray onto targeted spots or areas where insects may settle and not as a broad surface spray.
Application rate(s) and frequency	

6 SC (mL)	*Water volume for dilution (L)*	*Surface area treated (m2)*
25	*5*	*100*
12.5	*2.5*	*50*
5	*1*	*20*
2.5	*0.5*	*10*
1.25	*0.25*	*5*

	For example, for treating 20 m^2 surface area, 5 ml product is diluted in 1 litre water (1:200 dilution; spray concentration: 0.5% v/v). Residual Activity: The residual life of the deposit will vary depending upon the cleanliness and nature of the surface to which it is applied, and the extent to which the residue remains undisturbed. The product exhibits sustained residual activity, where residues remain undisturbed, for up to 1 month against ants (*Lasius niger*) and for up to 3 months against bedbugs (*Cimex lectularius*). Activity against German cockroaches is achieved only with fresh deposits. Activity against mosquitoes (*Culex spp.)* is achieved only with fresh deposits on non-porous surfaces (not on porous surfaces). Residual activity against houseflies (*Musca domestica*) is up to 3 months. Residual activity against wasps (*Vespula* spp.) is achieved only on non-porous surfaces (not on porous surfaces) for up to 3 months. Frequency: 1 – 2 applications per year.
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE, 0.5, 1 and 5L

2.1.6.1.2 Use-specific instructions for use

-

2.1.6.1.3 Use-specific risk mitigation measures

Must not be used for the treatment in private households.
For other general risk mitigation measures, please refer to Section 2.1.6.2.2 in Chapter 2.1.6.2 (General directions for use).

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

Please refer to Section 2.1.6.2.3 in Chapter 2.1.6.2 (General directions for use).

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

- Please refer to Section 2.1.6.2.4 in Chapter 2.1.6.2 (General directions for use).

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

-Please refer to Section 2.1.6.2.5 in Chapter 2.1.6.2 (General directions for use).

2.1.6.2 General directions for use

2.1.6.2.1 Instructions for use

Read the label before use.

- Estimate the surface area that needs to be treated.
- Prepare the spray solution by adding the appropriate volume of Fendona 6 SC to the required volume of clean water and agitate.
- **For professional users**, the appropriate volume of the product is measured using the Bettix dispensing product container or a standard dosing device.
- When empty, triple rinse the container and use the rinsate to make up the spray solution for application.
- The appropriate volume of the product is measured using the dosing device according to the table above (see Application rates & frequency).
- Apply using any conventional manual or power sprayer equipped to produce a coarse spray at low pressure.
- If a delay occurs between treatments, re-agitate before re-use.

Following application, insects that have contacted the deposit should show signs of knockdown within 30 – 60 minutes with noticeable impact on population numbers expected within a few days.

Mortality of German cockroaches is achieved 1 week after exposure of the insects to the treated surfaces.
Noticeable knockdown effect on bedbugs is expected within 24 h after contact with treated surfaces and mortality is achieved 1 week after exposure.

Mortality of mosquitoes (*Culex spp.)* is achieved between 2 and 4 days after exposure of the insects to the treated surfaces.
Noticeable knockdown effect on houseflies is expected within 6 hours after contact with the treated surfaces and mortality is achieved 24-72 hours after exposure.
Noticeable knockdown effect on wasps is expected within 6 hours after contact of the insects with non-porous treated surfaces and mortality is achieved at 24 hours.
Treated areas should be re-inspected after 2– 3 weeks. Where initial infestation was severe or new infestation is observed, a second application may be required particularly if the first treatment has been disturbed or some harbourages/landing sites were missed in the initial application. For the control of bedbugs 1 re-application is required.

Allow the applied solution to dry before re-entry into the treated areas by either humans or animals.

Strategies for managing the development of resistance:

- Where possible, application treatments should be recommended to be combined with non-chemical measures.
- To avoid the potential for insect resistance to the product, treatments should be alternated with insecticidal products having different modes of action.
- If resistance is confirmed, stop the use of the product immediately and rotate to an insecticide with alternative mode of action. By removing the selection pressure, the less-fit, resistant individuals will be removed over time and susceptibility should return to the population.
- Apply the recommended label dose rate during the proper timing to ensure complete control of the pest species. By allowing the fewest insects to survive, the spread of the resistant insects will be slowed.
- Follow good application techniques in order to maximize the product activity; deficient applications at less than the recommended label rate will allow the surviving insects to build up the population again, increasing the pest pressure against the product, which may trigger resistance problems in the future.
- Establish a baseline and monitor levels of effectiveness on populations in key areas in order to detect any significant changes in susceptibility to active substance. Information from resistance monitoring programs allows early detection of problems and gives information for correct decision making.
- The users should inform if the treatment is ineffective and report straightforward to the authorization holder. The authorization holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management.

2.1.6.2.2 Risk mitigation measures

Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information). A protective coverall (at least type 6, EN 13034) shall be worn.

Allow the applied solution to dry before re-entry into the treated areas by either humans or animals.
Do not use directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and animals.
Do not contaminate foodstuffs, eating utensils or food contact surfaces.
Do not apply to areas susceptible to routine wet cleaning.
In the case of bed bugs, do not use on regularly washed surfaces and textiles.

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

This product contains a mixture of isothiazolinones!
Likely direct or indirect effects

- May induce an allergic reaction.

First aid Instructions:

- In case of skin contact wash the affected area with plenty of water without scrubbing. If

skin irritation/sensitization occurs, persist or intensifies seek medical advice.
- In case of eye exposure; check for and remove contact lenses, wash eyes with plenty of water maintaining eye lids open for at least 15 minutes.
- Inhalation, keep the individual calm and at rest in half-sitting position, conserve body temperature and control breathing. If necessary, provide artificial respiration.
- In case of ingestion wash mouth with plenty of water, do NOT induce vomiting and do NOT give anything by mouth to an unconscious individual. If you experience severe abdominal pain or feel unwell seek medical advice.
- If necessary, take the affected individual to a healthcare center and bring packaging or label whenever possible.

NEVER LEAVE AN AFFECTED INDIVIDUAL UNATTENDED!

Advice for medical and healthcare personnel:

- Provide symptomatic and supportive treatment.

WHEN ASKING FOR MEDICAL ADVICE KEEP PACKAGING OR LABEL AT HAND AND CALL YOUR LOCAL POISON CONTROL CENTER [*INSERT LOCAL NUMBER HERE*].

Other cautions:
Use personal protective clothing.
Do not breathe vapour/spray.
Avoid contact with the skin, eyes and clothing.
If medical advice is needed, have product container or label at hand.
Keep out of the reach of children.
Keep away from food, drink and animal feeding stuffs.
When using do not eat, drink or smoke.
Avoid release to the environment.
Collect spillage.
Avoid prolonged contact of pets, particularly cats, to treated surfaces.

2.1.6.2.4 Instructions for safe disposal of the product and its packaging

Empty containers, unused product and other waste generated during the treatment are considered hazardous waste. Eliminate this waste in accordance with current regulations. Do not throw on unpaved floors, in watercourses, in the sink or in the drain.

Dispose of contents/container in accordance with local regulations.

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

Ensure thorough ventilation of stores and work areas.
Keep only in the original container.
Keep container tightly closed.
Keep in a safe place.

Shelf-life: The product remains stable for 3 years when stored in its original, unopened container under cool, dry and well-ventilated conditions.

2.1.6.2.6 Other information

The product contains: Alpha-cypermethrin. May cause paraesthesia

Application codes:
- main target organisms I3 (3.1.1, 3.3.1, 4.2, 8.1, 10.3, 11, 12.1*, 12.5, 12.6, 13.1).

*error in guidance: same code for moths and mosquitoes
- Developmental stages of target organisms to be controlled: II.1.5
- Mode of action: III1.3, III.2.2, III.4.2
- Field of use: IV.1.3.1-1.3.4
- User category: V.1, V.2
- Method of application: VI.1.1
- Application aim: VII.3

Type of formulation: VIII.3.1.1

2.1.7 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
Bottle or Bettix container or Jerry can	0.05, 0.1, 0.5, 1 and 5L	Blow moulded high-density polyethylene containers (HDPE)	Sealed by either a foil seals or a polyamide laminated PE-foam gasket, screw cap: polyethylene	Professional and non-professional	Yes

Major change application

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
Bottle or Bettix container or Jerry can	0.5, 1 and 5 litre	Blow moulded high-density polyethylene containers (HDPE)	Sealed by either a foil seals or a polyamide laminated PE-foam gasket, screw cap: polyethylene	Professional	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

New studies on the product have been submitted for the application for product authorisation of Fendona 6 SC. Core data such as efficacy effects, physico-chemical properties, storage stability and the analytical method of determination of the a.s. in the biocidal product have been investigated.

Further studies on acute toxicity, eye and skin irritation, dermal absorption and metabolism in livestock have been submitted.

[redacted]

Complete information details on the references are given at the end of the document in the list of studies of section 3.1.

Major change application

In this major change application one additional efficacy report has been submitted to support Use 1 (Urban Pest Control) species claims.

Furthermore, the risk assessment has been updated and is no longer refined with the tests performed with *Chironomus riparius* (as stated above). Instead, these studies, using Fendona 6 SC and Fendona 1.5 SC as test item, are included only to indicate the effects of the biocidal products under more realistic conditions compared to the study with the active substance.

2.1.8.2 Access to documentation

The applicant is part of BASF, who are the data owner of the active substance dossier that supported the approval of alpha-cypermethrin for use as a Product Type 18. Therefore, no letter of access is required.

2.2 Assessment of the biocidal product

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

Table 1. Intended use # 1 – Urban pest control (Large/Industrial/Commercial Buildings)

Product Type(s)	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	The product is a liquid concentrate used as a crack & crevice, and/or spot application indoors. The product is intended for control of crawling and flying insects. For crawling insects it is applied as a coarse spray to cracks & crevices, and/or onto targeted spots or areas where insects may crawl and hide. For flying insects it is applied as a coarse spray onto targeted spots or areas where insects may settle. The product contains 6.27% w/w of the active substance alpha-cypermethrin (TGAI).
Target organism (including development stage)	Crawling insects, including cockroaches (*Blattella germanica*, *Blatta orientalis*, *Periplaneta americana*), ants (*Lasius niger*), bedbugs *(Cimex lectularius),* and fleas *(Ctenocephalides felis).* Flying insects, including houseflies (*Musca domestica*)*,* mosquitoes (*Aedes aegypti, Culex spp*), and wasps *(Vespula spp).*
Field of use	Indoors, in large buildings/ industrial/ commercial premises, Domestic/Households/Private Areas
Application method(s)	Apply using any conventional manual or power sprayer equipped to produce a coarse spray at low pressure. Add the appropriate volume of Fendona 6 SC to the required volume of clean water and agitate. If a delay occurs between treatments, re-agitate before re-use. For crawling insects it is applied as a coarse spray to cracks & crevices, and/or onto targeted spots or areas where insects may crawl and hide. For flying insects it is applied as a coarse spray onto targeted spots or areas where insects may settle.
Application rate(s) and frequency	5 mL product is diluted in 1 L water (1:200; spray concentration:0.5% v/v) and apply the diluted product per 20 m² surface area. Frequency: 3-11 applications per year.
Category(ies) of user(s)	Professional operators (Pest Control Operator)
Pack sizes and packaging material	HDPE, 0.05 to 5 L bottles. Please refer to relevant section (2.1.7).

Table 2. Intended use # 2 – Rural hygiene (Animal Houses/Shelters)

Product Type(s)	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)

Where relevant, an exact description of the authorised use	The product is a liquid concentrate used as a spray application indoors. The product is intended for curative and control treatment. It is applied as a coarse spray for surface treatment, especially to cracks, crevices and any place where insects may hide and on surfaces over which they may crawl or settle. The product contains 6.27% w/w of the active substance alpha-cypermethrin (TGAI).
Target organism (including development stage)	Crawling insects, including cockroaches (*Blattella germanica*, *Blatta orientalis*, *Periplaneta americana*), ants (*Lasius niger*) and litter beetles *(Alphitobius diaperinus*) . Flying insects, including stable flies *(Stomoxys calcitrans)* , houseflies *(Musca domestica),*mosquitoes *(Aedes aegypti and Culex spp)* and wasps *(Vespula spp).*
Field of use	Indoors, in animal houses/ shelters including dairy cattle, piggeries, stables, poultry houses and similar places where high levels of hygiene are required.
Application method(s)	It is applied using any conventional manual or power sprayer equipped to produce a coarse spray at low pressure. The appropriate volume of the product is added to the required volume of clean water and agitated. If a delay occurs between treatments, re-agitation is needed before re-use. The product should be applied throughout the infested area as a coarse spray for surface treatment, especially to cracks, crevices and any place where insects may hide and on surfaces over which they may crawl or settle.
Application rate(s) and frequency	Low rate: 5 mL product is diluted in 1 L water (1:200; spray concentration: 0.5% v/v). 1 L of diluted product is applied per 20 m² surface area. High rate: 10 mL product is diluted in 1 L water (1:100; spray concentration: 1% v/v). 1L of diluted product is applied per 20 m² surface area. Frequency: up to 6 applications per year [**4 applications for animal (sub)categories**: Laying hen, battery cages without treatment, Laying hen, battery cages with forced drying, Laying hen, compact battery cages, Laying hen, free range with grating floor, parent broiler >18 weeks, free range with grating floor, parent broiler in rearing, free range with grating floor, **6 applications for animal (sub)categories**: Dairy cow, Beef, Veal Calf, Sow, individual pens, sows in groups, Fattening pig
Category(ies) of user(s)	Non-professional and professional (depending on the Member State's definition of professional in this use area description)
Pack sizes and packaging material	HDPE, 0.05 to 5 L bottles. Please refer to relevant section (2.1.7)

Major change application – Intended uses as applied for by applicant

In this major change application, there has been refinement to the species claimed compared to the initial application, which is reflected in the following two tables. The following Intended Use table also reflects the initial authorisation conditions.

Intended Use # 1 – Urban pest control (Large/Industrial/Commercial Buildings) – Professional

<table>
<tr><td>Product Type(s)</td><td>PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)</td></tr>
<tr><td>Where relevant, an exact description of the authorised use</td><td>Insecticide</td></tr>
<tr><td>Target organism (including development stage)</td><td>Crawling insects: German cockroaches (Blattella germanica), nymphs and adults; ants (Lasius niger), adults; bedbugs (Cimex lectularius), nymphs and adults.

Flying insects, including houseflies (Musca domestica), adults; mosquitoes (Culex spp.), adults; and wasps (Vespula spp.), adults.</td></tr>
<tr><td>Field of use</td><td>Indoors, in large buildings / industrial / commercial premises.

The product is a liquid concentrate used as a crack & crevice, and /or spot application for the control of crawling and flying insects.</td></tr>
<tr><td>Application method(s)</td><td>It is applied using any conventional manual or power sprayer equipped to produce a coarse spray at low pressure. The appropriate volume of the product is added to the required volume of clean water and agitated. If a delay occurs between treatments, re-agitation is needed before re-use.

For crawling insects, the product should be applied throughout the infested area as a coarse spray to cracks & crevices, and/or onto targeted spots or areas where insects may crawl and hide.

For flying insects, the product should be applied throughout the infested area as a coarse spray onto targeted spots or areas where insects may settle.</td></tr>
<tr><td>Application rate(s) and frequency</td><td>
<table>
<tr><th>6 SC (mL)</th><th>Water volume for dilution (L)</th><th>Surface area treated (m2)</th></tr>
<tr><td>25</td><td>5</td><td>100</td></tr>
<tr><td>12.5</td><td>2.5</td><td>50</td></tr>
<tr><td>5</td><td>1</td><td>20</td></tr>
<tr><td>2.5</td><td>0.5</td><td>10</td></tr>
<tr><td>1.25</td><td>0.25</td><td>5</td></tr>
</table>
For example, for treating 20 m^2 surface area, 5 ml product is diluted in 1 litre water (1:200 dilution; spray concentration: 0.5% v/v).

<u>Residual Activity:</u> The residual life of the deposit will vary depending upon the cleanliness and nature of the surface to which it is applied, and the extent to which the residue remains undisturbed.</td></tr>
</table>

	Against crawling insects the product exhibits sustained residual activity, up to 1 month, where residues remain undisturbed, against ants (*Lasius niger*) and up to 2 month on non-porous surfaces against German cockroaches (*Blattella germanica*). Residual activity against bedbugs (*Cimex lectularius*) is up to 3 months. Against flying insects the product is efficacious against mosquitoes (*Culex spp.) with fresh residues on non-porous surfaces,* wasps *(Vespula spp.)* with fresh deposits and for up to 3 months on non-porous surfaces and house flies *(Musca domestica)* for up to 3, when residues remain undisturbed. Frequency: 1 – 2 applications per year.
Category(ies) of user(s)	Professional
Pack sizes and packaging material	HDPE, 0.5, 1 and 5 L. Please refer to relevant section (2.1.7).

2.2.2 Physical, chemical and technical properties

Tested with the minimum and maximum use concentration rate of 0.5 % - 1.0 % (v/v).

Property	Guideline and Method	Purity of the test substance	Results	Reference
Physical state at 20	Visual examination	60 g/L	Liquid suspension No sedimentation was observed before and after storage	Kaestel, 2004, 2003/1018855

Property	Guideline and Method	Purity of the test substance	Results	Reference
°C and 101.3 kPa			(before and after 14 d/54°C, after 2 yr/30°C storage)	Randt, 2005, 2005/1026465
Colour at 20 °C and 101.3 kPa	Visual examination	60 g/L	White (before and after 14 d/54°C, after 2 yr/30°C storage)	Kaestel, 2004, 2003/1018855 Randt, 2005, 2005/1026465
Odour at 20 °C and 101.3 kPa	Olfactory examination	60 g/L	Faint aromatic	Kaestel, 2004, 2003/1018855
Acidity / alkalinity	CIPAC MT 75	60 g/L	Before and after 14 d/54°C storage: At room temperature: pH 7.5, undiluted; pH 6.9 (6.8), conc. 0.5% in CIPAC water D pH 7.0 (6.9), conc. 1.0% in CIPAC water D Before (after) 2 yr/30°C storage: pH undiluted: 7.5 (7.1) pH 6.9 (6.7), conc. 0.5% in CIPAC water D pH 7.0 (6.8), conc. 1.0% in CIPAC water D	Kaestel, 2004, 2003/1018855 Randt, 2005, 2005/1026465
Relative density / bulk density	OECD 109 EU A.3	60 g/L	Before and after 14 d/54°C storage: Relative density: 1.03 at 20 °C Bulk density: not applicable Before (after) 2 yr/30°C storage: Relative density: 1.03 at 20 °C Bulk density: not applicable Relative density: 1.03 at 40 °C	Kaestel, 2004, 2003/1018855 Randt, 2005, 2005/1026465 Kroehl, 2015, 2015/1169392
Storage stability test – **accelerated storage**	CIPAC MT 46.3 CIPAC Method: Alpha-cypermenthrin 454	60 g/L	More than 95% of active ingredient are left after accelerated storage of 2 weeks at 54 °C. The product is considered to be stable. Active substance concentration: 61.01/61.39 g/L before/after storage.	Kaestel, 2004, 2003/1018855

Property	Guideline and Method	Purity of the test substance	Results	Reference
			More than 95% of active ingredient are left after accelerated storage of 2 weeks at 54 °C in original container (HDPE). The product is considered to be stable. Active substance concentration: 5.86%/5.94% before/after storage.	Kroehl, 2015, 2015/1169392
Storage stability test – **long term storage at ambient temperature**	3 year study at 23 °C CIPAC Method: Alpha-cypermenthrin 454	Concentration of active ingredient: ca. 15 g/L (bridging from a similar product)	Appearance: Liquid suspension No sedimentation was observed before and after storage White Odourless (before and after 3 yr/23°C storage) pH: At room temperature: pH 7.3 (6.8), undiluted; pH 6.6-6.9 (6.5 -6.7), conc. 1%; pH 6.9-7.2 (6.6-6.9), conc. 4%. Active substance concentration: 15.0/15.1 g/L before/after storage. No corrosion and no other influence of the product on the original container (HDPE, 1L and 250 mL) was observed. Weight change over the storage period was negligible (- 0.07 %). Suspensibility (GC Chromatography): 1 % (v/v) in CIPAC water D: 98 % / 95 % 4 % (v/v) in CIPAC water D: 99 % / 98 % Spontaneity of dispersion: 1 % (v/v) in CIPAC water D: 93 % / 97 4 % (v/v) in CIPAC water D: 96 % / 94 % Wet sieve:	Kroehl, 2012, 2011/1269168

Property	Guideline and Method	Purity of the test substance	Results	Reference
			0.00 % (w/w) retention on a 75 µm sieve before and after storage Particle size distribution: D(50%) = 1.9 (1.9) µm D(10%) = 0.7 (0.8) µm D(90%) = 5.8 (6.2) µm (before and after 3 yr/23°C storage) Persistence foaming: 1.0 % in CIPAC water D: 20 mL / 20 mL 4 % in CIPAc water D: 28 mL / 32 mL (before and after 3 yr/23°C storage) Pourability: Initial 2.87 % / 0.34 % / 0.18 % After shelf life storage (3 yr/23°C) 2.75 % / 0.29 % / 0.20 %	
	2 year study at 30°C CIPAC Method: Alpha-cyperment hrin 454	60 g/L	Stable at 30°C for 2 years. Active substance concentration: 61.0/61.6 g/L before/after storage. No corrosion and no other influence of the product on the original container (HDPE, 1L and 250 mL) was observed. Weight change over the storage period was negligible (-1.0 %).	Randt, 2005, 2005/1026465 Siebecker,2017, 2017/1099849
Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3	60 g/L	After 7 days at 0 °C, the sample was homogeneous and no separated material was observed. After 7 days at 0 °C sample was homogeneous and no separated material was observed.	Kaestel, 2004, 2003/1018855 Kroehl, 2015, 2015/1204787
Effects on content of the active substance and technical characteristic	-	-	Not applicable as the packaging is light-proof. Therefore, the formulation is not exposed to light during storage.	-

Property	Guideline and Method	Purity of the test substance	Results	Reference
s of the biocidal product - **light**				
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	-	-	Not applicable because according to the label instructions the biocidal product has to be kept in original container, tightly closed, in a safe place. It has to be stored in a cool, dry and well vendilated place.	-
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	Accelerated storage, long term ambient storage, low temperature storage as described above	60 g/L	Before and after 14 d/54°C storage: No significant changes of packaging stability occurred during the tests. No influence of the product on the original container (HDPE) was observed after 2 weeks storage at 54°C and 7 days at 0°C. Weight change over the storage period was negligible (0.04 %). No corrosion and no other influence of the product on the original container (HDPE, 1L and 250 mL) was observed after 2 year storage at 30°C. Weight change over the storage period was negligible (-1.0 %).	Kaestel, 2004, 2003/1018855 Kroehl, 2015, 2015/1204787 Randt, 2005, 2005/1026465 Siebecker,2017, 2017/1099849
Wettability	–	–	Not applicable as the biocidal product is a liquid.	–

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance</th><th>Results</th><th>Reference</th></tr>
<tr><td>Suspensibility, spontaneity and dispersion stability</td><td>CIPAC MT 184
CIPAC MT 160</td><td>60 g/L</td><td><u>Initial/after 14 d/ 54°C storage /after 7 d/0°C storage</u>

Suspensibility: all results between 94-101%.
Spontenaeity:
all results acceptable as between 95-99%.

Suspensibility:
0.5 % (v/v) in CIPAC water D:
<table><tr><td>Initial</td><td>100 %</td></tr><tr><td>7d at 0°C</td><td>101 %</td></tr><tr><td>2w at 54°C</td><td>94 %</td></tr></table>
Suspensibility:
1.0 % (v/v) in CIPAC water D:
<table><tr><td>Initial</td><td>97 %</td></tr><tr><td>7d at 0°C</td><td>99 %</td></tr><tr><td>2w at 54°C</td><td>99 %</td></tr></table>
Suspensibility:
0.1 % (v/v) in CIPAC water D:
<table><tr><td>Initial</td><td>95 %</td></tr><tr><td>7d at 0°C</td><td>96 %</td></tr><tr><td>2w at 54°C</td><td>95 %</td></tr></table>
Spontaneity of dispersion:
0.5 % (v/v) in CIPAC water D:
<table><tr><td>Initial</td><td>98 %</td></tr><tr><td>2w at 54°C</td><td>95 %</td></tr></table>
Spontaneity of dispersion:
1.0 % (v/v) in CIPAC water D:
<table><tr><td>Initial</td><td>96 %</td></tr><tr><td>2w at 54°C</td><td>99 %</td></tr></table>
<u>2 years at 30°C storage:</u>

Suspensibility:
0.5 % (v/v) in CIPAC water D:
<table><tr><td>Initial</td><td>100 %</td></tr><tr><td>2y at 30°C</td><td>94 %</td></tr></table>
Suspensibility:
1.0 % (v/v) in CIPAC water D:
<table><tr><td>Initial</td><td>97 %</td></tr><tr><td>2y at 30°C</td><td>88 %</td></tr></table></td><td>Kaestel, 2004, 2003/1018855

Kroehl, 2015, 2015/1204787

Randt, 2005, 2005/1026465</td></tr>
</table>

Property	Guideline and Method	Purity of the test substance	Results	Reference
			Spontaneity of dispersion: 0.5 % (v/v) in CIPAC water D: Initial 98 % 2y at 30°C 89 % Spontaneity of dispersion: 1.0 % (v/v) in CIPAC water D: Initial 96 % 2y at 30°C 96 %	
Wet sieve analysis and dry sieve test	CIPAC MT 185	60 g/L	Initial/after 14 d/ 54°C storage /after 7 d/0°C storage: No wet sieve retentions observed, no evidence of a significant increase in particle size. 2 years at 30°C storage: Initial: 0.00 % (w/w) retention on a 75 µm sieve After 2 years at 30°C: 0.10 % (w/w) retention on a 75 µm sieve	Kaestel, 2004, 2003/1018855 Randt, 2005, 2005/1026465
Emulsifiability, re-emulsifiability and emulsion stability	–	–	Not applicable, the formulation is not an emulsifiable concentrate.	–
Disintegration time	–	–	Not applicable, the formulation is a liquid.	–
Particle size distribution, content of dust/fines, attrition, friability	CIPAC MT 187	60 g/L	D(v, 0.5) = 2.3 µm. 2 years at 30°C storage: Initial: D(10%) = 0.77 D(50%) = 2.28 D(90%) = 6.03 After 2 years storage at 30°C: D(10%) = 0.77 D(50%) = 2.21	Kaestel, 2004, 2003/1018855 Randt, 2005, 2005/1026465

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance</th><th>Results</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>D(90%) = 5.49</td><td></td></tr>
<tr><td>Persistent foaming</td><td>CIPAC MT 47.2
ASTM D 1173/53</td><td>60 g/L</td><td>Volume of foam:
all results between 2-26 ml after 1 min.

Foam after 1 min. in CIPAC Water D, concentration 0.5%:
Initial: 16 mL
After storage: 18 mL

Foam after 1 min. in CIPAC Water D, concentration 1.0%:
Initial: 32 mL
After storage: 34 mL

Foam after 1 min. in CIPAC Water D, concentration 0.1%:
Initial: 12 mL
After storage: 2 mL

<u>After 2 years storage at 30°C:</u>

Foam after 1 min. in CIPAC Water D, concentration 0.5%:
Initial: 16 mL
After storage: 18 mL

Foam after 1 min. in CIPAC Water D, concentration 1.0%:
Initial: 32 mL
After storage: 34 mL</td><td>Kaestel, 2004, 2003/1018855

Kroehl, 2015, 2015/1204787

Randt, 2005, 2005/1026465</td></tr>
<tr><td>Flowability/ Pourability/ Dustability</td><td>CIPAC MT 148</td><td>60 g/L</td><td><u>Initial/after 14 d/ 54°C storage</u>
Results after pouring: 3.1% and 2.9%; results after rinsing: 0.3% and 0.8%. Flowability and dustability not applicable as formulation is a liquid.

<u>After 2 years storage at 30°C:</u>

<table><tr><td></td><td>Initial</td><td>After storage</td></tr><tr><td>Residue</td><td>3.1%</td><td>3.3%</td></tr><tr><td>Rinsed residue 1</td><td>0.8%</td><td>0.32%</td></tr><tr><td>Rinsed residue 2</td><td>-</td><td>0.19%</td></tr></table></td><td>Kaestel, 2004, 2003/1018855

Randt, 2005, 2005/1026465</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance</th><th>Results</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>The standard approach recommends a triple-rinse step to avoid residue remainings in the commercial packs.</td><td></td></tr>
<tr><td>Burning rate — smoke generators</td><td>–</td><td>–</td><td>Not applicable, the formulaton is not a smoke generator.</td><td>–</td></tr>
<tr><td>Burning completeness — smoke generators</td><td>–</td><td>–</td><td>Not applicable, the formulaton is not a smoke generator.</td><td>–</td></tr>
<tr><td>Composition of smoke — smoke generators</td><td>–</td><td>–</td><td>Not applicable, the formulaton is not a smoke generator.</td><td>–</td></tr>
<tr><td>Spraying pattern — aerosols</td><td>–</td><td>–</td><td>Not applicable, the formulation is not an aerosol.</td><td>–</td></tr>
<tr><td>Physical compatibility</td><td>–</td><td>–</td><td>Not applicable as the biocidal product is not intended to be used with other products.</td><td>–</td></tr>
<tr><td>Chemical compatibility</td><td>–</td><td>–</td><td>Not applicable as the biocidal product is not intended to be used with other products.</td><td>–</td></tr>
<tr><td>Degree of dissolution and dilution stability</td><td>–</td><td>–</td><td>Not applicable as the product is a liquid.</td><td>–</td></tr>
<tr><td>Surface tension</td><td>OECD 115
EU A.5</td><td>60 g/L</td><td>40.7 mN/m at 20 °C (conc. 0.5% and 1%, both).</td><td>Kaestel, 2004, 2003/1018855</td></tr>
<tr><td>Viscosity</td><td>OECD 114</td><td>60 g/L</td><td>At shear ratio 100 1/s and 20 °C:
28 mPa s (true viscosity)
101 mPa s (apparent viscosity)

After 2 years storage at 30°C:
<table><tr><th>Measurement temp. 20°C</th><th>Initial</th><th>After storage</th></tr><tr><td>Apparent viscosity [mPas] at D=10s^{-1}</td><td>617</td><td>606</td></tr><tr><td>Apparent [mPas] at D=20s^{-1}</td><td>-</td><td>344</td></tr><tr><td>Apparent [mPas] at D=100s^{-1}</td><td>101</td><td>102</td></tr></table></td><td>Kaestel, 2004, 2003/1018855

Randt, 2005, 2005/1026465

Siebecker,2017, 2017/1099849</td></tr>
</table>

Property	Guideline and Method	Purity of the test substance	Results	Reference
			Apparent [mPas] at D=400s^{-1}: 39 / 39 Flow behaviour: plastic / Plastic Measurement temp. 40°C: Initial Apparent viscosity [mPas] at D=10s^{-1}: 528 Apparent viscosity [mPas] at D=20s^{-1}: 317 Apparent viscosity [mPas] at D=100s^{-1}: 96 Apparent viscosity [mPas] at D=400s^{-1}: 34 Flow behaviour: Shear thinning Kin. Viscosity [mm²/s]: 94 no significant changes of respective values after storage are observed.	Kroehl, 2015, 2015/1204787

Note: MMAD data are not submitted since:
a) products are sold separately from the spraying cans, the spraying can is not part of the authorisation (apart from definition: low, medium or high pressure spraying device; hand pumping device or trigger sprays or automated sprayers)
b) it is not an input parameter in human exposure assessment. Human exposure to aerosols of liquid formulations is mainly driven by the pressure applied during the spraying action and of course by the viscosity and surface tension of the formulation. All this factors influence and determine the size of droplets. Therefore human exposure scenarios distinguish between high- medium- and low pressure spraying. Human exposure is based on an indicative value from a spraying model which comprises also inhalative exposure.
c) it is not relevant for efficacy assessment.

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

The physico-chemical properties of the biocidal product have been evaluated and are deemed acceptable for the appropriate use, storage and transportation of the biocidal product. The effect of light was not tested as the packaging is light proof.

Conditions of storage:
Ensure throrough ventilation of stores and work areas.
Keep only in the original container.
Keep container tightly closed.
Keep in a safe place.

Shelf-life: The product remains stable for 3 years when stored in its original, unopened container under cool, dry and well-ventilated conditions.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	EU A.14	BAS 31027I, Batch-no. 1051, 61 g/l. The study no. is SIK-Nr. 03/1	Not explosive.	Loeffler, 2003, 2003/1023335
Flammable gases	–	–	Not applicable. The biocidal product is not a gas.	–
Flammable aerosols	–	–	Not applicable. The biocidal product is not an aerosol.	–
Oxidising gases	–	–	Not applicable. The biocidal product is not a gas.	–
Gases under pressure	–	–	Not applicable.	–
Flammable liquids	EU A.9 (Pensky-Martens closed cup) DIN EN 22719	BAS 31027I, Batch-no. 1051, 61 g/l	No flash point under ca. 100 °C (boiling point) at ambient pressure.	Kaestel, 2004, 2003/1018855
Flammable solids	–	–	Not applicable. The biocidal product is not a solid.	–
Self-reactive substances and mixtures	–	–	There are no ingredients with explosive or self-reactive properties present in the biocidal product. Therefore the	–

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			formulation is not self-reactive.	
Pyrophoric liquids	–	–	The study does not need to be conducted as based on experience in handling and use and the chemical structure of product contents, pyrophoric properties are not to be expected.	–
Pyrophoric solids	–	–	Not applicable. The biocidal product is not a solid.	–
Self-heating substances and mixtures	–	–	The study does not need to be conducted as the biocidal product is liquid. A liquid shows not self-heating behaviour if it is not absorbed on a large surface.	–
Substances and mixtures which in contact with water emit flammable gases	–	–	The biocidal product contains water, therefore an emission of flammable gases is not expected when the preparation comes in contact with water.	–
Oxidising liquids	EU A.21	Concentration of active ingredient: ca. 15 g/L (bridging from a similar product)	Not oxidising. Based on the compositions of	Loehr, 2009, 2009/1046735

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>BAS 310 22 I and BAS 310 27 I (see confidential annex).

For further information see confidential annex

Alpha-cypermetrin is not oxidising</td><td>Helvoirt, 1991, AL-356-001
Note: this report was submitted as part of the active substance dossier, in Section A3.1.6/01 and so is not presented again.</td></tr>
<tr><td>Oxidising solids</td><td>–</td><td>–</td><td>Not applicable. The biocidal product is not a solid.</td><td>–</td></tr>
<tr><td>Organic peroxides</td><td>–</td><td>–</td><td>Not applicable. The biocidal product is not an organic peroxide.</td><td>–</td></tr>
<tr><td>Corrosive to metals</td><td>ASTM G31-72</td><td colspan="3">Test substance: BAS 310 27 1

Results:
<table>
<tr><td>Material</td><td>General Corrosion liquid / phase boundary liquid-vapor / vapor phase Corrosion rate in mm/year</td><td>Local Corrosion Local corrosion rate in mm/year</td></tr>
<tr><td>Carbon Steel St 37</td><td>0.019 / 0.036 / 0.110</td><td>No local corrosion</td></tr>
<tr><td>Al 7075-T6</td><td>n/a / n/a / n/a</td><td>No local corrosion</td></tr>
</table></td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
				n/a - not applicable, weight gain 0.004% / 0.001% / 0.018%
		In accordance with the United Nations scheme for the classification of corrosive substances of Class 8, Packing Group III is not assigned to BAS 310 27 1, DocID 2019/1000541, as the corrosion rate is not exceeding 6.25 mm/year. Reference: Titz, 2019, Report 219.1111 TBOl		
Auto-ignition temperatures of products (liquids and gases)	EC method A.15	BAS 31027I, Batch-no. 1051, 61 g/l.	425 °C at ambient pressure	Loeffler, 2003, 2003/1023335
Relative self-ignition temperature for solids	–	–	Not applicable. The biocidal product is not a solid.	–
Dust explosion hazard	–	–	Not applicable. The biocidal product is liquid unable to produce dust.	–

Conclusion on the physical hazards and respective characteristics of the product
The safety relevant physico-chemical properties of the biocidal product have been evaluated (Flash point, autoflammability, explosive and oxidising properties). The biocidal product is non-hazardous provided its appropriate use, storage and transportation.

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 (%)**	**Precision**	**Limit of quantification (LOQ) or other limits**	**Reference**
Alpha-Cypermethrin (CIPAC Method 454)	GC-FID	50, 100 and 150% of the formulation	Correlation coefficient R = 0.9999	No interfering signals and no co-elutions were observed in the	The recovery rates ranged from 98.8% to 99.7%, mean	The precision based on 5 calibration solutions each	-	Frohn and Singer, 2014, 2014/1298640

				retention time range of interest between 28.0-31.0 min for alpha-cypermethrin	value 99.3%.	double injected Mean value 99.45% %RSD: 0.49%		
Analytical methods for monitoring of residues in feeding stuff: milk, eggs, meat, liver, kidney, fat								
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**	**Precision**	**Limit of quantification (LOQ) or other limits**	**Reference**
Alpha-cypermethrin	LC-MS/MS	Fortifications levels at LOQ (≤0.01 mg/kg per peak) and at 10xLOQ, each with 5 replicates per level and matrix type	≥ 0.99.	Apparent residues or interferences in blank control specimens were below 20 % of the LOQ.	70 % to 110 % for all matrices	RSD ≤ 20 %.	≤0.01 mg/kg for all matrices	Class T.,Bendig P., 2014 [2013/1361967]
Alpha-cypermethrin	LC-MS/MS	fortification levels at LOQ (≤ 0.01 mg/kg per isomer) and at 10xLOQ.	≥ 0.99.	No significant interference above 30 % of LOQ	70 % to 110 % for all matrices	RSD %) for all fortification levels were ≤20%.	≤ 0.01 mg/kg in all matrices	Schernikau N., 2014 [2014/1145882]

Validation of the BASF Analytical Method L0231/01: Method for the Determination of Individual or Combined Diastereomeric Forms of BAS 311 I (Cis I, Cis II [alpha-cypermethrin, BAS 310I], Trans III and Trans IV) in Animal Matrices

Authors: Thomas Class and Paul BendigSummary of Validation Results

Fortification Levels	Fragment Ion (m/z)	Cis I		Cis II		Trans III		Trans IV	
mg/kg		433→ 191	435→ 193	433→ 191	435→ 193	433→ 191	435→ 193	433→ 191	435→ 193
Whole Milk									
0.010 and 0.1	Average	92%	91%	86%	89%	103%	94%	80%	82%
	RSD	4%	4%	3%	4%	3%	5%	5%	6%
	Replicates	10	10	10	10	10	10	10	10
Meat									
0.010 and 0.1	Average	77%	78%	76%	76%	86%	85%	75%	73%
	RSD	7%	6%	5%	5%	10%	10%	3%	3%
	Replicates	10	10	10	10	10	10	10	10
Kidney									
	Average	80%	81%	85%	83%	87%	89%	74%	75%

0.010 and 0.1	RSD	9%	7%	6%	6%	10%	11%	4%	3%
	Replicates	10	10	10	10	10	10	10	10
Liver									
0.010 and 0.1	Average	88%	90%	87%	88%	88%	90%	89%	89%
	RSD	14%	13%	13%	13%	15%	13%	13%	8%
	Replicates	10	10	10	10	10	10	10	10
Egg (QuEChERS)									
0.010 and 0.1	Average	79%	78%	84%	84%	83%	82%	92%	90%
	RSD	6%	6%	3%	4%	13%	12%	10%	12%
	Replicates	10	10	10	10	10	10	10	10
Fat (DFG S19)									
0.010 and 0.1	Average	83%	78%	99%	100%	89%	87%	99%	96%
	RSD	13%	14%	12%	13%	10%	12%	14%	13%
	Replicates	10	10	10	10	10	10	10	10

Independent Laboratory Validation of the BASF Analytical Method L0231/01: Method for the Determination of Individual or Combined Diastereomeric Forms of BAS 311 I (Cis I, Cis II [alpha-cypermethrin, BAS 310I], Trans III and Trans IV) in Animal Matrices
Author(s): Nina Schernikau

Fortification Levels	Fragment Ion (m/z)	Cis I		Cis II		Trans III		Trans IV	
mg/kg		433→ 191	435→ 193	433→ 191	435→ 193	433→ 191	435→ 193	433→ 191	435→ 193
Whole Milk									
0.010 and 0.1	Average	77%	80%	82%	79%	77%	80%	91%	91%
	RSD	4.6%	3.8%	4.9%	7.2%	5.3%	5.6%	13%	14%
	Replicates	10	10	10	10	10	10	10	10
Meat									
0.010 and 0.1	Average	78%	78%	77%	77%	78%	78%	76%	79%
	RSD	4.4%	5.1%	4.2%	3.7%	4.0%	5.5%	4.1%	9.7%
	Replicates	10	10	10	10	10	10	10	10
Kidney									
0.010 and 0.1	Average	83%	84%	82%	82%	84%	86%	73%	74%
	RSD	7.9%	7.5%	3.1%	7.2%	9.9%	8.7%	4.1%	5.8%
	Replicates	10	10	10	10	10	10	10	10
Liver									
0.010 and 0.1	Average	84%	83%	82%	83%	85%	83%	74%	74%
	RSD	4.5%	4.6%	3.1%	3.9%	5.3%	8.3%	5.1%	4.3%
	Replicates	10	10	10	10	10	10	10	10
Egg (QuEChERS with water)									
0.010 and 0.1	Average	86%	88%	85%	84%	91%	92%	86%	83%
	RSD	7.8%	7.4%	6.5%	5.9%	11%	9.7%	7.9%	7.8%
	Replicates	10	10	10	10	10	10	10	10
Fat (DFG S19)									
0.010 and 0.1	Average	94%	93%	95%	93%	97%	103%	80%	77%
	RSD	8.7%	8.7%	4.5%	7.0%	7.5%	6.1%	8.1%	6.2%
	Replicates	10	10	10	10	10	10	10	10

Analytical methods for the determination of active substance is acceptable. The method is CIPAC Method.

Residues in relevant environmental media (soil, air and water) were not submitted for the biocidal product, since this point is covered by the data set of the active substance alpha-cypermethrin.

Analytical methods for the determination of active substance residues in milk, eggs, meat, liver, kidney and fat has been submitted and considered acceptable and validated. The method is highly specific and a confirmatory method is not required, ILV has also been submitted. The method L0231/01 is therefore considered suitable to determine individual (Cis-1, Cis-2, Trans-3 and Trans-4) or combined cypermethrin diastereomers forms in animal matrices (milk, liver, kidney, muscle, egg and fat) with an LOQ of 0.01 mg/kg for the Cis-1 and Trans-3 isomers and 0.00695 mg/kg for Cis-2 and 0.00423 mg/kg for Trans-4. The method L0231/01 can be recommended for enforcement/monitoring purposes.
Additionally, transformation of alpha-Cypermethrin (Cis II) to its Cis I diastereomeric form was not significant in the extracts.

Conclusion on the methods for detection and identification of the product
All submitted methods are considered acceptable no further data are required.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

The product Fendona 6 SC is an insecticide (PT18) intended to be used indoors for rural hygiene (Animal Houses/Shelters) by professional and non-professional users. The product is applied throughout the infested area as a coarse spray for surface treatment. Special attention should be paid to cracks, crevices and any place where insects may hide and on surfaces over which they may crawl or settle.

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

In animal houses/shelters the product is efficacious against German cockroaches (*Blattella germanica*), ants (*Lasius niger*), mosquitoes *(Culex spp.)* and wasps *(Vespula spp)*.

2.2.5.3 Effects on target organisms, including unacceptable suffering

Alpha-cypermethrin is a synthetic pyrethroid. Intoxication results in a rapid "knockdown" and resultant mortality. The affected insect shows uncoordinated movements and finally dies. Following application, insects that have contacted the deposit should show signs of knockdown within 30 – 60 minutes with noticeable impact on population numbers expected within a few days.

In addition to the "knockdown" effect, Fendona 6 SC exhibits also sustained residual activity, depending on the target organism, up to 3 months, where residues remain undisturbed.

2.2.5.4 Mode of action, including time delay

As a synthetic pyrethroid alpha-cypermethrin does not depend on conversion or degradation to an active form in order to exert its insecticidal activity. It acts by preventing transmission of impulses along nerves on adult insects. This effect is brought about by blocking the passage of positive sodium ions through sodium channels in nerve membranes, thus preventing action potentials passing down axons.

2.2.5.5 Efficacy data

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: Efficacy**	**Reference**
Insecticide; Control of flying and crawling insects	indoor application, crack and crevice treatment	Fendona 6 SC	*Blattella germanica* (German cockroach) (Nymphs and adults)	Field trial	For details on Test system / concentrations applied / exposure **see the following row ***	For details on test results **see the following row marked with ****	Estany, D., 2016a; DocID# 2016_1091548 Study Code 15/166CC Estany, D., 2016b; DocID# 2016_1091543 Study Code 15/166EE with Addendum: DocID_2017_1119568 Estany 2016a not accepted study Estany 2016b accepted study

*** Field trials**:
Sites with an infestation of German cockroaches were located, separated from any other infestations. A pre-monitoring assessment was conducted to establish the infestation level at the sites. The number of cockroaches trapped was recorded over a period of 24 or 48 hours, at 2 days prior to application. The treatment was then applied at the site. A further set of monitoring traps were placed at the same location as for the pre-monitoring assessment, and assessed at weekly intervals for a total of 4 weeks post initial treatment application (6 weeks in only one site at the low dose). The number of any visible knocked down and dead cockroaches were assessed. Applications were done to cracks and crevices in the treatment areas by using a pressurised sprayerwand at a rate of 15 and 30 mg a.i./m^2, in 5L solution per 100 m^2. 3 replicates were conducted.
In the study by Estany 2016a (15 mg a.i./m^2), the site 1 had not been treated before, in the site 2 no additional insecticide treatments were applied 3 months previous to the Fendona 6 SC test treatment, and the Site 3 was previously treated with another insecticidal product (D-tetramethrin 0.23%, Cyphenothrin 0.18%, Pyriproxyfen 0.0095%) about one month before the experimental treatment with Fendona 6 SC. The study by Estany 2016a is not valid due to the treatment history in site 3.
In the study by Estany 2016b (30 mg a.i/m2), in site 1 no additional insecticide treatments were applied 3 months previous to the Fendona 6 SC test treatment while the sites 2 and 3 had not been treated before. Hence, the study by Estany 2016b is valid.

**** Efficacy**:
The application of Fendona 6 SC at 15 mg a.i. per m^2 resulted in an average 86.0% reduction in German cockroaches after a 4 week period. The overall efficacy level (86%) was affected by the considerably low population reduction (77%) at site 2 which is justified by the moderate sanitation

level, the comparatively high pest activity before treatment (1.5 to 2 times higher than the other two sites), and possible re-invasion of cockroaches from adjacent areas should have been occurred according to the applicant. Population reduction of German cockroaches in sites 1 and 3 was 88.6% and 92.2%, respectively, after a 4-week period (90.4% in average). However, the results of the study by Estany 2016a are not valid due to the treatment history in site 3.

In addition, it was impossible to obtain 6-week residual data from two of the three sites treated with the low dose because those replicates were disturbed by the property owner. The application of Fendona 6 SC at 30mg a.i. per m^2 resulted in an average 96.9% reduction in German cockroaches after a 4 week period.
It can be concluded that Fendona 6 SC was effective at 30 mg a.i. per m^2 against German cockroaches in terms of population reduction.

Insecticide; Control of flying and crawling insects	indoor application, spotted treatment	Fendona 6 SC	*Lasius niger* (Garden ant)	Field trial	For details on Test system / concentrations applied / exposure **see the following row ***	For details on test results **see the following row marked with ****	Gibson, D., 2016a; DocID# 2016_1100538 Study Code 15/166 B Not accepted study

*** Field trial**:
Six sites with an infestation of black ants, *Lasius niger*, were located; three were treated and three were left untreated. Each site was observed to determine areas of ant activity near a nest. The number of ants present in a specific area (1 m² – 2 m²) was assessed. For each site the area of ant activity assessed was marked with spray paint at the corners and the treatment was then applied. The number of ants present was assessed in the same manner as for the pre-treatment, at 2, 7, 14, 21 and 28 days post treatment. Applications were done as spotted surface treatments by using a hand held pressurised sprayer at a rate of 24 mg a.i./50 mL water/m^2. Untreated control sites were included.

**** Efficacy:**
Application of Fendona 6 SC at 24 mg ai/m2 resulted in 98.9% reduction in black ants after a 7 day experimental period and 100% reduction after 14-28 days. High population reduction was observed in untreated controls as well, i.e. 24%, 31%, 42% and 75% after 7, 14, 21 and 28 days.

Insecticide; Control of flying and crawling insects	indoor application, surface treatment (spotted surface treatment against flying insects)	Fendona 6 SC	*Musca domestica* (House fly), *Alphitobius diaperinus* (Litter beetle), *Aedes aegypti* (Mosquitoes); adults, *Dermanyssus gallinae* (poultry red mite); mixed aged	Simulated use test	For details on Test system / concentrations applied / exposure **see the following row ***	For details on test results **see the following row marked with ****	Gibson, D., 2016b; DocID# 2017/1119573 Gibson, D., 2016c; DocID# 2017_1119306 Accepted studies

*** Simulated use trials**:
For the crawling test systems experiments were conducted in 1 m x 1 m black plastic arenas. The sides of the arenas were coated in Fluon (liquid PTFE) to prevent the insects/mites from escaping. The floor of the arena was covered in its entirety by plywood/ceramic tiles

(plywood/metal/painted plywood for the mites) – one half which were treated, while the other half remained untreated. Tiles were secured to the floor using sticky tape (so that insects/mites were unable to crawl underneath). Test systems were provided with a water source (moistened cotton wool pad) throughout the experimental period. The selection of treated/untreated halves within each test arena was randomised to avoid any potential positional bias. For the flying insects, experiments were conducted within plastic lined chambers with an approximate volume of 30 m^3. Treated plywood/ceramic tiles were placed at random around the room; on the floor and attached to the walls, covering an area of approximately 2 m2. Corresponding untreated tiles were also placed at random around the room, covering another 2 m2. The position of the treated/untreated tiles was mixed. Insects were provided with sugar cubes and water (upturned cup resting on cotton-wool wick) placed in each of the four corners of the test room. Fifty flies/mosquitoes were placed in the test room or thirty beetles/fifty mites were placed in the test arena after tile introduction. Knockdown and mortality was assessed over a period of 48 hours at intervals following insect introduction: at 2, 4, 6 and 24 and 48 hours. Dead insects/mites were removed at each assessment. Applications were done by using a hand held 1 L trigger bottle. For flying insects (flies/mosquitoes) the product was applied at a rate of 15 or 30 mg ai per m2 onto 15 x 15 cm ceramic (non-porous) and plywood (porous) surfaces. For the beetles and mites – the product was applied (at a rate of 15 or 30 mg ai per m2) onto 1m^2 tiled arenas; plywood and ceramic for the beetles, plywood, metal, and painted plywood for the mites. Efficacy was evaluated at 1 day and at 3 months (90 days). Three replicates were conducted for each treatment, for each surface type, for each ageing interval and for each species. Untreated controls were included.							
**** Efficacy**: Exposure to 1 day and 3 month aged deposits of Fendona 6 SC at 15 mg ai/m^2 on plywood (porous) and glazed ceramic (non-porous) surfaces in a simulated use environment resulted in >98% affected (knocked down and dead) mosquitoes (*Aedes aegypti*), houseflies (*Musca domestica*), and litter beetles (*Alphitobius diaperinus*), after a 24 and 48 hour experimental period. Exposure to the same treatment (1 day Fendona 6 SC 15 mg ai/m^2) on plywood/metal/painted plywood surfaces resulted in <18% affected chicken mites, after 24 and 48 hours. Exposure to 1 day and 3 month aged deposits of Fendona 6 SC at 30 mg ai/m^2 on plywood (porous) and glazed ceramic (non-porous) surfaces in a simulated use environment resulted in >98% affected (knocked down and dead) mosquitoes (*Aedes aegypti*), houseflies (*Musca domestica*), and litter beetles (*Alphitobius diaperinus*), after a 24 and 48 hour experimental period. Exposure to the same treatment (1 day Fendona 6 SC 30 mg ai/m^2) on plywood/metal/painted plywood surfaces resulted in <21% affected chicken mites, after 24 and 48 hours. Exposure to 3 month aged deposits resulted in >80% knock down 2 hours after exposure to the treated porous and non-porous surfaces at 15 and 30 mg ai/m^2 against mosquitoes, houseflies and litter beetles. Exposure to 1 day and 3 month aged deposits of Fendona 6 SC at 15 and 30 mg ai/m^2 on plywood (porous) and glazed ceramic (non-porous) surfaces in a simulated use environment resulted in <90% dead mosquitoes (*Aedes aegypti*), houseflies (*Musca domestica*), and litter beetles (*Alphitobius diaperinus*), after a 24 and 48 hour experimental period. Affected houseflies and litter beetles in the untreated control were 0-3.3% for the 24 and 48 hour experimental period. Dead mosquitoes for 1 day and 3 months aged surfaces in the untreated control were 7% and 10%-13.8% for the 24 and 48 hour experimental period, respectively. There are public references that indicate the existence of pyrethroids resistance in chicken red mites. No claim for chicken red mites will be made on the product label.							
Insecticide; Control of flying and crawling insects	indoor application, surface treatment	Fendona 6 SC	*Blatta* orientalis (Oriental cockroach), *Blattella germanica* (German cockroach),	Laboratory study	For details on Test systems / concentrations applied / exposure **see the following row ***	For details on test results **see the following row marked with ****	Gibson, D., 2016d; DocID# 2017_1118835 Gibson, D., 2016e;

			Musca domestica (House fly), *Alphitobius diaperinus* (Litter beetle), *Aedes aegypti* (Mosquitoe), *Stomoxys calcitrans* (Stable fly, *Lasius niger* (Garden ant), *Dermanyssus gallinae* (poultry red mite), *Vespula germanica* (German wasp), *Vespula vulgaris* (Common wasp)				DocID# 2017_1119303 Accepted studies

*** Laboratory bioassays**:
Ten insects were confined onto a tile within a plastic pint pot (568 mL), measuring 9 cm in diameter at its base. For the crawling insects – the inside of the pint pot was coated with liquid PTFE (Fluon) to prevent the insects from escaping. Wasps were confined individually onto the surfaces in transparent plastic tubes (4,5 cm diameter, 5 cm high) to prevent infighting. Chicken mites (30 per replicate) were confined within upturned petri dishes measuring 9 cm in diameter. Insects/mites were confined onto the surfaces for a 2 hour period; after 2 hours they were transferred into identical clean plastic containers. Water/sugar water was provided for all test systems after the 2 hour time point (moistened cotton-wool pad), and food was provided where necessary (bran pellet for cockroaches, sugar cube for ants). Assessments of knockdown and mortality were conducted over a period of 48 hours at 1, 2, 4, 6, 24, and 48 hours, post initial exposure to treatments. Applications were done by using a hand held pump-spray. The product was applied at a rate of 15 mg a.i. and at a rate of 30 mg a.i. per m^2 onto 15 x 15 cm ceramic (non-porous) and plywood (porous) surfaces (plywood/metal/painted plywood for the mites). Efficacy was evaluated at 1 day and at 3 months (90 days) after treatment. Surfaces were stored under ambient conditions prior to use. Four replicates were conducted for each treatment, for each surface type, for each ageing interval and for each species.

**** Efficacy**:
Two hours of exposure to 1 day and 3 month aged deposits of Fendona 6 SC 15 mg a.i./1 m² on plywood (porous) and glazed ceramic (non-porous) surfaces resulted in 100% affected (knocked down and dead) German cockroaches, Oriental cockroaches, Black ants, Mosquitoes (*Aedes aegypti*), House flies, Stable flies and Litter beetles, and 92.5%-100% affected Wasps, after a 24 and 48 hour experimental period, . Two hours of exposure to the same treatment (1 day / 3 month Fendona 6 SC 15 mg a.i./1 m²) on plywood/metal/painted plywood surfaces resulted in <17% affected Chicken mites, after 24 and 48 hours.
Two hours of exposure to 1 day and 3 month aged deposits of Fendona 6 SC at 15 mg a.i./1 m² on plywood (porous) and glazed ceramic (non-porous) surfaces resulted in <90% dead German cockroaches, Oriental cockroaches and litter beetles, and in >90% dead ants, mosquitoes and stable flies, after 24 and 48 hours. 1 day aged deposits at 15 mg a.i./1 m² on plywood (porous) and glazed ceramic (non-porous) surfaces resulted in <90% dead houseflies after 24 hours and >90% dead houseflies after 48 hours, while 3 months aged deposits gave >90% dead

houseflies after 24 and 48 hours. 1 day and 3 months aged deposits at 15 mg a.i./1 m² on plywood (porous) and glazed ceramic (non-porous) surfaces resulted in <90% dead wasps after 24 hours and >90% dead wasps after 48 hours.

Two hours of exposure to 1 day and 3 month aged deposits of Fendona 6 SC 30 mg a.i./1 m² on plywood (porous) and glazed ceramic (non-porous) surfaces resulted in 100% affected (knocked down and dead) German cockroaches, Oriental cockroaches, Black ants, Mosquitoes (*Aedes aegypti*), House flies, Stable flies and Litter beetles, and 92.5%-100% affected Wasps, after a 24 and 48 hour experimental period. Two hours of exposure to the same treatment (1 day / 3 month Fendona 6 SC 30 mg a.i./1 m²) on plywood/metal/painted plywood surfaces resulted in <17.5% affected Chicken mites, after 24 and 48 hours.
Two hours of exposure to 1 day and 3 month aged deposits of Fendona 6 SC at 30 mg a.i./1 m² on plywood (porous) and glazed ceramic (non-porous) surfaces resulted in <90% dead German cockroaches, Oriental cockroaches and litter beetles and in >90% dead ants, mosquitoes, houseflies and stable flies, after 24 and 48 hours. 1 day and 3 months aged deposits at 30 mg a.i./1 m² on plywood (porous) surfaces resulted in <90% dead wasps after 24 hours and >90% dead wasps after 48 hours, and on glazed ceramic (non-porous) surfaces resulted in >90% dead wasps after 24 and 48 hours.

Exposure to 3-month deposits resulted in >90% knock down against German cockroaches, Oriental cockroaches, Black ants, Mosquitoes (*Aedes aegypti*), House flies, Stable flies and Litter beetles after 1 hour exposure after 2 hours exposure to treated porous and non-porous surfaces at 15 and 30 mg a.i./m². Against wasps, exposure to 3-month deposits to porous and non-porous surfaces resulted in >90% knock down 4 hours after treatment at 15 mg a.i./m², and >87.5% knock down 6 hours after treatment at 30 mg a.i./m². Exposure of non-porous surfaces to fresh and 3-month deposits resulted in >90% knock down 1 hour after treatment at 15 and 30 mg a.i./m².
There are public references that indicate the existence of pyrethroids resistance in this pest. No claim for Chicken red mites will be made on the product label.
Affected insects in the untreated controls were 0-15% for all treatments. In the untreated control, the percentage of affected cockroaches in 24 hours for 1-day and 3-months deposits on both types of surfaces were 0% and 3% for German and Oriental cockroaches, respectively. In the untreated control, the percentage of affected (knocked-down + dead) ants in 24 hours for 1-day and 3-months deposits on both types of surfaces was 2.5%. In the untreated control, the percentage of affected (knocked-down + dead) houseflies in 48 hours for 1-day and 3-months deposits on both types of surfaces was 2.5%-7.8%.
In the untreated control, the percentage of dead mosquitoes in 24 hours for 1-day and 3-months deposits was 7.7% on porous surfaces and 10.25% on non-porous surfaces. The results on non-porous surfaces against mosquitoes are not valid due to high mortality in the untreated control. In the untreated control, mortality of litter beetles in 24 and 48 hours for 1-day and 3-months deposits on both types of surfaces was 0%-2.5%. The percentages of dead wasps in 24 hours in the untreated controls were: for fresh (1-day) deposits 7.5% and 15% on non-porous and porous surfaces, respectively; and for 3-month deposits 12.5% and 15% on non-porous and porous surfaces, respectively. The results on porous surfaces with fresh deposits in 24 hours against wasps are not valid due to high mortality in the untreated control. The percentages of dead wasps in 48 hours in the untreated controls were 12.5% - 22.5%, and therefore are considered not acceptable.

Insecticide; Control of flying and crawling insects	indoor application, surface treatment	Fendona 6 SC	*Cimex lectularius* (Bed bug), *Ctenocephalides felis* (Cat flea),	Laboratory study	For details on Test system / concentrations applied / exposure **see the following row ***	For details on test results **see the following row marked with ****	Loakes, S., 2011; DocID# 2011_1292613 Not accepted study
***Laboratory bioassay**:							

Ten insects were confined onto a tile within a plastic ring, measuring 9 cm in diameter at its base. Insects were confined onto the tile for a 1 hour period; after which insects were transferred into clean plastic containers. Treatments were applied onto glazed ceramic tiles, wall paper and fabric tiles for the bed bugs and glazed ceramic tiles, carpet and wood for cat fleas, each measuring 15 cm x 15 cm. Enough surfaces were treated to allow testing at 1 day, 1 month and 3 months. Surfaces were stored under ambient conditions prior to use. Assessments of knockdown and mortality for the bed bugs were made at 1 hour, 1 day, 1 and 2 weeks, and for the fleas at 1 hour, 1 and 2 days, post initial exposure to treatments. The product was applied at 30 mg ai/m2. The rate was equivalent to a rate of 50 mL of solution per m2 (approx. 1.125 g per tile). This solution was prepared with BAS 310 27 I, Fendona 60 g/L alpha-cypermethrin SC diluted 1:98 m/m formulation / water was assessed. Applications were done by using a hand held atomiser. Four replicates were conducted for each treatment, for each surface, for each ageing interval. Untreated controls were included.

**** Effects**:

Application onto all surface types and all ageing periods resulted in 100% affected (knocked down and dead) bed bugs after 24 hours observation period. Knock down records for bedbugs ranged between 92.5% and 100%, 1 hour post treatment for all treatments. Application onto all surface types and all ageing periods resulted in 95%-100% affected (knocked down and dead) cat fleas after 1 and 2 days observation period. Thus, it can be concluded that the product applied on porous and non-porous surfaces as residual spray at 30 mg a.i./m^2 is highly effective against *Cimex lectularius* and *Ctenocephalides felis* for 3 months post treatment. In the untreated controls, affected bedbugs were <5% at 24 hours observation period and affected fleas were <25% at 24 and 48 hours, for the 3-month aged surfaces.

Insecticide; Control of flying and crawling insects	indoor application, surface treatment	Fendona 1.5 SC; Product used for **read across**. A detailed justification for read across is given below the table	*Musca domestica* (House fly), *Alphitobius diaperinus* (Litter beetle), *Stomoxys calcitrans* (Stable fly)	Laboratory study.	For details on Test system / concentrations applied / exposure **see the following row ***	For details on test results **see the following row marked with ****	Lüpkes, K.-H., 2011; DocID# 2011_1291553 Accepted study

*** Laboratory bioassay**:

Flies, 20 at a time, were exposed to the treated surfaces under aluminium rings (diameter 10.5 cm, height 2 cm) with wire gauze (mesh 1 mm), the beetles, 20 at a time, were exposed to the treated surfaces inside talc-powdered glass rings (diameter 9.5 cm, height 5.5 cm). The flies were provided with a sugar water swab. For residual tests the insects were exposed to the treated surfaces at various test intervals, the first time 1 day after treatment, following 42, 84 and 126 days after treatment. Flies were exposed additionally after 182 days, litter beetles additionally after 203 days. The evaluations for knock down (followed by mortality) were made after 15, 30 and 60 minutes, 2, 3, 4, 5, 6, 8, and 24 hours after exposure. For efficacy on still wet surfaces the insects were exposed to the treated surfaces directly after treatment and tested for percentage of knock down (followed by mortality). The evaluation for 100% knock down (followed by mortality) was done permanent up to 2 hours, and also after 24 and 48 hours. Surfaces used were: plywood, concrete and unglazed tiles (flies), PVC, plywood, glazed tiles (litter beetles) (size 15 x 15 cm = 225 cm^2). The surfaces are sprayed in a fume hood in which the air extractor can be regulated so that the sprayed jet is unaffected. The formulations are dissolved or suspended in tap water. They are sprayed by the computer-controlled apparatus, which was developed for spraying insecticide formulations with residual activity on various surfaces: Track Sprayer. Application rates were 15 and 30 mg a.i./m^2 (flies) and 30 mg a.i./m^2 (litter beetles). 3 replicates were conducted. Untreated controls were included.

**** Efficacy**:

<table>
<tr><td colspan="8">Application onto all surface types and all ageing periods resulted in 100% affected (knocked down and dead) insects. Mortality records after 24 and 48 hours are considered invalid because the insects were exposed permanently to treated surfaces for too long. Nevertheless, 100% knockdown against houseflies and stable flies was recorded within 15-30 minutes after exposure to all types of surfaces (porous and non-porous) aged for 84 days at 15 and 30 mg a.i./m^2. For litter beetles 100% knockdown was recorded within 15 – 120 minutes after exposure to all types of surfaces (porous and non-porous) aged for 84 days at 30 mg a.i./m^2. In the untreated controls no knockdown was recorded for the fresh treated surfaces and no mortality was recorded for the aged surfaces in 24 hours measurements.</td></tr>
<tr><td>Insecticide; Control of flying and crawling insects</td><td>indoor application, surface treatment</td><td>Fendona 1.5 SC; Product used for read across. A detailed justification for read across is given below the table</td><td>Pheidole megacephala (Coastal brown ant)</td><td>Laboratory study.</td><td>For details on Test system / concentrations applied / exposure see the following row *</td><td>For details on test results see the following row marked with **</td><td>Miller, P.F. & Peters, B., 1989; DocID# 1989_8000001

Accepted study</td></tr>
<tr><td colspan="8">* Laboratory bioassay:
Efficacy of the product was assessed in terms of knockdown and residual time. Treatments were applied onto masonite plates. Solutions were sprayed onto 9 cm x 9 plates using a Potter Spray Tower at rates of 7.5, 15, and 30 mg a.i./m^2. Treated surfaces were aged for 2 and 24 hours, 1 week, 1, 2, and 3 months prior to exposure. Insects were confined onto each surface for a 1 and 3 hours exposure periods. 5 ants were exposed to insecticide on each plate and knockdown was noted after 1 and 3 hours. The knockdown was noted at 1 and 3 hours only, as any increased holding time resulted in unacceptable control mortality. There were four replicates for each treatment. The ants were confined on the plates by means of small plastic rings coated with Fluon. Control treatments consisted of plates which had not been sprayed with insecticide.</td></tr>
<tr><td colspan="8">** Efficacy:
All treatments gave good knockdown of ants at 3 hours exposure up to 1 month. After the one month assessment, the efficacy of the 7.5 mg a.i./m^2 application dropped rapidly. The 15 mg a.i./m^2 application gave good knockdown at 2 months (95%), however, knockdown dropped to 75% at 3 months. The 30 mg a.i./m^2 application gave good knockdown at 2 months (90%) and 3 months (80%). Control knockdown was low throughout the trial, the highest being 10%.</td></tr>
<tr><td>Insecticide; Control of flying and crawling insects</td><td>indoor application, surface treatment</td><td>Fendona 1.5 SC; Product used for read across. A detailed justification for read across is given below the table</td><td>Iridomyrmex glaber (Black house ant)</td><td>Laboratory study.</td><td>For details on Test system / concentrations applied / exposure see the following row *</td><td>For details on test results see the following row marked with **</td><td>Miller, P.F. & Peters, B., 1988a; DocID# 1988_8000003

Accepted study</td></tr>
<tr><td colspan="8">* Laboratory bioassay:
Efficacy of the product was assessed in terms of knockdown and residual time. Treatments were applied onto masonite plates. Solutions were sprayed onto 9 cm x 9 plates using a Potter Spray Tower at rates of 7.5, 15, and 30 mg a.i./m^2. Treated surfaces were aged for 2 and 24 hours, 1</td></tr>
</table>

week, 1, 2, and 3 months prior to exposure. Insects were confined onto each surface for a 1, 3 and 24 hours exposure period. 5 ants were exposed to insecticide on each plate and knockdown was noted after 1 and 3 hours. The knockdown was noted at 1 and 3 hours only, as any increased holding time resulted in unacceptable control mortality. There were four replicates for each treatment. The ants were confined on the plates by means of small plastic rings coated with Fluon.

**** Efficacy**:
The 7.5 mg a.i./m^2 application gave good knockdown up to one week, however, knockdown was poor in the later assessments. The 15 mg a.i./m^2 application gave 60% knockdown up to 1 month, but efficacy dropped quickly thereafter. The 30 mg a.i./m^2 gave 75% knockdown up to the 2 month assessment, whereas the 3 month assessment was poor.

Insecticide; Control of flying and crawling insects	indoor application, crack and crevice and surface treatment	Fendona 1.5 SC; Product used for **read across**. A detailed justification for read across is given below the table	*Periplaneta americana* (American cockroach), *Periplaneta australasiae* (Australian cockroach) (Nymphs and adults)	Field study	For details on Test system / concentrations applied / exposure **see the following row ***	For details on test results **see the following row marked with ****	Miller, P.F. & Peters, B., 1988b; DocID# 1988_8000001 Not accepted study

*** Field trial**: Efficacy of the product was assessed in terms of cockroach population reduction. Sticky traps were left out overnight in the different sites to check pre-treatment infestation levels. The cockroach populations were assessed by means of sticky cockroach traps. Three traps were left out at each property and these were always placed in the same location (by fridge, under sink and by stove). The data is expressed as number of cockroaches trapped per household per night. The same assessment method was used on the control properties. Assessment periods were: pre assessment in week prior to treatment, 2 weeks after treatment, 6 weeks after treatment, 4 months after treatment, 6 months after treatment. Each property was visited at each assessment period. The treatment was carried out by a professional pest control company. The treatment consisted of a crack and crevice treatment and surface spray, using a nine litre Nupest Riga. The kitchen in all properties was always treated and other areas where infestation was obvious were also sprayed. All treatments were sprayed at the rate of 1 litre of prepared spray per 20 m^2 with a dosage of 15 mg a.i/ m^2. Areas such as stoves, refridgerators and hot water services were dusted with Coopex dust (10g/kg permethrin).

**** Efficacy:**
The product gave 96.9%, 97.6% and 100% reduction of cockroach population 2 weeks, 6 weeks and 4-6 months, respectively, after treatment. . However, the control population decreased during the 4 and 6 month assessment due to winter time. In the control sites, cockroach population was reduced by 9.4% in 2 weeks, increased by 7.5% in 6 weeks and reduced by 21.7% and 38% in 4 and 6 months, respectively. However, a permethrin-based product was used at the same time with Fendona, and therefore it is unclear whether the observed effect was caused only by Fendona.

Insecticide; Control of flying and crawling insects	indoor application, surface treatment	Fendona 1.5 SC; Fendona 6 SC – Bridging trial	*Periplaneta americana* (American cockroach), *Blatella germanica*	Simulated use test	For details on Test system / concentrations applied / exposure **see**	For details on test results **see the following row marked with ****	Gibson, D., 2016f; DocID# 2017/1119575 Accepted study

			(German cockroach)		**the following row ***		

*** Simulated use trials**:
Experiments were conducted in 1m x 1m black plastic arenas. The sides of the arenas were coated in Fluon (liquid PTFE) to prevent the cockroaches from escaping. The floor of the arena was covered in its entirety by plywood/ceramic tiles – one half of which was treated, while the other half remained untreated. Tiles were secured to the floor using sticky tape (so that cockroaches were unable to crawl underneath).
Test systems were provided with a water source (moistened cotton wool pad), food (bran pellet), and a cardboard harbourage (one in each half) throughout the experimental period. The selection of treated/untreated halves within each test arena was randomised to avoid any potential positional bias. For the untreated control replicates both surface types were placed into the same arena (half plywood, half ceramic). Thirty cockroaches (10 females, 10 males, and 10 nymphs) were released into the test arena after tile introduction. Knockdown and mortality (dead) was assessed at intervals following insect introduction: at 2, 4, 6, 24 and 48 hours. Two products (Fendona 6 SC, and Fendona 1.5 SC) were assessed at 1 day and at 3 months (90 days) after treatment. Both products were applied at a rate of 15 mg ai per m2 onto ceramic (non-porous) and plywood (porous) surfaces using a hand held 1.5L pressurised sprayer (Coopler-Pegler CP 1.5), from a distance of approximately 20 cm. Four replicates were conducted for each treatment.

**** Efficacy:**
Exposure to 1 day and 3 month aged deposits of Fendona 6 SC and Fendona 1.5 SC both applied at 15mg ai/1m² on plywood (porous) and glazed ceramic (non-porous) surfaces in a simulated use environment resulted in >97.5% affected (knocked down + dead) German and American cockroaches (*Blatella germanica* & *Periplaneta americana*) after a 24 and 48 hour experimental period. No difference was found between the efficacy of both formulations.
Exposure to 3 month aged deposits of Fendona 6 SC and Fendona 1.5 SC both applied at 15mg ai/1m² on plywood (porous) and glazed ceramic (non-porous) surfaces resulted in 99-100% affected American cockroaches after a 24 hours experimental period.
Exposure to 3 month aged deposits of Fendona 6 SC and Fendona 1.5 SC both applied at 15mg ai/1m² on plywood (porous) and glazed ceramic (non-porous) surfaces resulted in 97.5-100% affected German cockroaches after a 24 hours experimental period.
Exposure to 3 month aged deposits of Fendona 6 SC and Fendona 1.5 SC both applied at 15mg ai/1m² on plywood (porous) and glazed ceramic (non-porous) surfaces resulted in >90% knockdown against German and American cockroaches 6 hours post treatment.
Affected insects in the untreated controls were 0-10% for all treatments.

Insecticide; Control of flying and crawling insects	indoor application, crack and crevice treatment	Fendona 6 SC	*Blatta* orientalis (Oriental cockroach) (Nymphs and adults)	Field trial	For details on Test systems / concentrations applied / exposure **see the following row ***	For details on test results **see the following row marked with ****	Estany, E., 2016c; DocID# 2016_1235738 Study Code 15/166CCC with Addendum: DocID 2017/1123697 Not accepted study

*** Field trial**:
Sites with an infestation of Oriental cockroaches, Blatta orientalis, were located, separated from any other infestations. A pre-monitoring assessment was conducted to establish the infestation level at the sites. A number (minimum of 5) of monitoring traps were placed at various locations around the infested sites. The number of cockroaches trapped was recorded over a period of 72 to 96 hours, at 2 days prior to

application. The treatment was then applied at the site, according to the sponsor's instructions. A further set of monitoring traps were placed at the same location as for the pre-monitoring assessment, and assessed at weekly intervals for a total of 4 to 6 weeks post initial treatment application. The number of any visible knocked down and dead cockroaches were assessed. Applications were done as crack and crevice treatments by using a pressurised sprayerwand at a rate of 15 mg a.i./m^2, in 5L solution per 100 m^2. 3 replicates were conducted.
The Site 1 had been treated with an unspecified non-professional spray product. No further information available. The site 2 had not been treated in the three months previous to the experimental treatment with Fendona 6 SC. The site 3 was treated with insecticide gel (ABAGEL FORTE; Abamectine: 0.07%, Permethrin: 0.01%) in bait stations, which were removed previously to the study. This study is not valid due to the treatment history sites 1 and 3.

**** Efficacy**:
Application of Fendona 6 SC at 15 mg a.i. per m^2 resulted in an average 85.3% reduction in oriental cockroaches after a 4 week period. This average population reduction was reduced due to the conditions in Site 2 where only 59.5% population reduction was recorded 4 weeks post treatment. The risk of re-invasion in Site 2 was deemed high because the area where the premises are located is known to harbour oriental cockroach populations. In addition, it was impossible to obtain 6-week residual data because 2 replicates were disturbed by the property owner. Population reduction of Oriental cockroaches in sites 1 and 3 was 98% and 98.4%, respectively, after a 4-week period (98.2% in average). However, the results of this study are not valid due to the treatment history sites 1 and 3.

Insecticide; Control of flying and crawling insects	indoor application, crack and crevice treatment	Fendona 6 SC	*Blatta* orientalis (Oriental cockroach), Periplaneta Americana (American cockroach) (Nymphs and adults)	Field trial	For details on Test systems / concentrations applied / exposure **see the following row ***	For details on test results **see the following row marked with ****	Estany, E., 2016d; DocID# 2016_1235740 Study Code 15/166EEE Not accepted study

*** Field trial**:
Sites with an infestation of oriental cockroaches, *Blatta orientalis* and American cockroaches, *Periplaneta americana*, were located, separated from any other infestations. A pre-monitoring assessment was conducted to establish the infestation level at the sites. A number (minimum of 5) of monitoring traps were placed at various locations around the infested sites. The number of cockroaches trapped was recorded over a period of 24 to 72 hours, at 2 days prior to application. The treatment was then applied at the site, according to the sponsor's instructions. A further set of monitoring traps were placed at the same location as for the pre-monitoring assessment, and assessed at weekly intervals for a total of 4 weeks post initial treatment application. The number of any visible knocked down and dead cockroaches were assessed. Applications were done as crack and crevice treatments by using a pressurised sprayerwand at a rate of 30 mg a.i./m^2, in 5L solution per 100 m^2. 3 replicates were conducted (2 for Oriental cockroaches and 1 for American cockroaches).
The site 2 had not been treated with another product three months before treatment with Fendona 6SC, whereas the sites 1 and 3 had been treated with unknown domestic products (no further info is provided) prior to treatment with Fendona 6SC. This study is not valid due to the treatment history in sites 1 and 3.

**** Efficacy**:
Application of Fendona 6 SC at 30 mg a.i. per m^2 resulted in an average 94.1% reduction in cockroaches (*B. orientalis* and *P. americana*) after a 4 week period.

Application of Fendona 6 SC resulted in a 99% reduction in oriental cockroach numbers at site 1 relative to pre-treatment levels, after 4 weeks post treatment application. At site 2, application of Fendona 6 SC resulted in a 91% reduction in oriental cockroach numbers after 4 weeks, relative to pre-treatment levels. The maximum percentage reduction achieved at site 2 was 93.2% after 2 weeks post treatment application. Application of Fendona 6 SC resulted in 92.3% reduction in American cockroach numbers at site 3 relative to pre-treatment levels, after 4 weeks post treatment application. However, the results of this study are not valid due to the treatment history in sites 1 and 3.							
Insecticide; Control of flying and crawling insects	indoor application, surface spotted treatment	Fendona 6 SC	*Stomoxys calcitrans (Stable fly)*	Field study	For details on Test systems / concentrations applied / exposure **see the following row ***	For details on test results **see the following row marked with ****	Estany, E., 2016e; DocID# 2016_1235742 with Addendum: DocID 2017/1121349 Not accepted study
*** Field trial**: Sites with an infestation of stable fly, Stomoxys calcitrans, were located, separated from any other infestations. A pre-monitoring assessment was conducted to establish the infestation level at the sites. A number (minimum of 10) of monitoring traps were placed at various locations around the infested sites. The number of stable flies trapped was recorded over a period of 48 to 72 hours, at 2 days prior to application. The treatment was then applied at the site, according to the sponsor's instructions. A further set of monitoring traps were placed at the same location as for the pre-monitoring assessment, and assessed at intervals 1-3. 4-5, 6-8, 14 and 21 post initial treatment application. The number of any visible knocked down and dead flies were assessed. Applications were done by using a pressurised sprayerwand at a rate of 15 mg a.i./m^2, in 5L solution per 100 m^2. 3 replicates were conducted.							
**** Efficacy**: In terms of the corrected percent control achieved, Henderson and Tilton calculations showed that Fendona 6 SC at 15 mg a.i. per m2 provided an average 73.8%, 77% and 80.5% H-T reduction in stable flies' numbers after a 7, 14 and 21 days period respectively. Application of Fendona 6 SC at 15 mg a.i. per m2 at site 1 resulted in a 79.8% and 94% H-T reduction in stable fly numbers after 4 and 21 days post treatment, respectively. At site 2, application of Fendona 6 SC resulted in a 63.8% and 73.6% H-T reduction in stable fly numbers after 7 and 21 days, relative to pre-treatment levels. Secondary re-infestations from outdoors premises (animal housing, etc.) at this site should be presumed, since only the milking room and adjacent sheltered areas were treated. Application of Fendona 6 SC resulted in a 73.2% and 73.9% H-T reduction in stable fly numbers at site 3 relative to pre-treatment levels at 3 and 21 days post treatment respectively.							
Insecticide; Control of flying and crawling insects	indoor application, surface spotted treatment	Fendona 6 SC	*Stomoxys calcitrans (Stable fly)*	Field study	For details on Test systems / concentrations applied / exposure **see the following row ***	For details on test results **see the following row marked with ****	Estany, E., 2016f; DocID# 2016_1235746 Not accepted study
*** Field trial**: Sites with an infestation of stable fly, Stomoxys calcitrans, were located, separated from any other infestations. A pre-monitoring assessment was conducted to establish the infestation level at the sites. A number (minimum of 10) of monitoring traps were placed at various locations around the infested sites. The number of stable flies trapped was recorded over a period of 48 to 72 hours, at 2 days prior to application. The treatment was then applied at the site, according to the sponsor's instructions. A further set of monitoring traps were placed at the same location as for the pre-monitoring assessment, and assessed at intervals 1-3. 4-5, 6-8, 14 and 21 post initial treatment							

application. The number of any visible knocked down and dead flies were assessed. The number of any visible knocked down and dead flies were assessed. Applications were done by using a pressurised sprayerwand at a rate of 30 mg a.i./m^2, in 5L solution per 100 m^2. 3 replicates were conducted.							
**** Efficacy**: In terms of the corrected percent control achieved, Henderson and Tilton calculations showed that Fendona 6 SC at 30 mg a.i. per m2 provided an average 80.1%, 62.2% and 71.4% H-T reduction in stable flies' numbers after a 7, 14 and 21 day period respectively. Application of Fendona 6 SC at 30 mg a.i. per m2 at site 1 provided an H-T reduction in stable fly numbers over 80% throughout the trial. It resulted in an 80.4%, 97.2% and 97.3% H-T reduction in stable fly numbers after 2, 7 and 21 days post treatment, respectively. At site 2, application of Fendona 6 SC resulted in a 57.4%, 65.6% and 51.1% H-T reduction in stable fly numbers after 3, 7 and 21 days post treatment, respectively. Secondary re-infestation from adjacent outdoor premises could be presumed responsible for the poorer product performance at this site. Application of Fendona 6 SC resulted in a 26.1%, 77.4% and 65.7% H-T reduction in stable fly numbers at site 3 relative to pre-treatment levels at 3, 7 and 21 days post treatment, respectively.							
Insecticide; Control of flying and crawling insects	indoor application, crack and crevice treatment	Fendona 6 SC	*Lasius niger* (Garden ant)	Field trial	For details on Test system / concentrations applied / exposure **see the following row ***	For details on test results **see the following row marked with ****	Gibson, D., 2016g; DocID# 2016_1235734 Study Code 15/166C Gibson, D., 2016h; DocID# 2016_1235736 Study Code 15/166D Accepted studies
*** Field trial**: Each site was observed to determine areas of ant activity near a nest. The number of ants present in a specific area (1 m^2) was assessed. For each site the area of ant activity assessed was marked with spray paint at the corners and the treatment was then applied. The number of ants present was assessed in the same manner as for the pre-treatment, at 2, 7, 14, 21 and 28 days post treatment. Applications were done as spotted treatments by using a pressurised sprayer (Cooper-Pegler CP1.5) which had an adjustable hollow-cone nozzle set at a rate of 15 mg a.i./m^2 and at a rate of 30 mg a.i./m^2 in 5L solution per 100 m^2. 3 replicates were conducted. Three untreated control sites were included.							
**** Efficacy**: Application of Fendona 6 SC at 15 and 30 mg a.i./m^2 resulted in 93.3% and 97.8% reduction in black ants, respectively, after a 28 day experimental period. No population reduction was recorded in untreated control sites. It can be concluded that Fendona 6 SC applied at 15 and 30 mg a.i./m^2 is effective against black ants, in terms of population reduction after a 28 day experimental period.							
Insecticide; Control of flying and crawling insects	indoor application, surface treatment	Fendona 6 SC	Mosquitoes *Culex quinquefasciatus*(Mixed sex and aged adults)	Laboratory study	For details on Test systems / concentrations applied / exposure **see**	For details on test results **see the following row marked with ****	Gibson, 2017a DocID# 2017/1223401 Accepted study

					the following row *		
*** Laboratory bioassays:** Ten mosquitoes were confined onto a tile within a transparent plastic pint pot (568 mL capacity), measuring 9 cm in diameter at its base (see Plate 1), for a 2 hour period; after 2 hours they were transferred into identical clean plastic containers. Sugar water was provided for all test systems after the 2 hour time point (moistened cotton-wool pad). Temperature and relative humidity was maintained at appropriate levels with respect to insect biology and dial cycle. Temperature ranged from 21.9°C- 26.2°C and relative humidity ranged from 43.1% - 75.0%. The product was applied at a rate of 15 mg a.i. per m² onto 15x15cm ceramic (non-porous) and plywood (porous) surfaces, using a hand held pump-spray, from a distance of approximately 20cm. The deposited amount per surface was recorded by weighing the spray bottle before and after application. Enough surfaces were treated to allow testing at 1 day and at 3 months (90 days). Surfaces were stored under ambient conditions prior to use. Four replicates were conducted for each treatment and for the control. Assessments of knockdown and mortality were conducted at 1, 2, 4, 6, 24, and 48 hours, post initial exposure to treatments. Moribound, live or dead mosquitoes were counted and compared with the pretreatment values. Untreated controls were included.							
**** Efficacy:** Two hours of exposure to 1 day and 3 month aged deposits of Fendona 6 SC 15mg ai/m² on plywood (porous) and glazed ceramic (non-porous) surfaces resulted in 97.2% mortality on plywood, and 100% mortality on ceramic tiles (fresh residues) at 24 hours after exposure; and 91.9% mortality on plywood and 100% mortality on ceramic tiles (3-month residues) at 24 hours after exposure. 100% dead mosquitoes (*Culex quinquefasciatus*) on both surfaces were observed after a 48 hour experimental period. 100% knockdown was recorded after two hours of exposure to the treated surfaces in all treatments. In the untreated controls, mortality was 2.5%-7.5% and 5%-10% in 24 and 48 hours after exposure, respectively. It can be concluded that Fendona 6 SC applied at 15mg ai/m² was highly effective against mosquitoes (*Culex quinquefasciatus*) in terms of knock-down and mortality, when applied as a residual treatment onto porous and non-porous surfaces, for up to 3 months.							
Insecticide; Control of flying and crawling insects	indoor application, surface treatment	Fendona 6 SC	Mosquitoes *Culex quinquefasciatus* (Mixed sex and aged adults)	Laboratory study	For details on Test systems / concentrations applied / exposure **see the following row ***	For details on test results **see the following row marked with ****	Gibson, 2017b DocID# 2017/1223402 Accepted study
*** Laboratory bioassays:** Ten mosquitoes were confined onto a tile within a transparent plastic pint pot (568 mL capacity), measuring 9 cm in diameter at its base (see Plate 1), for a 2 hour period; after 2 hours they were transferred into identical clean plastic containers. Sugar water was provided for all test systems after the 2 hour time point (moistened cotton-wool pad). Temperature and relative humidity was maintained at appropriate levels with respect to insect biology and dial cycle. Temperature ranged from 21.9°C- 26.2°C and relative humidity ranged from 43.1% - 75.0%. The product was applied at a rate of 30 mg a.i. per m² onto 15x15cm ceramic (non-porous) and plywood (porous) surfaces, using a hand held pump-spray, from a distance of approximately 20cm. The deposited amount per surface was recorded by weighing the spray bottle before and after application. Enough surfaces were treated to allow testing at 1 day and at 3 months (90 days). Surfaces were stored under ambient conditions prior to use.Four replicates were conducted for each treatment and for the control. Assessments of knockdown and mortality were							

conducted at 1, 2, 4, 6, 24, and 48 hours, post initial exposure to treatments. Moribound, live or dead mosquitoes were counted and compared with the pretreatment values. Untreated controls were included.

**** Efficacy:**

Two hours of exposure to 1 day and 3 month aged deposits of Fendona 6 SC 30mg ai/m² on plywood (porous) and glazed ceramic (non-porous) surfaces resulted in 97.2% mortality on plywood, and 100% mortality on ceramic tiles (fresh residue) at 24 hours after exposure; and 86.9% mortality on plywood and 92.5% mortality on ceramic tiles (3-month residues) at 24 hours after exposure. 100% dead mosquitoes (*Culex quinquefasciatus*) were observed on both surfaces after a 48 hour experimental period. 100% knockdown was recorded after two hours of exposure to the treated surfaces in all treatments.

In the untreated controls, mortality was 2.5%-7.5% and 5%-10% in 24 and 48 hours after exposure, respectively. In the untreated control on 3-month aged plywood surfaces, at 48 hours mortality was 5%.

It can be concluded that Fendona 6 SC applied at 30 mg ai/m² was highly effective against mosquitoes (*Culex quinquefasciatus*) in terms of knock-down and mortality, when applied as a residual treatment onto porous and non-porous surfaces, for up to 3 months.

Insecticide; Control of flying and crawling insects	indoor application, surface spotted treatment	Fendona 6 SC	Mosquitoes *Culex quinquefasciatus* *Culex pipiens* (Mixed sex and aged adults)	Simulated use test	For details on Test systems / concentrations applied / exposure **see the following row ***	For details on test results **see the following row marked with ****	Gibson, 2018a DocID# 2017/1223403 Accepted study

***Sim.Use trial:**

The product was applied at a rate of 15mg a.i. per m^2 onto 15cm x 15cm ceramic and plywood surfaces. Enough tiles were treated to cover a total area of 2m². Treatments were applied using a hand held 1L trigger bottle, from a distance of approximately 20cm. The deposited amount per surface was recorded by weighing the spray bottle before and after application. Enough surfaces were treated to allow testing at 1 day and 3 months (90 days) post treatment. Surfaces were stored under ambient conditions prior to use.

Experiments were conducted in plain white rooms (510cm x 240cm x 240cm) within plastic lined chambers with an approximate volume of 30m³. Treated plywood/ceramic tiles were placed at random around the room; on the floor and attached to the walls; covering an area of approximately $2m^2$. Corresponding untreated tiles were also placed at random around the room, covering another $2m^2$. The position of the treated/untreated tiles was mixed. Mosquitoes were provided with sugar-water (plastic sugar-water wells, with a cotton-wool wick) placed in each of the four corners of the test room.

Culex pipiens were used for the 3 month tests because the required numbers of *Culex quinquefasciatus* mosquitoes were not available from suppliers in sufficient quantity to meet with testing deadlines on aged surfaces.

Fifty mosquitoes were introduced into the test arenas immediately following surface introduction. Assessments of knockdown and mortality were carried out at 2, 4, 6, 24 and 48 hours post insect introduction. 4 replicates were performed for each treatment.

Both temperature and relative humidity were maintained at appropriate levels (20ºC ±5ºC, 20-80 % RH), and the rooms were set to an approximate 12:12 light: dark dial cycle.

**** Efficacy:**

Exposure to residual deposits of Fendona 6 SC 15mg ai/m² in a simulated use environment, resulted in 82% and 84% affected (knock down + dead) mosquitoes (*Culex quinquefasciatus*) on 1 day aged porous surfaces 24 and 48 hours post treatment, respectively, and 89.5% and 92%

affected (knock down + dead) mosquitoes (*Culex quinquefasciatus*) on 1 day aged non-porous surfaces 24 and 48 hours post treatment, respectively.
Exposure to residual deposits of Fendona 6 SC 15mg ai/m², resulted in 81% and 84% affected (knock down + dead) mosquitoes (*Culex pipiens*) on 3-month aged porous surfaces 24 and 48 hours post treatment, respectively, and 81.5% and 83% affected (knock down + dead) mosquitoes (*Culex pipiens*) on 3-month aged non-porous surfaces 24 and 48 hours post treatment, respectively.
Exposure to fresh (1 day) deposits of Fendona 6 SC at 15 mg ai/m² on porous and non-porous surfaces resulted in <90% dead mosquitoes (*Culex quinquefasciatus*) in 24 hours post treatment, however in 48 hours the treatment on non-porous surfaces resulted in >90% dead mosquitoes (*Culex quinquefasciatus*).
Less than 80% knockdown was recorded after two to six hours of exposure to the treated surfaces in all treatments.
In the untreated controls affected insects were 0-11%. For the fresh deposits on both types of surfaces in the untreated control, mortality was <10% in 24 hours.

Insecticide; Control of flying and crawling insects	indoor application, surface spotted treatment	Fendona 6 SC	Mosquitoes *Culex quinquefasciatus* *Culex pipiens* (Mixed sex and aged adults)	Simulated use test	For details on Test systems / concentrations applied / exposure **see the following row ***	For details on test results **see the following row marked with ****	Gibson, 2018b DocID# 2017/1223404 Accepted study

***Sim.Use trial:**
The product was applied at a rate of 30mg a.i. per m^2 onto 15cm x 15cm ceramic and plywood surfaces. Enough tiles were treated to cover a total area of 2m². Treatments were applied using a hand held 1L trigger bottle, from a distance of approximately 20cm. The deposited amount per surface was recorded by weighing the spray bottle before and after application. Enough surfaces were treated to allow testing at 1 day and 3 months (90 days) post treatment. Surfaces were stored under ambient conditions prior to use.
Experiments were conducted in plain white rooms (510cm x 240cm x 240cm) within plastic lined chambers with an approximate volume of 30m³. Treated plywood/ceramic tiles were placed at random around the room; on the floor and attached to the walls; covering an area of approximately $2m^2$. Corresponding untreated tiles were also placed at random around the room, covering another $2m^2$. The position of the treated/untreated tiles was mixed. Mosquitoes were provided with sugar-water (plastic sugar-water wells, with a cotton-wool wick) placed in each of the four corners of the test room.
Culex pipiens were used for the 3 month tests because the required numbers of Culex quinquefasciatus mosquitoes were not available from suppliers in sufficient quantity to meet with testing deadlines on aged surfaces.
Fifty mosquitoes were introduced into the test arenas immediately following surface introduction. Assessments of knockdown and mortality were carried out at 2, 4, 6, 24 and 48 hours post insect introduction.

Both temperature and relative humidity were maintained at appropriate levels (20ºC ±5ºC, 20-80 % RH), and the rooms were set to an approximate 12:12 light: dark dial cycle.

** **Efficacy:**
Exposure to residual deposits of Fendona 6 SC 30mg ai/m² in a simulated use environment, resulted in 89.5% and 92% affected (knock down + dead) mosquitoes (*Culex quinquefasciatus*) on 1 day aged porous surfaces 24 and 48 hours post treatment, respectively, and 89.5% and 93.5%

affected (knock down + dead) mosquitoes (*Culex quinquefasciatus*) on 1 day aged non-porous surfaces 24 and 48 hours post treatment, respectively.
Exposure to residual deposits of Fendona 6 SC 30mg ai/m², resulted in 86% and 88.5% affected (knock down + dead) mosquitoes (*Culex pipiens*) on 3-month aged porous surfaces 24 and 48 hours post treatment, respectively, and 87.5% and 89% affected (knock down + dead) mosquitoes (*Culex pipiens*) on 3-month aged non-porous surfaces 24 and 48 hours post treatment, respectively.
Exposure to fresh (1 day) deposits of Fendona 6 SC at 30 mg ai/m² on porous and non-porous surfaces resulted in <90% dead mosquitoes (*Culex quinquefasciatus*) in 24 hours post treatment, however in 48 hours the treatment on non-porous and porous surfaces resulted in >90% dead mosquitoes (*Culex quinquefasciatus*).
Less than 80% knockdown was recorded after two to six hours of exposure to the treated surfaces in all treatments.
In the untreated controls affected insects were 0-11%. For the fresh deposits on both types of surfaces in the untreated control, mortality was <10% in 24 hours.

Insecticide; Control of flying and crawling insects	indoor application, crack and crevice	Fendona 6 SC	Bed bugs *Cimex lectularius* (Nymphs and adults)	Field study	For details on Test systems / concentrations applied / exposure **see the following row ***	For details on test results **see the following row marked with ****	Foltan, 2017 DocID# 2017/1223408 Accepted study

*** Field trial:**

- Test sites consisting of individual flats with an infestation of bed bugs, *Cimex lectularius*, were located in the vicinity of Ceske Budejovice, Czech Republic. Ten test sites infested with *Cimex lectularius* were used for the trial. Only test sites with no previous treatment against the target species or any other arthropod pest in the last 60 days pre-treatment, were used in the study. Percentage product efficacy was calculated as percentage reduction of live bed bugs present at the test site after treatment in comparison to the pre-treatment assessment. Five of the sites were treated with 15 mg ai/50 ml water/m². 5 sites were treated with 30 mg ai/50 ml water/m². 2 applications were done 2 weeks apart. Parameters evaluated included: live or dead bed bugs, and cast skins; blood spotting on the sheets, along the mattress seams and other places where bed bugs hide; eggs, which tend to be laid in crevices in dark areas, and bed bug smell. The above parameters were recorded before treatment and at 2, 4, 8 and 14 weeks after application.

**** Efficacy:**

Following the first application of Fendona 6SC, the number of live bed bugs was reduced by 88.4 ±3.2 % after application at 30mg ai/m² and by 77.4± 11.3 % after treatment at 15 mg ai/m², two weeks post treatment Both application rates (30 and 15 mg ai/m²) resulted in 100% control of the bed bug populations following the second application, in 4 weeks up to 14 weeks after the first application. The results show that the product has a strong efficacy against bed bugs (*Cimex lectularius*).

Insecticide; Control of flying and crawling insects	indoor application, surface treatment	Fendona 6 SC	Bed bugs *Cimex lectularius* Cat fleas *Ctenocephalides felis*	Laboratory study	For details on Test systems / concentrations applied / exposure **see the following row ***	For details on test results **see the following row marked with ****	Gibson, 2017c DocID# 2017/1223405 Accepted study

			(Mixed sex and aged adults)				
***Lab trial:** The product was applied at a rate of 15mg a.i. per m² onto 15x15cm ceramic, plywood and carpet surfaces for the fleas; and ceramic, wallpaper and cotton fabric surfaces for the bed bugs. Treatments were applied using a hand held pump-spray, from a distance of approximately 20cm. The deposited amount per surface was recorded by weighing the spray bottle before and after application. Enough surfaces were treated to allow testing at 1 day, 1 month and 3 months (90 days) post treatment. There were 4 replicates per treatment. Surfaces were stored under ambient conditions prior to use. Ten fleas / bed bugs were confined onto a tile within a transparent plastic petri dish, measuring 90mm in diameter. Fleas were confined onto the tiles for a 2 hour period, and bed bugs were confined for a 6 hour period; after the confinement period (2 / 6 hours) insects were transferred into clean plastic holding containers (petri dishes with a glass tile lid) and provided with a moistened cotton-wool pad to maintain a high humidity environment. Temperature and relative humidity was maintained at appropriate levels with respect to insect biology and dial cycle. Assessments of knockdown and mortality were conducted at at 1, 2, 6, 24, and 48 hours, and at 1 and 2 weeks post initial exposure to treatments for the bed bugs; and for the fleas at 1, 2, 24 and 48 hours post initial exposure to treatments.							
****Efficacy:** <u>Bed bugs (*Cimex lectularius*)</u> Six hours of exposure to 1 day, 1 month and 3 month aged deposits of Fendona 6 SC 15mg ai/1m² on glazed ceramic, wallpaper and cotton fabric surfaces resulted in >95% affected (knocked-down & dead) bed bugs (*Cimex lectularius*) after a 24 hour experimental period; This cumulated in >92.5% mortality on all surfaces after 1 week post treatment (92.5% on cotton fabric and 100% on ceramic and wallpaper). Six hours post exposure 95-100% knock down was recorded in the 3-month aged deposits. For 1-day, 1-month and 3-month deposits against bedbugs on porous and non-porous surfaces the mortality in the untreated control was 0-7.5%, 1 hour to 1 week after exposure. <u>Cat Fleas (*Ctenocephalides felis*)</u> Two hours of exposure to 1 day, 1 month and 3 month aged deposits of Fendona 6 SC 15mg ai/1m² on glazed ceramic and plywood surfaces resulted in >97.5% affected (knocked-down + dead) fleas after a 24 hour experimental period, and >95% dead fleas (*Ctenocephalides felis*) after a 48 hour experimental period. Mortality after exposure to 3-months deposits on ceramic surfaces was 95% in 24 hours, on plywood 52.5% in 24 hours and 95% in 48 hours, and on carpets 25% in 24 hours and 85% in 48 hours. Fendona 6 SC was less effective when applied on carpet surfaces; two hours of exposure to 3 month aged deposits on carpet surfaces resulted in 82.5% affected (knocked-down + dead) fleas after a 24 hour experimental period and 85% dead fleas (*Ctenocephalides felis*) after a 48 hour experimental period. In the untreated control mortality was 0-17.5%. For 1-day, 1-month and 3-month deposits against fleas on porous and non-porous surfaces (except for carpets) the mortality in the untreated control was 5-7.5%, 24 hours after exposure. For the 3-month deposits against fleas mortality in the untreated control was 7.5% and 15% on ceramic surfaces in 24 hours and 48 hours, 7.5% and 17.5% on plywood, and 15% and 17.5% on carpets, respectively.							
Insecticide; Control of flying and crawling insects	indoor application, surface treatment (in support of spot, crack	Fendona 6 SC	Cat fleas, *Ctenocephalides felis* (Mixed sex and aged adults)	Simulated use test	For details on Test systems / concentrations applied / exposure **see the following row ***	For details on test results **see the following row marked with ****	Gibson, 2017d (interim report) DocID# 2017/1223406 Accepted study

	and crevice treatment)						
***Simulated use trial:** The product was applied at a rate of 15mg a.i. per m² onto 0.5m x 1m ceramic, plywood and carpet surfaces. Treatments were applied using a hand held pump-spray, from a distance of approximately 20cm. The deposited amount per surface was recorded by weighing the spray bottle before and after application. Enough surfaces were treated to allow testing at 1 day, 1 month and 3 months (90 days) post treatment. Surfaces were stored under ambient conditions prior to use. Experiments were carried out within 1m x 1m arenas; half of the floor-space (1m x 0.5m) was covered in treated surfaces, whilst the remaining half contained untreated surfaces. Each arena was 0.5m deep (in order to prevent the fleas from jumping out and escaping) and lined with plastic sheeting. Fleas were provided with a moistened cotton-wool pad (located on both treated and untreated surfaces). The selection of treated / untreated halves within each test arena was also randomised (in order to prevent any positional bias). Twenty fleas were introduced, centrally, into the test arenas following surface introduction. Assessments of knockdown and mortality were carried out at 24 and 48 hours post insect introduction. Four replicates (4) were conducted for each treatment. Temperature and relative humidity were maintained at appropriate levels with respect to flea biology and dial cycle.							
****Efficacy:** Exposure to 1 day and 3 month aged deposits of Fendona 6 SC 15mg ai/m² on glazed ceramic and plywood surfaces resulted in >90% affected (Knocked down + dead) cat fleas after a 48 hour experimental period. Fendona 6 SC was less effective when applied on carpet surfaces; with exposure to 1 day and 3 month aged deposits on carpet resulting in 83.75% and 70% affected fleas, respectively, after 48 hours. Exposure to 3 month aged deposits of Fendona 6 SC 15mg ai/m² on glazed ceramic, plywood and carpet surfaces resulted in 92.5%, 87.5% and 63.75 affected (Knocked down + dead) cat fleas after a 24 hour experimental period. Exposure to 1 day and 3 months deposits on porous and non-porous surfaces at 15 mg a.i./m^2 resulted in <90% dead Cat fleas (*Ctenocephalides felis*), 48 hours after exposure to treated plywood (porous), carpet (porous) and ceramic glazed (non-porous) surfaces. In the untreated control mortality was 7.5- 15% on porous and non-porous surfaces after 48 hoursFor 1-day and 3-month deposits against fleas on porous and non-porous surfaces (except for carpets) the mortality in the untreated control was 3.75-6.25%, 24 hours after exposure.							
Insecticide; Control of flying and crawling insects	indoor application, surface treatment (in support of spot, crack and crevice treatment)	Fendona 6 SC	Cat fleas, *Ctenocephalides felis* (Mixed sex and aged adults)	Simulated use test	For details on Test systems / concentrations applied / exposure **see the following row ***	For details on test results **see the following row marked with ****	Gibson, 2017e (interim report) DocID# 2017/1223407 Accepted study
***Simulated use trial:** The product was applied at a rate of 30mg a.i. per m² onto 0.5m x 1m ceramic, plywood and carpet surfaces. Treatments were applied using a hand held pump-spray, from a distance of approximately 20cm. The deposited amount per surface was recorded by weighing the spray bottle before and after application. Enough surfaces were treated to allow testing at 1 day, 1 month and 3 months (90 days) post treatment. Surfaces were stored under ambient conditions prior to use. Experiments were carried out within 1m x 1m arenas; half of the floor-space (1m x 0.5m) was covered in treated surfaces, whilst the remaining half contained untreated surfaces. Each arena was 0.5m deep (in order to prevent the fleas from jumping out and escaping) and lined with plastic sheeting.							

Fleas were provided with a moistened cotton-wool pad (located on both treated and untreated surfaces). The selection of treated / untreated halves within each test arena was also randomised (in order to prevent any positional bias). Twenty fleas were introduced, centrally, into the test arenas following surface introduction. Assessments of knockdown and mortality were carried out at 24 and 48 hours post insect introduction. Knockdown was defined as the inability of the pest to upright itself or make coordinated movements and mortality was defined as the immobility of the pest when gently prodded / agitated. Four replicates (4) were conducted for each treatment. Temperature and relative humidity were maintained at appropriate levels with respect to flea biology and dial cycle.

**** Efficacy**

Exposure to 1 day and 3 month aged deposits of Fendona 6 SC 30mg ai/m² on glazed ceramic and plywood surfaces resulted in >90% affected (Knocked down + dead) cat fleas after a 48 hour experimental period. Fendona 6 SC was less effective when applied on carpet surfaces; with exposure to 1 day and 3 month aged deposits on carpet resulting in 82.5% and 77.5% affected fleas, respectively, after 48 hours.
Exposure to 1 day and 3 months deposits on porous and non-porous surfaces at 30 mg a.i./m^2 resulted in <90% dead Cat fleas (*Ctenocephalides felis*), 48 hours after exposure to treated plywood (porous) and carpet (porous) surfaces and >90% dead insects on ceramic glazed (non-porous) surfaces.
In the untreated control mortality was 7.5- 15% on porous and non-porous surfaces after 48 hours (10% and 12.5% on non-porous surfaces for 1 day and 3 month deposits). For 1-day and 3-month deposits against fleas on porous and non-porous surfaces (except for carpets) the mortality in the untreated control was 3.75-6.25%, 24 hours after exposure.

Insecticide; Control of flying and crawling insects	indoor application, surface spotted treatment	Fendona 6 SC	Houseflies *Musca domestica* Stable flies *Stomoxys calcitrans*	Field study	For details on Test systems / concentrations applied / exposure **see the following row ***	For details on test results **see the following row marked with ****	Latorre, 2017a DocID# 2017/1223410 Not accepted study

***Field trial:**

Four test sites infested with both species of flies (*Musca domestica*) and (*Stomoxys calcitrans*) were used for the trial. A pre-monitoring assessment was conducted to establish the infestation level at four test sites. The area to be treated was the 50% of the total of the site considering for the calculation the floor, ceiling, walls and partitions. The floor was not treated and the application focused on places were flies congregate like pipes, window frames and barns partitions. A further set of monitoring traps were placed at the same location as for the pre-monitoring assessment, and assessed at intervals approximately 1-3, 4-6, 7-8, 14, 21, 30, 45, 60, 75 and 90 days post initial treatment application. One untreated control (no product applied) site was assessed concomitantly as the treated ones to monitor natural population fluctuations due to natural causes and compare those with the effect of the product applied on treated sites. To ensure that no treatment could affect the natural fluctuation of flies, untreated site was chosen where owners ensured that they were not using or planning to use any insecticidal products.

**** Efficacy:**

In terms of the corrected percent control achieved, Henderson and Tilton calculations showed that Fendona 6 SC at 15 mg a.i. per m², that is equal to 25 mL product in 5 L to treat 100 m² or 0.5% v/v, in terms of population reduction over a 90 day experimental period, provided an average for house flies of 39.4% population reduction during the first month, 43.8% during the second month and 49.1% during the third month. In stable flies, the average population reduction was of 28.4% during the first month, 30.7% during the second month and 37.9% during the third month.

Insecticide; Control of flying and crawling insects	indoor application, surface spotted treatment	Fendona 6 SC	Houseflies *Musca domestica* Stable flies *Stomoxys calcitrans*	Field study	For details on Test systems / concentrations applied / exposure **see the following row ***	For details on test results **see the following row marked with ****	Latorre, 2017b DocID# 2017/1223411 Not accepted study
***Field trial:** Four test sites infested with both species of flies (Musca domestica) and (Stomoxys calcitrans) were used for the trial. A pre-monitoring assessment was conducted to establish the infestation level at four test sites. The area to be treated was the 50% of the total of the site considering for the calculation the floor, ceiling, walls and partitions. The floor was not treated and the application focused on places were flies congregate like pipes, window frames and barns partitions. A further set of monitoring traps were placed at the same location as for the pre-monitoring assessment, and assessed at intervals approximately 1-3, 4-6, 7-8, 14, 21, 30, 45, 60, 75 and 90 days post initial treatment application. One untreated control (no product applied) site was assessed concomitantly as the treated ones to monitor natural population fluctuations due to natural causes and compare those with the effect of the product applied on treated sites. To ensure that no treatment could affect the natural fluctuation of flies, untreated site was chosen where owners ensured that they were not using or planning to use any insecticidal products.							
****Efficacy:** In terms of the corrected percent control achieved, Henderson and Tilton calculations showed that, despite the heavy re-invasion reported in 2 out of the 4 replicates, Fendona 6 SC at a rate of 30 mg a.i. per m², what corresponds to 50 mL of product diluted in 5 L of water to treat 100 m² or 1% v/v, , in terms of population reduction over a 90 day experimental period, provided an average for house flies of 31.7% population reduction during the first month, 33.2% during the second month and 24.2% during the third month. In stable flies, the population reduction was of 37.8% during the first month, 31.4% during the second month and 50.9% during the third month.							
Insecticide; Control of flying and crawling insects	indoor application, surface spotted treatment	Fendona 6 SC	Wasps *Vespula germanica / Vespula vulgaris* (Mixed population)	Simulated use test	For details on Test systems / concentrations applied / exposure **see the following row ***	For details on test results **see the following row marked with ****	Gibson, 2018c (final report) Accepted study
***Simulated use trial:** The product was applied at a rate of 15mg a.i. per m² onto 15cm x 15cm ceramic and plywood surfaces. Enough tiles were treated to cover a total area of 2m². Treatments were applied using a hand held 1L trigger bottle, from a distance of approximately 20cm. The deposited amount per surface was recorded by weighing the spray bottle before and after application. Enough surfaces were treated to allow testing at 1 day and 3 months post treatment. Surfaces were stored under ambient conditions prior to use. Experiments were conducted in plain white rooms (510cm x 240cm x 240cm) within plastic lined chambers with an approximate volume of 30m³. Treated plywood/ceramic tiles were placed at random around the room; on the floor and attached to the walls; covering an area of approximately 2m². Corresponding untreated tiles were also placed at random around the room, covering another 2m². The position of the treated/untreated							

tiles was mixed. Wasps were provided with sugar-water (plastic sugar-water wells, with a cotton-wool wick) placed in each of the four corners of the test room.
Twenty wasps were introduced into the test arenas immediately following surface introduction. Assessments of knockdown and mortality were carried out at 2, 4, 6, 24 and 48 hours post insect introduction. Four replicates were performed with treatments on plywood and ceramic surfaces, respectively.
Both temperature and relative humidity were maintained at appropriate levels, and the rooms were set to an approximate 12:12 light: dark dial cycle.

**** Efficacy:**
Exposure to 1 day and 3 month aged deposits of Fendona 6 SC 15mg ai/1m² on glazed ceramic (non-porous) surfaces, in a simulated use environment, resulted in 100% and 93.5% dead wasps (*Vespula* spp.) after a 24 hour experimental period, respectively. Knock down was >90% after exposure for 6 hours on glazed ceramic surfaces.. In the untreated control on non-porous and porous surfaces mortality was 7.5% in 24 hours.
Exposure to 1 day aged deposits of Fendona 6 SC 15mg ai/1m² on plywood (porous) surfaces, in a simulated use environment, resulted in 93.5% dead wasps (*Vespula* spp.) after a 24 hour experimental period. Exposure to 3 months aged deposits of Fendona 6 SC 15mg ai/1m² on plywood (porous) surfaces resulted in 77.5% and 90.6% dead wasps (*Vespula* spp.) after a 24 and 48 hour experimental period, respectively.
Knock down was <90% after exposure for 2-6 hours to 1 day and 3 months aged treated plywood surfaces.
In the untreated control on porous surfaces mortality was 10% and 20% in 24 and 48 hours, respectively.
The results on the porous surfaces are not valid due to the low knockdown values with the 1 day and 3 months deposits and the high mortality in the untreated control.

Insecticide; Control of flying and crawling insects	indoor application, surface spotted treatment	Fendona 6 SC	Wasps *Vespula germanica / Vespula vulgaris* (Mixed population)	Simulated use test	For details on Test systems / concentrations applied / exposure **see the following row ***	For details on test results **see the following row marked with ****	Gibson, 2018d (final report) Accepted study

***Simulated use trial:**
The product was applied at a rate of 30 mg a.i. per m² onto 15cm x 15cm ceramic and plywood surfaces. Enough tiles were treated to cover a total area of 2m². Treatments were applied using a hand held 1L trigger bottle, from a distance of approximately 20cm. The deposited amount per surface was recorded by weighing the spray bottle before and after application. Enough surfaces were treated to allow testing at 1 day and 3 months post treatment. Surfaces were stored under ambient conditions prior to use.
Experiments were conducted in plain white rooms (510cm x 240cm x 240cm) within plastic lined chambers with an approximate volume of 30m³. Treated plywood/ceramic tiles were placed at random around the room; on the floor and attached to the walls; covering an area of approximately 2m². Corresponding untreated tiles were also placed at random around the room, covering another 2m². The position of the treated/untreated tiles was mixed. Wasps were provided with sugar-water (plastic sugar-water wells, with a cotton-wool wick) placed in each of the four corners of the test room.
Twenty wasps were introduced into the test arenas immediately following surface introduction. Assessments of knockdown and mortality were carried out at 2, 4, 6, 24 and 48 hours post insect introduction. Four replicates were performed for each treatment.
Both temperature and relative humidity were maintained at appropriate levels, and the rooms were set to an approximate 12:12 light: dark dial cycle.

****Efficacy:**
Exposure to 1 day and 3 month aged deposits of Fendona 6 SC 30mg ai/m² on glazed ceramic (non- porous) surfaces, in a simulated use environment, resulted in 100% and 97.5% dead wasps (*Vespula* spp.) after a 24 hour experimental period, respectively. Knock down was >90% after exposure for 6 hours on glazed ceramic surfaces. In the untreated control on non-porous mortality was 7.5% in 24 hours.
Exposure to 1 day aged deposits of Fendona 6 SC 30mg ai/1m² on plywood (porous) surfaces, in a simulated use environment, resulted in 97.2% dead wasps (*Vespula* spp.) after a 24 hour experimental period. Exposure to 3 months aged deposits of Fendona 6 SC 30mg ai/1m² on plywood (porous) surfaces resulted in 80.6% and 94.9.6% dead wasps (*Vespula* spp.) after a 24 and 48 hour experimental period, respectively.
Knock down was >90% after exposure for 2 hours to 1 day aged treated plywood surfaces and <90% after 2-6 hours exposure to 3 months aged treated plywood surfaces.
In the untreated control on porous surfaces mortality was 10% and 20% in 24 and 48 hours, respectively.
The results on the porous surfaces are not valid due to the low knockdown values with the months deposits and the high mortality in the untreated control.

Insecticide; Control of flying and crawling insects	indoor application, surface treatment	Fendona 6 SC	*Blattella germanica* (German cockroach) *Periplaneta americana* (American cockroach), (Mixed sex and aged adults)	Laboratory study	For details on Test systems / concentrations applied / exposure **see the following row ***	For details on test results **see the following row marked with ****	Gibson, 2019a Accepted study

*** Laboratory bioassays**:
The product was applied at a rate of 15 mg a.i. per m^2 onto 15 x 15 cm ceramic (non-porous) and plywood (porous) surfaces. Applications were done by using a hand-held pump-spray. Insects were introduced onto the surfaces on Day 0 (once the product had dried). Surfaces were stored under ambient conditions prior to use.
Ten cockroaches were confined onto a tile within a plastic pint pot (568 mL), measuring 9 cm in diameter at its base. The inside of the pint pot was coated with liquid PTFE (Fluon) to prevent the insects from escaping. The insects were confined onto the surfaces for a 1 or 2 hour period; Following the confinement period, cockroaches were transferred into identical clean plastic containers. Cockroaches were provided with food (bran pellet) and water (damp cotton wool pad) following the 6 hour assessment. Assessments of knocked-down, moribund and dead insects were carried out at 1, 2, 4, 6, 24 and 48 hours, post initial exposure to treatments, and daily (1 day, 2 day, 3 day etc…) until 8 days post initial exposure.
Five replicates (5x) were conducted for each treatment (2x), for each surface type (2x), for each exposure period (2x), and for each species (2x). An untreated control is also assessed,
Temperature and relative humidity were maintained at appropriate levels with respect to insect biology and dial cycle. Temperature ranged from 22.1°C - 24.0°C and relative humidity ranged from 22.9% - 56.2%.

**** Efficacy:**
1 hour of exposure to fresh deposits of Fendona 6SC applied at 15mg ai/m² on plywood and ceramic surfaces resulted in 100% of German and American cockroaches being classified as knocked down at 1 to 6 hours. At 24 hours, 84-94% of German and 100% of American cockroaches were classified as moribund, while 6-16% of German and 0% of American cockroaches were classified as dead. At 24 hours and daily until 8 days

post initial exposure, 100% of cockroaches were inactive, being recorded as moribund or dead. At 7 days, 98-100 % of cockroaches were recorded as dead. Mortality in the corresponding untreated control cohort remained below 2% for the duration of the 8 day assessment period for German cockrocahes. Mortality in the corresponding untreated control cohort remained below 12% for the duration of the 8 day assessment period (below 4% until day 3) for American cockroaches**.** 2 hours of exposure to fresh deposits of Fendona 6SC applied at 15mg ai/m² on plywood and ceramic surfaces resulted in 100% of German and American cockroaches being classified as knocked down at 1 to 6 hours. At 24 hours, 86-92% of German and 100% of American cockroaches were classified as moribund, while 8-14% of German and 0% of American cockroaches were classified as dead. At 24 hours and daily until 8 days post initial exposure, 100% of cockroaches were inactive, being recorded as moribund or dead. At 7 days, 98-100 % of cockroaches were recorded as dead. Mortality in the corresponding untreated control cohort remained below 2% for the duration of the 8 day assessment period for German and American cockrocahes.							
Insecticide; Control of flying and crawling insects	indoor application, surface treatment	Fendona 6 SC	*Blattella germanica* (German cockroach), *Ctenocephalides felis, Cimex lectularius* (Bed bug) (adults)	Laboratory study.	For details on Test system / concentrations applied / exposure **see the following row ***	For details on test results **see the following row marked with ****	Lüpkes, K.-H., 2012 Accepted study (Not accepted for fleas)
*** Laboratory bioassays**: The product was applied at a rate of 15mg a.i. per m² onto glazed tiles (non-porous surfaces) and carpet surfaces (porous surfaces) against cockroaches and fleas, and on glazed tiles (non-porous surfaces) and plywood (porous surfaces) against bedbugs. The diluted product was equally distributed on the surfaces by a computer controlled spraying apparatus (spray robot) with a volume of 50 ml per 1 m^2. For the residual tests, the insects were exposed to the treated surfaces at various intervals, the first time 1 day after treatment, following 1, 2 and 3 months after treatment. Various contact times were used, for cockroaches 1 hour, for bedbugs 6 hours, for fleas 24 hours. The evaluations for cumulative knocked-down + moribund + dead insects were made after 1 and 2 days after exposure to the treated surfaces. Dead cockroaches and fleas were recorded 4 days after exposure to the treatment and dead bedbugs were recorded 7 days after exposure to the treated surfaces. Untreated controls were included. 5 replicates for each treatment were used, and 2 replicates for the control.							
**** Efficacy:** Cockroaches: 100% knocked down + moribund + dead insects were recorded 1 and 2 days after exposure and 100% dead cockroaches were recorded 4 days after exposure to 1 day, 1 month, 2 months and 3 months aged treated non-porous surfaces. On porous surfaces (carpets) 52%, 10% 22% and 0% dead insects were recorded in 4 days after exposure to 1 day, 1 month, 2 months and 3 months treated surfaces, respectively. Mortality in the untreated control was 0% on 1 day, 1 month and 3 months aged tiles, and 20% on 2 months aged tiles. Fleas: The exposure time of fleas is considered too long (24 hours) to be acceptable, and therefore the results against fleas are not valid. Bedbugs: 100% knocked down + moribund + dead insects were recorded 1 and 2 days after exposure and 100% dead bedbugs were recorded 7 days after exposure to 1 day, 1 month, 2 months and 3 months aged treated porous and non-porous surfaces. Mortality in the untreated control was 0%.							
Insecticide; Control of	indoor application,	Fendona 6 SC	*Blattella germanica*	Field trial	For details on Test system /	For details on test results **see the**	Serrano 2012

flying and crawling insects	spot, crack and crevice treatment		(German cockroach)		concentrations applied / exposure **see the following row ***	**following row marked with ****	Accepted study
*** Field trials**: The test was conducted in multi-family public housing buildings with high level of German cockroaches infestation. No chemical treatment was applied in the preceding 8 weeks. 10 Sticky traps were used by apartment as a monitoring device for cockroach population. The sticky traps are placed overnight in an apartment, collected the next morning and returned to the laboratory for processing. Two precounts are made 7 and 3 days before the day of treatment. The application was done by a professional Pest Control Operator. The product was sprayed as spot, crack and crevice treatment at a rate of 15 or 30 mg a.i./^{2} (50 ml water solution/m²) in the preferred insects locations as: under the fridge, under the kitchen sink, under the oven and the water-heater, and on all cracks and crevices that can be an harborage for cockroaches. Assessments of population reduction were done 1, 3, 7, 28, 56 and 84 days after treatment. 5 apartments were treated with each dose and 5 apartments were used as untreated controls.							
**** Efficacy**: The application of Fendona 6 SC at 15 mg a.i. per m^2 resulted in an average 52,7%, 85,4%, 93,3%, 98,1%, 94,7% and 82,3% reduction in German cockroaches 1, 3, 7, 28, 56 and 84 days after treatment, respectively. The application of Fendona 6 SC at 30 mg a.i. per m^2 resulted in an average 70,1%, 95,4%, 97,7%, 99,6%, 97,7% and 98,2% reduction in German cockroaches 1, 3, 7, 28, 56 and 84 days after treatment, respectively. Population reduction of cockroaches was <4% in the apartments used as untreated control.							
Insecticide; Control of flying and crawling insects	indoor application, crack and crevice treatment	Fendona 6 SC	*Blatta* orientalis (Oriental cockroach)	Field trial	For details on Test systems / concentrations applied / exposure **see the following row ***	For details on test results **see the following row marked with ****	Estany, E., 2016g; 15/166BBB Not accepted study
*** Field trial**: Sites with an infestation of Oriental cockroaches were located, separated from any other infestations. A pre-monitoring assessment was conducted to establish the infestation level at the sites. A number (minimum of 5) of monitoring traps were placed at various locations around the infested sites. The number of cockroaches trapped was recorded over a period of 48 to 72 hours, at 2 days prior to application. The treatment was then applied at the site, according to the sponsor's instructions. A further set of monitoring traps were placed at the same location as for the pre-monitoring assessment, and assessed at weekly intervals for a total of 4 weeks post initial treatment application. The number of any visible knocked down and dead cockroaches were assessed. Applications were done as crack and crevice treatments by using a pressurised sprayerwand at a rate of 12 mg a.i./m^2, in 5L solution per 100 m^2. 3 replicates were conducted. Site 1 had not been treated for about 1 year prior to treatment with Fendona 6SC, site 3 had not been treated for 8 weeks before Fendona 6SC treatment, whereas site 2 was previously treated with unknown domestic products before treatment with Fendona 6SC (no further info is provided). This study is not valid due to the treatment history in site 2.							
**** Efficacy**: Application of Fendona 6 SC at 12 mg a.i. per m^2 resulted in an average 94.7% reduction in Oriental cockroaches after a 4 week period. However, the results of this study are not valid due to the treatment history in site 2.							

Insecticide; Control of flying and crawling insects	indoor application, surface spotted treatment	Fendona 6 SC	Mosquitoes (*Culex quinquefasciatus*) Houseflies (*Musca domestica*) (Mixed aged females)	Simulated use test	For details on Test systems / concentrations applied / exposure **see the following row ***	For details on test results **see the following row marked with ****	Gibson, 2019b Accepted study

***Sim.Use trial:**
The product was applied at 15 mg ai/m^2. The bioassays were conducted within plain white rooms, measuring approximately 510 cm long x 240 cm wide x 240 cm high (approximately 29.4m^3). Lighting was set at a 12:12 light : dark photoperiod. The floor, walls and ceiling of the room were lined with plastic sheeting, which was replaced between replicates, in order to prevent contamination. One treated tile type was placed around the room; on the floor and attached to the walls, covering an area of approximately 2 m^2. The corresponding untreated tile type was also placed around the room, covering another 2 m^2. The position of the treated/untreated tiles was mixed. Insects were provided with sugar-water wells placed in each of the four corners of the test room between the treated/untreated tiles. Following test chamber preparation, 50 adult female mosquitoes/ house flies were introduced into the chamber to interact with the surfaces.
The product was applied to approximately 2m^2 surface area of each surface type, using a hand held pressure sprayer. Treatment was conducted outside of the experimental chamber, with the treated panels then being introduced into the test chamber 24 hours following application. An untreated control treatment was also included. Further tests were conducted after 3 months ageing of the treated surfaces to validate a claim of residual efficacy. Treated panels used at the acute stage (1-day post treatment) were stored under ambient and darkened conditions, outside of the experimental chamber, prior to use.
knock-down and mortality were evaluated after 30 minutes and after 1, 2, 4, 6, 24, 48 hours (and each subsequent day until 7 days post introduction or until 100% mortality had been observed) following introduction of the mosquitoes/ house flies into the chamber. The insects remained within the test chamber throughout the experimental period.
4 replicates are done each (untreated control: 4).

**** Efficacy:**
Exposure to 1-day residual deposits of Fendona 6SC applied at 15mg ai/m^2 on plywood and ceramic surfaces resulted in > 96.6% of houseflies (*Musca domestica*) being classified as knocked down at 6 hours and >90% being classified as dead at 24 hours; Exposure to 3-month residual deposits of Fendona 6SC applied at 15mg ai/m^2 on plywood and ceramic surfaces resulted in 95.9% and 79.6%, respectively, of houseflies (*Musca domestica*) being classified as knocked down at 6 hours and >90% being classified as dead for both types of surfaces at 24 hours. Mortality in the corresponding untreated control at 24 hours was 5% for 1-day and 3-months porous and non-porous deposits**.**

Exposure of mosquitoes (*Culex quinquefasciatus*) to 1-day residual deposits of Fendona 6SC applied at 15mg ai/m^2 on plywood and ceramic surfaces resulted in >90% mortality in 3 and 4 days, respectively; Exposure of mosquitoes to 3-month residual deposits of Fendona 6SC applied at 15mg ai/m^2 on plywood and ceramic surfaces resulted in >90% mortality in 2 and 3 days, respectively. Less than 80% knockdown of mosquitoes was recorded after two to six hours of exposure to the treated surfaces in all treatments.
Mortality in the corresponding untreated control cohort was 0-7.2% for the duration of the 4-day assessment period for 1-day and 3-months porous and non-porous deposits**.**

Conclusion on the efficacy of the product

Several efficacy studies (laboratory, simulated use and field studies) were submitted for Fendona 6 SC, using also studies conducted with Fendona 1.5 SC based on a bridging approach, which are sufficient to prove efficacy of Fendona 6 SC indoors in urban pest control (Intended use 1) by professionals at 15 mg a.s./m^2 and in animal houses/shelters (intended use 2) by professionals and non-professionals at 15 and 30 mg a.s./m^2 as follows:

In urban pest control (Intended use 1) the product is efficacious against German cockroaches (*Blattella germanica*), ants (*Lasius niger*) and bedbugs *(Cimex lectularius)*, as a coarse spray to cracks & crevices, and/or onto targeted spots or areas where insects may crawl and hide; and against mosquitoes (*Culex spp.*) and wasps *(Vespula spp)*, as a coarse spray onto targeted spots or areas where insects may settle, noting that:

- "Activity against German cockroaches is achieved only with fresh deposits.".
- "Mortality of German cockroaches is achieved 1 week after exposure of the insects to the treated surfaces".
- "Residual activity against ants (*Lasius niger*) is up to 1 month".
- "Activity against mosquitos (*Culex spp.)* is achieved only with fresh deposits on non-porous surfaces (not on porous surfaces)".
- "Mortality of mosquitos (*Culex spp.)* is achieved 48 hours after exposure of the insects to the treated surfaces".
- "Residual activity against wasps (*Vespula* spp.) is achieved only on non-porous surfaces (not on porous surfaces) for up to 3 months".
- "Noticeable knockdown effect on wasps is expected within 6 hours after contact of the insects with non-porous treated surfaces and mortality is achieved at 24 hours".
- "Residual activity against bedbugs is up to 3 months".
- "Mortality of bedbugs is achieved 1 week after exposure of the insects to the treated surfaces".
- "At least 1 re-application is required against bedbugs.".

In animal houses/shelters (intended use 2) the product is efficacious against German cockroaches (*Blattella germanica*), ants (*Lasius niger*), mosquitoes *(Culex spp.)* and wasps *(Vespula spp),* and is applied throughout the infested area as a coarse spray for surface treatment. Special attention should be paid to cracks, crevices and any place where insects may hide and on surfaces over which they may crawl or settle. The product is effective against the target organisms noting that:

- "Activity against German cockroaches is achieved only with fresh deposits.".
- "Mortality of German cockroaches is achieved 1 week after exposure of the insects to the treated surfaces".
- "An application rate 15 mg/m^2 is set for high hygiene shelter places against cockroaches, otherwise an application rate 30 mg/m^2 should be used".
- "Residual activity against ants (*Lasius niger*) is up to 1 month".
- "Activity against mosquitos (*Culex spp.)* is achieved only with fresh deposits on non-porous surfaces (not on porous surfaces) at the low dose and on porous and non-porous surfaces at the high dose".
- "Mortality of mosquitos (*Culex spp.)* is achieved 48 hours after exposure of the insects to the treated surfaces".
- "Residual activity against wasps (*Vespula* spp.) is achieved only on non-porous surfaces (not on porous surfaces) for up to 3 months".

- "Noticeable knockdown effect on wasps is expected within 6 hours after contact of the insects with non-porous treated surfaces and mortality is achieved at 24 hours".

2.2.5.6 Occurrence of resistance and resistance management

As regards resistance, the applicant provides the following information:
"Alpha-cypermethrin, a synthetic pyrethroid, is the active substance of Fendona 6 SC. According to the Insecticide Resistance Action Committee's (IRAC) resistance database http://www.pesticideresistance.org (status of April, 2016), resistance to pyrethroids has been reported for a number of pests in Europe and other areas. A comprehensive summary of these reported cases of resistance is provided.
The IRAC database shows known resistance to alpha-cypermethrin of the following insect species Aedes aegypti (yellow fever mosquito), Aphis gossypii (melon and cotton aphid), Bactrocera oleae (olive fruit fly), Bemisia tabaci (sweetpotato whitefly), Chrysoperla carnea (common green lacewing), Culex pipiens pallens (mosquito), Culex tritaeniorhynchus (Mosquito), Frankliniella occidentalis (western flower thrips), Halotydeus destructor (redlegged earth mite), Helicoverpa armigera (cotton bollworm), Helopeltis theivora (tea mosquito bug), Leptinotarsa decemlineata (colorado potato beetle), Meligethes aeneus (pollen beetle), Myzus persicae (green peach aphid), Thrips tabaci (onion thrips), and Tuta absoluta (tomato leafminer). Most of them are agricultural pest insects relevant for crops, however, resistance was also observed in species such as mosquitos which can be found in domestic and public areas. Red poultry mite is another species controlled by biocides where resistance to pyrethroids has been reported in studies such as McNair (2015), Abbas (2014), Sparagano et all (2009), Nordenfors et all (2001) and Chauve (1998). References to other species are mentioned in the CAR report to alpha-cypermethrin (Belgium, 2014) obtained in the scope of a literature search which give information on resistance of cockroaches but they are not conclusive.
Taking this into consideration, a development of resistance against alpha-cypermethrin is in principle possible in a wide range of insect taxa (including cross-resistance).

Management strategies:
Good treatment practice will most likely result in high control levels which in turn reduces the likelihood of resistance development.

Whilst resistance has occurred and is a real problem in agricultural use, its expression is by no means uniform. The continued threat of resistance must be managed in order to prevent its build in species where it has already developed and in order to minimise the risk of resistance developing in species which have not yet developed resistance to the synthetic pyrethroids. For this reason, strategies such as alternation of insecticides with different modes of action, mixtures of insecticides with different modes of action and avoidance of frequent and repeated use are standard practice."

Strategies for managing the development of resistance:

- Where possible, application treatments should be recommended to be combined with non-chemical measures.
- To avoid the potential for insect resistance to Fendona 6SC, treatments should be alternated with insecticidal products having different modes of action.
- If resistance is confirmed, stop the use of Fendona 6SC immediately and rotate to an insecticide with alternative mode of action. By removing the selection pressure, the

less-fit, resistant individuals will be removed over time and susceptibility should return to the population.
- Apply the recommended label dose rate during the proper timing to ensure complete control of the pest species. By allowing the fewest insects to survive, the spread of the resistant insects will be slowed.
- Follow good application techniques in order to maximize the product activity; deficient applications at less than the recommended label rate will allow the surviving insects to build up the population again, increasing the pest pressure against the product, which may trigger resistance problems in the future.
- Establish a baseline and monitor levels of effectiveness on populations in key areas in order to detect any significant changes in susceptibility to active substance. Information from resistance monitoring programs allows early detection of problems and gives information for correct decision making.
- The users should inform if the treatment is ineffective and report straightforward to the authorization holder. The authorization holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management.

2.2.5.7 Known limitations

The applicant states that "*No undesirable or unintended side effects e.g. on beneficial and other non-target organisms were observed.*".

In urban pest control (Intended use 1) the product was proved efficacious against German cockroaches (*Blattella germanica*), ants (*Lasius niger*) and bedbugs *(Cimex lectularius)*, as a coarse spray to cracks & crevices, and/or onto targeted spots or areas where insects may crawl and hide; and against mosquitoes (*Culex spp.*) and wasps *(Vespula spp)*, as a coarse spray onto targeted spots or areas where insects may settle, with the following limitations:
- "Activity against German cockroaches is achieved only with fresh deposits.".
- "Mortality of German cockroaches is achieved 1 week after exposure of the insects to the treated surfaces".
- "Residual activity against ants (*Lasius niger*) is up to 1 month".
- "Activity against mosquitos (*Culex spp.)* is achieved only with fresh deposits on non-porous surfaces (not on porous surfaces)".
- "Mortality of mosquitos (*Culex spp.)* is achieved 48 hours after exposure of the insects to the treated surfaces".
- "Residual activity against wasps (*Vespula* spp.) is achieved only on non-porous surfaces (not on porous surfaces) for up to 3 months".
- "Noticeable knockdown effect on wasps is expected within 6 hours after contact of the insects with non-porous treated surfaces and mortality is achieved at 24 hours".
- "Mortality of bedbugs is achieved 1 week after exposure of the insects to the treated surfaces".
- "At least 1 re-application is required against bedbugs.".

In animal houses/shelters (intended use 2) the product was proved efficacious against German cockroaches (*Blattella germanica*), ants (*Lasius niger*), mosquitoes *(Culex spp.)* and wasps *(Vespula spp),* and is applied throughout the infested area as a coarse spray for surface treatment. Special attention should be paid to cracks, crevices and any place where insects may hide and on surfaces over which they may crawl or settle. The product is effective against the target organisms with the following limitations:
- "Activity against German cockroaches is achieved only with fresh deposits.".
- "Mortality of German cockroaches is achieved 1 week after exposure of the insects to the treated surfaces".

- "An application rate 15 mg/m^2 is set for high hygiene shelter places against cockroaches, otherwise an application rate 30 mg/m^2 should be used".
- "Residual activity against ants (*Lasius niger*) is up to 1 month".
- "Activity against mosquitos (*Culex spp.)* is achieved only with fresh deposits on non-porous surfaces (not on porous surfaces) at the low dose and on porous and non-porous surfaces at the high dose".
- "Mortality of mosquitos (*Culex spp.)* is achieved 48 hours after exposure of the insects to the treated surfaces".
- "Residual activity against wasps (*Vespula* spp.) is achieved only on non-porous surfaces (not on porous surfaces) for up to 3 months".
- "Noticeable knockdown effect on wasps is expected within 6 hours after contact of the insects with non-porous treated surfaces and mortality is achieved at 24 hours".

2.2.5.8 Evaluation of the label claims

According to the submitted PAR and SPC, the intended uses (label claims) as applied for by the applicant including target organisms, dose rates and application methods are as follows:

The product is intended for use indoors by professionals and non-professionals in rural hygiene and by professionals in urban pest control.
For urban pest control (intended use 1) the product is intended to be used against crawling insects, including cockroaches (*Blattella germanica*, *Blatta orientalis*, *Periplaneta americana*); nymphs and adults, ants (*Lasius niger*)*;* mixed age except eggs, bedbugs *(Cimex lectularius)*; nymphs and adults*,* and fleas *(Ctenocephalides felis)*; adults*,* as well as against flying insects, including houseflies *(Musca domestica)*; adults*,* mosquitoes (*Aedes* mosquitoes, *Aedes aegypti, Culex spp, Culex quinquefasciatus*); adults, and wasps *(Vespula spp)*; adults*.* In urban settings, Fendona 6 SC will be applied in households, domestic and private areas. It will be applied as a crack and crevice treatment and/or onto targeted spots or areas where insects may crawl or hide for crawling insects; and onto targeted spots or areas where insects may crawl or settle for flying insects.

For rural hygiene (intended use 2), the product is intended to be used against crawling insects, including cockroaches (*Blattella germanica*, *Blatta orientalis*, *Periplaneta americana*); nymphs and adults, ants (*Lasius niger*); mixed age except eggs, and litter beetles (*Alphitobius diaperinus*); adults, as well as against flying insects, including stable flies *(Stomoxys calcitrans)*; adults, houseflies *(Musca domestica)*; adults*,* mosquitoes *(Aedes mosquitoes, Aedes aegypti, Culex spp, Culex quinquefasciatus)*; adults*,* and wasps *(Vespula spp)*; adults*.*
In rural hygiene situations, Fendona 6 SC will be applied in animal houses and shelters as a coarse spray for surface treatment, especially to cracks, crevices and any place where insects may hide and on surfaces over which they may crawl or settle.

The biocidal product will be applied by low pressure spraying. The application rates of FENDONA 6 SC are 25 mL product diluted in 5 L water for 100 m^2 (15 mg a.i./m²) for urban pest control areas (intended use 1); and 25 or 50 mL product diluted in 5 L water for 100 m^2 (15 or 30 mg a.i./m²) for animal houses/shelters (intended use 2).

Fendona 6 SC exhibits sustained residual activity, up to 3 months, where residues remain undisturbed.

Trials submitted by the applicant to substantiate label claims:

To support the label claims, the applicant submitted the following efficacy data from laboratory, simulated use, and field tests using a variety of different experimental designs.

Cockroaches

- In the bridging simulated use test by Gibson 2016f the application of Fendona 6SC and Fendona 1.5 SC under the same lamboratory conditions as surface treatment with 1 day and 3 months deposits on porous and non-porous surfaces at 15 mg a.i./m^2 resulted in >97.5% affected (knocked down + dead) German and American cockroaches (*Blatella germanica* & *Periplaneta americana*) after a 24 and 48 hour experimental period. Exposure to 3 month aged deposits of both products applied at 15 mg ai/m² on plywood (porous) and glazed ceramic (non-porous) surfaces resulted in >90% knockdown against German and American cockroaches 6 hours post treatment. No difference was found between the efficacy of both formulations.

Based on the results of this bridging simulated use study using two cockroach species as representative target organisms (one small and one large species), the two products (Fendona 6SC and Fendona 1.5 SC) may be considered equivalent in terms of their efficacy when applied as surface treatments. Hence, the extrapolation of efficacy between these products as surface treatment at the same dose rate of active substance is applicable.

- In the laboratory studies by Gibson 2016d and 2016e the application of Fendona 6SC as surface treatment with 1 day and 3 months deposits on porous and non-porous surfaces at 15 and 30 mg a.i./m^2 resulted in <90% dead German cockroaches, Oriental cockroaches and litter beetles and >90% dead ants, mosquitoes and stable flies.
  At 15 mg a.i/m^2, 1 day aged deposits on porous and non-porous surfaces resulted in <90% dead houseflies after 24 hours and >90% dead houseflies after 48 hours, while 3 months aged deposits gave >90% dead houseflies after 24 and 48 hours. At 30 mg a.i/m^2, 1 day and 3 months aged deposits on porous and non-porous surfaces resulted in >90% dead houseflies after 24 and 48 hours.
  At 15 mg a.i./1 m², 1 day and 3 months aged deposits on porous and non-porous surfaces resulted in <90% dead wasps after 24 hours and >90% dead wasps after 48 hours. At 30 mg a.i./1 m², 1 day and 3 months aged deposits on porous surfaces resulted in <90% dead wasps after 24 hours and >90% dead wasps after 48 hours, while 1 day and 3 months aged deposits on non-porous surfaces resulted in >90% dead wasps after 24 and 48 hours.

  Exposure to 3-month deposits resulted in >90% knock down against German cockroaches, Oriental cockroaches, Black ants, Mosquitoes (*Aedes aegypti*), House flies, Stable flies and Litter beetles after 1 hour after 2 hours exposure to treated porous and non-porous surfaces at 15 and 30 mg a.i./m². Against wasps, exposure to 3-month deposits to porous and non-porous surfaces resulted in >90% knock down 4 hours after treatment at 15 mg a.i./m², and 87.5% knock down on porous surfaces 6 hours after exposure and 100% knockdown on non-porous surfaces 1 hour after treatment at 30 mg a.i./m².

  The results on non-porous surfaces against mosquitoes are not valid due to high mortality in the untreated control (10.25%).
  The results on porous surfaces with fresh deposits in 24 hours against wasps are not valid due to high mortality in the untreated control (15%). The percentages of dead wasps with 1 day and 3 months aged deposits in 48 hours in the untreated controls were 12.5% - 22.5%, and therefore are considered not acceptable.

Hence, the results of these laboratory studies support efficacy of Fendona 6SC as surface treatment for 3 months post treatment at 15 and 30 mg a.i./m^2 on porous and non-porous surfaces against Black ants (*Lasius niger*), House flies (*Musca domestica*) and Stable flies (*Stomoxys calcitrans*), on porous surfaces against Mosquitoes (*Aedes aegypti*), and at 30 mg a.i./m^2 on non-porous surfaces against wasps (*Vespula* spp.) noting that mortality against wasps was achieved in 24 hours after exposure to the treated surfaces and that noticeable knockdown was recorded in 1 hour after contact with the treated surfaces.
Also, the results of these laboratory studies do not support efficacy of Fendona 6SC as surface treatment for 1 day to 3 months post treatment at 15 and 30 mg a.i./m^2 on porous and non-porous surfaces against German cockroaches, Oriental cockroaches and litter beetles.

- In the field study by Estany 2016a (15 mg a.i./m2), site 1 had not been treated before, in site 2 no additional insecticide treatments were applied 3 months previous to the Fendona 6 SC test treatment, and site 3 was previously treated with another insecticidal product about one month before the experimental treatment with Fendona 6 SC. Hence, the study by Estany 2016a is not valid due to the treatment history in one of the tested sites. In the field study by Estany 2016b the application of Fendona 6SC as crack and crevice treatment resulted in 96.9% reduction in Gerrman cockroaches (*Blatella germanica*) at 30 mg a.i./m^2, in 5L solution per 100 m^2, 4 weeks post treatment.

Hence, the results of these field studies support efficacy of Fendona 6SC as crack and crevice treatment at 30 mg a.i./m^2, in 5L solution per 100 m^2, against German cockroaches, 4 weeks post treatment.

- In the field study by Estany 2016c, site 1 had been treated with an unspecified non-professional spray product (no further information available), site 2 had not been treated in the three months previous to the experimental treatment with Fendona 6 SC and site 3 was treated with insecticidal gel in bait stations, which were removed previously to the study. Hence, this study is not valid due to the treatment history in two of the tested sites.

Hence, the results of this field study do not support efficacy of Fendona 6SC as crack and crevice treatment at 15 mg a.i./m^2, against Oriental cockroaches.

- In the field study by Estany (2016d), the site 2 had not been treated with another product three months before treatment with Fendona 6SC, whereas the sites 1 and 3 had been treated with unknown domestic products (no further info is provided) prior to treatment with Fendona 6SC. Hence this study is not valid due to the treatment history in two of the tested sites.

Hence, the results of this field study do not support efficacy of Fendona 6SC as crack and crevice treatment against Oriental and American cockroaches at 30 mg a.i./m^2, in 5L solution per 100 m^2, 4 weeks post treatment.

- In the field study by Miller and Peters (1988b) the application of Fendona 1.5SC as crack and crevice and surface treatment resulted in 96.9% - 100% population reduction in American and Australian cockroaches (*Periplaneta americana* and *Periplaneta australasiae*) at 15 mg a.i./m^2, in 5L solution per 100 m^2, 2 weeks to 6 months post treatment. However, according to the study report, a permethrin-based product was used at the same time with Fendona, and therefore it is unclear whether the observed effect was caused only by Fendona.

Hence, the results of this field study do not support efficacy of Fendona 6SC (read across from Fendona 1.5SC) as crack and crevice and surface treatment at 15 mg a.i./m^2 against American and Australian cockroaches.

- In the laboratory study by Gibson 2019a the application of Fendona 6SC as surface treatment with fresh deposits for 1-2 hours on porous and non-porous surfaces at 15 mg a.i./m^2 resulted in 100% knocked down German cockroaches (*Blattella germanica*) and American cockroaches (*Periplaneta americana*) in 1 to 6 hours. At 24 hours post treatment, <90% of treated German and American cockroaches were recorded as dead. However, at 24 hours and daily until 8 days post initial exposure for 1-2 hours, 100% of German and American cockroaches were inactive, being recorded as moribund and/or dead. At 7 days, after 1 or 2 hours exposure on both types of treated surfaces, 98-100 % of German and American cockroaches were recorded as dead. It is noted that the results concerning the mortality of American cockroaches after 1 hour exposure at 7 days post treatment are not valid due to the high mortality in the control 4 days post treatment (12%).

Hence, the results of this laboratory study support efficacy of Fendona 6SC as surface treatment on porous and non-porous surfaces with fresh deposits at 15 mg a.i./m^2 against German cockroaches (*Blattella germanica*) and American cockroaches (*Periplaneta americana*), with the note that mortality was achieved 1 week after exposure of the insects to the treated surfaces.

- In the laboratory study by Lupkes 2012 the application of Fendona 6SC as surface treatment resulted in 100% knocked down + moribund + dead German cockroaches in 1 and 2 days after exposure and 100% dead German cockroaches 4 days after exposure to 1 day, 1 month, 2 months and 3 months aged treated non-porous surfaces. However, on porous surfaces (carpets) <90% dead German cockroaches were recorded in 4 days after exposure to 1 day, 1 month, 2 months and 3 months treated surfaces.

Hence, the results of this laboratory study support efficacy of Fendona 6SC as surface treatment on non-porous surfaces with 1 day to 3 months deposits at 15 mg a.i./m^2 against German cockroaches (*Blattella germanica*), with the note that mortality was achieved 4 days after exposure of the insects to the treated surfaces.

- In the field study by Estany (2016g) against Oriental cockroaches with crack and crevice treatment at 12 mg a.i./m^2, site 1 had not been treated for about 1 year prior to treatment with Fendona 6SC, site 3 had not been treated for 8 weeks before Fendona 6SC treatment, whereas site 2 was previously treated with unknown domestic products before treatment with Fendona 6SC (no further info is provided). Hence, the study is not valid due to the treatment history in one of the tested sites.

Hence, the results of this field study do not support efficacy of Fendona 6SC as crack and crevice treatment against Oriental cockroaches at 12 mg a.i./m^2, in 5L solution per 100 m^2, 4 weeks post treatment.

- In the field study by Serrano (2012) against German cockroaches, the application of Fendona 6SC with spot, crack and crevice treatment at 15 mg a.i./m^2 resulted in >90% population reduction at 7 until 56 days after treatment. The application of Fendona 6SC with spot, crack and crevice treatment at 30 mg a.i./m^2 resulted in >90% population reduction at 3 until 84 days after treatment.

Hence, the results of this field study support efficacy of Fendona 6SC as spot, crack and crevice treatment against German cockroaches at 15 mg a.i./m^2, in 5L solution per 100 m^2,

for 2 months post treatment; and at 30 mg a.i/m^2, in 5L solution per 100 m^2, for 3 months post treatment.

Ants

- In the laboratory study by Miller and Peters (1989) the application of Fendona 1.5SC as surface treatment resulted in 95% and 90% knockdown of Coastal brown ant (*Pheidole megacephala*) at 15 and 30 mg a.i./m^2, respectively, 2 months post treatment.

However, the study protocol did not include mortality records and therefore the results do not adequately support the efficacy of Fendona 6SC (read across from Fendona 1.5SC) against Coastal brown ants (*Pheidole megacephala*).

- In the laboratory study by Miller and Peters (1988a) the application of Fendona 1.5SC as surface treatment resulted in <75% knockdown of Black house ants (*Iridomyrmex glaber*) at 15 and 30 mg a.i./m^2, respectively, 1-3 months post treatment after 3 hours exposure to the treated surfaces.

The study protocol did not include mortality records and therefore the results do not adequately support the efficacy of Fendona 6SC (read across from Fendona 1.5SC) against Black house ants (*Iridomyrmex glaber*).

- The results of the laboratory studies by Gibson 2016d and 2016e (described in the section for cockroaches) support efficacy of Fendona 6SC as surface treatment on porous and non-porous surfaces at 15 and 30 mg a.i./m^2 against Black ants (*Lasius niger*) for 3 months post treatment.

- In the field study by Gibson 2016a Fendona 6SC was applied as spotted surface treatment at a rate of 24 mg a.i./50 mL water/m^2 against black garden ants (*Lasius niger*).

However, the results do not adequately prove efficacy of Fendona 6SC due to high population reduction in the untreated control nests 7-28 post treatment (24-75%).

- In the field studies by Gibson (2016g) and Gibson (2016h) the application of Fendona 6SC as surface spotted treatment resulted in 93.3% and 97.8% reduction of black garden ants (*Lasius niger*) population at 15 and 30 mg a.i./m^2, in 5L solution per 100 m^2, 28 days post treatment.

Hence, the results of these field studies can be used to support efficacy of Fendona 6SC as spotted surface treatment against black garden ants (*Lasius niger*) at 15 and 30 mg a.i./m^2, in 5L solution per 100 m^2, 4 weeks post treatment.

Flies

- The results of the laboratory studies by Gibson 2016d and 2016e (described in the section for cockroaches) support efficacy of Fendona 6SC as surface treatment on porous and non-porous surfaces at 15 and 30 mg a.i./m^2 against House flies (*Musca domestica*) and Stable flies (*Stomoxys calcitrans*) for 3 months post treatment.

- In the laboratory study by Lupkes 2011 the application of Fendona 1.5SC as surface treatment with 3 months deposits on porous and non-porous surfaces at 15 and 30 mg a.i./m^2 resulted in 100% knockdown against houseflies and stable flies within 15-30 minutes after exposure. For litter beetles 100% knockdown was recorded within 15 –

120 minutes after exposure to porous and non-porous surfaces aged for 3 months. In this study the mortality records after 24 and 48 hours is considered invalid because the insects were exposed permanently to treated surfaces for too long.

Hence, the results of this laboratory study support efficacy of Fendona 6SC (read across from Fendona 1.5SC), in terms of knockdown, as surface treatment on porous and non-porous surfaces against House flies (*Musca domestica*) and Stable flies (*Stomoxys calcitrans*) at 15 and 30 mg a.i./m^2 for 3 months.

- In the simulated use studies by Gibson 2016b and 2016c the application of Fendona 6SC as surface treatment with 1 day and 3 months deposits on porous and non-porous surfaces at 15 and 30 mg a.i./m^2 resulted in >98% affected (knocked down and dead) mosquitoes (*Aedes aegypti*), houseflies (*Musca domestica*) and litter beetles (*Alphitobius diaperinus*), and <18% affected Chicken red mites (*Dermanyssus gallinae*) 24 and 48 hours after exposure to the treated surfaces. Exposure to 3 month aged deposits resulted in >80% knock down 2 hours after exposure to the treated porous and non-porous surfaces at 15 and 30 mg ai/m^2 against mosquitoes, houseflies and litter beetles. However, exposure to 1 day and 3 month aged deposits of Fendona 6 SC at 15 and 30 mg ai/m^2 on porous and non-porous surfaces in a simulated use environment resulted in <90% dead mosquitoes (*Aedes aegypti*), houseflies (*Musca domestica*), and litter beetles (*Alphitobius diaperinus*), after a 24 and 48 hour experimental period.
  It is noted that for the flying insects the product was applied as a spotted surface treatment.

Hence, the results of these simulated use studies do not support efficacy of Fendona 6SC as surface spotted treatment against mosquitoes (*Aedes aegypti*) and houseflies (*Musca domestica*), and surface treatment against litter beetles (*Alphitobius diaperinus*), on porous and non-porous surfaces at 15 and 30 mg a.i./m^2 for 1 day to 3 months post treatment.

- In the field study by Estany 2016e the application of Fendona 6SC as spotted surface treatment at 15 mg a.i. per m^2 in animal houses provided an average 73.8%, 77% and 80.5% population reduction, in terms of corrected percent control achieved, in stable flies' numbers after a 7, 14 and 21 days period, respectively. The treatment resulted in 94%, 73.6% and 73.9% reduction in stable fly numbers after 21 days, relative to pre-treatment levels, at sites 1, 2 and 3 respectively. For the low population reduction at site 2, secondary re-infestations from outdoors premises (animal housing, etc.) should be presumed according to the applicant, however the low stable fly population reduction at site 3 is not justified.

Hence, the results of this field study, due to the low efficacy levels (73.8%, 77% and 80.5% population reduction 7, 14 and 21 days post treatment, respectively), do not adequately support efficacy of Fendona 6SC as spotted surface treatment at 15 mg a.i. per m2 in animal houses against stable flies (*Stomoxys calcitrans*). It is noted that the residual effect was tested for 3 weeks, not for 3 months as claimed by the applicant.

- In the field study by Estany 2016f the application of Fendona 6SC as spotted surface treatment at 30 mg a.i. per m2 in animal houses provided an average 80.1%, 62.2% and 71.4% population reduction, in terms of corrected percent control achieved, in stable flies' numbers after a 7, 14 and 21 days period, respectively. The treatment resulted in 97.3%, 51.1% and 65.7% reduction in stable fly numbers after 21 days, relative to pre-treatment levels, at sites 1, 2 and 3 respectively. For the low population reduction at site 2, secondary re-infestations from adjacent outdoors premises could be

presumed according to the applicant, however the low stable fly population reduction at site 3 is not justified.

Hence, the results of this field study, due to the low efficacy level (80.1%, 62.2% and 71.4% population reduction 7, 14 and 21 days post treatment, respectively), do not adequately support efficacy of Fendona 6SC as spotted surface treatment at 30 mg a.i. per m2 in animal houses against stable flies (*Stomoxys calcitrans*). It is noted that the residual effect was tested for 3 weeks, not for 3 months as claimed by the applicant.

- In the field study by Latorre 2017a, the application of Fendona 6SC as spotted surface treatment at 15 mg a.i. per m^2 in animal houses provided, in terms of corrected percent control achieved, for house flies an average of 39.4% population reduction during the first month, 43.8% during the second month and 49.1% during the third month post treatment. In stable flies, the average population reduction was of 28.4% during the first month, 30.7% during the second month and 37.9% during the third month.

  In the field study by Latorre 2017b, the application of Fendona 6SC as spotted surface treatment at 30 mg a.i. per m^2 in animal houses provided, in terms of corrected percent control achieved, for house flies an average of 31.7% population reduction during the first month, 33.2% during the second month and 24.2% during the third month. In stable flies, the population reduction was of 37.8% during the first month, 31.4% during the second month and 50.9% during the third month.

  The applicant justifies the low efficacy levels by stating the following: *"It should be noted that stables and other animal buildings are considered very challenging situations in which to control houseflies, because of the continuous risk of reinvasion from adjacent premises. In these situations, even what is considered a low % of control - when comparing to other pests and/or other situations – is still perceived as a positive effect in these cases. Considering that the residual activity provided by some of the most widely used fly baits does not exceed 35% in 5 weeks (the applicant provided two relevant supporting literature papers), this is the reason why multiple applications are recommended, and that the % population reduction provided by Fendona for up to 3 months after the application is expected to be highly appreciated in animal buildings."*.

However, the eCA does not agree with the applicant's statement and considers that the very low overall efficacy levels of <50% fly population reduction in the aforementioned field studies do not adequately support efficacy of Fendona 6SC as spotted surface treatment at 15 and 30 mg a.i. per m^2 in animal houses against houseflies (*Musca domestica*) and stable flies (*Stomoxys calcitrans*).

- In the simulated use study by Gibson 2019b the application of Fendona 6SC as surface spotted treatment with 1-day deposits on porous and non-porous surfaces at 15 mg a.i./m^2 against *Musca domestica* resulted in >90% knock down in 6 hours and >90% mortality in 24 hours. Exposure of houseflies to 3-month residual deposits of Fendona 6SC applied at 15mg ai/m^2 on porous and non-porous surfaces resulted in 95.9% and 79.6% knockdown, respectively, in 6 hours and >90% mortality for both types of surfaces in 24 hours.

Hence, the results of this simulated use study support the efficacy of Fendona 6SC as surface spotted treatment with fresh (1-day) and 3-month deposits on porous and non-porous surfaces at 15 mg a.i./m^2 against houseflies (*Musca domestica*).

Mosquitoes

- The results of the laboratory studies by Gibson 2016d and 2016e (described in the section for cockroaches) support efficacy of Fendona 6SC as surface treatment on porous surfaces at 15 and 30 mg a.i./m^2 against Mosquitoes (*Aedes aegypti*), for 3 months post treatment.

- In the laboratory study by Gibson 2017a, the application of Fendona 6SC as surface treatment with 1 day and 3 months deposits on porous and non-porous surfaces at 15 mg a.i./m^2 against mosquitoes (*Culex quinquefasciatus*) resulted in 91.9% - 100% dead mosquitoes 24 and 48 hours after exposure to the treated surfaces. Also, 100% knockdown was recorded after two hours of exposure to the treated surfaces in all treatments.

  In the laboratory study by Gibson 2017b the application of Fendona 6SC as surface treatment with 1 day and 3 months deposits on porous and non-porous surfaces at 30 mg a.i./m^2 against mosquitoes (*Culex quinquefasciatus*) resulted in 86.9% mortality on porous surfaces and 92.5% mortality on non-porous surfaces with the 3-month residues at 24 hours after exposure. However, mortality was increased after a 48 hour experimental period reaching 100% on both surfaces. It is noted that mortality in the untreated control on 3-month aged porous surfaces at 48 hours was 5%. Therefore, the 86.9% mortality level at 24 hours is considred acceptable. Also, 100% knockdown was recorded after two hours of exposure to the treated surfaces in all treatments.

Hence, the results of these laboratory studies support efficacy of Fendona 6SC as surface treatment on porous and non-porous surfaces at 15 and 30 mg a.i./m^2 against mosquitoes (*Culex quinquefasciatus*) for 3 months post treatment.

- The results of the simulated use tests by Gibson 2016b and 2016c (described in the section for flies) do not support efficacy of Fendona 6SC as surface spotted treatment against mosquitoes (*Aedes aegypti*) on porous and non-porous surfaces at 15 and 30 mg a.i./m^2, for 1 day and 3 months post treatment.

- In the simulated use study by Gibson 2018a the application of Fendona 6SC as surface spotted treatment with 1 day and 3 months deposits on porous and non-porous surfaces at 15 mg a.i./m^2 against *Culex quinquefasciatus* resulted in 82% and 84% affected (knock down + dead) mosquitoes on 1 day aged porous surfaces 24 and 48 hours post treatment, respectively, and 89.5% and 92% affected (knock down + dead) mosquitoes on 1 day aged non-porous surfaces 24 and 48 hours post treatment, respectively. Exposure to residual deposits of Fendona 6 SC 15mg ai/m^2, resulted in 81% and 84% affected (knock down + dead) mosquitoes (*Culex pipiens*) on 3-month aged porous surfaces 24 and 48 hours post treatment, respectively, and 81.5% and 83% affected (knock down + dead) mosquitoes (*Culex pipiens*) on 3-month aged non-porous surfaces 24 and 48 hours post treatment, respectively. Exposure to fresh (1 day) deposits of Fendona 6 SC at 15 mg ai/m^2 on porous and non-porous surfaces resulted in <90% dead mosquitoes (*Culex quinquefasciatus*) in 24 hours post treatment, however in 48 hours the treatment on non-porous surfaces resulted in >90% dead mosquitoes (*Culex quinquefasciatus*).

  In the simulated use study by Gibson 2018b the application of Fendona 6SC as surface spotted treatment with 1 day and 3 months deposits on porous and non-porous surfaces at 30 mg a.i./m^2 against *Culex quinquefasciatus* mosquitoes resulted in 89.5% and 92% affected (knock down + dead) mosquitoes on 1 day aged porous surfaces 24 and 48 hours post treatment, respectively, and 89.5% and 93.5% affected (knock down + dead) mosquitoes on 1 day aged non-porous surfaces 24 and 48 hours post treatment,

respectively. Exposure to residual deposits of Fendona 6 SC 30mg ai/m², resulted in 86% and 88.5% affected (knock down + dead) mosquitoes *Culex pipiens* on 3-month aged porous surfaces 24 and 48 hours post treatment, respectively, and 87.5% and 89% affected (knock down + dead) mosquitoes on 3-month aged non-porous surfaces 24 and 48 hours post treatment, respectively.
Exposure to fresh (1 day) deposits of Fendona 6 SC at 30 mg ai/m² on porous and non-porous surfaces resulted in <90% dead mosquitoes (*Culex quinquefasciatus*) in 24 hours post treatment, however in 48 hours the treatment on non-porous and porous surfaces resulted in >90% dead mosquitoes (*Culex quinquefasciatus*).

Hence, the results of these simulated use studies support efficacy of Fendona 6SC as surface spotted treatment with fresh deposits (1 day old) on non-porous surfaces at 15 mg a.i./m^2, and on porous and on non-porous surfaces at 30 mg a.i./m^2 against *Culex quinquefasciatus*, noting that mortality is achieved 48 hours after exposure of the insects to the treated surfaces.

- In the simulated use study by Gibson 2019b the application of Fendona 6SC as surface spotted treatment with 1 day deposits on porous and non-porous surfaces at 15 mg a.i./m^2 against *Culex quinquefasciatus* resulted in <90% mortality in 24 hours, however the treatment resulted in >90% dead mosquitoes in 3 and 4 days, respectively. Exposure of mosquitoes to 3-month residual deposits of Fendona 6SC applied at 15mg ai/m² on porous and non-porous surfaces resulted in <90% mortality in 24 hours, however the treatment resulted in >90% dead mosquitoes in 2 and 3 days, respectively. Less than 80% knockdown of mosquitoes was recorded after two to six hours of exposure to the treated surfaces in all treatments. Mortality in the corresponding untreated control cohort was 0-7.2% for the duration of the 4-day assessment period for 1-day and 3-months porous and non-porous deposits.

Hence, the results of this simulated use study support the killing effect of Fendona 6SC as surface spotted treatment with fresh (1-day) and 3-month deposits on porous and non-porous surfaces at 15 mg a.i./m^2 against *Culex quinquefasciatus*, noting that mortality is achieved 2-4 days after exposure of the insects to the treated surfaces.

Wasps

- The results of the laboratory studies by Gibson 2016d and 2016e (described in the section for cockroaches), support efficacy of Fendona 6SC as surface treatment for 3 months post treatment at 30 mg a.i./m^2 on non-porous surfaces against wasps (*Vespula* spp.) noting that mortality against wasps was achieved in 24 hours after exposure to the treated surfaces and that noticeable knockdown was recorded in 1 hour after contact with the treated surfaces.

- In the simulated use studies by Gibson 2018c and 2018d the application of Fendona 6SC as surface spot treatment with 1 day and 3 months deposits on non-porous surfaces at 15 and 30 mg a.i./m^2 resulted in >90% dead Wasps (*Vespula germanica* and *Vespula vulgaris*) 24 hours after exposure to the treated surfaces. Knock down was >90% after exposure at 15 and 30 mg a.i./m^2 for 6 hours on non-porous surfaces. The results on porous surfaces are considered not valid due to the high mortality in the untreated control (10% and 20% in 24 and 48 hours, respectively) for both tested doses (15 and 30 mg a.i./m^2) and the low knockdown values (<90%) after 2-6 hours exposure to 1 day and 3 months deposits at 15 mg a.i/m^2 and 3 months deposits at 30 mg a.i/m^2.

Hence, the results of the simulated studies by Gibson 2018c and 2018d support efficacy of Fendona 6SC as surface spot treatment at 15 and 30 mg a.i./m^2 against wasps (*Vespula* spp.) for up to 3 months, noting however that residual activity against wasps (*Vespula* spp.) was achieved only on non-porous surfaces (not on porous surfaces) for up to 3 months, and that noticeable knockdown effect on wasps was observed within 6 hours after contact of the insects with non-porous treated surfaces and mortality was achieved at 24 hours.

Litter beetles

- The results of the laboratory study by Lupkes 2011 (described in the section for flies) support efficacy of Fendona 1.5SC, in terms of knockdown, as surface treatment on porous and non-porous surfaces against litter beetles (*Alphitobius diaperinus*) at 30 mg a.i./m^2 for 3 months.

- The results of the laboratory studies by Gibson 2016d and 2016e (described in the section for cockroaches) do not support efficacy of Fendona 6SC as surface treatment on porous and non-porous surfaces at 15 and 30 mg a.i./m^2 against Litter beetles (*Alphitobius diaperinus*), for 1 day to 3 months post treatment.

- The results of the simulated use studies by Gibson 2016b and 2016c (described in the section for flies) do not support efficacy of Fendona 6SC as surface treatment against litter beetles (*Alphitobius diaperinus*), on porous and non-porous surfaces at 15 and 30 mg a.i./m^2, for 1 day to 3 months post treatment.

Bedbugs

- In the laboratory study by Loakes 2011 the application of Fendona 6SC as surface treatment with 1 day, 1 month and 3 months deposits on two porous and one non-porous surfaces at 30 mg a.i./m^2 against Bedbugs (*Cimex lectularius*) resulted in 100% affected (knocked down and dead) insects after 24 hours observation period with the 3 month deposits. Knock down records for bedbugs ranged between 92.5% and 100%, 1 hour post treatment for all ageing times and types of surfaces.

Hence, the results of this laboratory study support efficacy of Fendona 6SC as surface treatment against Bedbugs (*Cimex lectularius*) on porous and non-porous surfaces at 30 mg a.i./m^2 for 3 months post treatment. However, this study is not relevant for efficacy evaluation of label claims since the product is intended to be use against bedbugs at the lower dose of 15 mg a.s./m^2.

- In the laboratory study by Gibson 2017c the application of Fendona 6SC as surface treatment with 1 day, 1 month and 3 months deposits on porous and non-porous surfaces at 15 mg a.i./m^2 resulted in >95% affected (knocked down and dead) Bedbugs (*Cimex lectularius*), 24 hours after exposure to the treated surfaces. Exposure to 3-month deposits resulted in >95% knock down against Bedbugs after 6 hours exposure to the treated porous and non-porous surfaces at 15 mg a.i./m^2. Although 24 hours after exposure to 3-months deposits resulted in <95% dead bedbugs, in 1 week post exposure mortality reached 92.5% and 100% in two porous surfaces (cotton fabric and wallpaper, respectively) and 100% in one non-porous (glazed ceramic) surface.

Hence, the results of this laboratory study support efficacy of Fendona 6SC as surface treatment on porous and non-porous surfaces at 15 mg a.i./m^2 against Bedbugs (*Cimex lectularius*) for 3 months post treatment, noting however that mortality is achieved 1 week after exposure of the insects to the treated surfaces.

- In the field study by Foltan 2017 the application of Fendona 6SC as crack and crevice treatment resulted in 88.4% and 77.4% population reduction of bedbugs 2 weeks after application at 30mg ai/m² and 15 mg ai/m², respectively. Both application rates resulted in 100% control of the bed bug populations for 14 weeks following the second application.
  It is noted that the treatment regime of 2 subsequent applications that provided 100% control of bedbugs at the end, is justified by the following requirement of the TNsG for bedbug control: "Treatment repeats usually are necessary in bedbug control. At the end of a treatment, 100 % efficacy should be achieved".

Hence, the results of this field study support efficacy of the product as crack and crevice treatment at 15 mg ai/m² against bed bugs (*Cimex lectularius*) for 3 months post treatment, noting that at least 1 re-application is required after initial application. Also, the results of this study support the claim that "Treated areas should be re-inspected after 2– 3 weeks. Where initial infestation was severe a second application may be required particularly if the first treatment has been disturbed or some harbourages/landing sites were missed in the initial application."

- In the laboratory study by Lupkes 2012 the application of Fendona 6SC as surface treatment resulted in 100% knocked down + moribund + dead bedbugs 1 and 2 days after exposure and 100% dead bedbugs in 7 days after exposure to 1 day, 1 month, 2 months and 3 months aged treated porous and non-porous surfaces.

Hence, the results of this laboratory study support efficacy of Fendona 6SC as surface treatment on porous and non-porous surfaces with 1 day to 3 months deposits at 15 mg a.i./m^2 against bedbugs, with the note that mortality was achieved 7 days after exposure of the insects to the treated surfaces.

Fleas

- In the laboratory study by Loakes 2011 the application of Fendona 6SC as surface treatment with 1 day, 1 month and 3 months deposits on two porous and one non-porous surfaces at 30 mg a.i./m^2 against Cat fleas (*Ctenocephalides felis*) resulted in 95-100% affected (knocked down and dead) insects after 24 and 48 hours observation period with the 3 month deposits.

Hence, the results of this laboratory study support efficacy of Fendona 6SC as surface treatment against Cat fleas (*Ctenocephalides felis*) on porous and non-porous surfaces at 30 mg a.i./m^2 for 3 months post treatment. However, this study is not relevant for efficacy evaluation of label claims since the product is intended to be use against fleas at the lower dose of 15 mg a.s./m^2.

- In the laboratory study by Gibson 2017c the application of Fendona 6SC as surface treatment with 3 months deposits on porous and non-porous surfaces at 15 mg a.i./m^2 gave the following results concerning mortality against Cat fleas (*Ctenocephalides felis*): 95% in 24 hours after exposure to treated ceramic glazed (non-porous) surfaces, 52.5% in 24 hours and 95% in 48 hours on plywood, and 25% in 24 hours and 85% in 48 hours on carpets For the 3-month deposits against fleas mortality in the untreated control was 7.5% and 15% on ceramic surfaces in 24 hours and 48 hours, 7.5% and 17.5% on plywood, and 15% and 17.5% on carpets, respectively.. In cases where mortality in the untreated controls was >10% the results are considered not valid.

Hence, the results of this laboratory study support efficacy of Fendona 6SC as surface treatment on non-porous surfaces at 15 mg a.i./m^2, against Cat fleas (*Ctenocephalides felis*) for 3 months post treatment.

- In the simulated use studies by Gibson 2017d and 2017e the application of Fendona 6SC as surface treatment with 1 day and 3 months deposits on porous and non-porous surfaces at 15 and 30 mg a.i./m^2 resulted in >90% affected (knocked down + dead) Cat fleas (*Ctenocephalides felis*), 48 hours after exposure to treated plywood (porous) and ceramic glazed (non-porous). Exposure to 3-month deposits resulted in 70% and 77.5% affected Cat fleas at 15 and 30 mg a.i./m^2, respectively, 48 hours after exposure to treated carpet (porous). Exposure to 1-day deposits resulted in 83.7% and 82.5% affected Cat fleas at 15 and 30 mg a.i./m^2, respectively, 48 hours after exposure to treated carpet (porous).
  Exposure to 1 day and 3 months deposits on porous and non-porous surfaces at 15 mg a.i./m^2 resulted in <90% dead Cat fleas (*Ctenocephalides felis*), 48 hours after exposure to treated plywood (porous), carpet (porous) and ceramic glazed (non-porous) surfaces. Exposure to 1 day and 3 months deposits on porous and non-porous surfaces at 30 mg a.i./m^2 resulted in <90% dead Cat fleas (*Ctenocephalides felis*), 48 hours after exposure to treated plywood (porous) and carpet (porous) surfaces and >90% dead insects on ceramic glazed (non-porous) surfaces. The results of exposure to 3 month deposits on non-porous surfaces in 48 hours are considered not valid due to high mortality in the untreated control (12.5%). It is noted that against fleas only the low dose of 15 mg a.i./m^2 is claimed by the applicant.

  It is noted that in terms of the application method that was used in these simulated use tests the applicant clarifies that *"the simulated-use test design that was used, provided the insects with the option to crawl onto the treated or untreated area and in addition provided places where the insects could hide (between tiles, underneath the surfaces), and as such mimics as far as possible the practical use situation.".* Therefore, the study design supports the claimed spot, crack and crevice application method against fleas.

However, considering that <90% mortality of cat fleas was recorded 48 hours after exposure to 1 day and 3 months deposits on porous and non-porous surfaces, the results of the simulated use-test by Gibson 2017d do not support efficacy of Fendona 6SC as spot, crack and crevice treatment on porous and non-porous surfaces at 15 mg a.i./m^2 against Cat fleas (*Ctenocephalides felis*) for 1 day to 3 months post treatment.

- In the laboratory study by Lupkes 2012 the exposure time of fleas onto the treated surfaces under confined conditions (24 hours) is considered too long to be acceptable, and therefore the results against fleas are not valid.

Hence, the results of this laboratory study do not support efficacy of Fendona 6SC as surface treatment at 15 mg a.i./m^2 against fleas.

Further to the results of the submitted efficacy studies, the eCA highlights the following critical points for efficacy evaluation:

- The applicant provided the following justification, which is accepted by the eCA, for read across of data from the product FENDONA 1.5 SC to FENDONA 6 SC: *"In addition to the studies performed with the product FENDONA 6 SC (BAS 310 27I), additional studies with FENDONA 1.5 SC (BAS 310 22I) are presented to reinforce the different claims. The compositions of both products (please refer to the confidentional annex) are very similar, and indeed are almost identical when considering the spray solution concentrations*

(where the products are diluted to give the same alpha-cypermethrin concentration for the same rate of application per m²). Therefore, the slight variations in the composition of the two products will have no impact on the efficacy of the product, which is supported by the results of the studies conducted with Fendona 1.5 SC (1988/8000001, DocID 1988/8000003, DocID 1989/8000001, DocID 2011/1291553) and the bridging trial conducted with both products (DocID 2016/1136390).".

- In the study reports for studies by Gibson 2016b, 2016c, 2016d, 2016e, 2016f, 2017c, 2017d, 2017e, 2018a, 2018b and Loakes 2011, the definitions of the terms "knocked down", "dead" and "affected" insects are clarified by the applicant as follows: *"Knock-down was defined as: "the test system is unable to right-itself, or make co-ordinated, directional movements, but small and/or infrequent movement of appendages are detected with (or without) probing"; dead was defined as: "test system has no response to tactile stimuli". In collating the data in preparation for the report, the term 'Affected' is used to report the efficacy of the product – this is a calculation of the combined totals of both the 'knocked down' and 'dead' insects. In this experiment the definition of knocked down also encompassed moribund insects & insects that were paralysed and very unlikely to recover - it can be assumed that most if not all of the insects falling within this category of 'knockdown' (at 24 and 48 hours) would have gone on to die a short time afterwards. As such the term 'Affected' is used to report the data-set instead of the term mortality – but both can be assumed to measure the same parameters of efficacy."*

In opposition to the afore-mentioned justification by the applicant, the efficacy evaluation of the product in the submitted lab and simulated use studies is based on the dead insects, not "affected" (dead + knocked down insects), following the efficacy criteria that are set in the efficacy guidance (TNsG).

- The applicant supports the general surface treatment, especially to cracks and crevices, against crawling insects and cockroaches in animal houses (intended use 2), using the results of the field studies where the product was applied in apartments as a crack and crevice treatment.

  To support this claim, the applicant provided the following justification, which is accepted by the eCA: "*Considering the efficacy observed against both species of cockroaches following the crack and crevice or spot application technique to a limited area, it is technically feasible to assume that using the general surface treatment the efficacy levels will be the same or even higher. This is because a crack and crevice or spot application is a targeted or focused application to the area needed to be treated. The area of a crack and crevice or spot application will therefore be less than that of a general surface treatment. Therefore, if the presented trials show control of cockroaches using a crack and crevice and/or spot application, then it can be concluded that the control achieved using a general surface application will be the same or even higher. Therefore, Intended Use 2 should be covered by the submitted trials which cover both the low and high rates to be claimed for control of crawling insects in both intended use scenarios of urban pest (Intended Use 1) and rural hygiene (Intended Use 2)*.".

Based on the results of the aforementioned efficacy studies, and considering the conclusions of the teleconference on 5 March 2019 and the outcome of the discussions of 34th CG meeting on 12 March 2019 concerning the Referral to the Coordination Group of a disagreement on Mutual recognition (MR) in accordance with Article 35(2) of the Regulation (EU) No 528/2012 (BPR) for Fendona 6SC, the

intended uses of Fendona 6 SC, from an efficacy point of view, are acceptable as applied for by the applicant (2.2.1, tables 1 & 2), with the following limitations per target organism:

Cockroaches

In both intended uses 1 & 2, it is claimed that the residual activity of the product against crawling insects and cockroaches is up to 3 months.
The applicant in order to justify the 3-month residual activity against cockroaches using the data only from laboratory and simulated use-tests, provided the following statement, which is not accepted by the eCA: *"The residual effect of the product was evaluated using the lab and simulated use tests submitted (Gibson, 2016d, Gibson 2016e and Gibson 2016f). In all those studies no differences in efficacy were observed between 1-day-treated and 3 month-treated materials. In both cases >90% efficacy after 24 h was achieved (refer to raw data tables). The reason for evaluating the residual activity in the lab and simulated use tests and not in the field was to avoid the imposition of having a professional pest control operator having to frequently enter the structure to evaluate the treatment and request that the owner not disturb the location of the trial – i.e. not cleaning or moving things around for a 90-day period. Maintaining access to a site for several months is never practically easy to arrange with the property owner. Thus, the efficacy in the lab and simulated use tests provide robust information of undisturbed material for 90 days in a way that a field trial for 90 days is very difficult in practice to achieve.".*

The eCA notes that according to the TNsG, in case of general surface treatment by professionals against cockroaches, efficacy of the product needs to be supported by field studies. Normally, the same applies for the claimed crack and crevice treatment by professionals. Regardless, however, the category of use (professional or non-professional), the claimed crack and crevice treatment against cockroaches is appropriately proved through the submitted field studies using this particular application method.

The eCA also notes that according to the TNsG, for a general claim against crawling insects and cockroaches, efficacy should be proved against one small cockroach species (German cockroach) and one large cockroach species (Oriental or American cockroach).

Overall, based on the results of the lab studies by Gibson 2019 and the field study by Serrano 2012, Fendona 6SC was effective against only German cockroaches for both intended uses 1 & 2 with the following limitations:
- "Activity against German cockroaches is achieved only with fresh deposits.".
- "Mortality of German cockroaches is achieved 1 week after exposure of the insects to the treated surfaces".
- For the intended use 2, "An application rate 15 mg/m^2 is set for high hygiene shelter places against cockroaches, otherwise an application rate 30 mg/m^2 should be used".
- Efficacy of the product against Oriental and American cockroaches is not sufficiently proved. Hence, the general claims against "cockroaches" and "crawling insects" are not sufficiently supported and will be removed from the authorized uses in the PAR and SPC.

Ants

In both intended uses 1 & 2, it is claimed that the residual activity of the product against ants is up to 3 months. Although efficacy against ants (*Lasius niger*) was proved for 3 months in the laboratory studies (Gibson 2016d, 2016e), in the submitted field studies the residual activity was proved for 28 days (Gibson 2016g, 2016h).
The applicant in order to justify the 3-month residual activity against ants using the data only from laboratory tests, provided the following statement: *"The reason for evaluating the*

residual activity in the lab and simulated use tests and not in the field, was to avoid the imposition of having a professional Pest Control Operator (PCO) having to frequently enter the structure to evaluate the treatment and request that the owner does not disturb the location of the trial i.e. not cleaning or moving things around for a 90-day period – this is difficult in practice to achieve. Thus, the efficacy in the lab studies provide robust information of undisturbed material for 90 days which supports the residual activity of the product, and so additional studies should not be required.".
The eCA notes that according to the TNsG, in case of general surface treatment by professionals against ants, efficacy of the product needs to be supported by field studies. Normally, the same applies for the claimed surface spotted treatment by professionals. Regardless, however, the category of use (professional or non-professional), the claimed spotted treatment against ants is appropriately proved through the submitted field studies using this particular application method.

- Hence, the eCA does not accept the aforementioned justification by the applicant, and proposes to address in both intended uses 1 & 2 that "Residual activity against ants (*Lasius niger*) is up to 1 month".

Flies

In the intended use 2, it is claimed that the product is intended to be used in animal houses against flying insects, including stable flies (*Stomoxys calcitrans*) and houseflies (*Musca domestica*), with residual activity of 3 moinths. The eCA notes that according to the TNsG, for application in animal houses against flies (houseflies, stable flies), field trials are normally required. However, in the submitted field studies by Estany 2016e and 2016f, the product performed low efficacy levels at both claimed doses against stable flies over a 3-weeks period in animal houses. Also, in the field studies by Latorre 2017a and 2017b the product performed low efficacy levels at both claimed doses against houseflies and stable flies over a 3-month period in animal houses.
Also, it is noted that according to the TNsG for a general claim against flying insects, tests against flies (houseflies + stable flies in case of use in animal houses) are required.

The applicant provided the following justification in order to justify how the low efficacy levels in the field studies by Latorre 2017a and 2017b could be used to support efficacy against houseflies and stable flies in animal houses (intended use 2): *"It should be noted that stables and other animal buildings are considered very challenging situations in which to control houseflies, because of the continuous risk of reinvasion from adjacent premises. In these situations, even what is considered a low % of control - when comparing to other pests and/or other situations – is still perceived as a positive effect in these cases. Considering that the residual activity provided by some of the most widely used fly baits does not exceed 35% in 5 weeks (please refer to the two attached published papers), this is the reason why multiple applications are recommended, the % population reduction provided by Fendona for up to 3 months after the application is expected to be highly appreciated in animal buildings*".

- The eCA does not agree with the aforementioned justification and considers that in the intended use 2 (rural hygiene/ animal houses), the general claim for use against "flying insects" and the specific claims for use against "stable flies" *(Stomoxys calcitrans)* and "houseflies" *(Musca domestica)* are not adequately supported by the submitted efficacy studies, and therefore proposes not to include them into the target organisms of the product.

In the intended use 1, it is claimed that the product is intended to be used against flying insects, including houseflies (*Musca domestica*), with residual activity of 3 moinths. The eCA

notes that according to the TNsG, for application in houses against houseflies, simulated use studies are normally required. However, the results of the submitted simulated use studies by Gibson 2016b and 2016c do not support efficacy of Fendona 6SC as surface spotted treatment against houseflies (*Musca domestica*).

- Hence, efficacy against "houseflies" and therefore the general claim against "flying insects" is not supported for the intended use 1.

Mosquitoes

In both intended uses 1 & 2, it is claimed that the product is intended to be used against flying insects, including mosquitoes (*Aedes aegypti, Culex spp*) with a residual activity up to 3 months.
It is noted that according to the TNsG, efficacy against *Culex* mosquitoes is required to support the general claims against "mosquitoes" and "flying insects". Also, for the claim against mosquitoes simulated use tests are required, while efficacy cannot be supported only by lab studies.
In the simulated use studies by Gibson 2018a and 2018b efficacy of the product as surface spotted treatment against *Culex quinquefasciatus* was proved on non-porous surfaces at 15 mg a.i./m^2, and on porous and on non-porous surfaces at 30 mg a.i./m^2, only with fresh deposits, noting however that mortality is achieved 48 hours after exposure of the insects to the treated surfaces.

The applicant provided the following statement, which is not accepted by the eCA, in order to justify how the low efficacy levels in the simulated use studies by Gibson 2018a and 2018b (81-81.5% and 86-87.5% "affected" mosquitoes at 15 and 30 mg a.s./m^2, respectively, for the 3-month deposits 24 hours post treatment), can be used to support the 3-month residual efficacy against *Culex* mosquitoes, and therefore against mosquitoes and flying insects: *"Among flying insects, mosquitoes are some of the ones of the most difficult insects to control using a surface treatment. Based on Gibson 2017 a & b, there is a technical evidence of the intrinsic activity of the products (Fendona 6 SC and 1.5 SC) against Culex spp, even with 3-month undisturbed residues – they were forced to be in contact with treated surfaces and they could not select where to fly or settle. The potency of the product is confirmed with the 1-day results in Gibson 2018 a & b – where there was not a forced exposure. Regarding the 3-month results, although slightly lower are representative to what can be observed in the field, which is still an effective product to control Culex spp. These may be slightly below the criteria required to support control according to the TNsG, but this should not affect the general claim for control of flying insects with freshly applied product*.".

Overall, based on the results of the lab studies by Gibson 2017a and 2017b and the simulated use studies by Gibson 2018a, 2018b, 2016b and 2016c, efficacy of the product is sufficiently proved against mosquitos (*Culex spp.)* for both intented uses 1 & 2 with the following limitations:
For the intended use 1:
- "Activity against mosquitos (*Culex spp.)* is achieved only with fresh deposits on non-porous surfaces (not on porous surfaces)".
- "Mortality of mosquitos (*Culex spp.)* is achieved 48 hours after exposure of the insects to the treated surfaces".

For the intended use 2:
- "Activity against mosquitos (*Culex spp.)* is achieved only with fresh deposits on non-porous surfaces (not on porous surfaces) at the low dose and on porous and non-porous surfaces at the high dose".

- "Mortality of mosquitos (*Culex spp.)* is achieved 48 hours after exposure of the insects to the treated surfaces".

It is noted also that the results of the simulated use tests by Gibson 2016b and 2016c do not support efficacy of Fendona 6SC as surface spotted treatment against *Aedes aegypti* on porous and non-porous surfaces at 15 and 30 mg a.i./m^2, for 1 day and 3 months post treatment.

- Hence, the use against *Aedes* mosquitoes is not sufficiently supported by the efficacy data for both intended uses 1 & 2.

Wasps

Based on the results of the simulated use studies by Gibson 2018c and 2018d, efficacy of the product against wasps (*Vespula* spp.) has been proved for both intended uses 1 & 2 with the following limitations:

- "Residual activity against wasps (*Vespula* spp.) is achieved only on non-porous surfaces (not on porous surfaces) for up to 3 months".
- "Noticeable knockdown effect on wasps is expected within 6 hours after contact of the insects with non-porous treated surfaces and mortality is achieved at 24 hours".

Litter beetles

Based on the results of the lab studies by Gibson 2016d and 2016e, and the simulated use studies by Gibson 2016b and 2016c, efficacy of the product against litter beetles has not been sufficiently proved for the intended use 2.

Bedbugs

Based on the results of the lab studies by Gibson 2017c and Lupkes 2012, and the field study by Foltan 2017, efficacy against bedbugs is sufficiently proven for the intended use 1 (15 mg a.i/m^2) for up to 3 months post treatment, with the following limitations:

- "Mortality of bedbugs is achieved 1 week after exposure of the insects to the treated surfaces". "At least 1 re-application is required against bedbugs.".

Fleas

Based on the results of the simulated use study by Gibson 2017d, efficacy of the product against fleas has not been sufficiently proved for the intended use 1.

- In intended use 1, it is claimed that *"For flying insects, Fendona 6 SC should be applied throughout the infested area as a coarse spray onto targeted spots or areas where insects may crawl or settle"*. However, we propose to delete the word "crawl" as not applicable for flying insects.

- The application method in intended use 2 should be clarified as follows": "Fendona 6 SC should be applied throughout the infested area as a coarse spray for surface treatment. Special attention should be paid to cracks, crevices and any place where insects may hide and on surfaces over which they may crawl or settle."

Overall, based on the submitted efficacy studies and after evaluation process in all sections, the eCA concludes into the proposed authorized uses of the product as described in 2.1.4.

Major change application

Conclusion on the efficacy of the product based on trials submitted to support the MAC
The applicant submitted a major change application in order to include the Intended Use 1 (Urban pest control) as shown in the highlighted table in 2.2.1 (Major change application – Intended uses as applied for by applicant) along with the following claimed instructions for use in terms of efficacy: Following application, insects that have contacted the deposit should show signs of knockdown within 30 – 60 minutes with noticeable impact on population numbers expected within a few days. Mortality of German cockroaches is achieved 1 week after exposure of the insects to the treated surfaces. Noticeable knockdown effect on bedbugs is expected within 24 h after contact with treated surfaces and mortality is achieved 1 week after exposure. For the control of bedbugs at least 1 re-application is required. Mortality of mosquitos (*Culex spp.)* is achieved between 2 and 4 days after exposure of the insects to the treated surfaces. Noticeable knockdown effect on houseflies is expected within 6 hours after contact with the treated surfaces and mortality is achieved 24-72hours after exposure. Noticeable knockdown effect on wasps is expected within 6 hours after contact of the insects with non-porous treated surfaces and mortality is achieved at 24 hours. Treated areas should be re-inspected after 2– 3 weeks. Where initial infestation was severe or new infestation is observed, a second application may be required particularly if the first treatment has been disturbed or some harbourages/landing sites were missed in the initial application. Strategies for managing the development of resistance: • Where possible, application treatments should be recommended to be combined with non-chemical measures. • To avoid the potential for insect resistance to Fendona 6SC, treatments should be alternated with insecticidal products having different modes of action. • If resistance is confirmed, stop the use of Fendona 6SC immediately and rotate to an insecticide with alternative mode of action. By removing the selection pressure, the less-fit, resistant individuals will be removed over time and susceptibility should return to the population. • Apply the recommended label dose rate during the proper timing to ensure complete control of the pest species. By allowing the fewest insects to survive, the spread of the resistant insects will be slowed. • Follow good application techniques in order to maximize the product activity; deficient applications at less than the recommended label rate will allow the surviving insects to build up the population again, increasing the pest pressure against the product, which may trigger resistance problems in the future. • Establish a baseline and monitor levels of effectiveness on populations in key areas in order to detect any significant changes in susceptibility to active substance. Information from resistance monitoring programs allows early detection of problems and gives information for correct decision making. • The users should inform if the treatment is ineffective and report straightforward to the authorization holder. The authorization holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management.

In addition to the several efficacy studies (laboratory, simulated use and field studies) originally submitted for the MRP Fendona 6 SC dossier, using also studies conducted with Fendona 1.5 SC based on a bridging approach, one new study (Gibson 2019b) against mosquitoes and houseflies has been submitted by the applicant and included in the PAR to support efficacy of Fendona 6 SC indoors in urban pest control (Intended use 1) by professionals at 15 mg a.s./m^2 against the following claimed target pests:

- Crawling insects: German cockroaches (*Blattela germanica*), ants (*Lasius niger*) and bedbugs (*Cimex lectularius*)
- Flying insects, including houseflies (*Musca domestica*), mosquitoes (*Culex* spp) and wasps (*Vespula* spp)

Taking into consideration the efficacy evaluation already performed by the eCA for both intended uses 1 & 2 based on the efficacy studies submitted for MRP Fendona 6SC dossier, the new submitted study by Gibson 2019b, and the conclusions of the teleconference on 5 March 2019 and the outcome of the discussions of 34th CG meeting on 12 March 2019 concerning the Referral to the Coordination Group of a disagreement on Mutual recognition (MR) in accordance with Article 35(2) of the Regulation (EU) No 528/2012 (BPR) for Fendona 6SC, the intended use 1 (urban pest control) of Fendona 6 SC, from the efficacy point of view, is acceptable as applied for a major change by the applicant (2.2.1), noting that:

In urban pest control (Intended use 1) the product is efficacious against German cockroaches (*Blattella germanica*), ants (*Lasius niger*) and bedbugs *(Cimex lectularius)*, as a coarse spray to cracks & crevices, and/or onto targeted spots or areas where insects may crawl and hide; and against flying insects including houseflies (*Musca domestica*), mosquitoes (*Culex* spp.) and wasps *(Vespula* spp*)*, as a coarse spray onto targeted spots or areas where insects may settle, with the following limitations per target organism:

- "Activity against German cockroaches is achieved only with fresh deposits.".
- "Mortality of German cockroaches is achieved 1 week after exposure of the insects to the treated surfaces".
- "Residual activity against ants (*Lasius niger*) is up to 1 month".
- "Activity against mosquitoes (*Culex* spp*.)* is achieved only with fresh deposits on non-porous surfaces (not on porous surfaces)".
- "Mortality of mosquitoes (*Culex* spp*.)* is achieved between 2 and 4 days after exposure of the insects to the treated surfaces".
- "Noticeable knockdown effect on houseflies is expected within 6 hours after contact with the treated surfaces and mortality is achieved 24-72 hours after exposure".
- "Residual activity against wasps (*Vespula* spp.) is achieved only on non-porous surfaces (not on porous surfaces) for up to 3 months".
- "Noticeable knockdown effect on wasps is expected within 6 hours after contact of the insects with non-porous treated surfaces and mortality is achieved at 24 hours".
- "Noticeable knockdown effect on bedbugs is expected within 24 h after contact with treated surfaces and mortality is achieved 1 week after exposure".
- "For the control of bedbugs at least 1 re-application is required".

.

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

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

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

The toxicological properties of the active substance (a.s.) alpha-cypermethrin are summarised in the CA report (RMS BE).

Acute toxicity tests as well as tests for skin and eye irritation and skin sensitisation have been conducted with the biocidal product (b.p.) Fendona 6 SC.

The b.p. Fendona 6 SC does not need to be classified for Acute Toxicity, Skin Irritation/Corrosion, Eye Damage/Irritation and Skin Sensitisation.

Skin corrosion and irritation
(*cf.* IUCLID Section 8.1)

Summary table of animal studies on skin corrosion /irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Duration of exposure**	**Results**	**Remarks**	**Reference**
Skin irritation *in vivo*, OECD 404, GLP: yes, RL 2	Rabbit, New Zealand White, 4 males and 2 females	Fendona 6 SC, Unchanged (no vehicle), 100%, 4 h	Mean scores of 6 animals (24, 48, 72 h): erythema: 0.33 oedema: 0.0 erythema: fully reversible within 72 h, oedema: not applicable	no experimental 48 h reading performed (the 48 h values were assumed to be the same as those at 24 h)	[redacted] Section No. in IUCLID: 8.1

For skin corrosion and irritation no human data is available.

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not irritating
Justification for the value/conclusion	A dermal irritation study similar to OECD Guideline 404 is available for Fendona 6 SC. However, as no experimental 48 hr reading was performed, the study is not considered acceptable. The applicant's approach to assume that the 48 hrs scores are the same as those at 24 hrs is considered arbitrary. Based on the above, and in order to conclude on the skin irritation potential of Fendona 6 SC the calculation method in accordance with the criteria laid down in Regualtion (EC) No 1272/2008, has been applied. No classification is triggered for skin irritation properties. The detailed assessment is included in the confidential Annex of the PAR.

Classification of the product according to CLP	Not classified

Eye irritation
(*cf.* IUCLID Section 8.2)

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, reversibility*	**Remarks**	**Reference**
Eye irritation *in vivo*, OECD 405, GLP: yes, RL 1	Rabbit, New Zealand White, 5 males	Fendona 6 SC, Unchanged (no vehicle), 100%, 24 h	Mean score of 5 animals (24, 48, 72 h): Cornea: 0 Iris: 0 Conjunctivae: 0 Chemosis: 0 Reversibility: not applicable		[redacted] Section No. in IUCLID: 8.2

For eye damage and eye irritation no human data is available.

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Not irritating
Justification for the value/conclusion	The eye irritation potential of the test substance Fendona 6 SC was tested in 5 young adult male New Zealand White rabbits similar to OECD Guideline 405. At all evaluation time points the individual scores for cornea, iris, conjunctivae and chemosis were 0.
Classification of the product according to CLP	Not classified

Respiratory tract irritation

For respiratory tract irritation no human data is available.

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	Not irritating to the respiratory tract.
Justification for the conclusion	No data on respiratory tract irritation is available for the b.p. Toxicological properties and classification of the b.p. was deduced from the respective properties of the a.s. and the co-formulants using the the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP).
Classification of the product according to CLP	Not classified

Data waiving	
Information requirement	Study scientifically unjustified
Justification	The a.s. alpha-cypermethrin is classified with STOT SE 3, H335: May cause respiratory irritation. The concentration of alpha-cypermethrin in the b.p. is 5.83% (w/w), and thus, below the trigger of 20% as provided in the CLP regulation. The b.p. contains not more than one substance classified with STOT-SE Category 3. Therefore, the b.p. has not to be classified with respect to STOT-SE Category 3 effects.

Skin sensitization

(*cf.* IUCLID Section 8.3)

Summary table of animal studies on skin sensitisation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, duration of exposure Route of exposure**	**Results** *(Number of animals sensitized/total number of animals)*	**Remarks**	**Reference**
Buehler test, OECD 406, GLP: yes, RL 1	Guinea pigs, New Zealand White, Male, 10 (control group), 20 (treated group)	Fendona 6 SC, Unchanged (no vehicle), Induction and challenge: 100%, epicutaneous	Negative control: 0/10 Test group: 0/20		[redacted] Section No. in IUCLID: 8.3

For skin sensitisation no human data is available.

Conclusion used in Risk Assessment – Skin sensitisation

Value/conclusion	Not sensitising
Justification for the value/conclusion	A study for skin sensitisation in guinea pigs was conducted with the test substance Fendona 6 SC using the Buehler Test Method (OECD Guideline 406, 1997). No skin reactions were observed upon challenge with test substance.
Classification of the product according to CLP	Not classified

Respiratory sensitization (ADS)
(*cf.* IUCLID Section 8.4)

For respiratory sensitisation no human data is available.

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not sensitising.
Justification for the value/conclusion	No data on respiratory sensitisation is available for the b.p. Toxicological properties and classification of the b.p. was deduced from the respective properties of the a.s. and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP).
Classification of the product according to CLP	Not classified.

Data waiving	
Information requirement	Study scientifically unjustified.
Justification	According to chapter 8.4 "Respiratory sensitisation" of the "Guidance on information requirements" (Version 1.1, ECHA Nov. 2014), testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid dow n in Regulation (EC) No 1272/2008 (CLP). The toxicity of the a.s. and the co-formulants is known. Thus, toxicological properties and classification of the b.p. can be deduced from the respective properties of the a.s. and the co-formulants using the criteria for classifying mixtures under CLP. Following evaluation of the a.s. alpha-cypermethrin by the Rapporteur Member State (RMS) Belgium, no indication was reported from the studies performed that alpha-cypermethrin would cause respiratory sensitisation. In the b.p. neither the a.s. nor any of the co-formulants is classified with respect to a respiratory sensitisation. Therefore, the b.p. does not need to be classified with respect to respiratory tract sensitisation.

Acute toxicity

Acute toxicity by oral route
(cf. IUCLID Section 8.5.1)

Summary table of animal studies on acute oral toxicity						
Method Guideline GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance Dose levels, Type of administration**	**Signs of toxicity**	**Value LD_{50}**	**Remarks**	**Reference**
Acute Oral Toxicity in Rats, OECD 423, GLP: yes, RL 1	Rat, Wistar, Female, 6 (3 per step)	Fendona 6 SC, 100%, 2000 mg/kg bw, Gavage	No mortality, No clinical signs of toxicity, No effects on body weight, No pathology changes at necropsy	> 2000 mg/kg bw		[redacted] Section No. in IUCLID: 8.5.1

For acute oral toxicity no human data is available.

Value used in the Risk Assessment – Acute oral toxicity	
Value	Not harmful
Justification for the selected value	In an acute oral toxicity study according to the Acute Toxic Class Method of OECD Guideline 423 (2001), six young female rats (Wistar), were given a single oral dose, by gavage, of the test item Fendona 6 SC at the limit dose of 2000 mg/kg bw. There were no mortalities or any signs of toxicity, all animals gained the expected weight. No pathology changes were observed at necropsy. The oral LD_{50} exceeds 2000 mg/kg bw.
Classification of the product according to CLP	Not classified

Acute toxicity by inhalation
(cf. IUCLID Section 8.5.2)

Summary table of animal studies on acute inhalation toxicity						
Method, Guideline, GLP status , Reliability	**Species, Strain, Sex, No/group**	**Test substance, form and particle size (MMAD) Concentration, Type of administration**	**Signs of toxicity**	**LC_{50}**	**Remarks**	**Reference**
Acute inhalation toxicity study in rats OECD 403, GLP: yes, RL 1	Rat, Wistar / HanBrl: WIST (SPF), male/female, 5	Fendona 6 SC, Aerosol, MMAD: 4.8 and 5.3 µm, 2.06 mg/L (mean analytical concentration), Nose/head only	No mortality, Visually accelerated respiration, squatting posture and smeared fur in all animals (reversible), Tremor in 2 male and 2 female rats (reversible), No effects on body weight (exception: mean body weight of the female animals decreased slightly during the first post exposure period), No gross pathological abnormalities	> 2.06 mg/L	2.06 mg/L is the maximum attainable measured aerosol concentration	[redacted] Section No. in IUCLID : 8.5.2

For acute inhalation toxicity no human data is available.

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Not harmful
Justification for the selected value	Fendona 6 SC was tested for acute inhalation toxicity in male and female rats in accordance with OECD Guideline method 403. No mortality did occur. Reversible signs of visually accelerated respiration, squatting posture and smeared fur were observed in all exposed animals. Tremor was observed in 2 male and 2 female rats. Clinical findings were observed from beginning of exposure until including study day 3. The mean body weight of the male animals increased throughout the whole study period. The mean body weight of the female animals decreased slightly during the first post exposure week but increased during the second week. No gross pathological abnormalities were noted in the animals necropsied at termination of the post exposure observation period. The 4 h LC_{50} exceeds 2.06 mg/L air (maximum attainable measured aerosol concentration).
Classification of the product according to CLP	Not classified

Acute toxicity by dermal route
(cf. IUCLID Section 8.5.3)

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**	**LD_{50}**	**Remarks**	**Reference**
Acute Dermal Toxicity in Rats, OECD 402, GLP: yes, RL 1	Rat, Wistar, Male/female, 5	Fendona 6 SC, Unchanged (no vehicle), 2000 mg/kg bw, 10% of body surface	No mortality, No clinical signs of toxicity, No effects on body weight, No gross pathological abnormalities	> 2000 mg/kg bw		[redacted] Section No. in IUCLID: 8.5.3

For acute dermal toxicity no human data is available.

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not harmful
Justification for the selected value	In an acute dermal toxicity study according to OECD Guideline 402, rats were exposed to the test item Fendona 6 SC in a limit test. No mortalities or signs of overt toxicity were observed; all animals gained the expected weight. The dermal LD_{50} for male and female rats exceeds 2000 mg/kg bw.
Classification of the product according to CLP	Not classified

Information on dermal absorption
(*cf.* IUCLID Section 8.6)

Summary table of *in vitro* studies on dermal absorption					
Method, Guideline, GLP status, Reliability	**Species, Number of skin samples tested per dose, Other relevant information about the study**	**Test substance, Doses**	**Absorption data for each compartment and final absorption value**	**Remarks**	**Reference**
OECD 428, GLP: yes Reliability 1	Human skin, 8 replicates, 8 h exposure, 24 h monitoring	BAS 310 27 I (Fendona 6 SC) concentrate, 60 mg/mL alpha-cypermethrin, Label: [^{14}C]-alpha-cypermethrin	Absorbed dose: 0.45 ± 0.25% (for absorption data for each compartment please refer to the table below)	> 75% of total absorption occurred within half of the study duration	[redacted] Section No. in IUCLID: 8.6
		BAS 310 27 I (Fendona 6 SC), 15 mg/mL alpha-cypermethrin, Label: [^{14}C]-alpha-cypermethrin	Absorbed dose: 0.82 ± 0.26% (for absorption data for each compartment please refer to the table below)	> 75% of total absorption occurred within half of the study duration	
		BAS 310 27 I (Fendona 6 SC), 0.3 mg/mL alpha-cypermethrin, Label: [^{14}C]-alpha-cypermethrin	Potentially absorbed dose: 3.06 ± 2.22% (for absorption data for each compartment please refer to the table below)	< 75% of total absorption occurred within half of the study duration, one cell was not included in statistics	

***In-vitro* dermal penetration of alpha-cypermethrin formulated as BAS 310 27 I through human skin - Recovery data (Rieken, C., 2016)**							
Dose group		**High dose**		**Mid dose**		**Low dose**	
		BAS 310 27 I concentrate		**Spray dilution 1:4**		**Spray dilution 1:200; equiv. to in-use dilution**	
Target concentration	[mg/mL]	60		15		0.3	
Target dose	[µg/cm²]	600		150		3	
Mean actual applied dose	[µg/cm²]	582.08		149.43		2.96	
Number of cells used/Valid cells		8		8		7	
		Recovery [%]		**Recovery [%]**		**Recovery [%]**	
		Mean	**S.D.**	**Mean**	**S.D.**	**Mean**	**S.D.**
Dislodgeable dose							
Skin washing after 8 hours		95.80	2.54	97.65	1.44	91.04	6.08
Skin washing after 24 hours		0.12	0.09	0.30	0.49	4.82	4.61
Donor chamber wash		0.02	0.01	0.01	0.02	0.00	0.00
Dose associated to skin							
Tape strips: 1st sample, strips 1 + 2		0.02	0.02	0.01	0.01	0.29	0.23
Tape strips: 2nd sample; strips 3 - 6		0.03	0.02	0.01	0.01	0.92	0.76
Skin preparation		0.10	0.12	0.11	0.10	1.52	1.38
Absorbed dose							
Sum receptor samples incl. wash out		0.13	0.08	0.30	0.06	0.15	0.07
Receptor fluid		0.11	0.06	0.19	0.05	0.38	0.15
Receptor chamber wash		0.12	0.06	0.23	0.07	0.10	0.06
Total recovery[1]		96.44	2.48	98.81	1.29	99.22	0.70
Absorption essentially complete at end of study (>75% absorption within half the study duration)		**Yes**		**Yes**		**No (72%)**	
Absorption estimates when absorption not essentially completed (= absorbed dose + dose associated to skin + tape strips sample 2)[2]		NA		NA		3.06	2.22
Absorption estimates when absorption essentially completed (= absorbed dose + dose associated to skin)		0.45	0.25	0.82	0.26	NA	
Absorption estimate normalized[3]		NA		NA		NA	

Relevant absorption estimate[4]	0.70	1.08	5.28
Absorption estimates used for risk assessment[4]	**0.7**	**1**	**5**

[1] values may not calculate exactly due to rounding of figures
[2] In accordance with the EFSA Guidance on Dermal Absorption (EFSA Journal 2012;10(4):2665) the radioactivity in the second tape-strip pool (3rd to 6th tape strip) is considered potentially absorbable if less than 75% of the absorption occurred in the first half of the study. Finally, the skin preparation is also considered potentially absorbable.
[3] Cells with insufficient recovery (<95%) were corrected by normalization of absorption estimate to 100% recovery
[4] In accordance with the EFSA Guidance on Dermal Absorption (EFSA Journal 2012;10(4):2665) one standard deviation was added to the mean% dermal penetration in cases where the standard deviation was ≥ 25% of the mean value. This value was then rounded to the required number of significant figures.

Values used in the Risk Assessment – Dermal absorption		
Substance	Fendona 6 SC, concentrate	Fendona 6 SC, in-use dilution
Values	1%	5%
Justification for the selected values	Dermal absorption has been set to 1% for harmonisational reasons with the Fendona 1.5 SC product dossier. 0.7% dermal absorption value was derived from the *in vitro* human dermal penetration study for the concentrates containing 60 mg/mL (6%) alpha-cypermethrin.	Dermal absorption has been set to 5% derived from the *in vitro* human dermal penetration study for the in-use dilutions containing 0.3 mg/mL (0.03%) or higher amounts (i.e. 0.06%) of alpha-cypermethrin (taken into account the generally inverse relationship between concentration and dermal absorption).

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

Fendona 6 SC contains 1,2-Propylene Glycol at levels of 14%. An IOEL of 10 mg/m^3 for 1,2-Propylene Glycol is available in the GESTIS International Limit Values (http://limitvalue.ifa.dguv.de/ and as such, it should be considered as a SoC.

Available toxicological data relating to a mixture

Toxicological data relating to a mixture that a substance of concern is a component of are not required.

ED Hazard assessment of the product

Active substance alpha-cypermethrin:
According to the BPC Opinion on the application for approval of the active substance Alpha-cypermethrin PT18 (ECHA/BPC/009/2014), *Alpha-cypermethrin is not classified as Carc. 2 or Repr. 2 and has not been identified as having endocrine disrupting properties*.

Co-formulants:

Based on the information included in the Material Safety Data Sheets (MSDSs) none of the co-formulants is classified for carcinogenic or reproductive toxicity properties or as STOT-RE (May cause damage to the thyroid through prolonged or repeated exposure).
In addition, none of the co-formulants is included in the Candidate List of SVHCs (https://echa.europa.eu/candidate-list-table) and either of them has been assessed under REACH Substance Evaluation (https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table) due to an initial concern regarding potential endocrine disruption.

Other

Germ Cell Mutagenicity, Carcinogenicity and Reproductive Toxicity:
Neither alpha-cypermethrin nor any of the co-formulants are classified for germ cell mutagenicity, carcinogenicity and reproductive toxicity, respectively. Thus, the b.p. does not need to be classified for germ cell mutagenicity, carcinogenicity or reproductive toxicity.

Aspiration hazard:
Neither alpha-cypermethrin nor any of the co-formulants are classified for aspiration toxicity. Thus the b.p. does not need to be classified for aspiration toxicity.

Specific Target Organ Toxicity – Repeated Exposure (STOT-RE):
The a.s. alpha-cypermethrin is classified with STOT-RE 2; H373: May cause damage to the Central Nervous System through prolonged or repeated exposure. The concentration of alpha-cypermethrin in the b.p. is 5.83% (w/w), and thus, below the trigger value of 10% as provided in the CLP regulation for classifying a mixture as STOT-RE 2. Thus, the b.p. does not need to be classified for STOT-RE effects.

The b.p. contains 1,2-benzisothiazolin-3-one that is classified as sensitising to skin. The specific concentration limit of 0.05% is specified. Since the sensitising substance is present at a concentration greater than one tenth of the specific concentration limit, the b.p. is labelled with EUH208 "Contains 1,2-benzisothiazolin-3-one. May produce an allergic reaction".

Alpha-cypermethrin belongs to the group of synthetic pyrethroids. The following statement is added to the label: "The product contains: Alpha-cypermethrin. May cause paraesthesia."

The b.p. is used as insecticide in urban and rural environments by professionals and general public. The treatment of animal house surfaces with alpha-cypermethrin-containing insecticidal product may lead to residues in animal commodities (meat, milk, eggs).

Cow feeding study
(*cf.* IUCLID Section 8.8)

Study Reference	Dose groups[1]	Residues found in milk[2] [mg/kg milk]	Residues found in muscle, liver, kidney[3] [mg/kg tissue]	Residues found in fat[3] [mg/kg tissue]
Oral feeding for 28 days, 3 cows/group, Test substance: alpha-cypermethrin [redacted]	A. control	No detectable residues	No detectable residues	No detectable residues
	B. 77 mg/animal/day 0.188 mg/kg bw/day	No detectable residues	No detectable residues	0.058 - 0.064
	C. 231 mg/animal/day 0.354 mg/kg bw/day	0.02	No detectable residues	0.16
	D. 769 mg/animal/day 1.183 mg/kg bw/day	0.08	No detectable residues	0.87

[1] Body weight of dairy cattle: 650 kg
[2] Limit of detection: 0.01 mg/kg milk
[3] Limit of detection: 0.05 mg/kg tissue

At the lowest feeding level (77 mg/animal/day), residues of alpha-cypermethrin were present only in fat (0.058-0.064 mg/kg). All samples of whole milk from the low dose group were below the limit of determination of the analytical method (0.010 mg/kg) for alpha-cypermethrin.

No **pig** feeding study available, thus the cow feeding study was used as to estimate the feeding levels in pigs.

As to justify this approach the conclusion from the Annex I Renewal of alpha-cypermethrin under Regulation (EC) N° 1107/2009 was considered.

In the data review process for Annex I Renewal under plant protection product regulation (EC) N° 1107/2009, the following statement is cited in the section Metabolism in livestock (Regulation (EU) N° 283/2013, Annex Part A, points 6.2.2, 6.2.3, 6.2.4, 6.2.5 6.7.1):
"*The general metabolic pathway in rodents (rats) and ruminants (goats) is comparable*".

Therefore, additional studies for the generation of data in relation to the nature of the residues in pigs derived as results of the exposure towards alpha-cypermethrin exposure via plant protection products or biocides was not considered required.Based on the demonstrated similarity of metabolism in two species (rat and cow), the feeding study results from the cow feeding study was further considered appropriate to derive residue results for pigs as a worst case approach in order to investigate the dietary risk of consumers.

Thus, based on the medium treatment group of the cow feeding study equivalent feeding levels would be:
Fattening pig: 0.354 mg/kg bw/day x 100 kg = 35.4 mg / animal / day
Breeding pig: 0.354 mg/kg bw/day x 260 kg = 92.0 mg / animal / day

At medium cow feeding level (231 mg/animal/day) residues of alpha-cypermethrin are present only in fat (0.16 mg/kg) and milk (<0.02 mg/kg).

Hen Feeding Study

(*cf.* IUCLID Section 8.8)

Study Reference	**Dose groups[1]**	**Max Residues found in egg[2] [mg/kg milk]**	**Max Residues found in muscle, liver, kidney[3] [mg/kg tissue]**	**Max Residues found in fat[3] [mg/kg tissue]**
Oral feeding for 28 days, 12 hens/group, Test substance: alpha-cypermethrin [redacted]	A. control	No detectable residues	No detectable residues	No detectable residues
	B. 0.68 mg/animal/day 0.076 mg/kg bw/day	No detectable residues	No detectable residues	No detectable residues
	C. 0.72 mg/animal/day 0.38 mg/kg bw/day	0.0125	No detectable residues	0.085
	D. 2.00 mg/animal/day 0.76 mg/kg bw/day	0.023	No detectable residues	0.235

[1] Body weight of laying hen: 1.9 kg
[2] Limit of detection: 0.01 mg/kg egg
[3] Limit of detection: 0.05 mg/kg tissue

At lowest feeding level (0.68 mg/animal/day) no residues of alpha-cypermethrin are detectable in eggs, muscle, liver or fat.

2.2.6.2 Exposure assessment

Identity
Fendona 6 SC is a water-based product containing 6% w/v of the a.s. alpha-cypermethrin. The molecular weight is 416.3 g/mol. The pure active ingredient (PAI) has a vapour pressure of 3.8 x 10^{-7} Pa at 20°C and is considered of low volatility. Technical alpha-cypermethrin has a water solubility of 3 µg/L at 20°C and pH 6.5.

Intended use and user sector
Fendona 6 SC is intended as a crack and crevice treatment to any surface where the insect pests may crawl or settle, for use indoors in urban situations (large/industrial/commercial premises like restaurants, takeaways, bakeries, bars, hotels, hospitals, factories, and domestic/households/private areas) and animal houses/shelters (stables, cattle sheds, pig units, poultry houses).
The intended use-rate range from 15 mg a.s./m² corresponding to 25 mL Fendona 6 SC in 5 L water for 100 m², which corresponds to a dilution of 1:200 (urban pest control by professionals) to 30 mg a.s./m², corresponding to 50 mL Fendona 6 SC in 5 L water for 100 m², i.e. 1:100 (animal housings by professionals and amateurs). The application volume per m² is 50 mL.

An overview of the intended worst case uses for Fendona 6 SC is given in the following table:

Worst case application rate	**Worst case scenario**	**Use Situation**	**Exposed Bystander Populations**
15 mg a.s. /m²	Crack and crevice /low pressure spray low pressure)	Urban & domestic pest control (industrial/commercial premises and domestic/households, indoor)	Adults Children Toddlers Infants
30 mg a.s. /m²*	Surface treatment / low pressure spray (low pressure)	Animal houses/shelters (indoor)	Adults

**This application rate also covers the rural low concentration rate scenario at 15 mg a.s. / m²*

Exposure data
Generic information on human exposure to water-based insecticidal products to control other arthropods is given in the "Best practice Guideline (BPG (PT18)) and in the technical notes for guidance (EC, DG environment 2002).

Product use

Overview of primary exposure to Fendona 6 SC

Exposed population	**Exposure Situation**	**Worst case scenario**	**Exposure Routes**

Professional (trained professionals and pest control operators, PCO)	Animal buildings (indoor) (worst case) Urban pest control (industrial, commercial premises) (indoor)*	Surface treatment / low pressure spray (low pressure) at 30 mg a.s./m²	Inhalation, dermal during mixing/loading/application
Non-professional (Amateur user / consumer)	Animal buildings (indoor)	Surface Treatment / low pressure spray (low pressure) at 30 mg a.s./m²	Inhalation, dermal during mixing/loading/application

** This covers also the domestic scenario, as the type/method of application and use rates are identical*

Post-application
Post-application is limited to unblocking nozzles and replacing seals (professionals).

Disposal
Products are generally used up. Packaging is returned to the supplier or treated as special waste (professional) or domestic waste (non-professional).

Secondary exposure
Secondary exposure can occur either by acute exposure or chronically to individuals after prolonged exposure. As a worst case it is assumed that treated areas are indoors without ventilation. Different scenarios are considered; in the rural and urban & domestic pest control scenario it is assumed that secondary exposure is either acute and affects adults via inhalation and dermal by accidental contamination from treated areas or chronic for professional users that launder contaminated working clothes at home. The other scenarios are specific for the domestic area, where exposure can either affect adults, children, toddlers and infants by multiple exposure routes when entering and/or accidentally touching treated areas. Taking into account that for domestic areas the maximum number of applications is 11 per year (see Point 2.1.4.1 of PAR, Use description #1) this scenario is considered as chronic.
An overview of the expected secondary exposure scenarios for Fendona 6 SC is given in the following table.

Exposure Situation	Exposed Bystander	Acute Exposure Route	Chronic Exposure Route
Urban pest control (industrial/commercial premises, indoor)	Adults	Inhalation, Dermal	(Inhalation), Dermal
Domestic (indoor)	Adults Children Toddlers Infants	Inhalation, dermal Inhalation, dermal Inhalation, dermal, oral Inhalation, dermal, oral	(Inhalation), dermal
Animal buildings (indoor)	Adults	Inhalation, Dermal	(Inhalation), Dermal

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

Summary table: relevant paths of human exposure							
Exposure path	Primary (direct) exposure			Secondary (indirect) exposure			
	Industrial use	Professional use	Non-professional use	Industrial use	Professional use	General public	Via food
Inhalation	n.a.	yes	yes	n.a.	yes (acute)	yes (acute)	no
Dermal	n.a.	yes	yes	n.a.	yes	yes	no
Oral	n.a.	no	no	n.a.	no	yes (infants, toddlers)	yes

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
1.	Rural exposure scenario for professional users	Primary exposure, direct Dilution of the product and application by knapsack or compression sprayers, High concentration rate rural hygiene scenario (also covers low concentration rate rural hygiene scenario)	Professionals (trained and pest-control-officers PCO)
2.	Urban & domestic exposure scenario for professional users	Primary exposure, direct Dilution of the product and application by knapsack or compression sprayers, Urban & domestic pest control	Professionals (trained and pest-control-officers PCO)
3.	Rural exposure scenario for non-professional users	Primary exposure, direct Dilution of the product and application by manually diluted hand-held pump or trigger sprayers, High concentration rate rural hygiene scenario (also covers low concentration rate rural hygiene scenario)	Non-professionals
4.	Rural exposure scenario – for professional and non-professionals	Primary exposure, indirect Exposure via the dermal route - laundering work clothes High concentration rate rural hygiene scenario	Professionals, Non-professionals
5.	Urban & domestic exposure scenario – for professional users	Primary exposure, indirect Exposure via the dermal route (laundering their work clothes) Urban & domestic pest contol and low concentration rate rural hygiene scenario	Professionals, (trained and pest-control-officers PCO)
6.	Animal buildings/rural exposure scenario	Secondary exposure, Exposure is acute and affects adults via inhalation and dermal route by accidental contamination from treated areas, High concentration rate rural pest control scenario	General public (adults)
7.	Urban exposure scenario	Secondary exposure, Exposure is acute and affects adults via inhalation and dermal route by accidental contamination from treated areas, Urban pest contol and low concentration rate rural hygiene scenario	General public (adults)
8.	Domestic exposure scenario	Secondary exposure, Exposure is chronic and affects adults, children, infants and toddlers via inhalation, dermal and oral route after crack and crevice treatment in a low pressure application scenario	General public (adults, children, infants and toddlers)

9.	Rural exposure scenario – for professional and non-professionals	Primary exposure, indirect Exposure via the dermal route – cleaning of the spray equipment High concentration rate rural hygiene scenario	Professionals, Non-professionals
10	Urban & domestic exposure scenario for professional users	Primary exposure, indirect Exposure via the dermal route – cleaning of the spray equipment	Professionals, (trained and pest-control-officers PCO)

Industrial exposure

No industrial exposure foreseen.

Professional exposure

Product application is by trained professional operators or Pest Control Operators. The in-use dilution of the product is 0.03% for urban & domestic and rural low concentration rate pest control situation applying 50 mL per m² to give 15 mg a.s./m² and 0.06% for rural high concentration rate scenario applying 50 mL per m² to give 30 mg a.s./m², which is considered the overall worst case scenario. Dermal penetration is 1% for the concentrate of 60 g/L and 5% for the in-use dilutions. Application is by knapsack or compression sprayers. A daily use is anticipated, with a median duration of application of 120 minutes several times per day (TNsG Chapter 3, p.110).
It is recommended that the professional trained operator wears gloves, coverall and RPE during application.
Predicted exposure is modeled based on a low-pressure insecticide application scenario including mixing and loading liquid compression sprayers and applying at 1 to 3 bar pressure as a coarse or medium spray, indoors and outdoors, overhead and downwards. (Reference: ECHA Biocides Human Health Exposure Methodology, p.204) (Spraying Model 1; TNsG Chapter 3, p.143) (Descriptor 1.3.1).

Model data for professional operators taken from Spraying Model 1; TNsG Chapter 3, p.143 – Indicative exposure values as proposed in the ECHA Biocides Human Health Exposure Methodology p. 204

Description of Model	**Application Method**	**Indicative Exposures**
Professional mixing and loading liquids and powders in compression sprayers or dusting applicators, and applying indoors and outdoors in overhead or downward direction. This model relates to insecticide application to various surfaces and articles in domestic and public (e.g. schools, nursing homes, restaurants, hospitals) areas. The model may also apply to other operations involving application via hand-held compression sprayers. Hand exposure is actual exposure inside gloves. *Spraying model 1 TNsG part 2, p 143* *Another model (model 10) describing exposures resulting from low pressure spraying of insecticides can be found in part 2 p 156*	Hand-held low pressure (1-3 bar) spraying Medium/coarse spray Spot, crack and crevice and broadcast applications	Hands 10.7 mg/min Hands (potential) 181 mg/min Body 92 mg/min Inhalation 104 mg/m^3

Scenario [1] RURAL EXPOSURE SCENARIO FOR PROFESSIONAL USERS

Description of Scenario [1]		
The professional exposure assessment is based on the following assumptions:		
	Parameters	**Value**
Tier 1	Operator body weight	60 kg
	Clothing penetration[1]	100%
	Dermal penetration of the a.s.[2]	5%
	Inhalation rate[3]	1.25 m³/h
	Inhalation uptake	100%
	Conc. of a.s. in treatment solution[4]	0.06%
	Application duration[5]	120 min
	Inhalation/dermal exposure during mixing/loading/application	Spraying Model 1; TNsG Chapter 3, p.143; HSE survey EH74/3
Tier 2	Clothing penetration[6]	20%
	Efficiency of potential RPE	90%

[1] no PPE, Tier 1 assessment, i.e. potential exposure
[2] overlay conservative as used for mixing, loading and application
[3] 0.021 m³/min, HEEG Opinion 17, 2013
[4] 0.03% (urban pest control, rural hygiene low concentration rate) and 0.06% (rural hygiene, worst case) (w/v, 25 and 50 mL Fendona 6 SC per 5 litre of spraying solution)
[5] TNsG, worst-case maximum figure for low-pressure insecticide spraying, see Model 1, p.143, where "less than two hours per day using pesticides" is denoted as "typical"
[6] 80% protection factor for coated coverall for PT18 according to ECHA Biocides Human Health Exposure Methodology (p. 156)

By default, trained professionals wear suitable protective clothing (coveralls), protective gloves and RPE during application of Fendona 6 SC. Nevertheless, a full assessment including Tier 1 was performed for completeness. The resulting expected total systemic doses, including the total potential exposure (no PPE, RPE used) as well as the application with protective clothing and gloves but no RPE or with the use of PPE and RPE are summarized. The chosen model is applicable for surface treatment by low pressure sprayers indoors and outdoors. For the use in crack and crevice treatment in the urban & domestic scenario this model is considered the worst case as the volumes applied would be rather below those used in the rural scenario. Nevertheless this model has been chosen to cover the rural as well as the urban & domestic exposure scenario.

Please refer to Annex 3.2, Table 1 for calculations.

Scenario [2] URBAN & DOMESTIC EXPOSURE SCENARIO FOR PROFESSIONAL USERS

Description of Scenario [2]
The situation for low concentration rate rural hygiene and urban & domestic pest control is reduced by 50% as compared to the high concentration rate rural hygiene scenario based on a final application rate of 15 mg a.s./m².

Calculations for Scenario [1, 2]

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		mg/kg bw/day			
Scenario [1]	1 / no PPE	0.0026	0.0164	-	0.0190
	2 / gloves, coverall	0.0026	0.0018	-	0.0044
	2 / gloves, coverall, RPE	0.00027	0.0018	-	0.0021
Scenario [2]	1 / no PPE	0.0013	0.0082	-	0.0095
	2 / gloves, coverall	0.0013	0.0009	-	0.0022
	2 / gloves, coverall, RPE	0.00014	0.0009	-	0.0010

Non-professional exposure

Product application is by non-professionals (amateurs/consumers) who use the product infrequently. Non-professional users are not trained and may wear gloves, though this should not be assumed in the risk assessment. The concentrated product is 6% and the in-use dilutions are 0.03% and 0.06% (rural hygiene scenarios), applying 25 mL or 50 mL of the undiluted product per m² to give 15 mg to 30 mg a.s./m² respectively. Dermal penetration is 1% for the concentrate and 5% for the spray dilution.
Mixing and loading comprises dilution of the concentrate to the desired in-use dilution. Dermal exposure in the mixing/loading scenario has been assessed using the Mixing loading Model 2 for non-professionals (dermal exposure), TNsG Chapter 3, p.134, (Reference: ECHA Biocides Human Health Exposure Methodology, p.215;). For inhalation exposure the indicative exposure value based on EUROPOEM has been used, (TNsG Chapter 3, p.135).

Model data for mixing and loading by non-professional operators (consumers) taken from Mixing and Loading Model 2 and 3; TNsG Chapter 3, p.134 & p.135 - – Indicative dermal exposure values as proposed in the ECHA Biocides Human Health Exposure Methodology p. 215

Mixing/Loading		**Indicative value in-use product**
Potential dermal exposure (bare hands and forearms)	Worst case single event	12.8 mg/event
Exposure by inhalation	95th % value	0.1 mg/kg a.s.

Application in animal houses/shelters is performed manually using either hand-held pump or trigger sprayers (worst case). The application scenario used in the risk assessment is based on hand-held trigger surface spraying (Reference: ECHA Biocides Human Health Exposure Methodology, p.220; Consumer spraying and dusting model 2 TNsG part 2, p 197).

Model data for application by non-professional operators (consumers) taken from Consumer spraying and dusting model 2 TNsG part 2, p 197- Indicative exposure values as proposed in the ECHA Biocides Human Health Exposure Methodology p. 220

Description of Exposure Model	**Application Method**	**Indicative Exposures**	**Uncertainty**

Non-professional surface spraying insecticide, indoors, on soft furnishings, carpets, skirting boards and shelves with dust applicators trigger sprays and aerosol cans. The models are derived from the following simulated volunteer studies: 1. Includes crack and crevice treatment for ants in a kitchen (skirting, shelves, horizontal laminate floors) using a fine powder (45% of particles less than 75 microm) and broadcast flea treatment (carpet) using coarse granules (95% of particles greater than 180 microm). 2. Crack and crevice insecticide treatment (skirting, shelves, horizontal/vertical laminate surfaces) using a ready for use liquid spray. *3.* Broadcast treatment of small room (sofa, skirting dining chairs and carpet) using liquid spray. *HSL 2001; ACP – SC 11000 - Consumer exposure to non-agricultural pesticide products* *Consumer spraying and dusting model 2 TNsG part 2, p 197*	Hand-held trigger sprayer	Hand/forearm 36.1 mg/min Legs/feet/face 9.7 mg/min Inhalation 10.5 mg/m^3	Uncertainty is *moderate.* 90 % C.I. for 75^{th} are 26-50 (hands), 7.6-12.4 (legs), 9.0-12.2 (inhalation).

Scenario [3] RURAL EXPOSURE SCENARIO FOR NON-PROFESSIONAL USERS (CONSUMERS)

Description of Scenario [3]		
The Consumer (non-professional) exposure assessment is based on the following assumptions:		
	Parameters	Value
Tier 1[1]	Operator body weight	60 kg
	Clothing penetration[1]	100%
	Dermal penetration of the a.s. [2]	1% / 5%
	Inhalation rate[3]	1.25 m³/h
	Inhalation uptake	100%
	Conc. of a.s. in concentrate	6% w/v
	Conc. of a.s. in treatment solution[4]	0.06%
	Application duration[5]	7 min / once a week
	Dermal Exposure during mixing/loading	Mixing and loading Model 2, non-professionals, TNsG p.134; HSL 2001
	Inhalation exposure during mixing/loading	Mixing and loading Model 3, professionals, TNsG p.135; EUROPOEM
	Consumer exposure during application	Application via hand-held trigger spray (Consumer spraying and dusting model 2 TNsG part 2, p 197, hand-held trigger spray)
Tier 2	Clothing penetration[6]	50% (for long sleeved shirts and trousers)
[1] no clothing (bare hands and forearms), Tier 1 assessment, i.e. potential exposure [2] 1% for the concentrate and 5% for the spray dilution [3] 0.021 m³/min, HEEG Opinion 17, 2013 [4] 0.03% (rural hygiene low concentration rate) and 0.06% (rural hygiene high concentration rate, worst case) (w/v, 25 and 50 mL Fendona 6 SC per 5 litre of spraying solution) [5] TNsG, p.114, PT18, non-professionals performing the following process/operation: surface trigger spray indoor; crack and crevice application [6] HEEG Opinion 9, 2010 and Recommendation no. 8 of the BPC Ad hock Working Group on Human Exposure, 2015		
One event in several weeks. Please refer to Annex 3.2, Table 2 and 3 for calculations.		

Calculations for Scenario [3]

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		mg/kg bw/day			
Scenario [3]					
Mixing/loading	1 / potential exposure	1×10^{-4}	1.28×10^{-4}	-	2.28×10^{-4}
Application	1 / potential exposure	1.5×10^{-5}	1.6×10^{-4}	-	1.75×10^{-4}
	2 / normal clothing	1.5×10^{-5}	1.4×10^{-4}	-	1.55×10^{-4}
Total	1 / potential exposure	1.15×10^{-4}	2.88×10^{-4}	-	**4.03×10^{-4}**
	2 / normal clothing	1.15×10^{-4}	2.68×10^{-4}	-	**3.83×10^{-4}**

Indirect exposure

Scenario [4] ANIMAL BUILDINGS/RURAL EXPOSURE SCENARIO for professionals and non-professionals

Description of Scenario [4]

Adult professional and non-professional – cleaning work clothes at home

It is proposed that the people at risk are adults using a washing machine to launder contaminated coveralls at home. The worst-case exposure is via the dermal route – mainly to the hands – from handling the contaminated clothing prior to introduction into the washing machine.

The amount of product contaminating the coverall is considered to be equivalent to the potential dermal exposure estimated by the TNsG model (TNsG, Part 2, p.143). The indicative figure (75th percentile) is 11040 mg spray solution/day. With an a.s. concentration in the spray solution of 0.06% (max. concentration rate, i.e. worst case assumption), the potential contamination is 6.62 mg a.s./day. It is assumed that the coverall is washed weekly, after 5 days wear. Therefore, following 5 days wear, the total maximum residues accumulated on the coverall would be:

5 days × 6.62 mg a.s./day = 33.12 mg a.s./week

It is assumed that the total outer surface area of a medium sized coverall is 22700 cm². Therefore, the accumulated residue expressed as mg a.s./cm² of coverall amounts to 1.5 x 10^{-3} mg a.s./cm².

For an adult, the total area of both hands is 820 cm² (HEEG Opinion 17, 2013) with 100% hand contamination at 100% surface concentration (TNsG Part 3, p.43ff, wood preservatives). The transfer coefficient for contamination (dried fluid) from cotton, knitwear to wet hands is 30% (TNsG, Part 2, p.204). A dermal penetration rate of 5% is assumed for alpha-cypermethrin. The systemic dose for a 60 kg adult hence can be calculated as:

(a.s. on coverall × hand surface area × hand contamination x transfer coefficient × dermal absorption rate) / body weight

= (0.0015 mg a.s./cm² × 820 cm² x 0.3 × 0.05) / 60 kg bw

= 3.07 x 10^{-4} mg / kg bw/week

= 4.4 x 10^{-5} mg/kg bw/d

Exposed Population	Route and Exposure Levels [mg/kg bw/d]*
	Cleaning work clothes at home
Adults	4.4 x 10^{-5}

* based on a body weight for adults of 60 kg according to HEEG Opinion 17, 2013

Scenario [5] URBAN & DOMESTIC EXPOSURE SCENARIO for professional users

Description of Scenario [5]

Adult professional – cleaning work clothes at home

It is proposed that the people at risk are adults using a washing machine to launder contaminated coveralls at home. The worst-case exposure is via the dermal route – mainly to the hands – from handling the contaminated clothing prior to introduction into the washing machine.

The amount of product contaminating the coverall is considered to be equivalent to the potential dermal exposure estimated by the TNsG model (TNsG Part 2, p.143). The indicative figure (75th percentile) is 11040 mg spray solution/day. With an a.s. concentration in the spray solution of 0.03%, the potential contamination is 3.3 mg a.s./day. It is assumed that the coverall is washed weekly, after 5 days wear. Therefore, following 5 days wear, the total maximum residues accumulated on the coverall would be:

5 days × 3.3 mg a.s./day = 16.56 mg a.s./week

It is assumed that the total outer surface area of a medium sized coverall is 22700 cm². Therefore, the accumulated residue expressed as mg a.s./cm² of coverall amounts to 7.2 x 10^{-4} mg a.s./cm².

For an adult, the total area of both hands is 820 cm² (HEEG Opinion 17, 2013) with 100% hand contamination at 100% surface concentration (TNsG Part 3, p.43ff, wood preservatives). The transfer coefficient for contamination (dried fluid) from cotton, knitwear to wet hands is 30% (TNsG Part 2, p.204). A dermal penetration rate of 5% is assumed for alpha-cypermethrin. The systemic dose for a 60 kg adult hence can be calculated as:

(a.s. on coverall × hand surface area × hand contamination x transfer coefficient × dermal absorption rate) / body weight

= (0.00072 mg a.s./cm² × 820 cm² x 0.3 × 0.05) / 60 kg bw

= 1.5 x 10^{-4} mg/kg bw/week

= 2.1 x 10^{-5} mg/kg bw/d

Exposed Population	Route and Exposure Levels [mg/kg bw/d]*
	Cleaning work clothes at home
Adults	2.1 x 10^{-5} mg/kg bw/d

* based on a body weight for adults of 60 kg according to HEEG Opinion 17, 2013

Scenario [9] ANIMAL BUILDINGS/RURAL EXPOSURE SCENARIO for professionals and non-professionals

Description of Scenario [9]

Adult professional and non-professional – cleaning of spraying equipment
Exposure can also occur *via* hands and body during cleaning of the spraying equipment. For the assessment and in the absence of a more relevant model, the Recommendation no. 4 of the BPC Ad hoc Working Group on Human Exposure "Cleaning of spray equipment in antifouling use (PT21)" has been applied. More specifically the surrogate values from BEAT model database have been used.

Exposure Description	
Hand	
indicative value (rate of deposition of product : µL in-use product/min) task duration (default value = 20 min/day) product on hands (µL /day)	35.87 20 717.4
Body	
indicative value (rate of deposition of product : µL in-use product/min) task duration (default value = 20 min/day) potential amount of product on rest of body (µL /day) clothing penetration (default value = 100%) actual dermal deposit of product on rest of body (µL /day) total actual dermal exposure to product (µL /day)	19.28 20 385.6 100% 385.6 1103
Total dermal exposure to a.s. *via* hands and body (mg) [(in-use product contains 0.06%)] skin penetration (5%)#	0.00066 0.05
Total systemic exposure to a.s. *via* dermal exposure (mg a.s./person/day)	0.000033
Total systemic exposure to a.s. for a 60 kg adult (mg a.s./kg bw/day)	5.5×10^{-7}

Exposed Population	Route and Exposure Levels [mg/kg bw/d]
	Cleaning of spraying equipment
Adults	5.5×10^{-7} mg/kg bw/d

Scenario [10] URBAN & DOMESTIC EXPOSURE SCENARIO for professional users

Description of Scenario [10]

Adult professional – cleaning of spraying equipment

Exposure can also occur *via* hands and body during cleaning of the spraying equipment. For the assessment and in the absence of a more relevant model, the Recommendation no. 4 of the BPC Ad hoc Working Group on Human Exposure "Cleaning of spray equipment in antifouling use (PT21)" has been applied. More specifically the surrogate values from BEAT model database have been used.

Exposure Description	
Hand	
indicative value (rate of deposition of product : µL in-use product/min) task duration (default value = 20 min/day) product on hands (µL /day)	35.87 20 717.4
Body	
indicative value (rate of deposition of product : µL in-use product/min) task duration (default value = 20 min/day) potential amount of product on rest of body (µL /day) clothing penetration (default value = 100%) actual dermal deposit of product on rest of body (µL /day) total actual dermal exposure to product (µL /day)	19.28 20 385.6 100% 385.6 1103
Total dermal exposure to a.s. *via* hands and body (mg) [(in-use product contains 0.03%)] skin penetration (5%)#	0.00033 0.05
Total systemic exposure to a.s. *via* dermal exposure (mg a.s./person/day)	0.000016
Total systemic exposure to a.s. for a 60 kg adult (mg a.s./kg bw/day)	2.6 X 10^{-7}

Exposed Population	Route and Exposure Levels [mg/kg bw/d]
	Cleaning of spraying equipment
Adults	2.6 x 10^{-7} mg/kg bw/d

Exposure of the general public

Secondary exposure

Scenario [6] ANIMAL BUILDINGS/RURAL EXPOSURE SCENARIO – ACUTE PHASE

Description of Scenario [6]

The rural pest control exposure scenario covers adults exposed to alpha-cypermethrin at 30 mg a.s./m² (worst case) after surface treatment in a low pressure application scenario.

A. Adults – inhalation route (volatilised residues indoors)

In a conservative approach it is assumed that the indoor air is saturated with alpha-cypermethrin vapour. The approach described in HEEG Opinion 13 has been followed:
Exposure = SVC (mg/m^3) x ir (m^3/hr)/ bw (kg)
SVC = 0.41 x mw x vp (mg/m^3)

The vapour pressure of alpha-cypermethrin at 25°C is 5.6×10^{-7} Pa (see active ingredient Biocide Doc. II-A, Chapter 1.3). and its molecular weight 416.3 g/mol.
The SVC for alpha-cypermethrin is thus $0.41 \times 416.3 \times 5.6 \times 10^{-7} = 9.56 \times 10^{-5}$ mg/m³.
The body weight and inhalation rate (light exercise) for adults is 60 kg and 1.25 m³/h, respectively (HEEG Opinion 17, 2013).
The following systemic dose is calculated for an 8 h (worst case assumption for acute exposure scenario where exposure occurs in a single treated room, without ventilation and without product breakdown) exposure:

Overview of human exposure after acute exposure in the rural pest control scenario and corresponding estimates of inhalational exposure in bystanders applying Fendona 6 SC by low-pressure spraying.

Exposed Population	Route and Exposure Levels [mg/kg bw/d]*
	Inhalation (8 h)
Adults	1.6×10^{-5}

* based on a body weight for adults of 60 kg according to HEEG Opinion 17, 2013

B. Adults – dermal exposure to residues on treated surfaces

Dermal exposure is expected to occur for bystanders accidentally via direct contact to deposits of the biocide on the surface of contact, i.e. after surface application.
It is assumed that in the surface application scenario secondary exposure occurs to adults working in the vicinity of treated surface, thereby accidentally touching a treated area with their bare hands. The following parameters have been considered: hand surface of 410 cm^2 for both palms (as given in HEEG opinion 17, 2013), 100% hand contamination at 100% surface concentration (TNsG Part 3, p.43ff, wood preservatives) and dislodgeable fraction of 5.3 g/m² (TNsG Part 2, p.261). The dermal absorption rate of alpha-cypermethrin at low concentrations was determined at 5%. Assuming that a concentration rate of 0.50 mL Fendona/m² (30 mg alpha-cypermethrin /m²; 0.06%) was used for treatment, the following systemic doses are resulting from dermal exposure (Please refer to Annex 3.2, Table 4 for details).

Overview of human exposure after acute exposure in the rural pest control scenario and corresponding estimates of dermal exposure in bystanders accidentally getting

Description of Scenario [6]

into contact with contaminated surfaces

Exposed Population	Route and Exposure Levels [mg/kg bw/d]*
	Dermal
Adults	1.09×10^{-4}

* based on a body weight for adults of 60 kg and hand surfaces of both hands of 410 cm² adults according to HEEG Opinion 17, 2013

C. Combined acute secondary exposure in the high concentration rural exposure scenario

Overview of human exposure after acute exposure in the high concentration rate rural pest control scenario and corresponding estimates of relevant exposure in bystanders following application of Fendona 6 SC by low-pressure spraying.

Exposed Population	Route and Exposure Levels [mg/kg bw/d]*			Total Exposure [mg/kg bw/d]
	Inhalation (8 h)	Dermal	Oral	
Adults*	1.6×10^{-5}	1.09×10^{-4}	Not applicable	1.25×10^{-4}

* based on a body weight for adults of 60 kg according to HEEG Opinion 17, 2013

Scenario [7] URBAN EXPOSURE SCENARIO – ACUTE PHASE

Description of Scenario [7]

The urban (industrial/commercial premises, indoors; non-domestic) pest control exposure scenario covers adults exposed to alpha-cypermethrin at 15 mg a.s./m² after crack and crevice treatment in a low pressure application scenario.

A. Adults – inhalation route (volatilised residues indoors)

In a conservative approach it is assumed that the indoor air is saturated with alpha-cypermethrin vapour. The approach described in HEEG Opinion 13 has been followed:
Exposure = SVC (mg/m^3) x ir (m^3/hr)/ bw (kg)
SVC = 0.41 x mw x vp (mg/m^3)

The vapour pressure of alpha-cypermethrin at 25°C is 5.6×10^{-7} Pa (see active ingredient Biocide Doc. II-A, Chapter 1.3). and its molecular weight 416.3 g/mol.
The SVC for alpha-cypermethrin is thus $0.41 \times 416.3 \times 5.6 \times 10^{-7} = 9.56 \times 10^{-5}$ mg/m³.
The body weight and inhalation rate (light exercise) for adults is 60 kg and 1.25 m³/h, respectively (HEEG Opinion 17, 2013).
The following systemic dose is calculated for an 8 h (worst case assumption for acute exposure scenario where exposure occurs in a single treated room, without ventilation and without product breakdown) exposure:

Overview of human exposure after acute exposure in the rural pest control scenario and corresponding estimates of inhalational exposure in bystanders applying Fendona 6 SC by low-pressure spraying.

Exposed Population	Route and Exposure Levels [mg/kg bw/d]*
	Inhalation (8 h)
Adults	1.6×10^{-5}

* based on a body weight for adults of 60 kg according to HEEG Opinion 17, 2013

B. Adults – dermal exposure to residues on treated surfaces

Dermal exposure is expected to occur for bystanders accidentally via direct contact to deposits of the biocide on the surface of contact, i.e. after crack and crevice application.
It is assumed that in the crack and crevice application scenario secondary exposure occurs to adults working in the vicinity of treated surface, thereby accidentally coming in contact with a treated area with their bare hands. The following parameters have been considered: hand surface of 410 cm^2 for both palms (as given in HEEG opinion 17, 2013), 100% hand contamination at 100% surface concentration (TNsG Part 3, p.43ff, wood preservatives) and a dislodgeable fraction of 11.6 g/m² in the crack and crevice scenario (Pest Control Consexpo Factsheet). The dermal absorption rate of alpha-cypermethrin at low concentrations was determined at 5%. Assuming that a concentration rate of 0.25 mL Fendona/m² (15 mg alpha-cypermethrin /m²; 0.03%) was used for treatment, the following systemic doses are resulting from dermal exposure (Please refer to Annex 3.2, Table 5 for details).

Overview of human exposure after acute exposure in the urban pest control scenario and corresponding estimates of dermal exposure in bystanders applying Fendona 6 SC by low-pressure spraying.

	Route and Exposure Levels [mg/kg bw/d]*

Description of Scenario [7]

Exposed Population	Dermal
Adults	1.2 x 10^{-4}

* based on a body weight for adults of 60 kg and hand surfaces of both hands of 410 cm² adults according to HEEG Opinion 17, 2013

C. Combined acute secondary exposure in the urban pest control hygiene exposure scenario

Overview of human exposure after acute exposure in the urban pest control scenario by crack and crevice application and corresponding estimates of relevant exposure in bystanders following application of Fendona 6 SC by low-pressure spraying.

Exposed Population	Route and Exposure Levels [mg/kg bw/d]*			Total Exposure [mg/kg bw/d]
	Inhalation (8 h)	Dermal	Oral	
Adults*	1.6 × 10^{-5}	1.2 x 10^{-4}	Not applicable	1.36 × 10^{-4}

* based on a body weight for adults of 60 kg according to HEEG Opinion 17, 2013

Scenario [8] DOMESTIC EXPOSURE SCENARIO – CHRONIC PHASE

Description of Scenario [8]

The domestic pest control exposure scenario covers adults, children, infants and toddlers exposed to alpha-cypermethrin at 15 mg a.s./m² after crack and crevice treatment in a low pressure application scenario.

A. Adults, children, infants and toddlers – inhalation route (volatilised residues indoors)

According to HEEG opinion 13 (2013), inhalation exposure of volatilised biocide a.s., that is the amount of a.s. volatilizing from surfaces after application with the product, can be considered negligible if the following is true for a toddler (worst case compared to adults) based on an inhalation rate of 8 m³/24 h and a bw of 10 kg and using an AEL in mg/kg bw/d:
$0.328 \times mw \times vp / AEL_{long\text{-}term} \leq 1$
where mw denotes the molecular weight (416.3 g/mol) and vp the vapour pressure in Pa (5.6×10^{-7} Pa at 25°C).
Considering an $AEL_{Long\text{-}term}$ of 0.009 mg/kg bw/d, the assessment results in
0.328×416.3 g/mol $\times 5.6 \times 10^{-7} / 0.009$ mg/kg bw/d $= 8.5 \times 10^{-3} \leq 1$
being true.
Therefore the inhalation risk for toddlers as well as for infant, children and adults is **negligible** in long-term exposure.

B. Adults, children, toddler and infants – dermal exposure to residues on treated surfaces after crack & crevice application

Dermal exposure is expected to occur for bystanders in the domestic area after cracks and crevices application which includes treatment areas such as wall voids, spaces between walls and cabinets or other small spaces that could be in the reach of children, toddler and infants. Adults may touch treated surface by accident, too. Therefore, exposure could occur in the crack and crevice model via direct contact to deposits of the biocide on the surface of contact after product application.
It is assumed that in the crack and crevice application scenario secondary exposure occurs to infants, toddlers and children crawling/playing or adults working around treated surfaces, thereby accidentally touching a treated area with their bare hands. Hand surfaces as given in HEEG opinion 17, 2013 with 100% hand contamination at 100% surface concentration (TNsG Part 3, p.43ff, wood preservatives) have been considered along with a dislodgeable fraction of 11.6 g/m² (Pest Control Consexpo Factsheet). The dermal absorption rate of alpha-cypermethrin at low concentrations was determined at 5.0%. Assuming that a concentration rate of 1.0 mL Fendona/m² (15 mg alpha-cypermethrin/m²; 0.03%) was used for treatment, the following systemic doses are resulting from dermal exposure, estimated for infants, toddlers, children and adults (please refer to Annex 3.2, Table 6 for details).

Overview of human exposure after exposure in the domestic pest control scenario and corresponding estimates of dermal exposure in bystanders applying Fendona 6 SC by low-pressure spraying.

Exposed Population	Route and Exposure Levels [mg/kg bw/d]*
	Dermal
Adults	1.2×10^{-4}
Children	3.1×10^{-4}

Description of Scenario [8]

Toddlers	4×10^{-4}
Infants	4.2×10^{-4}

* based on a body weight for infants of 8 kg, toddlers of 10 kg, children of 23.9 kg and adults of 60 kg and hand surfaces of both hands of 196.8 cm², 230.4 cm², 427.8 cm², 410 cm² for infants, toddlers, children, adults, respectively according to HEEG Opinion 17, 2013

C. Infants & Toddlers – oral exposure after hand-to-mouth transfer

Small children exhibit a great deal of hand-to-mouth (HTM) contact. Therefore, a part of the alpha-cypermethrin residues present on the hands will be dislodged by saliva and eventually ingested.

For hand-to-mouth exposure and as indicated in HEEG Opinion 7, hands form about 20% of the total uncovered skin and is assumed that 50% of the product ending up on the hands is taken orally. The parameters used in the calculation are described in detail below:

Exposure parameter	**Value**
Transfer coefficient, (Recommendation no. 12 of the BPC Ad hoc Working Group on Human Exposure)	2000 cm^2/hr
Contact time	1 h
Oral absorption	45%
Body weight, (HEEG Opinion 17)	8 kg (infant), 10 kg (toddler)

Based on these assumptions, oral exposure of infants via HTM transfer can be calculated as presented in Table 7 (Annex 3.2).

Overview of human exposure after acute exposure in the domestic pest control scenario and corresponding estimates of oral exposure in bystanders applying Fendona 6 SC by low-pressure spraying.

Exposed Population	Route and Exposure Levels [mg/kg bw/d]*
	Oral by ingestion
Toddlers	3.1×10^{-3}
Infants	3.9×10^{-3}

* based on a body weight for infants of 8kg and toddlers of 10kg according to HEEG Opinion 17, 2013

D. Combined acute secondary exposure in the domestic pest control exposure scenario

Overview of human exposure after acute exposure in the domestic pest control scenario and corresponding estimates of relevant exposure in bystanders applying Fendona 6 SC by low-pressure spraying.

Exposed population	Route and exposure levels [mg/kg bw/d]*			Total exposure [mg/kg bw/d]
	Inhalation	Dermal	Oral	

Description of Scenario [8]

Adults	negligible	1.2×10^{-4}	Not applicable	1.2×10^{-4}
Children	negligible	3.1×10^{-4}	Not applicable	3.1×10^{-4}
Toddlers	negligible	4×10^{-4}	3.1×10^{-3}	3.5×10^{-3}
Infants	negligible	4.2×10^{-4}	3.9×10^{-3}	4.3×10^{-3}

* based on a body weight for infants of 8 kg, toddlers of 10 kg, children of 23.9 kg and adults of 60 kg according to HEEG Opinion 17, 2013

Calculations for Scenario [4, 5, 6, 7, 8, 9, 10]

Summary table: systemic exposure					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		mg/kg bw/day			
Scenario [4]	1 / potential exposure	n.a	2.19×10^{-5}	n.a.	2.19×10^{-5}
Scenario [5]	1 / potential exposure	n.s	1.05×10^{-5}	n.a.	1.05×10^{-5}
Scenario [6]	1 / potential exposure	1.6×10^{-5}	1.09×10^{-4}	n.a.	1.25×10^{-4}
Scenario [7]	1 / potential exposure	1.6×10^{-5}	1.2×10^{-4}	n.a.	1.36×10^{-4}
Scenario [8] Adults Children Toddlers Infants	1 / potential exposure	 Negligible Negligible Negligible negligible	 1.2×10^{-4} 3.1×10^{-4} 4×10^{-4} 4.2×10^{-4}	 n.a. n.a. 3.1×10^{-3} 3.9×10^{-3}	 1.2×10^{-4} 3.1×10^{-4} 3.5×10^{-3} 4.3×10^{-3}
Scenario [9]	1 / potential exposure	n.a	5.5×10^{-7}	n.a.	5.5×10^{-7}
Scenario [10]	1 / potential exposure	n.a	2.6×10^{-7}	n.a.	2.6×10^{-7}

Combined exposure

For combined exposure the following senarios have been considered:
- A professional user (rural areas) cleaning the spraying equipment and laudering his work clothes [Scenarios 1 + 4 + 9]
- A professional user (urban/domestic areas) cleaning the spraying equipment and laudering his work clothes [Scenarios 2 + 5 + 10]
- A non-professional user (rural areas) cleaning the spraying equipment and laudering his work clothes [Scenarios 3 + 4 + 9]

- A non-professional user (rural areas) entering the animal house/shelter following appplication [Scenarios 3 + 6].

Summary table: systemic combined exposure					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		mg/kg bw/day			
Scenarios [1 + 4 + 9]	2 / gloves, coverall 1 / potential exposure 1 / potential exposure	0.0026	0.0018	n.a.	0.0044
Scenarios [2 + 5 + 10]	2 / gloves, coverall 1 / potential exposure 1 / potential exposure	0.0013	0.00091	n.a.	0.0022
Scenarios [3 + 4 + 9]	1 / potential exposure	0.000115	0.00031	n.a.	0.00042
Scenarios [3 + 6]	1 / potential exposure	0.000131	0.000397	n.a.	0.00053

Monitoring data

No further information on surveys or studies with the actual product or with a surrogate is submitted.

Dietary exposure

The b.p. Fendona 6 SC is used as insecticide (product type 18) in urban & domestic and rural environments by professionals and general public. The treatment of animal house surfaces with alpha-cypermethrin-containing insecticidal product may lead to residues in animal commodities (meat, milk, eggs).

The b.p. Fendona 1.5 SC may be used to treat any surface in animal housing facilities (including walls, floors, ceilings, window and door frames, pen enclosures etc.) as well as bedding and manure. Animals can be exposed orally (by licking of and chewing treated surfaces, consumption of dead insects, eating straw from the bedding or the floor), dermally (through contact with treated surfaces) and via inhalation (e.g. for volatile substances).

List of scenarios

The only relevant dietary exposure represents the transfer of alpha-cypermethrin into swine, bovine, poultry, milk and eggs due to exposure of ruminants, pigs and birds after surface disinfection of animal houses.

Summary table of main representative dietary exposure scenarios			
Scenario number	**Type of use**	**Description of scenario**	**Subject of exposure**
[9]	Animal husbandry	Transfer of alpha-cypermethrin into swine, bovine, poultry, milk and eggs due to exposure of ruminants, pigs and birds after surface disinfection of animal houses.	swine, bovine, poultry, milk and eggs

Information of non-biocidal use of the active substance

Summary table of other (non-biocidal) uses			
	Sector of use	**Intended use**	**Reference value(s)**
1.	Plant protection products	Insecticide	MRL: 0.05 – 2 mg/kg (products of plant and animal origin)[1] ADI: 0.015 mg/kg bw/day[1] ARfD: 0.04 mg/kg bw[1] AOEL: 0.01 mg/kg bw/day[1]
2.	Veterinary use	Insecticide	MRL for all ruminants: 20 µg/kg (muscle, liver, kidney, milk)[2] 200 µg/kg (fat)[2] MRL for chicken: 50 µg/kg (muscle, fat, liver, kidney, eggs)[3]

[1] EU Pesticide Database, alpha-cypermethrin (http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.detail&language=EN&selectedID=937)
[2] Cypermethrin (Extrapolation to all ruminants): Summary report (4) - Committee for Veterinary Medicinal Products, 2004 (http://www.ema.europa.eu/ema/index.jsp?curl=pages/includes/document/document_detail.jsp?webContentId=WC500013075&mid=WC0b01ac058006488e)
[3] Cypermethrin: Summary report (2) - Committee for Veterinary Medicinal Products, 2001 (http://www.ema.europa.eu/ema/index.jsp?curl=pages/includes/document/document_detail.jsp?webContentId=WC500013073&mid=WC0b01ac058006488e)

Estimating Livestock Exposure to Active Substances used in Biocidal Products

Animal exposure calculations were conducted according to European Commission Draft Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products.

Scenario [9]

Calculations for estimating livestock exposure

Exposure of ruminants

The treatment of animal house surfaces with alpha-cypermethrin-containing insecticidal product will be done with an application rate of 15 or 30 mg a.s./m². The calculation of the animal biocide intake was conducted with 30 mg a.s./m² as a worst case assumption since it will cover the 15 mg a.s./m² use.
The animal exposure calculations were conducted according to European Commission Draft Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products (CA-Dec10-Doc.6.2.b).

Oral exposure:
Grown ruminants generally prefer the salt licks provided to them, while calves frequently lick other surfaces and objects (e.g. walls). Feed remaining in troughs may unintentionally be contaminated if it is present in the treated area during application of a biocide. It is assumed as a worst-case that troughs are not covered during biocidal treatment and that all residues contained on the bottom and sides of the trough migrate into the next feed batch that is given after biocidal treatment. It follows that all of the residue contained in the trough is taken up by the animal.

Dermal exposure:
Large slaughter animals, e.g. cattle, frequently rub against surfaces such as walls and pen enclosures. These surfaces are often treated with biocides, providing a source of exposure. It is assumed that all a.s. (except for the vapourised fraction) has settled on surfaces and that animals are not exposed to the spray during application. The exposure estimate covers dermal uptake as well as oral intake from grooming.

Inhalation exposure:
It is assumed that the animal is exposed to air containing the a.s. at its saturated vapour concentration (SVC). This represents a worst-case as the a.s. cannot achieve a higher concentration in the air.

	Parameters		**Value**		
			Calf	Beef cattle	Dairy cattle
Tier 1	Application rate[1]	mg a.s./m²	30	30	30
	Area treated (walls)[2]	m²	330	1000	1670
	Area treated (floor)[2]	m²	160	370	1170
	Number of animals per stable[2]		80	125	100
	Body weight[2]	kg	200	500	650
	Tongue surface area[2]	m²	0.008	n.a.	n.a.
	Licks per day[2]		10	n.a.	n.a.
	Emission factor of spraying (floor)[2]		0.11	0.11	0.11
	Emission factor of spraying (wall)[2]		0.85	0.85	0.85
	Body surface area in contact with treated surface[2]	m²	0.87	1.44	1.68
	Exposed feed surface area[2]	m²	0.5	0.7	2.9

Exposure of ruminants					
	Alveolar ventilation rate[2]	m³/day	25	50	62
	Vapour pressure 20°C	Pa	$2.50x10^{-7}$	$2.50x10^{-7}$	$2.50x10^{-7}$
	Vapour pressure 25°C[4]	PA	$5.60x10^{-7}$	$5.60x10^{-7}$	$5.60x10^{-7}$
	Molecular weight[3]	g/mol	416.3	416.3	416.3
	Temperature 20°C	K	293	293	293
	Temperature 25°C	K	298	298	298
	Gas const.	J/K mol	8.31451	8.31451	8.31451

Exposure of ruminants

[1] worst case assumption
[2] European Commission Draft Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products (CA-Dec10-Doc.6.2.b).
[3] Assessment report, RMS BE
[4] a value 3.8 x 10-7 was used based on the renewal assessment report of alpha-cypermethrin as a PPP. the value of 5.60x10-7 cited in this dossier for 25°C appears more conservative, thus the inhalation exposure of animals was performed with the more conservative value as to address this difference.

Realistic worst-case estimate:

Oral exposure through licking of surface [mg/animal/day]:
Application rate × Emmision factor for spraying (wall) × Tongue surface area × Licks per day

Oral exposure through uptake of contaminated feed [mg/animal/day]:
Application rate × Emission factor for spraying (floor) × Exposed feed surface

Dermal exposure through rubbing against surfaces [mg/animal/day]:
Application rate × Emmision factor for spraying (wall) × Body surface area in contact with surface

Inhalation exposure:

SVC
= (vapour pressure × molecular weight) / (gas constant × temperature in degrees Kelvin)
= 4.27×10^{-5} mg a.s./m³ at 20°C and
= 9.41×10^{-5} mg a.s./m³ at 25°C (used for calculation of realistic wirst case estimate)

Inhalation exposure [mg/animal/day]= SVC × Alveolar ventilation rate

	Calf [mg/animal/day]	**Beef cattle [mg/animal/day]**	**Dairy cattle [mg/animal/day]**
Oral exposure through licking of surface	2.04	n.a. (grown ruminants generally prefer the salt licks provided to them)	
Oral exposure through uptake of contaminated feed	1.65	2.31	9.57
Dermal exposure through rubbing against surfaces	22.19	36.72	42.84
Inhalation exposure	0.0024	0.0047	0.0058
Sum (Realistic worst case estimate)	**25.88**	**39.03**	**52.41**

Exposure of pigs

The treatment of animal house surfaces with alpha-cypermethrin-containing insecticidal product will be done with an application rate of 15 or 30 mg a.s./m². The calculation of the animal biocide intake was conducted with 30 mg a.s./m² as a worst case assumption since it will cover the 15 mg a.s./m² use.
The animal exposure calculations were conducted according to European Commission Draft Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products (CA-Dec10-Doc.6.2.b).

Oral exposure:
Pigs do not usually lick walls, but prefer metal objects. Feed remaining in troughs may unintentionally be contaminated if it is present in the treated area during application of a biocide. It is assumed as a worst-case that troughs are not covered during biocidal treatment and that all residues contained on the bottom and sides of the trough migrate into the next feed batch that is given after biocidal treatment. It follows that all of the residue contained in the trough is taken up by the animal.

Dermal exposure:
Large slaughter animals, e.g. pigs, frequently rub against surfaces such as walls and pen enclosures. These surfaces are often treated with biocides, providing a source of exposure. It is assumed that all a.s. (except for the vapourised fraction) has settled on surfaces and that animals are not exposed to the spray during application. The exposure estimate covers dermal uptake as well as oral intake from grooming.

Inhalation exposure:
It is assumed that the animal is exposed to air containing the a.s. at its saturated vapour concentration (SVC). This represents a worst-case as the a.s. cannot achieve a higher concentration in the air.

	Parameters		**Value**		
			Fattening pig	Breeding pig (individual housing)	Breeding pig (group housing)
Tier 1	Application rate[1]	mg a.s./m²	30	30	30
	Area treated (walls and roof)[2]	m²	970	910	1160
	Number of animals per stable[2]		400	132	132
	Body weight[2]	kg	100	260	260
	Emission factor of spraying (floor)[2]		0.11	0.11	0.11
	Emission factor of spraying (wall)[2]		0.85	0.85	0.85
	Body surface area in contact with treated surface[2]	m²	0.45	0.84	0.84
	Exposed feed surface area (direct treatment of toughts)[2]	m²	1.2	2.4	2.8
	Alveolar ventilation rate[2]	m³/day	14	30	30
	Vapour pressure 20°C	Pa	2.50×10^{-7}	2.50×10^{-7}	2.50×10^{-7}
	Vapour pressure 25°C	Pa	5.60×10^{-7}	5.60×10^{-7}	5.60×10^{-7}

Exposure of pigs					
	Molecular weight[3]	g/mol	416.3	416.3	416.3
	Temperature 20°C	K	293	293	293
	Temperature 25°C	K	298	298	298
	Gas const.	J/K mol	8.31451	8.31451	8.31451

[1] worst case assumption
[2] European Commission Draft Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products (CA-Dec10-Doc.6.2.b).
[3] Assessment report, RMS BE

Realistic worst-case estimate:

Oral exposure through uptake of contaminated feed [mg/animal/day]:
Application rate × Emission factor for spraying (floor) × Exposed feed surface area

Dermal exposure through rubbing against surfaces [mg/animal/day]:
Application rate × Emmision factor for spraying (wall) × Body surface area in contact with surface

Inhalation exposure:

SVC
= (vapour pressure × molecular weight) / (gas constant × temperature in degrees Kelvin)
= 4.27 × 10-5 mg a.s./m³ at 20°C and
= 9.41 × 10-5 mg a.s./m³ at 25°C (used for calculation of realistic worst case estimate)

Inhalation exposure [mg/animal/day]= SVC × Alveolar ventilation rate

	Fattening pig [mg/animal/day]	**Breeding pig (individual housing) [mg/animal/day]**	**Breeding pig (group housing) [mg/animal/day]**
Oral exposure through uptake of contaminated feed	3.96	7.92	9.24
Dermal exposure through rubbing against surfaces	11.48	21.42	21.42
Inhalation exposure	0.0013	0.0028	0.0028
Sum (Realistic worst case estimate)	**15.44**	**29.34**	**30.66**

Exposure of birds

The treatment of animal house surfaces with alpha-cypermethrin-containing insecticidal product will be done with an application rate of 15 or 30 mg a.s./m². The calculation of the animal biocide intake was conducted with 30 mg a.s./m² as a worst case assumption since it will cover the 15 mg a.s./m² use.
The animal exposure calculations were conducted according to European Commission Draft Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products (CA-Dec10-Doc.6.2.b).

Oral exposure:
Poultry do not engage in licking surfaces. The b.p. is used in animal housing to control flies and other insects. Consumption of insects killed by the biocide provides a source of biocidal exposure. Poultry seek out dead insects intentionally. For an exposure calculation, the amount of b.p. consumed by an insect in 24 hours is multiplied by the number of dead insects consumed by livestock. Feeding practices for poultry differ from those for cattle and pigs. Depending on whether poultry is held in battery cages or allowed to roam across the floor, feed is provided to them on conveyor belts or gutters (cages) or in dispenser bowls (ground). Poultry kept free range with access to the outside feed directly from the ground or from dispenser bowls. Dispenser bowls are equipped with a cylinder mounted on the bowl from where stored feed slides into the bowl as it is being emptied. Providing feed in dispenser bowls, on conveyor belts or in gutters allows poultry to feed throughout the day and some portion of the daily feed and water rations is always exposed to the environment, therefore allowing contamination with biocides.

Dermal exposure:
Small animals such as poultry do not engage in rubbing against surfaces. But dermal exposure can occur from spray hitting poultry during treatment. The exposure estimate includes dermal uptake as well as oral intake from grooming.

Inhalation exposure:
It is assumed that the animal is exposed to air containing the a.s. at its saturated vapour concentration (SVC). This represents a worst-case as the a.s. cannot achieve a higher concentration in the air.

	Parameters		**Values for broiler chickens**		
			Broiler Chickens	Parent Broiler Chicken	Broiler chickens, rearing
			Free range, litter floor	Free range, grating floor	Free range, grating floor
Tier 1	Application rate[1]	mg a.s./m²	30	30	30
	Area treated (walls and roof)[2]	m²	1600	600	750
	Number of animals per stable[2]		20000	7000	9000
	Body weight[2]	kg	1.7	1.7	1.7
	b.p. consumption by flies	mg b.p./fly/day	3.5	3.5	3.5
	# fly consumption	/day	10	10	10

Exposure of birds					
	Emission factor of spraying (floor)[2]		0.11	0.11	0.11
	Body surface area in contact with treated surface[2]	m²	0.015	0.015	0.015
	Exposed feed surface area[2]	m²	only applies for laying hen in battery		
	Alveolar ventilation rate[2]	m³/day	0.2	0.2	0.2
	Concentration a.s. in product	g/L	0.6	0.6	0.6
	Coverage of floo by hens	% (factor)	0.5	0.5	0.5
	Vapour pressure 20°C	Pa	2.50×10^{-7}	2.50×10^{-7}	2.50×10^{-7}
	Vapour pressure 25°C	Pa	5.60×10^{-7}	5.60×10^{-7}	5.60×10^{-7}
	Molecular weight[3]	g/mol	416.3	416.3	416.3
	Temperature 20°C	K	293	293	293
	Temperature 25°C	K	298	298	298
	Gas const.	J/K mol	8.31451	8.31451	8.31451

	Parameters		**Values for laying hens**			
			Battery without trough	Battery with trough	Free range, litter floor	Free range, grating floor
Tier 1	Application rate[1]	mg a.s./m²	30	30	30	30
	Area treated (walls and roof)[2]	m²	1100	1100	2030	1822
	Number of animals per stable[2]		21000	21000	10000	20000
	Body weight[2]	kg	1.9	1.9	1.9	1.9
	b.p. consumption by flies	mg b.p./fly/day	3.5	3.5	3.5	3.5
	# fly consumption	/day	10	10	10	10
	Emission factor of spraying (floor)[2]		0.11	0.11	0.11	0.11
	Body surface area in contact with treated surface[2]	m²	0.015	0.015	0.015	0.015
	Exposed feed surface area[2]	m²	0	0.01	only applies for laying hen in battery	
	Alveolar ventilation rate[2]	m³/day	0.2	0.2	0.2	0.2
	Concentration a.s. in product	g/L	0.6	0.6	0.6	0.6
	Coverage of floor by hens	% (factor)			0.5	0.5
	Vapour pressure 20°C	Pa	2.50×10^{-7}	2.50×10^{-7}	2.50×10^{-7}	2.50×10^{-7}
	Vapour pressure 25°C	Pa	5.60×10^{-7}	5.60×10^{-7}	5.60×10^{-7}	5.60×10^{-7}
	Molecular weight[3]	g/mol	416.3	416.3	416.3	416.3
	Temperature 20°C	K	293	293	293	293
	Temperature 25°C	K	298	298	298	298

	Parameters		**Values for laying hens**			
	Gas const.	J/K mol	8.31451	8.31451	8.31451	8.31451

[1] worst case assumption
[2] European Commission Draft Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products (CA-Dec10-Doc.6.2.b).
[3] Assessment report, RMS BE

Realistic worst-case estimate:

Oral exposure through ingestion of flies [mg/animal/day]:
Fly consumption × a.s. consumption of flies (0.0021 mg a.s./fly/day)

Oral exposure through uptake of contaminated feed [mg/animal/day]:
Application rate × Emission factor for spraying (floor) × Exposed feed area

Dermal exposure through spray treatment:

% of spray hitting hens
= fraction emitted to floor during surface treatment (0.11) × 50% (assuming that 50% of the floor is covered by hens)
= 5.5%

Dermal exposure [mg/animal/day]:
Application rate × treated area × % of spray hitting hens / Number of animals

Inhalation exposure:

SVC
= (vapour pressure × molecular weight) / (gas constant × temperature in degrees Kelvin)
= 4.27 × 10-5 mg a.s./m³ at 20°C and
= 9.41 × 10-5 mg a.s./m³ at 25°C (used for calculation of realistic wirst case estimate)

Inhalation exposure [mg/animal/day]: SVC × Alveolar ventilation rate

	Broiler Chickens [mg/animal/day]	**Parent Broiler chickens [mg/animal/day]**	**Broiler chickens, rearing [mg/animal/day]**	
	Free range, litter floor	Free range, grating floor	Free range, grating floor	
Oral exposure (fly consumption	0.0210	0.0210	0.0210	
Oral exposure (feed)	0.0	0.0	0.0	
Dermal exposure	0.132	0.141	0.138	
Inhalation exposure	0.00002	0.00002	0.00002	
Sum (Realistic worst case estimate)	**0.153**	**0.162**	**0.159**	
	Laying hens [mg/animal/day]			
	Battery without trough	Battery with trough	Free range, litter floors	Free range, grating floor
Oral exposure (fly consumption	0.0210	0.0210	0.0210	0.0210
Oral exposure (feed)	0.0	0.033	0.0	0.0
Dermal exposure	~~0.173~~ 0.0864	~~0.173~~ 0.0864	0.335	0.150
Inhalation exposure	0.00002	0.00002	0.00002	0.00002
Sum (Realistic worst case estimate)	**~~0.194~~ 0.107**	**~~0.227~~ 0.14**	**0.356**	**0.171**

Summary: Animal biocide intake calculation from all exposure routes

Ruminants

	Biocide Intake [mg/animal/day]		
	Calf	Beef cattle	Dairy cattle
Realistic worst case estimate	25.87	39.03	52.41

Pigs

	Biocide Intake [mg/animal/day]		
	Fattening pig	Breeding pig (individual housing)	Breeding pig (group housing)
Realistic worst case estimate	15.44	29.34	30.66

Poultry

	Biocide Intake [mg/animal/day]			
	Broiler Chickens	Parent Broiler chickens	Broiler chickens, rearing	
	Free range, litter floor	Free range, grating floor	Free range, grating floor	
Realistic worst case estimate	0.153	0.162	0.159	
	Laying hens			
	Battery without trough	Battery with trough	Free range, litter floors	Free range, grating floor
Realistic worst case estimate	~~**0.194**~~ **0.107**	~~**0.227**~~ **0.14**	0.356	0.171

Conclusion
Please refer to Section "Risk for consumers via residues in food"

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

The only relevant exposure represents the transfer of alpha-cypermethrin into swine, bovine, poultry, milk and eggs due to exposure of ruminants, pigs and birds after surface disinfection of animal houses. Please refer to Section "Estimating Livestock Exposure to Active Substances used in Biocidal Products".

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

The only relevant exposure represents the transfer of alpha-cypermethrin into swine, bovine, poultry, milk and eggs due to exposure of ruminants, pigs and birds after surface disinfection of animal houses. Please refer to Section "Estimating Livestock Exposure to Active Substances used in Biocidal Products".

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

Fendona 6 SC is manufactured by converting alpha-cypermethrin TC to a slurry with part of the co-formulants and milling in a bead mill to achieve the appropriate particle size. The remaining co-formulants are added thereafter. The resulting technical concentrate is homogenized subsequently with the additional co-formulants required by the Fendona 6 SC formulation. Quality control examines every batch of the product for essential parameters like a.s. content, density, particle size and wet sieving residue. This guarantees the constant quality of the end-use product Fendona 6 SC according to its specification.

The potential exposure of industrial workers during the production and formulation of the b.p. should be addressed under other EU legislation (e.g. REACh) and not repeated under Regulation (EU) 528/2012 (BPR). The Biocides Technical Meeting (TMI06) agreed that a risk assessment for production and formulation of the a.s. was not required, unless the a.s. was totally new to the EU market and manufactured in the EU. This is not the case for alpha-cypermethrin which is an existing biocidal a.s. within the EU.
Furthermore, formulation of the b.p. is not considered to give rise to a health concern as industrial users are supposed to respect working hygiene.

Summary of exposure assessment

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group**	**Tier/PPE**	**Estimated total uptake**
1.	Professionals, (trained and pest-control-officers PCO)	1 / no PPE	0.0190
		2 / gloves, coverall	0.0044
		2 / gloves, coverall, RPE	0.0021
2.	Professionals, (trained and pest-control-officers PCO)	1 / no PPE	0.0095
		2 / gloves, coverall	0.0022
		2 / gloves, coverall, RPE	0.0010
3.	Non-professionals	1 / potential exposure	$4.03\ 10^{-4}$
		2 / normal clothing	$3.83\ 10^{-4}$
4.	Professionals, (trained and pest-control-officers PCO) & Non-professionals	1 / potential exposure	$2.19\ 10^{-5}$
5.	Professionals, (trained and pest-control-officers PCO)	1 / potential exposure	$1.05\ 10^{-5}$
6.	General public (adults)	1 / potential exposure	$1.25\ 10^{-4}$
7.	General public (adults)	1 / potential exposure	1.36×10^{-4}
1 + 4 + 9.	Professionals, (trained and pest-control-officers PCO)	2 / gloves, coverall + 1 / potential exposure+ 1 / potential exposure	0.0044
2 + 5 + 10.	Professionals, (trained and pest-control-officers PCO)	2 / gloves, coverall + 1 / potential exposure+ 1 / potential exposure	0.0022
3 + 4 + 9.	Non-professionals	1 / potential exposure+ 1 / potential exposure	0.00042
3 + 6.	Non-professionals	1 / potential exposure	0.00053
8.	General public Adults Children Toddlers Infants	1 / potential exposure	1.2×10^{-4} 3.1×10^{-4} 3.5×10^{-3} 4.3×10^{-3}
9	Professionals, (trained and pest-control-officers PCO) & Non-professionals	1 / potential exposure	5.5×10^{-7}
10.	Professionals, (trained and pest-control-officers PCO)	1 / potential exposure	2.6×10^{-7}

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation

Reference Dose		Value	Unit	Remarks
Short-term	$NOAEL_{short\text{-}term}$	4.0	mg/kg bw/d	Acute neurotoxicity study
	$NOAEL_{short\text{-}term,\ systemic}$	1.8	mg/kg bw/d	Applying a factor of 0.45 for gastric absorption
	$AEL_{short\text{-}term,\ systemic}$	**0.018**	mg/kg bw/d	Applying an assessment factor of 100
Medium-term	$NOAEL_{90\text{-}day\ oral\ dog}$	3.5	mg/kg bw/d	Short-term toxicity study
	$NOAEL_{medium\text{-}term,\ systemic}$	1.575	mg/kg bw/d	Applying a factor of 0.45 for gastric absorption
	$AEL_{medium\text{-}term,\ systemic}$	**0.016**	mg/kg bw/d	Applying an assessment factor of 100
Long-term	$NOAEL_{1\text{-}year\ oral\ dog}$	2.0	mg/kg bw/d	Chronic toxicity study
	$NOAEL_{long\text{-}term,\ systemic}$	0.9	mg/kg bw/d	Applying a factor of 0.45 for gastric absorption
	$AEL_{long\text{-}term,\ systemic}$	**0.009**	mg/kg bw/d	Applying an assessment factor of 100

In the CAR of alpha-cypermethrin, the exposure levels for the professional users are compared with the medium-term AEL (occupational). However, for the current risk assessment and for professionals, [Pest-control-officers (PCO)], it is considered more relevant to use the long-term AEL value i.e. 0.009 mg/kg b.w./d.

The EU toxicological endpoints for alpha-cypermethrin are:

Reference values		Source
ADI	0.015 mg/kg bw/day	Commission Directive 2004/58/EC
ARfD	0.04 mg/kg bw	Commission Directive 2004/58/EC

Maximum residue limits or equivalent

Animal metabolism:
In the framework of registering alpha-cypermethrin under Council Directive 91/414/EEC metabolism studies were conducted in laying hen and in lactating cow.

Residue definition:
Cypermethrin (sum of constituent isomers) - for risk assessment and MRL setting

MRLs or other relevant reference values	Reference	Relevant commodities	Value [mg/kg]
MRL	EU – Maximum Residue Levels (Reg. (EC) No 396/2005) Legislation: Cypermethrin MRLs (Reg. (EU) No 626/2017)	**Swine and Bovine:** Muscle Fat tissue Liver Kidney Edible offals **Poultry:** Muscle Fat tissue Liver Kidney Edible offals **Milk:** Cattle **Bird eggs:** Chicken	 2 2 0.2 0.2 0.2 0.1 0.1 0.05* 0.05* 0.05* 0.05 0.05*

* Indicates lower limit of analytical determination

Specific reference value for groundwater
No specific reference value for groundwater was established. Thus, the European standard value of 0.1 µg/L for the maximum admissible concentration of pesticides in drinking water (Council Directive 98/83/EC) does apply.

Risk for industrial users

Not relevant.

Risk for professional users

Systemic effects

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]						
Professional long-term	1 (no PPE)	0.9	0.009	0.0190	211	No
	2 (gloves, coverall)	0.9	0.009	0.0044	49	Yes
	2 (gloves, coverall, RPE)	0.9	0.009	0.0021	23	Yes
Scenario [2]						
Professional long-term	1 (no PPE)	0.9	0.009	0.0095	105	No
	2 (gloves, coverall)	0.9	0.009	0.0022	24	Yes
	2 (gloves, coverall, RPE)	0.9	0.009	0.0010	11	Yes
Scenarios [1 + 4 + 9]						
Professional long-term	2 (gloves, coverall) / 1 potential / 1 potential	0.9	0.009	0.0044	49	Yes
Scenarios [2 + 5 + 10]						
Professional long-term	2 (gloves, coverall) / 1 potential / 1 potential	0.9	0.009	0.0022	24	Yes

Local effects

There is no need to consider local effects separately.

Substance of Concern (SoC)

Fendona 6 SC contains 1,2-Propylene Glycol at levels of 14%. An IOEL of 10 mg/m^3 for 1,2-Propylene Glycol is available in the GESTIS International Limit Values (http://limitvalue.ifa.dguv.de/ and as such, it should be considered as a SoC.

According to the Biocides Guidance on Human Health Risk Assessment (Parts B and C), Feb.2017_v.4, *For SoCs for which Community workplace exposure limits (IOELVs –Indicative Occupational Exposure Limit Values) have been set, a quantitative inhalation risk assessment for the professional operator against the IOELV should always be conducted*. Based on the above, a quantitative inhalation risk assessment for the professional user should be performed.

Considering the indicative inhalation exposure value of 104 mg/m^3 (professional exposure; Spraying Model 1; TNsG Chapter 3, p. 143, HSE survey HE74/3) and the concentration of 1,2-Propylene glycol in the spraying dilution i.e. 0.14% and 0.07% for Scenario 1 and 2 respectively, the aerial concentration of 1,2-Propylene glycol is calculated to be 0.146 mg/m^3

and 0.073 mg/m^3 for Scenario 1 and 2, respectively. These values correspond to 1.46% and 0.73% of the IOELV of 10 mg/m^3. Therefore, an acceptable risk is identified at Tier 1 level without the use of any RPE for both scenarios.

Conclusion
For the professional user a safe use could be shown with gloves and coverall (but without RPE) when applying Fendona 6 SC at 30 and/or 15 mg a.s./m² on rural and urban/domestic areas.
In addition, no risk has been identified following combined exposure for a professional user applying the product, cleaning of the spraying equipment and laundering his workwear.

No risk has been identified for the professional user due to the presence of 1,2-Propylene Glycol in the product.

Risk for non-professional users

Systemic effects

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 [3]						
Non-professional acute	1 (potential expsoure)	1.8	0.018	4.03×10^{-4}	2.2	Yes
	2 (normal clothing)	1.8	0.018	3.83×10^{-4}	2.1	Yes
Non-professional medium-term	1 (potential expsure)	1.575	0.016	4.03×10^{-4}	2.5	Yes
	2 (normal clothing)	1.575	0.016	3.83×10^{-4}	2.4	Yes
Scenarios [3 + 4 + 9]						
Non-professional medium-term	1 (potential exposure) / 1 potential	1.575	0.016	0.00042	2.6	Yes
Scenarios [3 + 6]						
Non-professional acute	1 (potential expsure)	1.8	0.018	0.00053	2.9	Yes

Local effects

There is no need to consider local effects separately.

Conclusion

For the non-professional user (consumer) a safe use could be shown without the use of PPE/RPE when applying Fendona 6 SC on rural areas. In addition, no risk has been identified for a non-proffesional user applying the product, cleaning of the spraying equipment and laundering afterwards his workwear. Finally, a safe use was demonstrated for a non-proffesional user applying the product and then entering the treated area.

Risk for the general public

Secondary risk assessment

Systemic effects

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 [6] General public adults acute	1 (potential exposure)	1.8	0.018	1.25×10^{-4}	0.7	Yes
Scenario [7] General public adults acute	1 (potential exposure)	1.8	0.018	1.36×10^{-4}	0.76	Yes
Scenario [8] Adults Children Toddlers Infants long-term	1 (potential exposure)	0.9	0.009	1.2×10^{-4} 3.1×10^{-4} 3.5×10^{-3} 4.3×10^{-3}	1.3 3.4 39 48	Yes Yes Yes Yes

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

Conclusion
Secondary exposure of the general public, to alpha-cypermethrin in Fendona 6 SC does not pose an unacceptable health risk. The AEL is neither reached nor exceeded by the estimated exposure.

Risk for consumers via residues in food

Comparison of animal feeding study levels with calculated biocide intake

Animal	Housing type	Calculated Biocide Intake* [mg/animal /day]	Indicated feeding study level** [mg/animal /day]
Calf		25.9	77.0
Beef Cattle		39.0	77.0
Dairy cattle		52.4	77.0
Fattening pig		15.4	35.4
Breeding pig	individual housing	29.3	92.0
Breeding pig	group housing	30.7	92.0
Broiler chickens	free range, litter floor	0.15	0.68
Parent broiler chickens	free range, grating floor	0.16	0.68
Broiler chickens, rearing	free range, grating floor	0.16	0.68
Laying hen	battery without trough	0.11	0.68
Laying hen	battery with trough	0.14	0.68
Laying hen	free range, litter floor	0.36	0.68
Laying hen	free range, grating floor)	0.17	0.68

* please refer to Section "Estimating Livestock Exposure to Active Substance used in Biocidal Products" (Chapter 2.2.3.1)
** please refer to feeding studies in Section "Other" (Chapter 2.2.3.1)

All biocide exposure calculations for **ruminants** are below the lowest feeding level and are therefore covered by the risk assessment conducted using the maximum residues derived from the cow feeding study at lowest feeding level as input parameters.

All biocide exposure calculations for **pigs** are below the medium feeding level and are therefore covered by the risk assessment conducted using the maximum residues derived from the cow feeding study at medium feeding level as input parameters.

All biocide exposure calculations for **poultry** resulted in values below the lowest feeding level and are therefore covered by the risk assessment conducted using the maximum residues derived from the hen feeding study at lowest feeding level as input parameters.

Based on the results of the feeding studies at the indicated levels (see table above) maximum residues data, shown in the table below (column 2), were derived. In column 3 approved MRLs of alpha-cypermethrin are shown (Reg. (EU) No 626/2017).

Column 1	Column 2	Column 3
Groups and examples of individual products to which the MRLs apply	Maximum residues derived from feeding study at indicated level [mg/kg]	Cypermethrin MRLs (Reg. (EU) No 626/2017) [mg/kg]
Swine		
Muscle	0.05[1]	2
Fat tissue	0.16	2
Liver	0.05[1]	0.2
Kidney	0.05[1]	0.2
Edible offals	0.05[1]	0.2
Bovine		
Muscle	0.05[1]	2
Fat tissue	0.064	2
Liver	0.05[1]	0.2
Kidney	0.05[1]	0.2
Edible offals	0.05[1]	0.2
Poultry		
Muscle	0.05[1]	0.1
Fat tissue	0.05[1]	0.1
Liver	0.05[1]	0.05[2]
Kidney	0.05[1]	0.05[2]
Edible offals	0.05[1]	0.05[2]
Milk		
Cattle	0.01[1]	0.05
Birds eggs		
Chicken	0.01[1]	0.05[2]

[1] Indicates lower limit of detection
[2] Indicated lower limit of analytical determination

The calculated residue concentration from biocide intake is shown to be lower than the residue concentration in animal commodities derived from the lowest feeding level of the indicated animal feeding studies. As the animal commodity MRLs are calculated from the results of the lowest feeding study level, the animal commodity residue concentration derived from the biocide use are covered by the existing MRLs.

A dietary risk assessment for consumers was conducted based of the following maximum residues derived from the feeding studies. These maximum residues are considered to be worst case values regarding the Fendona 6 SC rural hygiene biocide use.

0.05 mg/kg for swine meat, liver, kidney and edible offals
0.16 mg/kg for swine fat
0.05 mg/kg for bovine meat, liver, kidney and edible offals
0.064 mg/kg for bovine fat
0.05 mg/kg for poultry meat, fat, liver, kidney and edible offals
0.01 mg/kg for milk
0.01 mg/kg for eggs

Assessments of the potential chronic and acute dietary consumer risk due to exposure to residues of alpha-cypermethrin were performed using the EFSA model for chronic and acute risk assessment - rev. 2_0 (Model PRIMo). The EFSA model was used since it considers all the different diets in the EU and all consumer groups.
The ADI and ARfD for the a.s. alpha-cypermethrin are 0.015 mg/kg bw/day and 0.04 mg/kg bw, respectively.

Results of the chronic dietary risk assessment

The chronic dietary risk assessment was conducted using EFSA PRIMo (Rrev.2) and the highly conservative maximum residues for animal commodities as shown above. A more realistic chronic dietary risk assessment has also been conducted with the highest residues from feeding studies as outlined in the table above taking into account, that over lifetime the daily consumption of produce of animal origin at the MRL level is highly unlikely.

I addition, a dietary risk assessment was conducted using the consumption data from the standard EMA food basket. This dietary exposure assessment was also conduced using the animal commodity MRLs as outlined above in addition to the residue levels as derived from the animal feeding studies to derive a theoretical maximum daily intake (TMDI).

Chronic dietary risk assessment	**% ADI**	
Input values	MRL	Feeding study residuelevel
EFSA PriMo (Rev.2)	48%	4.0%
EMA standard food basket - Ruminants	89%	4.5%
EMA standard food basket - Pigs	81%	3.4%
EMA standard food basket - Poultry	5.3%	2.9%

* ADI: 0.015 mg/kg bw/day

When calculating the chronic exposure of consumers using the EMA standard food basket and using the highly conservative MRLs of the animal commodities under investigation as input parameters, it was demonstrated that none of the commoditieds exceeded the acceptable daily intake (ADI), with the highest use being produce of ruminant origin with 89%. When replacing the MRIs with the much more realistic values derived from the animal feeding studies, it becomes apparent that all commodities range belkow 5% of the ADI.

The use of PriMo (Rev. 2), taking into account pan-European and WHO listed diets as tool for the exposure assessment of the concerned population, shows that the use of the highly conservative MRL values for alpha-cypermethrin biocidal uses will not exceed a TMDI of 40% of the acceptable daily intake (ADI).

Results of the acute dietary risk assessment

The acute dietary risk assessment was performed according to the EFSA PriMo (Rev. 2), applying the maximum residue levels (MRLs). These maximum residues are considered to be worst case values regarding the Fendona 6 SC rural hygiene biocide use and taking into account that for short term exposure (acute dietary exposure) the use of the highly conservative MRLs as exposure input parameter are adressing the requirement to investigate potential consumption of single large portion at the maximum residue level. As the EMA standatrd food basket does not provide a respective value for singler larger portions, the EFSA PriMo (Rev. 2) was only used to derive this acute dietary risk assessment.

The top 5 commodities are reported. The IESTI (International Estimated Short Term Intake) is lower than 90%. Please refer to Annex 3.2, Table 10 for details.

Results of acute risk assessment: children		**Results of acute risk assessment: adults**	
	Highest exposure		**Highest exposure**
	IESTI 1 – % of ARfd*		**IESTI 1 – % of ARfD***
Bovine: Meat	64	Bovine: Meat	30
Swine: Meat	42	Swine: Meat	25
Cattle: Milk and milk products	16	Goat: Meat	8
Bovine: Fat	10	Swine: Fat	7
Swine: Fat	6	Bovine: Fat	3

* ARfD: 0.04 mg/kg bw/day

The acute risk assessment showed no exceedance of the ARfD for children and adults for both IESTI calculations.

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

No substances of concern were identified. Therefore exposure to several a.s. or substances of concern within the products is not relevant.

Major change application

The changes / additional data scoped in the major change application do not impact on the properties of the product regarding human health, or the output of the exposure assessment.

2.2.7 Risk assessment for animal health

General remarks

Based on the data requirements laid down in the Biocidal Products Regulation (BPR), the safety of animals after application of b.p. has to be addressed as well. For this reason, the safety of alpha-cypermethrin for livestock animals housed in stables treated with Fendona 6 SC is being assessed.

The livestock animal safety assessment is conducted for the following animal species:

- Calf, beef cattle, dairy cattle
- Fattening pig, breeding pig
- Broiler chickens, laying hen

Orientating tolerable intake value deduction for alpha-cypermethrin in the animal safety assessment

Repeated dose toxicity studies showed that the main target organ of alpha-cypermethrin is the nervous system (CNS and peripheral motor nerves). Signs of acute toxicity in rats following oral administration included clonic convulsions, salivation, ataxia, lethargy, piloerection and diarrhoea. Alpha-cypermethrin was found to have a low magnitude of toxicity by dermal and inhalation routes of exposure. In repeated-dose studies, symptoms of toxicity were described as hypersensitivity to external stimuli, ataxia, nervousness, hyperactivity, tremors and splayed gait. Again, this was confirmed in an acute oral neurotoxicity study in rats. A 4-weeks neurotoxicity study in rats aiming at the identification of the toxic mechanism showed that the effects of alpha-cypermethrin are likely due to a pharmacological effect rather than the consequence of structural damage, despite sporadic incidences of slight degeneration of the sciatic nerve.
Since the exposure scenarios for the animals are considered as acute scenarios and as the substance is not subject to bioaccumulation and recovery from acute neurotoxicity effects can be assumed to occur relatively quickly following exposure, the NOAEL value for the derivation of the AEL_{acute} was used to derive an orientating tolerable intake value for the livestock safety assessment. Based on the CAR of alpha-cypermethrin, the NOAEL of the acute neurotoxicity study in rats is selected in agreement with the toxic mechanism of alpha-cypermethrin. The NOAEL for acute neurotoxicity effects could be established at 4.0 mg/kg bw/day. Taking into account the oral absorption factor of 0.45 and dividing the NOAEL value of 4.0 mg/kg bw/day by an inter-species assessment factor of 10, an orientating tolerable oral intake value of **0.18 mg/kg bw/day** is derived. An assessment factor of 10 is considered conservative for the purpose of the animal safety assessment as a factor of 5 is taken into consideration for long-term exposure according to the EFSA Guidance on Risk Assessment for Birds and Mammals (first published Dec. 2009)[1]. For this reason, the deduction of an orientating tolerable intake value for livestock animals has been based on very conservative assumptions.

1 Guidance of EFSA, Risk Assessment for Birds and Mammals, on request form EFSA, Question No EFSA-Q-2009-00223, first published on 17 December 2009

Animal exposure calculations

Animals can be exposed to the biocidal a.s. by different routes of exposure: inhalation, oral uptake and dermal uptake.
Animal exposure calculations were conducted according to European Commission Draft Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products (see Section "Estimating Livestock Exposure to Active Substances used in Biocidal Products").

Data on distribution, metabolism and excretion on the a.s. showed that following a single oral application, approximately 43% of the dose is absorbed and eliminated within 24 hours via urinary excretion (CAR, Belgium). Thus, for the animal exposure assessment it is proposed to take into account the oral absorption factor of 0.45.
The default dermal absorption value of 75% based on the most recent EFSA Guidance on Skin Absorption (2012) was considered in the assessment of animal exposure towards alpha-cypermethrin.

The exposure estimations for the respective livestock animal species are presented in the following tabe.

	Biocide intake, Tier 1 [mg/animal/ day]	**Biocide intake, Tier 1 [mg/kg bw/day]**	**Absorption factor**	**Biocide intake, Tier 2 [mg/kg bw/day]**
Calf (body weight: 200 kg)				
Oral exposure through licking of surface	2.04	0.0102	0.45	0.0046
Oral exposure through uptake of contaminated feed	1.65	0.0083	0.45	0.0037
Dermal exposure through rubbing against surfaces	22.19	0.1110	0.75	0.0832
Inhalation exposure	0.0016	0.00001	1	0.00001
Sum, Tier 2 (Realistic worst case estimate)				**0.0915**
Beef cattle (body weight: 500 kg)				
Oral exposure through uptake of contaminated feed	2.31	0.0046	0.45	0.0021
Dermal exposure through rubbing against surfaces	36.72	0.0734	0.75	0.0551
Inhalation exposure	0.0032	0.00001	1	0.00001
Sum, Tier 2 (Realistic worst case estimate)				**0.0572**
Dairy cattle (body weight: 650 kg)				
Oral exposure through uptake of contaminated feed	9.57	0.0147	0.45	0.0066

	Biocide intake, Tier 1 [mg/animal/ day]	Biocide intake, Tier 1 [mg/kg bw/day]	Absorption factor	Biocide intake, Tier 2 [mg/kg bw/day]
Dermal exposure through rubbing against surfaces	42.84	0.0659	0.75	0.0494
Inhalation exposure	0.0040	0.00001	1	0.00001
Sum, Tier 2 (Realistic worst case estimate)				**0.0561**
Fattening pig (body weight: 100 kg)				
Oral exposure through uptake of contaminated feed	3.96	0.0396	0.45	0.0178
Dermal exposure through rubbing against surfaces	11.48	0.1148	0.75	0.0861
Inhalation exposure	0.0009	0.00001	1	0.00001
Sum, Tier 2 (Realistic worst case estimate)				**0.1039**
Breeding pig (individual housing) (body weight: 260 kg)				
Oral exposure through uptake of contaminated feed	7.92	0.0305	0.45	0.0137
Dermal exposure through rubbing against surfaces	21.42	0.0824	0.75	0.0618
Inhalation exposure	0.0019	0.00001	1	0.00001
Sum, Tier 2 (Realistic worst case estimate)				**0.0755**
Breeding pig (group housing) (body weight: 260 kg)				
Oral exposure through uptake of contaminated feed	9.24	0.0355	0.45	0.0160
Dermal exposure through rubbing against surfaces	21.42	0.0824	0.75	0.0618
Inhalation exposure	0.0019	0.00001	1	0.00001
Sum, Tier 2 (Realistic worst case estimate)				**0.0778**
Broiler Chickens (Free range, litter floor) (body weight: 1.7 kg)				
Oral exposure (fly consumption	0.0210	0.0124	0.45	0.0056
Dermal exposure	0.132	0.0776	0.75	0.0582
Inhalation exposure	0.00001	0.00001	1	0.00001
Sum, Tier 2 (Realistic worst case estimate)				**0.0638**

	Biocide intake, Tier 1 [mg/animal/ day]	Biocide intake, Tier 1 [mg/kg bw/day]	Absorption factor	Biocide intake, Tier 2 [mg/kg bw/day]
Parent Broiler chickens (free range, grating floor) (body weight: 1.7 kg)				
Oral exposure (fly consumption	0.0210	0.0124	0.45	0.0056
Dermal exposure	0.141	0.0829	0.75	0.0622
Inhalation exposure	0.00001	0.00001	1	0.00001
Sum, Tier 2 (Realistic worst case estimate)				**0.0678**
Broiler chickens, rearing (free range, grating floor) (body weight: 1.7 kg)				
Oral exposure (fly consumption	0.0210	0.0124	0.45	0.0056
Dermal exposure	0.138	0.0812	0.75	0.0609
Inhalation exposure	0.00001	0.00001	1	0.00001
Sum, Tier 2 (Realistic worst case estimate)				**0.0664**
Laying hens (Battery without trough) (body weight: 1.9 kg)				
Oral exposure (fly consumption	0.0210	0.0111	0.45	0.0050
Dermal exposure	~~0.173~~ 0.086	~~0.0911~~ 0.045	0.75	~~0.0683~~ 0.034
Inhalation exposure	0.00001	0.00001	1	0.00001
Sum, Tier 2 (Realistic worst case estimate)				**~~0.0733~~ 0.039**
Laying hens (Battery with trough) (body weight: 1.9 kg)				
Oral exposure (fly consumption	0.0210	0.0111	0.45	0.0050
Oral exposure (feed)	0.033	0.0174	0.45	0.0078
Dermal exposure	~~0.173~~ 0.086	~~0.0911~~ 0.045	0.75	~~0.0683~~ 0.034
Inhalation exposure	0.00001	0.00001	1	0.00001
Sum, Tier 2 (Realistic worst case estimate)				**~~0.0811~~ 0.047**
Laying hens (free range, litter floors) (body weight: 1.9 kg)				
Oral exposure (fly consumption	0.0210	0.0111	0.45	0.0050
Dermal exposure	0.335	0.1763	0.75	0.1322
Inhalation exposure	0.00001	0.00001	1	0.00001
Sum, Tier 2 (Realistic worst case estimate)				**0.1372**
Laying hens (free range, grating floors) (body weight: 1.9 kg)				
Oral exposure (fly consumption	0.0210	0.0111	0.45	0.0050
Dermal exposure	0.150	0.0789	0.75	0.0592

	Biocide intake, Tier 1 [mg/animal/ day]	Biocide intake, Tier 1 [mg/kg bw/day]	Absorption factor	Biocide intake, Tier 2 [mg/kg bw/day]
Inhalation exposure	0.00001	0.00001	1	0.00001
Sum, Tier 2 (Realistic worst case estimate)				**0.0642**

Livestock animal risk assessment

The exposure estimations for the respective livestock animal species and the comparison with the reference value are presented in the following table.

Animal species	Biocide intake, Tier 2 [mg/kg bw/day]	Hazard Quotient[1]	MoE[2]	Acceptable (yes/no)
Calf	0.0915	0.51	20	Yes
Beef cattle	0.0572	0.32	31	Yes
Dairy cattle	0.0561	0.31	32	Yes
Fattening pig	0.1039	0.58	17	Yes
Breeding pig (individual housing)	0.0755	0.42	24	Yes
Breeding pig (group housing)	0.0778	0.43	23	Yes
Broiler Chickens (free range, litter floor)	0.0638	0.35	28	Yes
Parent Broiler Chicken (free range, grating floor	0.0678	0.38	27	Yes
Broiler chickens, rearing (free range, grating floor	0.0664	0.37	27	Yes
Laying hens (battery without trough)	~~0.0733~~ 0.039	~~0.41~~ 0.22	25	Yes
Laying hens (battery with trough)	~~0.0811~~ 0.047	~~0.45~~ 0.26	22	Yes
Laying hens (free range, litter floor)	0.1372	0.76	13	Yes
Laying hens (free range, grating floor)	0.0642	0.36	28	Yes

[1] Hazard Quotient: Exposure/Orientating tolerable intake value (0.18 mg/kg bw/day)
[2] based on $NOAEL_{acute,\ systemic}$ of 1.8 mg/kg bw/day from acute neurotoxicity study in rats; based on the EFSA guidance document on birds and mammals, a TER of ≥ 5 is sufficient for chronic/long-term exposure

The exposure of livestock animals following treatment of surfaces in animal houses with Fendona 6 SC is considered safe and all exposure estimates are below the orientating reference value of 0.18 mg/kg bw/day as derived for the purpose of the livestock animal safety assessment. The margins of exposure (MoE) are sufficiently high as according to the EFSA guidance document for birds and mammals, a TER ratio of ≥ 5 provides a sufficient margin of safety for chronic/long-term exposure for birds and mammals.

Major change application

The changes / additional data scoped in the major change application do not impact on the properties of the product regarding animal health, or the output of the risk assessment.

2.2.8 Risk assessment for the environment

The biocidal product (b.p.) Fendona 6 SC is claimed for use by professional users in urban pest control as well as by professional and non-professional users in rural hygiene (Animal Houses/Shelters) as insecticide in product type (PT) 18. It is a concentrate and contains 60 g of the a.s. alpha-cypermethrin per L.

2.2.8.1 Effects assessment on the environment

The following PNEC values are taken directly from the Assessment Report of the active substance alpha-cypermethrin[2]:

- $PNEC_{STP}$: 100 mg/L
- $PNEC_{Surface\ water}$: 4.8E-06 mg/L
- $PNEC_{Sediment}$: 9.78E-04 mg/kg_{ww} (EU agreed)
- $PNEC_{Soil}$: 0.882 mg/kg_{ww}
- $PNEC_{oral,\ mammals}$: 2.67 mg/kg_{food}
- $PNEC_{oral,\ birds}$: 5.0 mg/kg_{food}

[redacted] **the risk assessment will be performed considering the EUagreed endpoint of 9.78E-04 mg/kg_{ww}.**

Major change application

The risk assessment has been updated and is no longer refined with the new tests performed with *Chironomus riparius* (as stated above). The endpoints of these studies are now considered as supportive information only as in this application they will not be used in the risk assessment because they are not EU-agreed. The risk assessment will be performed considering the EU-agreed endpoint of 9.78E-04 mg/kg_{ww}.

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

The classification of the biocidal product is based on the classification of the active substance alpha-cypermethrin (H400, M-factor: 1,000; H410, M-factor: 1,000). Taking the classification of the active substance into account and according to summation method described in the CLP Regulation, the biocidal product is classified as Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410).

Further Ecotoxicological studies

2 http://dissemination.echa.europa.eu/Biocides/ActiveSubstances/1238-18/1238-18_Assessment_Report.pdf

[redacted]

Summary table - Further ecotoxicological studies

[redacted]

Summary table of further ecotoxicological studies									
Method, Guideline, GLP status, Reliability	Species	Endpoint	Exposure		Results			Remarks	Reference
			Design	Duration	NOEC	EC_{50}	EC_{100}		
OECD 218, GLP, reliability 1	*Chironomus riparius*	Emergence and development rate	static	28 d	≥100 µg a.s./kg_{dw}	Not given	Not given	-	Gonsior, G. (2016b) IUCLID 9.2.1.9

[redacted]

Conclusion used in Risk Assessment – Further ecotoxicological studies	
Value/conclusion	See next row.
Justification for the value/conclusion	[redacted] **the risk assessment will be performed considering the EUagreed endpoint of 9.78E-04 mg/kg_{ww}.**

Major change application

The endpoints of these studies are considered as supportive information only and they will not be used in the risk assessment because they are not EU-agreed. The risk assessment will be performed considering the EU agreed endpoint of 9.78E-04 mg/kg_{ww}.

Data waiving	
Information requirement	Effects on aquatic organisms
Justification	[redacted], no further ecotoxicity data are available for the biocidal product (b.p.) Fendona 6 SC. The toxicity of the active substance (a.s.) and the co-formulants is known and no synergistic effects are expected. [redacted] Ecotoxicological properties and classification of the b.p. can be deduced from the respective properties of the a.s. and the co-formulants using the conventional method described in the guidance for classifying mixtures under Regulation (EC) No 1272/2008 (CLP). The a.s. alpha-cypermethrin is classified for the environment with Aquatic Acute 1 (H400), M-factor 1,000 and Aquatic Chronic 1 (H410), M-factor 1,000. Only two additional components of the b.p. are classified for environmental hazards. The remaining components of the b.p. are not classified for the environment. However, since alpha-cypermethrin exhibits the most stringent environmental classification and the additional ingredients are only present at a lower concentration compared to the a.s., alpha-cypermethrin alone is driving the environmental classification of the b.p. as Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410). The route of environmental exposure of alpha-cypermethrin is via STP to surface water (incl. sediment) in the urban pest control and via slurry/manure application to soil with subsequent run-off to surface water (incl. sediment). For the a.s., data on sludge microorganisms, on acute and chronic toxicity to fish, invertebrates, algae as well as chronic studies with sediment dwelling organisms are available. For the terrestrial compartment, an acute study with earthworms and a nitrogen/carbon mineralization study are available. The BCF was also determined experimentally. The formulation type of the b.p. is not expected to change the mode of action of the active substance or its bioavailability. Hence, also in view of Article 21 (1(a)) of EU Regulation No 528/2012 (22 May 2012) and owing to the use and exposure considerations as mentioned above, there is no need to further investigate the ecotoxicological effects for the b.p..

Data waiving	
Information requirement	Effects on terrestrial organisms
Justification	Please see justification under point *"Further Ecotoxicological studies – Effects on aquatic organisms"*.

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

Data waiving	
Information requirement	Information on the risks to any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)
Justification	Please see justification under point *"Further Ecotoxicological studies – Effects on aquatic organisms"*.

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

Data waiving	
Information requirement	Information on the risks to non-target organisms under field conditions is not required.
Justification	Please see justification under point *"Further Ecotoxicological studies – Effects on aquatic organisms"*.

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

Data waiving	
Information requirement	Information on the acceptance by ingestion of the biocidal product by any non-target organisms is not need required.
Justification	The b.p. does not contain any lure which could be attractive for non-target organisms. Therefore, ingestion by non-target organisms is no matter of concern. Moreover, the b.p. is not marketed in the form of granules.

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

The b.p. is a concentrate to be used by professionals and non-professionals in Product Type 18. The mode of application is spraying in closed facilities (e.g. in household, large public buildings and stable disinfection). The b.p. as such will therefore not enter the environment directly but only via manure/slurry application on land or via the STP route. Thus, non-target organisms are not directly exposed to the b.p.. A large space application of the biocidal product to water body, wetland, forest or field is not intended and information on secondary ecological effects is therefore not required.

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

Formulation of the biocidal product
Fendona 6 SC (BAS 310 27 I) is manufactured by converting alpha-cypermethrin TC to a slurry with part of the co-formulants and milling in a bead mill to achieve the appropriate particle size. The remaining co-formulants are added thereafter. The resulting technical concentrate is homogenized subsequently with the additional co-formulants required by the BAS 310 27 I formulation. Quality control examines every batch of the product for essential parameters like active substance content, density, particle size and wet sieving residue. This guarantees the constant quality of the end-use product Fendona 6 SC (BAS 310 27 I) according to its specification.

No environmental exposure is anticipated during the formulation process. The production facility utilizes controls to prevent environmental release and exposure of any of the components of the biocidal product. The finished biocidal product is packaged and sealed to prevent leakage.
The ingredients and finished product are not volatile. Therefore, gaseous emissions are negligible. All waste containing residue of the active substance are collected separately and sent to a treatment plant for incineration. The effluents from the formulation steps and the cleaning of the apparatus are disposed according to local regulations and according to the BASF principle of responsible care.

In conclusion, from the formulation of the biocidal product no emissions to the environment occur and therefore, no risk assessment was conducted for this life cycle stage.

Application and use of the biocidal product
The biocidal product Fendona 6 SC is used as insecticide in PT 18, both in urban pest control (Large/Industrial/Commercial Buildings and Domestic/Households/Private Areas) as well as in rural hygiene applications (Animal Houses/Shelters). It is used indoors by professionals in urban pest control as well as by professionals and non-professionals in rural hygiene. The b.p. is a concentrate, which will further be diluted with water and applied by spraying. In detail, the following uses are covered:

- Scenario 1: Urban pest control in domestic houses and large buildings (professionals)
- Scenario 2: Rural hygiene in animal houses/shelters (professionals and non-professionals)

For the urban scenario, the route of exposure of alpha-cypermethrin to the environment is via STP, which is the primary receiving compartment, to surface water, sediment, soil and groundwater (via sludge application). For the use in rural hygiene, the route of exposure is via application of manure/slurry to agricultural land. Release from the facility drain to an STP and subsequent compartments was not considered for the use in rural hygiene as Fendona 6 SC must not be used in stables/animal housings connected to a sewage treatment plant. Relevant receiving compartments are soil, groundwater and surface water.

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

Data waiving	
Information requirement	Further studies on fate and behaviour in the environment are not required.
Justification	Direct emissions of the biocidal product to the environmental compartments surface water (incl. sediment) and soil are unlikely. The data on the active substance gives sufficient information regarding its fate and behaviour in the environment and there are no indications of risk due to specific properties of the biocidal product as it does not contain any substance of concern for the environment. The formulation type is not expected to change the mode of action of the active substance or its bioavailability. The fate of alpha-cypermethrin is covered by the data provided for the active substance.

Leaching behaviour (ADS)

Leaching is not relevant for the use of the biocidal product in PT 18.

Testing for distribution and dissipation in soil (ADS)

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

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

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

Testing for distribution and dissipation in air (ADS)

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

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

Data waiving	
Information requirement	Information on risks to aquatic organisms or plants under field conditions in not required.
Justification	The b.p. is only applied via spraying in closed facilities like e.g. private houses or stables. No outdoor use is foreseen. An overspray study is therefore considered to be unnecessary.

Data waiving	
Information requirement	Information on aquatic chronic toxicity is not required.
Justification	No direct emissions of the b.p. to surface water occur. Moreover, chronic data on aquatic toxicity of the a.s. gives sufficient information about the ecotoxicity of the b.p. as there are no indications of risk due to specific properties of the biocidal product.

Data waiving	
Information requirement	Information on aquatic bioconcentration is not required.
Justification	No direct emissions of the b.p. to surface water occur. Moreover, a bioconcentration study was conducted with the a.s. giving sufficient information about the bioconcentration potential of the b.p. as there are no indications of bioconcentration due to specific properties of the biocidal product.

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

The b.p. is not intended to be used outside and there are is no potential for large scale formation of dust. Therefore, the risk to bees and non-target arthropods under field conditions has not further to be assessed.

2.2.8.2 Exposure assessment

The current section relates to the environmental exposure assessment for the biocidal product Fendona 6 SC, a water-based concentrate containing 60g alpha cypermethrin per litre, corresponding to 6.27 % (w/w) active substance (technical grade active ingredient, TGAI).

General information

Assessed PT	PT 18
Assessed scenarios	Scenario 1: Urban pest control in private houses (professionals) Scenario 2: Rural hygiene in animal houses/shelters (professionals and non-professionals)
ESD(s) used	Emission Scenario Documents for Product Type 18: Emission Scenario Document for Insecticides, Acaricides and Products to Control Other Arthropods for Household and Professional use; July 2008[3] Emission Scenario Document for Insecticides for Stables and Manure Storage Systems; January 2006[4]
Approach	Scenario 1: Average consumption Scenario 2: Average consumption
Distribution in the environment	Calculated based on the ESDs for PT18 and on Guidance on the Biocidal Products Regulation, Volume IV Environment - Assessment & Evaluation, Part B (TGD; EC, 2017).
Groundwater simulation	No higher tier modelling, using e.g. FOCUS was performed
Confidential Annexes	No
Life cycle steps assessed	Scenarios 1 and 2: Production: No Formulation Yes (qualitatively) Use: Yes
Remarks	No remarks

Releases into the environment can take place from processes at any stage of the life-cycle of a substance. However, from the formulation of the biocidal product no environmental exposure is anticipated. The production facility utilises controls to prevent environmental release and exposure of any of the components of the biocidal product. The local scale environmental emissions associated with the Applicant's envisaged use (indoor use exclusively) for Fendona, as a professional spray product, are considered to represent the worst case scenario in terms of predicted environmental concentrations (PECs). Since the

3 http://echa.europa.eu/documents/10162/16908203/pt18_oecd_esd_household_professional_uses_en.pdf

4 http://echa.europa.eu/documents/10162/16908203/pt18_insecticides_for_stables_and_manure_en.pdf

use pattern of Fendona is exclusively indoor and due to low tonnage (See confidential annex – Appendix I to Document III-A), it is not relevant to assess the regional risk. The environmental exposure assessment is performed only on a **local basis**.

In the following emission estimation for the product, alpha-cypermethrin is used for the emission calculations, as the exclusive active substance, of the given biocidal product.

The environmental exposure assessment has been produced using all available information taken from the Assessment Report for alpha cypermethrin. Information and guidance was derived from the Biocidal Products Regulation, Volume IV Environment - Assessment & Evaluation, Part B (TGD; EC, 2017). Under the intended uses of the product, i.e., (1) urban pest control in domestic houses and large buildings & (2) rural hygiene in animal houses/shelters, Emission Scenario Document (ESD) (PT 18) for (1) 'Insecticides, acaricides and products to control arthropods for household and professional use' (July 17, 2008) & (2) ESD for Insecticides for Stables and Manure Storage Systems (Jan, 25, 2006) were included to derive the PEC values for risk assessment evaluation.

Distribution in the environment is calculated based on the above guideline documents.

Table 1. Application details for Scenario 1 – Urban pest control (Large/Industrial/Commercial Buildings)

Application method(s)	Apply using any conventional manual or power sprayer equipped to produce a coarse spray at low pressure. Add the appropriate volume of Fendona 6 SC to the required volume of clean water and agitate. If a delay occurs between treatments, re-agitate before re-use. For crawling insects it is applied as a coarse spray to cracks & crevices, and/or onto targeted spots or areas where insects may crawl and hide. For flying insects the product should be only applied to the infested area as a coarse spray onto targeted spots or areas where insects may settle and not as a broad surface spray.
Application rate(s) and frequency	5 mL product is diluted in 1 L water (1:200; spray concentration:0.5% v/v) and applied per 20 m² surface area. Frequency: 1-2 applications per year.
Category(ies) of user(s)	Professional operators (Pest Control Operator)

Table 2. Application details for Scenario 2 – Rural hygiene (Animal Houses/Shelters)

<table>
<tr><td>Application method(s)</td><td>It is applied using any conventional manual or power sprayer equipped to produce a coarse spray at low pressure. The appropriate volume of Fendona 6 SC is added to the required volume of clean water and agitated. If a delay occurs between treatments, re-agitation is needed before re-use.</td></tr>
<tr><td>Application rate(s) and frequency</td><td>
<table>
<tr><th>Fendona 6 SC (mL) LOW DOSE RATE</th><th>Fendona 6 SC (mL) HIGH DOSE RATE</th><th>Water volume for dilution (L)</th><th>Surface area treated (m2)</th></tr>
<tr><td>25</td><td>50</td><td>5</td><td>100</td></tr>
<tr><td>12,5</td><td>25</td><td>2.5</td><td>50</td></tr>
<tr><td>5</td><td>10</td><td>1</td><td>20</td></tr>
<tr><td>2.5</td><td>5</td><td>0.5</td><td>10</td></tr>
<tr><td>1.25</td><td>2.5</td><td>0.25</td><td>5</td></tr>
</table>
e.g., for treating 20 m^2 surface area at the low dose rate:
5 ml product is diluted in 1 liter water (1:200; spray concentration: 0.5% v/v).
For the high dose rate: 10 ml product is diluted in 1 liter water (1:100; spray concentration: 1% v/v).

Frequency: up to 6 applications per year
4 applications for animal (sub)categories:
Laying hen, battery cages without treatment,
Laying hen, battery cages with forced drying,
Laying hen, compact battery cages,
Laying hen, free range with grating floor,
Parent broiler >18 weeks, free range with grating floor,
Parent broiler in rearing, free range with grating floor,
6 applications for animal (sub)categories: Dairy cow, Beef, Dairy cow,
Beef,
Veal Calf,
Sow, individual pens, sows in groups,
Fattening pig</td></tr>
<tr><td>Category(ies) of user(s)</td><td>Non-professional and professional (depending on the Member State’s definition of professional in this use area description)</td></tr>
</table>

No substance of concern is contained in the b.p. with regards to the environment.

Fate and distribution in exposed environmental compartments

- **Sewage treatment plants (STP)**

  Sewage water treatment plants are regarded as the only pathway of alpha-cypermethrin emissions after use as indoor insecticide. Possible entry pathways of wastewater during normal use of the product are via wet cleaning operations of treated surfaces, which will result in very low rates of active substance, which might be washed from treated surfaces.

The consecutive cleaning of the spraying equipment can also be a possible source for alpha-cypermethrin to the sewer system.

- **Surface water and sediment**

  Due to the intended indoor use, there are no direct emissions of alpha-cypermethrin to surface water and sediments. The exposure to surface water and sediment is indirect via STP effluents.

- **Soil, groundwater and air**

  Due to the exclusive indoor use-pattern of alpha-cypermethrin as an insecticide potential direct contamination of the environment via the pathways air, soil or groundwater is considered negligible. However, STP sludge might be applied to soils. Therefore, the STP sludge concentration and the concentrations in soil after one year and ten years of sludge application are calculated.

- **Biota**

  Indirect exposures to biota are possible via water sediment (potential bioconcentration in fish or mammals leading to secondary poisoning of fish-eating birds or fish-eating mammals).

➢ **Parameters assessed for the fate and distribution of alpha-cypermethrin in the environment**

A brief summary on fate and distribution in the environment of alpha-cypermethrin is presented below. The values taken from the Assessment Report for the active substance have been incorporated into the various equations and calculations (by TGD) to derive the PECs for alpha-cypermethrin.

Table 3: Parameters used in environmental exposure scenario

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

Degradation of alpha-cypermethrin in the different environmental compartments

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

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

In the water-sediment degradation studies using samples from natural aquatic systems, alpha-cypermethrin incubated in the dark disappeared rapidly from the water phase due to strong adsorption to the sediment and metabolisation. Alpha-cypermethrin was also readily eliminated in the sediment phase, by metabolisation and formation of bound residues. Alpha-cypermethrin quickly moves from the water phase into the sediment with DT_{50} in water ranging between 0.8 and 4 days, and in sediment between 12 and 67 days. BE CA recalculated DT_{50} water of 2.22 days and DT_{50} sediment of 28.13 days at 12°C (TGD, Part B, formula 25).

The main degradation products formed were cis-2,2-dimethyl-3-(2',2'-dichlorovinyl)cyclopropane carboxylic acid isomers (CL 912554) and 3-phenoxybenzoic acid (CL 206128), both of which underwent further degradation to $^{14}CO_2$. The DT_{50} of CL 912554 in the total system ranged between 27 and 70 days, and the DT_{50} of CL 206128 ranged between 4 and 6 days.

Although there is no direct exposure, surface water and sediment are assessed for the environmental risk and PEC values calculated to cover the effects of alpha-cypermethrin residues in the STP effluent.

Information on the metabolites is available in the Assessment Report. The ecotoxicity data show that the metabolites are far less toxic to aquatic organisms compared to parent alpha-cypermethrin:

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

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

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

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

- ***Degradation of alpha-cypermethrin in soils***

Degradation of alpha-cypermethrin was investigated under aerobic conditions in a sandy loam soil (Gedik and Keirs, 2001). Alpha-cypermethrin seems to degrade in this type of soil with DT_{50} of 39.1 days at 12°C with CO_2 as the principal degradation product (~35% at 12°C). Four minor degradation products, including 3-phenoxybenzoic acid (CL 206128) (≤5.44% AR) and three unknowns, as well as polar materials, were also extracted from the soil (<9% of AR).

In addition to laboratory studies, field soil dissipation studies were also conducted (Doc. III-A7.2.2.2/01-09). Alpha-cypermethrin degradation was followed during three years with one application of EC alpha-cypermethrin formulation (0.5 kg a.s./ha). DT_{50} values ranged from <14 to 112 days. In all of these studies, 90% of the dissipation occurred within a year. The degradation product, 3-phenoxybenzoic acid (CL 206128), is degraded more rapidly than the parent compound.

Based on reliable adsorption/desorption data (Hill, 1993) it can be concluded that alpha-cypermethrin is strongly adsorbed in soil (Koc range 26492 to 144652, mean 76344ml/g, n = 12). Based on common mobility classification schemes (McCall *et al*., 1983; Fate of Chemicals in the Environment, ACS, pp. 105-123) alpha-cypermethrin is classified as immobile in soil (Koc > 5000).

A further study of the effect of sunlight on a soil surface indicated that alpha-cypermethrin is not rapidly degraded through photodegradation on soil surfaces with DT_{50} of 113.5 days at 12°C. The major product of photodegradation is 3-phenoxybenzoic acid (CL 206128) (16.4% AR) and 3-phenoxybenzaldehyde (CL 206969) is a minor degradation product (<3%).

- ***Degradation of alpha-cypermethrin in the atmosphere***

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

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

Emission estimation

SCENARIO 1 – Urban pest control; professional use in private houses and large buildings

Fendona 6 SC is a water-based concentrate containing 60 g alpha-cypermethrin per litre, corresponding to 6.27% (w/w) technical grade active ingredient, TGAI. According to the use instructions, it should be diluted with water 1:200 and the maximum prescribed application rate is defined as 0.25 mL b.p. /m². This results in an active substance concentration of 16 mg a.i. / m^2 treated area. The information is summarized in the table below.

Table 4. Input parameters for calculating the local emission		
Scenario 1: Urban pest control; professional use in private houses and large buildings (3-11 appl. per year)		
Application rate of biocidal product (concentrate)	0.25 or 0.258	mL/m² g/m^2
Concentration of active substance in the product	60	g/L
Active substance concentration per treated m^2	16	mg/m^2

Fendona 6 SC is intended to be used in targeted applications indoors by spraying with compressed sprayer (1-3 bars) in cracks and crevices.
In the crack and crevice scenario, together with spot treatment, the product is only sprayed on targeted spots with a limited area. The total surface treated in a crack and crevices application in private houses is 2.0 m^2 and in commercial buildings it is 9.3 m^2. Regarding the number of private houses and commercial buildings, 4000 private houses and 300 large buildings are used as default values (Technical Agreement for Biocides (TAB), August 2018).

The estimations of environmental emissions are based on crack and crevices treatment approach. For emission calculations the following formulas (ESD for PT18 products, July 2008) were used to calculate daily local emission to STP (as STP is regarded as the only pathway of direct alpha-cypermethrin emissions after indoor use of Fendona):

<u>Mixing/loading step</u>

(1) $E_{prep,air} = Q_{prod,prep} \times F_{AI} \times N_{prep,building} \times F_{prep,air} \times 10^{-3}$

(2) $E_{prep,applicator} = Q_{prod,prep} \times F_{AI} \times N_{prep,building} \times F_{prep,applicator} \times 10^{-3}$

(3) $E_{prep,floor} = Q_{prod,prep} \times F_{AI} \times N_{prep,building} \times F_{prep,floor} \times 10^{-3}$

Application step

(4) $E_{application,air} = N_{appl,building} \times F_{appl.,air} \times Q_{prod} \times F_{AI} \times AREA_{treated}$

(5) $E_{application,applicator} = N_{appl,building} \times F_{appl.,applicator} \times Q_{prod} \times F_{AI} \times AREA_{treated}$

(6) $E_{application,floor} = N_{appl,building} \times F_{appl.,floor} \times Q_{prod} \times F_{AI} \times AREA_{treated}$

(7) $E_{application,treated} = N_{appl,building} \times F_{appl.,treated} \times Q_{prod} \times F_{AI} \times AREA_{treated}$

Releases to wastewater and STP

(8) $E_{applicator,ww} = (E_{prep,applicator} + E_{appl.,applicator}) \times F_{applicator,ww}$

(9) $E_{treated,ww} = (E_{prep,floor} + E_{appl.,floor} + E_{appl.,treated}) \times F_{ww} \times F_{CE}$

(10) $E_{waste\ water} = E_{applicator,ww} + E_{treated,ww}$

(11) $Elocal_{waste\ water,total} = ((E_{waste\ water} \times N_{houses}) + (E_{waste\ water} \times N_{larger\ buildings})) \times F_{simultaneity}$

The input parameter used for the environmental exposure assessment for urban pest control in cracks and crevices in private houses and large buildings are shown in Table 5. The following assumptions have been made:

- Number of applications per day per building ($N_{appl,building}$) is 1 both for the use in private houses and in large buildings.
- Number of preparations per day per building is ($N_{prep,building}$) is 1 for private houses and 3 for large buildings
- Fraction emitted to floor during mixing/loading ($F_{prep,floor}$) was set to 4.0E-04, assuming 5 L containers as worst case with unspecific design
- Fraction emitted to floor during application ($F_{application,floor}$) was set to 0.128 for compressed spraying with a pressure of 1-3 bars (ESD PT 18, Table 3.3-3, p 53).
- Fraction emitted to applicator during application ($F_{application\ applicator}$) was set to 2.3E-03 for compressed spraying with a pressure of 1-3 bars (ESD PT 18, p 174).
- Fraction emitted to waste waters by the applicator during the cleaning step: $\boldsymbol{F_{applicator\ ww}}$. is equal to 1 as 100% of the coveralls are considered washable;
- Fraction emitted to waste waters during the cleaning step: $\boldsymbol{F_{ww}}$. is equal to 1 as 100% of the treated surfaces are washed with water;
- Cleaning efficiency for the cracks and crevices treatment: $\boldsymbol{F_{CE}}$ is 0.25 (ESD PT 18, Table 3.3-8, p.64)

Table 6: Calculation of the local emissions to waste water – Scenario 1: Indoor crack and crevice treatment by professional users. Application – dose rate 16 mg a.i./m²

Input	Symbol	Unit	Houses	Larger buildings	S/D/O*
Amount of active substance	Qai	Kg/m^2	1.60×10^{-5}		
Fraction of active substance in the commercial product	F_{AI}	-	0.0627		S
Mixing / Loading stage					
Container volume		L	0.5		S
Area treated/wet rooms	$AREA_{treated}$	m^2	2	9.3	D
Fraction emitted to air during preparation step	$F_{prep,air}$	-	0	0	D
Fraction emitted to applicator during preparation step	$F_{prep,applicator}$	-	$1.2x10^{-3}$		D
Fraction emitted to floor during preparation step	$F_{prep,floor}$	-	4×10^{-4}		D
Quantity of commercial product used for the preparation per day	$Q_{prod,prep}$	g	5.15	5.15	S
Number of preparations per day	$N_{prep,building}$	d^{-1}	1	3	S
Emission to the air during preparation step (1)	**$E_{prep,air}$**	**kg/d**	**0**	**0**	**O**
Emission to the applicator during preparation step (2)	**$E_{prep,applicator}$**	**kg/d**	**3.87E-07**	**1.16E-06**	**O**
Emission to floor during preparation step (3)	**$E_{prep,floor}$**	**kg/d**	**1.29E-07**	**3.87E-07**	**O**
Application					
Fraction emitted to air during application	$F_{application,\ air}$	-	0.02		D
Fraction emitted to applicator during application	$F_{application,applicator}$	-	2.3×10^{-3}		D
Fraction emitted to floor during application	$F_{application,floor}$	-	0.128		D
Fraction emitted to treated surfaces during application	$F_{application,treated}$	-	0.85		D
Number of application per day per building	$N_{application,building}$	d^{-1}	1	1	D

Quantity of commercial product applied	Q_{prod}	kg/m²	2.57×10^{-4}		S
Emission to the air during application step (4)	**$E_{application,air}$**	**kg/d**	**6.45E-07**	**3.00E-06**	**O**
Emission to the applicator during application step (5)	**$E_{application,applicator}$**	**kg/d**	**7.41E-08**	**3.45E-07**	**O**
Emission to floor during application step (6)	**$E_{application,floor}$**	**kg/d**	**4.13E-06**	**1.92E-05**	**O**
Emission to treated surfaces during application (7)	**$E_{application,treated}$**	**kg/d**	**2.74E-05**	**1.27E-04**	**O**
Cleaning and Release parameters					
Fraction ww from applicator	$F_{applicator,ww}$	-	1		D
Fraction ww during cleaning	F_{ww}	-	1		D
Cleaning efficiency for floor and treated surfaces	F_{CE}	-	0. 25		D
Emission to waste water from air	**$E_{air,\ ww}$**	**Kg/d**	**negligible**		
Emission to waste water from applicator (8)	**$E_{applicator,\ ww}$**	**kg/d**	**4.62E-07**	**1.51E-06**	**O**
Emission to waste water from floor and treated surfaces (9)	**$E_{treated,ww}$**	**kg/d**	**7.91E-06**	**3.67E-05**	**O**
Emission to waste water (Eapplicator, ww + Etreated surface, ww) (10)	**E_{ww}**	**kg/d**	**8.37E-06**	**3.82E-05**	**O**
Simultaneity factor %	$F_{simultaneity}$	-	0.815		D S
Number of treated houses	Nhouses	-	4000	300	D
Local Emission to waste water	**$E_{localww}$**	**kg/d**	**2.73E-04**	**9.35E-05**	**O**

* O/S/D: Output/Set/Default value

Table 7: Total local emissions to waste water resulting from a cracks and crevices treatment

Compartment	**Total Local Emission (Elocal $_{waste\ water,\ total}$) from houses and larger buildings [kg/d] (11)**
STP	

Fsim=0.81%	**3.66E-04**

Major change application

RMM:

- a frequency of application of 1-2 applications per year

- application to large buildings only

Input parameters for calculating the local emission		
Scenario 1: Urban pest control; professional use in large buildings (1-2 appl. per year)		
Application rate of biocidal product (concentrate)	0.25 or 0.258*	mL/m² g/m²
Concentration of active substance in the product	60	g/L
Active substance concentration per treated m²	16	mg/m²

*the product density equals 1.03 g cm^{-3}

Emissions to waste water resulting from a cracks and crevices treatment – Fsim = 0.204%

Input	**Symbol**	**Unit**	**Large buildings**	**S/D/O***
Amount of active substance	Qai	Kg/m^2	1.60×10^{-5}	
Fraction of active substance in the commercial product	F_{AI}	-	0.0627	S
Mixing / Loading stage				
Container volume		L	**1**	S
Area treated/wet rooms	$AREA_{treated}$	m²	9.3	D
Fraction emitted to air during preparation step	$F_{prep,air}$	-	0	D
Fraction emitted to applicator during preparation step	$F_{prep,applicator}$	-	$1.2x10^{-3}$	D
Fraction emitted to floor during preparation step	$F_{prep,floor}$	-	**10^{-4}**	D
Quantity of commercial product used for the preparation per day	$Q_{prod,prep}$	g	5.15	S
Number of preparations per day	$N_{prep,building}$	d^{-1}	3	S

Emission to the air during preparation step (1)	**$E_{prep,air}$**	**kg/d**	**0**	**O**
Emission to the applicator during preparation step (2)	**$E_{prep,applicator}$**	**kg/d**	**1.16E-06**	**O**
Emission to floor during preparation step (3)	**$E_{prep,floor}$**	**kg/d**	**9.69E-08**	**O**
Application				
Fraction emitted to air during application	$F_{application,\ air}$	-	0.02	D
Fraction emitted to applicator during application	$F_{application,applicator}$	-	2.3×10^{-3}	D
Fraction emitted to floor during application	$F_{application,floor}$	-	0.128	D
Fraction emitted to treated surfaces during application	$F_{application,treated}$	-	0.85	D
Number of application per day per building	$N_{application,building}$	d^{-1}	1	D
Quantity of commercial product applied	Q_{prod}	kg/m²	2.58×10^{-4}	S
Emission to the air during application step (4)	**$E_{application,air}$**	**kg/d**	**3.00E-06**	**O**
Emission to the applicator during application step (5)	**$E_{application,applicator}$**	**kg/d**	**3.45E-07**	**O**
Emission to floor during application step (6)	**$E_{application,floor}$**	**kg/d**	**1.92E-05**	**O**
Emission to treated surfaces during application (7)	**$E_{application,treated}$**	**kg/d**	**1.27E-04**	**O**
Cleaning and Release parameters				
Fraction ww from applicator	$F_{applicator,ww}$	-	1	D
Fraction ww during cleaning	F_{ww}	-	1	D
Cleaning efficiency for floor and treated surfaces	F_{CE}	-	**0.5**	D
Emission to waste water from air	**$E_{air,\ ww}$**	**Kg/d**	**negligible**	
Emission to waste water from applicator (8)	**$E_{applicator,\ ww}$**	**kg/d**	**1.51E-06**	**O**
Emission to waste water from floor and treated surfaces (9)	**$E_{treated,ww}$**	**kg/d**	**7.33E-05**	**O**

Emission to waste water (Eapplicator, ww + Etreated surface, ww) (10)	**E_{ww}**	**kg/d**	**7.48E-05**	**O**
Simultaneity factor %	$F_{simultaneity}$	-	0.204	S
Number of treated houses	Nhouses	-	300	D
Local Emission to waste water	**$E_{localww}$**	**kg/d**	**4.58E-05**	**O**

Total local emissions to waste water resulting from a cracks and crevices treatment:

Compartment **STP**	**RMM, Total Local Emission ($E_{local\ waste\ water,\ total}$) from large buildings only [kg/d]**
RMM, Fsim = 0.204%	**4.58E-05**

PEC calculations for Scenario 1

In this section, Predicted Environmental Concentrations (PEC) for the active substance, alpha-cypermethrin, are calculated for the influent ($Clocal_{inf}$) and effluent ($Clocal_{eff}$ = PEC_{STP}) of a sewage treatment plant (STP) and for the environmental compartments surface water ($PEC_{surface\ water}$) and sediment ($PEC_{sediment}$). In addition to that, the concentration in STP sludge (C_{sludge}) and the PEC for the active substance in soil after one year and ten years of sludge application (PEC_{soil}, PEC_{soil10}) are calculated. $PEC_{groundwater}$ was regarded as the concentration in soil porewater following sludge application. PEC_{air} is considered negligible, as alpha-cypermethrin is not considered as volatile.

- **PEC in aquatic compartment (STP, surface water, sediment and groundwater)**

Insecticides applied indoor will eventually be cleaned. This cleaning step will therefore lead to release to waste water generally through wet cleaning methods. Therefore, the sewage treatment plant (STP) is considered as one of the main "receiving compartment" where insecticides will be released through wet cleaning events. Then, the "final" environmental compartment will logically be the surface water, the sediment, the groundwater (through STP), the soil (from sludge application) and air. Releases into the environment are split in three steps: mixing loading step, application step and cleaning step.

- **PEC for Sewage Treatment Plant (PEC_{STP})**

Local emission rates to waste water ($Elocal_{water}$) for cracks and crevices applications were calculated. For the risk assessment, a population of 10,000 inhabitants per public STP is taken as a typical example for rural populations where sewage water treatment plants are located. The public sewage treatment plant effluent discharge rate ($EFFLUENT_{stp}$) based on an averaged wastewater flow of 200L per capita per day for a population of 10,000

inhabitants is 2,000,000 L/d ($EFFLUENT_{stp}$) corresponding to the guidance document (TGD, Part B, Table 9).

The influent concentration in a sewage treatment plant, $Clocal_{inf,}$ is then calculated with the following equation, according to (TGD, Part B, Eq 35)

$$C_{in} = \frac{E_{local}}{E} \cdot \frac{1}{F_{stp}} \cdot \frac{10^6}{EFFLUENT_{stp}}$$

Where:

$Clocal_{inf}$ = concentration in untreated water (mg l^{-1})
$EFFLUENT_{stp}$ = (2 x 10^6 L d^{-1}; default)
$Elocal_{water}$ = local emission to wastewater during episode (kg d^{-1})

With $Clocal_{inf}$, we are able next to calculate the STP effluent concentrations ($Clocal_{eff}$) by the equation (according to TGD, Part B, Eq.36):

$$Clocal_{eff} = Clocal_{inf} \times Fstp_{water}$$

To calculate $Clocal_{eff}$, the fraction of the emission to wastewater directed to effluent ($Fstp_{water}$) was estimated at a value of 16% by ECA, using the EUSES. A negligible fraction (5,74 10^{-3} %) of the active substance is directed to air, while assuming no biodegradability, 84 % of the active substance will be directed to sludge by STP. Results are presented in the table below.

Table 8. Calculated fate and distribution in the STP (emission fractions given by EUSES Simple Treat 3.1).

Compartment	Percentage [%]
$F_{STP,air}$	5.74×10^{-3}
$F_{STP,water}$	16
$F_{STP,sludge}$	84
$F_{STP,degraded}$	0

The parameter $Clocal_{eff}$ can also be regarded as the **PEC_{STP}** of alpha-cypermethrin (TGD, Part B, Eq. 41),

$$PEC_{STP} = Clocal_{eff}$$

which represents the worst-case concentration the micro-organisms in the sewage treatment plant are exposed to. The $Clocal_{eff}$ is calculated in Table 9.

Table 9: Calculation of the STP effluent concentration ($Clocal_{eff}$ =PEC_{STP})

Influent concentration in untreated waste water [mg/L]	$Clocal_{inf}$	Fsim=0.81% 1.83E-04	**RMM, only buildings, Fsim=0.204% 1.15E-05**
Fraction of emission directed to water by STP [-]	$Fstp_{water}$	0.16	
Effluent concentration in untreated waste water [mg/L]	**$Clocal_{eff}$ = PEC_{STP}**	**Fsim=0.81% 2.93E-05**	

Major change application

To calculate $Clocal_{eff}$, the fraction of the emission to wastewater directed to effluent ($Fstp_{water}$) was estimated at a value of 15% by the SimpleTreat model v4. A negligible fraction of the active substance is directed to air, while assuming no biodegradability, 85% of the active substance will be directed to sludge by STP. Results are presented in the table below.

Calculated fate and distribution in the STP (based on Simple Treat v.4):

Compartment	Percentage [%]
$F_{STP,air}$	0
$F_{STP,water}$	15
$F_{STP,sludge}$	85
$F_{STP,degraded}$	0

The parameter $Clocal_{eff}$ can also be regarded as the **PEC_{STP}** of alpha-cypermethrin (TGD, Part B, Eq. 41),

$$PEC_{STP} = Clocal_{eff}$$

which represents the worst-case concentration the micro-organisms in the sewage treatment plant are exposed to. The $Clocal_{eff}$ is calculated in the following table.

Calculation of the STP effluent concentration ($Clocal_{eff}$ =PEC_{STP}):

Influent concentration in untreated waste water [mg/L]	$Clocal_{inf}$	**RMM, only large buildings, Fsim=0.204% 2.29E-05**

Fraction of emission directed to water by STP [-]	$Fstp_{water}$	0.15
Effluent concentration in untreated waste water [mg/L]	**$Clocal_{eff}$ = PEC_{STP}**	**3.66E-06**

- **PEC for surface water ($PEC_{surface\ water}$)**

The indoor use pattern of Fendona does not allow for direct exposure to surface waters, only the potential for indirect exposure via an STP. The local concentration arising from the indirect emission to a watercourse via the STP during the proposed use of this product was calculated to take into account dilution and removal to suspended sediments (ECHA guidance on ERA).

The solid-water partition coefficient in suspended matter (Kp_{susp}) can be calculated from the Koc value and the fraction of organic carbon in the compartment (Foc_{susp}) (according to Eq. 23 of TGD Part B), presenting in Table 10. The fraction of organic carbon in suspended soils is set as default value at 0.1 kg/kg (following the TGD for Risk Assessment).

Table 10: Calculation of partition coefficient solid-water in suspended matter

Parameter	Symbol	Value
Weight fraction organic carbon in suspended soils [$kg_{organic\ carbon}/kg_{solid}$]	Foc_{susp}	0.1
Partition coefficient organic carbon-water [L/kg]	K_{oc}	76344
Partition coefficient solid-water in suspended matter [L/kg]	**Kp_{susp} = Foc_{susp} × K_{oc}**	**7634.4**

The resulting Kp_{susp} is then used to calculate the local concentration in surface water ($Clocal_{water}$) and so the **$PEClocal_{water}$** by the equation that follows (TGD Part B, Eq. 48).

$$C_{w} = \frac{C_{e} \times f_{l}}{(1 + K_{s} \times S_{p} \times 10^{-6}) \times D_{w} \times S_{r}}$$

The concentration of suspended matter (dry weight) in river ($SUSP_{water}$) and DILUTION are default values, according to the TGD for Risk Assessment (Part B). Input parameters and the calculated **$Clocal_{water}$ = $PEClocal_{water}$** is presented in the table below:

Table 11: Calculation of local concentration in surface water ($Clocal_{water}$ = $PEClocal_{water}$).

Parameter	Symbol	Value
Partition coefficient solid-water in suspended matter [L/kg]	Kp_{susp}	7634.4
Effluent concentration in untreated waste water [mg/L]	$Clocal_{eff}$	**Fsim=0.81%** **2.93×10^{-5}**
Concentration of suspended matter (dry weight) [$mg_{solid}\ l_{water}^{-1}$]	$SUSP_{water}$	15
Dilution Factor	DILUTION	10
Local concentration of alpha-cypermethrin in surface water during emission episode [mg/L]	**$Clocal_{water}$ = $PEClocal_{water}$**	**Fsim=0.81%** **2.63×10^{-6}**

Major change application

Calculation of local concentration in surface water ($Clocal_{water}$ = $PEClocal_{water}$):

Parameter	Symbol	Value
		RMM, large buildings only **Fsim = 0.204%**
Partition coefficient solid-water in suspended matter [L/kg]	Kp_{susp}	7634
Effluent concentration in untreated waste water [mg/L]	$Clocal_{eff}$	**3.66E-06**
Concentration of suspended matter (dry weight) [$mg_{solid}\ l_{water}^{-1}$]	$SUSP_{water}$	15
Dilution Factor	DILUTION	10
Local concentration of alpha-cypermethrin in surface water during emission episode [mg/L]	**$Clocal_{water}$ = $PEClocal_{water}$**	**3.28E-07**

- **PEC for Sediment ($PEClocal_{sed}$)**

To assess the Predicted Environmental Concentration in sediment ($PEClocal_{sed}$), wet bulk density of suspended matter (RHO_{susp}) and the suspended matter-water partitioning coefficient ($K_{susp\text{-}water}$) are calculated below.

The wet bulk density of suspended matter (RHO_{susp}) is calculated in Table 12 according to TGD for Risk Assessment. $Fsolid_{susp}$, RHO_{solid}, $Fwater_{susp}$, and RHO_{water} are default values of TGD (Part B, Table 3).

$$RHO_{susp} = Fsolid_{susp} \times RHO_{solid} + Fwater_{susp} \times RHO_{water}$$

Table 12: Calculation of wet bulk density of suspended matter, **RHO_{susp}**

Parameter	Symbol	Value
Fraction solids in suspended matter [m³/m³]	$Fsolid_{susp}$	0.1
Bulk density of the solid phase [kg/m³]	RHO_{solid}	2500
Fraction water in suspended matter [kg/m³]	$Fwater_{susp}$	0.9
Density of the water phase [kg/m³]	RHO_{water}	1000
Bulk density of wet suspended matter [kg/m³]	**RHO_{susp}**	**1150**

The suspended matter-water partitioning coefficient ($K_{susp\text{-}water}$) is next calculated (Eq. 27 of TGD Part B).

$K_{susp\text{-}water} = Fwater_{susp} + Fsolid_{susp} \times Kp_{susp}/1000 \times RHO_{solid}$

According to the TGD for Risk Assessment, default values for $Fwater_{susp}$, $Fsolid_{susp}$ and for RHO_{solid} are used for the calculation of **$K_{susp\text{-}water}$,** presenting below in Table 13, with the value for Kp_{susp} as previously calculated in Table 10.

Table 13: Calculation of suspended matter-water partitioning coefficient, **$K_{susp\text{-}water}$**

Parameter	Symbol	Value
Fraction water in suspended matter [m³/m³]	$Fwater_{susp}$	0.9
Fraction solids in suspended matter [m³/m³]	$Fsolid_{susp}$	0.1
Partition coefficient solid-water in suspended matter [L/kg]	Kp_{susp}	7634.4
Density of the solid phase [kg/m³]	RHO_{solid}	2500
Suspended matter-water partitioning coefficient [m³/m³]	**$K_{susp\text{-}water}$**	**1910**

The concentration in freshly deposited sediment is taken as the PEC for sediment. Hence, the PEClocal for sediment is calculated by the following equation (TGD Part B, Eq. 53). Results are shown in Table 14.

$$PEC_{sed} = \frac{K_{susp\text{-}water} \times PEC_{water} \times f_{sed}}{RHO_{solid}}$$

Table 14: Calculation of PEClocal for sediment, **$PEClocal_{sed}$**

Parameter	*Symbol*	Value
Suspended matter-water partitioning coefficient [m³/m³]	$K_{susp\text{-}water}$	1910
Local concentration of alpha-cypermethrin in surface water during emission episode [mg/L]	$Clocal_{water}$ $=PEClocal_{water}$	**Fsim=0.81%** **2.63×10^{-6}**

Density of the solid phase [kg/m³]	RHO_{susp}	1150
Local concentration of alpha cypermethrin on sediment during emission episode [mg/kg]	***PEClocal*$_{sed}$**	**Fsim=0.81%** **4.37×10^{-3}**

Major change application

Calculation of PEClocal for sediment, PEClocal$_{sed}$:

Parameter	***Symbol***	**Value**
		RMM, large buildings only **Fsim = 0.204%**
Suspended matter-water partitioning coefficient [m³/m³]	$K_{susp\text{-}water}$	1910
Local concentration of alpha-cypermethrin in surface water during emission episode [mg/L]	$Clocal_{water} = PEClocal_{water}$	1.58E-07
Density of the solid phase [kg/m³]	RHO_{susp}	1150
Local concentration of alpha cypermethrin on sediment during emission episode [mg/kg]	***PEClocal*$_{sed}$**	**5.45E-04**

- ***PEC for groundwater $PEC_{groundwater}$ (via the application of sludge to agricultural land***

The **BE CA** considers that there is very low exposure to groundwater due to use pattern (indoor use). Risk to groundwater is via sewage sludge application on soil. Based on reliable adsorption/desorption data, it can be concluded that alpha-cypermethrin is strongly adsorbed by soil components (mean Koc = 76344 L/kg). Therefore, $PEC_{groundwater}$ can be regarded as the concentration in soil porewater following sludge application, $PEClocal_{soil,porewater}$ (calculated by the Eq. 70 of the TGD for Risk Assessment, Part B).

- ***PEC in atmosphere compartment (PEC_{air})***

Based on the vapour pressure (5.6×10^{-7} Pa at 25°C) and the Henry's constant (0.069 Pa × m³/mol at 25°C), volatilisation of alpha-cypermethrin is negligible. Calculations of the chemical lifetime in the troposphere (document II-A section 4.2.2.1) resulted in a half-life of 3.47 hours (QSAR estimates). According to this result ($t_{1/2} < 2$ days), alpha-cypermethrin is rapidly degraded by photochemical processes and no accumulation of alpha-cypermethrin in the air is to be expected. The calculation of PEC_{air} is therefore of no relevance.

- ***PEC in terrestrial compartment (PECsoil)***

Exposure of the soil compartment as a result of the indoor crack and crevice use of alpha-cypermethrin can be considered as coming indirectly via the application of sewage sludge to land. Therefore, for the assessment of the soil compartment, concentration of alpha-cypermethrin in the STP sludge and its concentration in soil during the first year and after ten years of sludge application were thoroughly calculated.

The concentration of active substance in dry sewage sludge can be calculated using the equations below taken from the ECHA guidance (Eq. 36 and 39, Part B) on ERA plus default parameters presented in the same guidance document:

$$C_{sludge} = \frac{F_{stp_{sludge}} \times E_{daily} \times 1000}{SLUDGERATE}$$

where, $SLUDGERATE = 2/3 \times SUSPCONC_{inf} \times EFFLUENT_{stp} + SURPLUS_{sludge} \times CAPACITY_{stp}$

and: $EFFLUENT_{stp} = CAPACITY_{stp} \times WASTEW_{inhab}$

The rate of sludge application, *SLUDGERATE,* is calculated without considering anaerobic degradation in the STP. According to the TGD for Risk Assessment, default values for $SUSPCONC_{inf}$, for $SURPLUS_{sludge}$ and for $CAPACITY_{stp}$ are used for the calculation, as presented in Table 15 below.

Table 15: Calculation of the rate of sewage sludge production in the STP (**SLUDGERATE)**

Parameter	Symbol	Value
Concentration of suspended matter in STP influent [kg/m³]	$SUSPCONC_{inf}$	0.45
Effluent discharge rate of STP [m³/d]	$EFFLUENT_{stp}$	2000
Surplus sludge per inhabitant equivalent [kg/d × eq]	$SURPLUS_{sludge}$	0.011
Capacity of the STP [eq]	$CAPACITY_{stp}$	10 000
Rate of sewage sludge production [kg/d]	**SLUDGERATE**	**710**

Using SLUDGERATE value, the concentration in dry sewage sludge (C_{sludge}) was then calculated. The fraction of the emission directed to sludge by STP ($Fstp_{sludge}$) is set 84%, according to EUSES. Results are presented in Table 16 below.

Table 16: Calculation of the STP sludge concentration **(Csludge)**

Parameter	Symbol	Value

Local emission rate to waste water during episode [kg/d]	$Elocal_{water}$	**Fsim=0.81%** **3.66E-04**
Rate of sewage sludge production [kg/d]	SLUDGERATE	710
Fraction of emission directed to sludge by STP	$Fstp_{sludge}$	0.84
Concentration in dry sewage sludge [mg/kg]	**Csludge**	**Fsim=0.81%** **0.433**

Major change application

Calculation of the rate of sewage sludge production in the STP (**SLUDGERATE)**

Parameter	**Symbol**	**Value**
Concentration of suspended matter in STP influent [kg/m³]	$SUSPCONC_{inf}$	0.45
Effluent discharge rate of STP [m³/d]	$EFFLUENT_{stp}$	2000
Surplus sludge per inhabitant equivalent [kg/d × eq]	$SURPLUS_{sludge}$	0.019
Capacity of the STP [eq]	$CAPACITY_{stp}$	10 000
Rate of sewage sludge production [kg/d]	**SLUDGERATE**	**790**

Using SLUDGERATE value, the concentration in dry sewage sludge (C_{sludge}) was then calculated. The fraction of the emission directed to sludge by STP ($Fstp_{sludge}$) is set 85%, according to Simple Treat v.4. Results are presented in the table below.

Calculation of the STP sludge concentration (Csludge):

Parameter	**Symbol**	**Value**
		RMM, large buildings only **Fsim = 0.204%**
Local emission rate to waste water during episode [kg/d]	$Elocal_{water}$	**4.58E-05**
Rate of sewage sludge production [kg/d]	SLUDGERATE	790
Fraction of emission directed to sludge by STP	$Fstp_{sludge}$	0.85

Concentration in dry sewage sludge [mg/kg]	**Csludge**	**0.0487**

Next, the concentration in soil just after the first sludge application, Csludge soil (0), and the fraction accumulation in one year, Facc, are calculated. Results are shown in Table 17 and 18, respectively. The initial soil concentration after ten applications of sludge, $Csludge_{soil\ 10}$ (0), is also assessed (Table 19).

- For $Csludge_{soil\ 1}$ (0) calculation (TGD, Part B, Eq. 61), default values for $APPL_{sludge}$ and $DEPTH_{soil}$ are used (TGD, Part B, Table 11), as well as for bulk density of soil (RHO_{soil}) (TGD, Part B, Table 3).

  $PEC_{soil} = Csludge_{soil\ 1}(0) = C_{sludge} \times APPL_{sludge} / DEPTH_{soil} \times RHO_{soil}$

Table 17: Calculation of the concentration in soil due to sludge in first year (**$Csludge_{soil\ 1}$ (0)**).

Parameter	Symbol	Value
Dry sludge application rate [kg/m² y]	$APPL_{sludge}$	0.5
Concentration in dry sewage sludge [mg/kg]	C_{sludge}	0.39
Mixing depth of soil [m]	$DEPTH_{soil}$	0.2
Bulk density of soil [kg/m³]	RHO_{soil}	1700
Concentration in soil due to sludge in first year at t = 0 [mg/kg]	**$Csludge_{soil\ 1}$ (0) = PEC_{soil}**	**Fsim=0.81%** **6.4E-04**

Major change application

Calculation of the concentration in soil due to sludge in first year ($Csludge_{soil\ 1}$ (0)).

Parameter	Symbol	Value
		RMM, large buildings only Fsim = 0.204%
Dry sludge application rate [kg/m² y]	$APPL_{sludge}$	0.5
Concentration in dry sewage sludge [mg/kg]	C_{sludge}	0.025
Mixing depth of soil [m]	$DEPTH_{soil}$	0.2
Bulk density of soil [kg/m³]	RHO_{soil}	1700
Concentration in soil due to sludge in first year at t = 0 [mg/kg]	**$Csludge_{soil\ 1}$ (0) = PEC_{soil}**	**7.16E-05**

These values can also be regarded as the PEC_{soil} values of alpha-cypermethrin, which represent the concentration soil organisms are exposed to just after the first year of sludge application. The fraction of the substance that remains in the topsoil layer (20 cm) at the end of a year is given by Table 18. For the calculation of the k-rate (taking biodegradation in soil into account), according to Eq. 56 & 32 of TGD, PART B, a maximum DT50 field value in soil of 112 days is considered.

$$\mathbf{k} = k_{volat} + k_{leach} + k_{bio\ soil}, \quad \text{where } k_{volat} \text{ and } k_{leach} \sim 0, \quad \text{thus } \mathbf{k = k_{bio\ soil}}$$

$k_{bio\ soil}$ = ln 2 / $DT_{50\ bio\ soil}$, where $DT_{50\ bio\ soil}$ is set to 112 days.

Table 18: Calculation of the fraction accumulation in one year (Facc)

Parameter	Symbol	Value
First order rate constant for removal from top soil [d^{-1}]	k	0.0062
Fraction accumulation in one year [-]	**Facc = $e^{-365\ k}$**	**0.104**

The resulting fraction accumulation in one year is 0.104. The results obtained in Table 17 and Table 18 are used for the calculation in Table 19 to ascertain the concentration after ten years of sludge application (immediately after the tenth application) with the following equation (Eq. 63 of TGD, Part B).

$Csludge_{soil\ 10}\ (0) = Csludge_{soil}\ (0) \times [1+\sum^{9}_{n=1} Facc^{n}]$

Table 19: Calculation of initial concentration after ten applications of sludge **($PEC_{soil\ 10}$)**

Parameter	Symbol	Value
Concentration in soil due to sludge after ten applications (mg/kg)	**$Csludge_{soil\ 10}$ (0) = $PEC_{soil\ 10}$**	**Fsim=0.81%** **7.07E-04**

Major change application

Calculation of initial concentration after ten applications of sludge ($PEC_{soil\ 10}$):

Parameter	Symbol	Value
		RMM, large buildings only **Fsim = 0.204%**
Concentration in soil due to sludge after ten applications (mg/kg)	**$Csludge_{soil\ 10}$ (0) = $PEC_{soil\ 10}$**	**7.910E-05**

The parameter $Csludge_{soil\ 10}$ (0) (= $C_{soil\ 10}$ (0)), (deposition via air can be excluded) can also be regarded as the $PEC_{soil\ 10}$ of alpha-cypermethrin which represents the concentration soil organisms are exposed to after ten applications of sludge (immediately after the tenth application). A PEC time-weight average soil ($PEC_{twa\ soil}$) was also calculated after the tenth application of sludge over 30 and 180 days (TGD, Part B Eq. 66). Results are summarized in Table 20.

D_{air} = $DEPtotal_{ann}$ / $DEPTH_{soil}$ × RHO_{soil} (TGD, Part B, Eq. 52)

$DEPtotal_{ann}$ = DEP_{total} × $T_{emission}$ / 365, where DEP_{total} is equal to 0.0005 (TGD, Part B, Eq. 47) and $T_{emission}$ is equal to 365 (appendix IIB of TGD, Part B).

Table 20: Calculation of time-weight average concentration on 30 days and 180 days after ten applications of sludge **($C_{soil\ 10}$ (180)).**

Parameter	Symbol	Value
Concentration (30 d) in soil due to sludge after ten applications (mg/kg)	**$C_{soil\ 10}$ (30)**	**Fsim=0.81%** **6.64E-04**
Concentration (180 d) in soil due to sludge after ten applications (mg/kg)	**$C_{soil\ 10}$ (180)**	**Fsim=0.81%** **5.20E-04**

Major change application

Calculation of time-weight average concentration on 30 days and 180 days after ten applications of sludge (Csoil 10 (180)):

Parameter	Symbol	Value
		RMM, large buildings only Fsim = 0.204%
Concentration (30 d) in soil due to sludge after ten applications (mg/kg)	**$C_{soil\ 10}$ (30)**	**7.187E-05**
Concentration (180 d) in soil due to sludge after ten applications (mg/kg)	**$C_{soil\ 10}$ (180)**	**4.763E-05**

- **PEC in soil porewater** (**$PECloca l_{soil,\ porewater}$**)

Soil porewater is an important factor. The concentration of alpha-cypermethrin in soil porewater ($C_{porewater}$ = $PECloca l_{soil,\ porewater}$) is outlined in Table 23, with the aid of the results of Table 21 & Table 22. Predicted environmental concentration in porewater is calculated according to Eq. 70 of the guidance document. The calculation, shown below, is very simplistic, takes no account of soil characterisation and neglects consideration of transformation plus dilution in deeper soil layers. Whilst noted as being a simplistic approach, these values represent concentrations in porewater of non-specific "agricultural soil" significantly below the current quality standard set at 0.1 µg l^{-1} by the EU Drinking Water Directive (98/83/EC).

$$PECloca l_{soil,\ porewater} = \frac{PECloca l_{soil} \times RHO_{soil}}{K_{soil\text{-}water} \times 1000}$$

$PECloca l_{soil}$ is the highest predicted environmental concentration in agricultural soil (arable soil mg kg_{wwt}^{-1}). Thus, as an input, the PEClocal $_{soil}$ after 10 consecutive sludge applications considering biodegradation over a period of 180 days after the last sludge application event is used. The bulk density of wet soil, $RHO_{soil,}$ is taken as a default value of 1700 kg m^{-3} (TGD, Part B, Table 5). $K_{soil\text{-}water}$ is the soil-water partitioning co-efficient, calculated using the Eq. 24 of TGD, Part B.

$$K_{soil\text{-}water} = Fair_{soil} \times K_{air\text{-}water} + Fwater_{soil} + Fsolid_{soil} \times Kp_{soil} / 1000 \times RHO_{solid}$$

With the default values from TGD as inputs, shown in the following tables 22 & 23), the air-water partitioning coefficient and the partition coefficient solid-water in soil were calculated. Both parameters are used to derive $K_{soil\text{-}water}$.

Table 21: Calculation of air-water partitioning coefficient (**$K_{air\text{-}water}$**)

Parameter	Symbol	Value
Henry's law constant [Pa × m³/mol]	HENRY	0.069
Gas constant [Pa × m³/mol × k]	R	8.314
Temperature at the air water interface [K]	TEMP	285
Air-water partitioning coefficient [-]	**$K_{air\text{-}water}$ = HENRY / (R × TEMP) (Eq. 22, TGD)**	**2.91×10^{-5}**

Table 22: Calculation of partition coefficient solid-water in soil (**$K_{soil-water}$**)

Parameter	Symbol	Value
Weight fraction organic carbon in soil [kg/kg]	Foc_{soil}	0.02
Partition coefficient organic carbon-water [L/kg]	Koc	76344
Partition coefficient solid-water in soil [L/kg]	**$Kp_{soil} = Foc_{soil} \times Koc$ (Eq. 23, TGD)**	**1526.9**
Fraction air in soil [m³/m³]	$Fair_{soil}$	0.2
Air-water partitioning coefficient [-]	$K_{air-water}$	2.91×10^{-5}
Fraction water in soil [m³/m³]	$Fwater_{soil}$	0.2
Fraction solids in soil [m³/m³]	$Fsolid_{soil}$	0.6
Density of the solid phase [kg/m³]	RHO_{solid}	2500
Soil-water partitioning coefficient [m³/m³]	**$K_{soil-water}$**	**2290.5**

- The resulting soil-water partitioning coefficient amounts to 2290.5 m³/m³.

Finally, the concentration of alpha-cypermethrin in soil porewater ($PEClocal_{soil,porewater}$) is calculated in Table 23, taking into account: (a) the $Csludge_{soil10}$ (180) concentration (as calculated in Table 20), (b) the soil-water partitioning coefficient of 2290.5 m³/m³ and (c) the bulk density of soil, $RHO_{soil,}$ of 1700 kg/m³ (TGD, Part B).

Table 23: Calculation of the concentration in soil porewater

Parameter	Symbol	Value
Predicted Environmental Concentration in soil [mg/kg]	$PEClocal_{soil} = Csludge_{soil10}$ (180)	3.41×10^{-4}
Soil-water partitioning coefficient [m³/m³]	$K_{soil-water}$	2290.5
Bulk density of soil [kg/m³]	RHO_{soil}	1700
Predicted Environmental Concentration in porewater [mg/L]	**PEC local $_{soil,porewater}$**	**Fsim=0.81%** **3.86E-07**

Major change application

Calculation of the concentration in soil porewater:

Parameter	Symbol	Value
		RMM, large buildings only **Fsim = 0.204%**
Predicted Environmental Concentration in soil [mg/kg]	$PEClocal_{soil}$ = $Csludge_{soil10}$ (180)	4.763E-05
Soil-water partitioning coefficient [m³/m³]	$K_{soil-water}$	2290.5
Bulk density of soil [kg/m³]	RHO_{soil}	1700
Predicted Environmental Concentration in porewater [mg/L]	**PEC local $_{soil,porewater}$**	**3.535E-08**

Summary of PEC values

A summary of all derived PEC values is outlined in Table 24.

Table 24: Summary of PEC values of alpha-cypermethrin in all exposed environmental compartments.

PEC	Value
	Fsim=0.81%
PEC_{STP} [mg/L]	**2.93E-05**
$PEC_{surface\ water}$ [mg/L]	**2.63E-06**
$PEC_{sediment}$ [mg/kg wwt]	**4.37E-03**
$PEC_{soil,\ 1}$ (0) * [mg/kg]	**6.40E-04**
$PEC_{soil,\ 10}$ (0) ** [mg/kg]	**7.07E-04**
$PEC_{soil,\ 10}$ (30) # [mg/kg]	**6.64E-04**
$PEC_{soil,\ 10}$ (180) ## [mg/kg]	**5.20E-04**
$PEC_{soil,porewater}$ [mg/L]	**3.86E-07**
PEC_{air}	**negligible**

* = immediately after the first application = Csludgesoil (0)
** = immediately after the tenth application = Csludgesoil 10 (0)
# = average concentration over 30 days after the tenth application = Csludgesoil 10 (30)
=average concentration over 180 days after the tenth application = Csludgesoil 10 (180)

Major change application

Summary of PEC values of alpha-cypermethrin in all exposed environmental compartments:

PEC	Value
	RMM, large buildings only **Fsim = 0.204%**
PEC_{STP} [mg/L]	**3.660E-06**
$PEC_{surface\ water}$ [mg/L]	**3.280E-07**

$PEC_{sediment}$ [mg/kg wwt]	**5.450E-04**
$PEC_{soil, 1}$ (0) * [mg/kg]	**7.162E-05**
$PEC_{soil, 10}$ (0) ** [mg/kg]	**7.910E-05**
$PEC_{soil, 10}$ (30) # [mg/kg]	**7.187E-05**
$PEC_{soil, 10}$ (180) ## [mg/kg]	**4.763E-05**
$PEC_{soil,porewater}$ [mg/L]	**3.535E-08**
PEC_{air}	**negligible**

* = immediately after the first application = Csludgesoil (0)
** = immediately after the tenth application = Csludgesoil 10 (0)
# = average concentration over 30 days after the tenth application = Csludgesoil 10 (30)
=average concentration over 180 days after the tenth application = Csludgesoil 10 (180)

SCENARIO 2 – Professional & non-professional use in rural hygiene (animal houses/shelters)

Fendona 6 SC is a water-based concentrate containing 60 g alpha-cypermethrin per litre, corresponding to 6.27 % (w/w) active substance. There are two possible use concentrations and hence two possible dilutions; low rate of 1:200 (0,5% v/v), as well as high rate of 1:100 (1% v/v). 1 litres of spray dilution should be applied to a surface of 20 m^2, resulting in a maximum active substance concentration of 32 mg a.i. per m^2 treated area, for the high rate application. The environmental exposure and risk assessment is carried out with this higher value, which represents the worst case.

Fendona 6 SC is intended to be used in rural hygiene applications indoors in animal houses/shelters by spraying with compressed sprayer (1-3 bars). It is used by professionals and non-professionals.

It is intended to be used in animal categories (i1=1-7, 9, 10, 13-15) according to the ESD for Insecticides for Stables and Manure Storage Systems in PT18 (2006).

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

Cat-Subcat (Nb)	**Animal subcategory and manure storage type**
1	Dairy cow
2	Beef
3	Veal Calf
4	Sow, individual pens
5	sows in groups
6	Fattening pig
7	Laying hen, battery cages without treatment
9	Laying hen, battery cages with forced drying
10	Laying hen, compact battery cages
13	Laying hen, free range with grating floor
14	parent broiler >18 weeks, free range with grating floor
15	parent broiler in rearing, free range with grating floor

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

Table 25. Input parameter for calculating the local emission – scenario 2		
Scenario: Rural hygiene; professional and non-professional use in animal houses/shelters		
Content of substance in formulation	6.27	%w/w
Amount of b.p. (concentrate) prescribed to be used for area specified for application	0.51	g/m^2
Active substance concentration per treated m^2	32	mg/m^2

The route of exposure of alpha-cypermethrin to the environment from pest control in animal housings is mainly via direct application of manure/slurry to arable land and grassland. Exposed compartments are surface water, sediment, soil and groundwater as well as biota. The waste water route for animal categories (i1=8, 11,12, 16-18) was not considered for the risk assessment, as the product must not be used in stables/animal housings connected to a sewage treatment plant.

- In the following table, the compartments which are exposed from the use of alpha-cypermethrin in rural hygiene (animal houses/shelters) by professionals and non-professionals are given:

Table 26. Identification of relevant receiving compartments based on the exposure pathway – scenario 2 *									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
Scenario 2	Yes*	Yes*	No	No	No**	n.a.	Yes*	Yes*	-

* Exposure can occur via the route usage in animal houses/shelters → application of slurry/manure to soil → runoff to surface water / leaching to groundwater.

** In some animal categories, STP are directly exposed. However, for Fendona 6 SC this route was not considered further for the risk assessment as the product must not be used in stables/animal housings connected to a sewage treatment plant.

Emission Estimation for Scenario 2

The input parameter used for the environmental exposure assessment for professional and non-professional use in rural hygiene (stables *i.e.* animal houses/shelters) is taken from the ESD for Insecticides for Stables and Manure Storage Systems in PT18 (OECD ESD No. 14) and the Technical Agreement for Biocides TAB (ENV86). Additional calculations were performed according to the Guidance on the biocidal products regulation. Volume IV Environment - Part B Risk Assessment (active substances) (BPR, ECHA, 2015b), as well as from output values given by EUSES.

Default values regarding e.g. number of animals, the fractions of a.i. released to the relevant streams, number of insecticide applications etc. were directly used in accordance with the ESD for PT18 (2006) and associated documents. There were no deviations from the defaults given in the ESD for PT 18. The treated area in the stables, which is used for calculations, is the total area of the housing (floor, walls and ceiling) plus the slatted areas and other areas, taken the worst case scenario.

Calculations were done for i1 = 1-7, 9, 10, 13-15 animal sub-categories and for i2 = 2 (Insecticide (adulticide) against other insects or arthropods (blood sucking pests). The mode of application was spraying (i3 = 1) and the exposure streams considered were i4 = 1 (manure) and i4= 3 (slurry).

Predicted environmental concentrations (PECs) were estimated for the terrestrial compartment, including groundwater and for the aquatic compartment (incl. sediment) due to run-off from soil. The estimation of PECs is based on the emissions from animal housings due to slurry/manure applications on arable land and grassland. This assessment was carried out according to maximum nitrogen or phosphate immission limits (Europe).

According to the Technical Agreement for Biocides TAB (ENV 86), it was decided to use the nitrogen immission standards from the EC Nitrates Directive (91/676/EC) of 170 kg N ha^{-1} yr^{-1} for all soils (arable land and grassland).

The calculations of the releases of alpha-cypermethrin during slurry/manure applications are accomplished for all animal categories and sub-categories according to PT 18, ESD No. 14. For soil, the calculation of initial environmental concentrations **(PIECs)** assumes application of slurry/manure onto arable and grassland soils without taking biodegradation of alpha-cypermethrin into account in the first instance. The predicted soil concentration, after 10 years of consecutive manure/slurry applications, $PIEC_{10\_degr}$, is used as the PECsoil in risk assessment, considering the worst case scenario (according to the WG(V) November, 2015 for risk assessment, after the calculation corrections for PIECsoil_grassland after 10 years, agreed at the WG-I-2018, January 2018).

In accordance with the guidance presented in the TGD, Part B, for the groundwater risk assessment , the concentration in porewater is used for the initial groundwater assessment. The PEC in porewater **($PEC_{ground\ water}$)** was calculated considering degaradation processes in soil after 10 concecutive years of manure application, i.e., $PIEC_{10degr}$ was used as an input for soil concentration (in line with the WG(V) November, 2015 for risk assessment) using TGD equations for equilibrium partitioning.

$PEC_{surface\ water}$ and **$PEC_{sediment}$** were calculated for the route of exposure of alpha-cypermethrin via slurry/manure to soil and subsequent run-off to surface water (incl. sediment). $PEC_{surface\ water}$ was derived by diluting the $PEC_{groundwater}$ by a factor of 10 (OECD ESD No. 14). $PEC_{sediment}$ was calculated according to equation (50) of the Guidance on BPR IV/B (2015) using default parameter as given in Table 5 of the guidance document together with the Koc of 76344 L/kg to calculate a bulk density of suspended matter (RHO_{susp}) of 1150 kg/m^3 and a suspended matter-water partitioning coefficient ($K_{susp\text{-}water}$) of 1910 m^3/m^3.

- **Definitions of all input parameters, intermediate output values and the corresponding equations are given below for the animal categories (1-7, 9, 10, 13-15) and biocide type, i2=2, bloodsucking pests.**

Input	Symbol	Value	Unit
Default area of the housing for application (total area)	$AREA_{i1}$	var.	[m²]
Content of a.i. in formulation	Fbioc	6.27	%
Area to be treated with amount prescribed for application	$AREAui_{i1}$	1	[m²]
Amount of diluted product prescribed to be used for area specified for application	$Qprod\text{-}uins_{i1,i2,i3}$	0.51	[g]
Fraction of active ingredient released to the relevant stream	$F_{i1,i2,i3,i4}$	var.	[-]
Insecticide application interval	Tbioc-int	var.	[d]
Maximum number of insecticide applications	Napp-bioc	var.	[-]
Number of land applications for arable land	Napp-arab	1	[-]
Number of land applications for grassland	Napp-grass	4	[-]
Manure storage time arable land in new scenario	$Tmanure\text{-}int_{ar2}$	212	[d]
Land application interval for grassland	Tgr-int	53	[d]
Number of animals in housing for every relevant category i1	N_{i1}	var.	[-]
Amount of phosphate per animal for every relevant category i1	$Qphosph_{i1}$	var.	[kg/d]
Amount of nitrogen per animal for every relevant category i1	$Qnitrog_{i1}$	var.	[kg/d]
Phosphate immission standard for one year on grassland	$Q_{P2O5,grassland}$	110	[kg/ha]
Phosphate immission standard for one year on arable land	$Q_{P2O5,arable\_land}$	85	[kg/ha]
Nitrogen immission standard for one year on grassland	$Q_{N,grassland}$	170	[kg/ha]

Input	Symbol	Value	Unit
Nitrogen immission standard for one year on arable land	$Q_{N,arable\_land}$	170	[kg/ha]
Mixing depth with soil for grassland	$DEPTH_{grassland}$	0.05	[m]
Mixing depth with soil for arable land	$DEPTH_{arable\_land}$	0.20	[m]
Density of wet bulk soil	$RHOsoil_{wet}$	1700	[kg/m^3]
Half-life for biodegradation in bulk soil	$DT50bio_{soil}$	112	[d]
Number of land applications for arable land in 10 years	$Napp_{arab,10}$	10	[-]
Land application interval for arable land	Tar_2-int	365	[d]
Interval between last (of four) manure application and the first application of a new series	$Tgr\text{-}int_{no\_manure}$	365 (WGI2018_ENV_7-7)	[d]
Fraction air in soil	Fair	0.2	[-]
Fraction water in soil	$Fwater_{soil}$	0.2	[-]
Fraction solid in soil	$Fsolid_{soil}$	0.6	[-]
Bulk density of solids	RHOsolid	2500	[kg/m^3]
Gas constant	R	8.314	[Pa*m^3/(mol*K)]
Temperature at the air-water interface	Temp_air-wat	285	[K]
Dilution factor for run-off water into surface water	$Dilution_{run\text{-}off}$	10	-
Bulk density of suspended matter	RHOsusp	1150	[kg/m^3]
Fraction water in suspended matter	$Fwater_{susp}$	0.9	[-]
Fraction solid in suspended matter	$Fsolid_{susp}$	0.1	[-]

Intermediate output	Symbol	Value	Unit
Amount of a.s. to be used in housing storage for one application	Qai-prescr$_{i1,i2,i3}$	var.	[kg]
Amount of a.s. in relevant stream i4 after one application	Qai$_{i1,i2,i3,i4}$	var.	[kg]
Number of biocide applications during manure storage period for application on grassland	Napp-manure$_{gr}$	var.	[-]
Number of biocide applications during manure storage period for application on arable land	Napp-bio$_{manure_ar2}$	var.	[-]
Amount of a.i. in manure/slurry after the relevant number of biocide applications for the manure application to grassland	Qai-grass$_{i1,i2,i3,i4}$	var.	[kg]
Amount of a.i. in manure/slurry after the relevant number of biocide applications for the manure application to arable land	Qai-arab$_{i1,i2,i3,i4}$	var.	[kg]
Amount of P_2O_5 produced during the relevant period for every relevant (sub)category of animal/housing i1 for grassland	Qphosph-grass$_{i1,4}$	var.	[kg/yr]
Amount of P_2O_5 produced during the relevant period for every relevant (sub)category of animal/housing i1 for arable land	Qphosph-arab $_{i1,i4}$	var.	[kg/yr]
Amount of N produced during the relevant period for every relevant (sub)category of animal/housing i1 for grassland	Qnitrog-grass$_{i1,4}$	var.	[kg/yr]
Amount of N produced during the relevant period for every relevant (sub)category of animal/housing i1 for arable land	Qnitrog-arab $_{i1,i4}$	var.	[kg/yr]

Amount of active ingredient to be used in housing or manure for one application:

$$Qai-prescr_{i1,i2,i3} = 10^{-5} * Qprod-uins_{i1,i2,i3} * Fbioc * AREA_{i1}/AREAui_{i1}$$ Eq. 1

Amount of active ingredient in relevant stream after one application:

$$Q_{ai,i1i2i3,4,5} = F_{i1i2i3,4,5} * Q_{ai-prod,i1i2}$$ Eq. 2

Number of biocide applications during the manure storage period:

- **For arable land:**

If Tbioc-int ≥ $Tmanure\text{-}int_{ar2}$, then

$$Napp\text{-}bio_{manure\_ar2} = 1$$ Eq. 3

If Tbioc-int < $Tmanure\text{-}int_{ar2}$, then

$$Napp\text{-}bio_{manure\_ar2} = ROUND[n](Tmanure\text{-}int_{ar2} / Tbioc\text{-}int) \quad n=1$$ Eq. 4

$ROUND[n]$ with n=1 is the sign for rounding off to a whole number with 1 decimal

If $Napp\text{-}bio_{manure\_ar2}$ > Napp-bioc

$$Napp\text{-}bio_{manure\_ar2} = Napp\text{-}bioc$$ Eq. 5

- **For grassland:**

If Tbioc-int ≥ Tgr-int, then

$$Napp\text{-}manure_{gr} = 1$$ Eq. 6

If Tbioc-int < Tgr-int, then

$$Napp\text{-}manure_{gr} = ROUND[n](Tgr\text{-}int / Tbioc\text{-}int) \quad n=1$$ Eq. 7

$ROUND[n]$ with n=1 is the sign for rounding off to a whole number with 1 decimal

If $Napp\text{-}manure_{gr}$ > Napp-bioc

$$Napp\text{-}manure_{gr} = Napp\text{-}bioc$$ Eq. 8

Amount of active ingredient which goes to manure or slurry for grassland:

$$Q_{ai-gr,i1i2i3,4,5} = Q_{ai,i1i2i3,4,5} * Napp\text{-}manure_{gr}$$ Eq. 9

Amount of active ingredient which goes to manure or slurry for arable land:

$$Q_{ai-ar,i1i2i3,4,5} = Q_{ai,i1i2i3,4,5} * Napp\text{-}bio_{manure\_ar2}$$ Eq. 10

Amount of phosphate and nitrogen in manure produced during the relevant period:

$$Q_{\text{phosphate, produced}} = \sum_{i} N_{a,i} \cdot Q_{\text{phosphate, excreted}} \cdot T_{\text{phosphate}} \quad \text{Eq. 11}$$

$$Q_{\text{phosphate, applied}} = \sum_{i} N_{a,i} \cdot Q_{\text{phosphate, excreted}} \cdot b_{i} \cdot T_{\text{phosphate}} \quad \text{Eq. 12}$$

$$Q_{\text{nitrogen, produced}} = \sum_{i} N_{a,i} \cdot Q_{\text{nitrogen, excreted}} \cdot T_{\text{nitrogen}} \quad \text{Eq. 13}$$

$$Q_{\text{nitrogen, applied}} = \sum_{i} N_{a,i} \cdot Q_{\text{nitrogen, excreted}} \cdot b_{i} \cdot T_{\text{nitrogen}} \quad \text{Eq. 14}$$

Input parameters and intermediate output for calculating the local emission to soil (relevant for all biocide types)									
	Animal category (i1)								
Parameter	**1**	**2**	**3**	**4**	5	**6**	**7**	**9**	
N_{i1} [-]	100	125	80	132	132	400	21000	21000	
$Qphosph_{i1}$ [kg/d]	0.0405	0.0286	0.0142	0.0557	0.0557	0.0203	0.0012	0.0011	
$Qnitrog_{i1}$ [kg/d]	0.1432	0.1286	0.0238	0.0711	0.0711	0.0304	0.0020	0.0018	
$AREA_{i1}$ [m^2]	3230	1750	650	1930	2200	2020	3210	3210	
$Qai\text{-}prescr_{i1,i2,i3}$ [kg]	0.097	0.052	0.019	0.058	0.066	0.061	0.096	0.096	
$Qnitrog\text{-}grass_{i1,4}$ [kg/yr]	758.7	852.2	101	497	497	645	2248	2015	
$Qnitrog\text{-}arab_{i1,i4}$ [kg/yr]	5225.3	5868.7	695	3424	3424	4443	1583	13874	
$Qphosph\text{-}grass_{i1,4}$ [kg/yr]	214.8	189.7	60	389	389	431	1358	1235	
$Qphosph\text{-}arab_{i1,i4}$ [kg/yr]	1479.3	1306.2	415.2	2681.7	2682	2682	2968	8508	
Parameter	**10**	**13**	**14**	**15**					
N_{i1} [-]	21000	20000	7000	9000					
$Qphosph_{i1}$ [kg/d]	0.0011	0.0011	0.0019	0.0008					
$Qnitrog_{i1}$ [kg/d]	0.0018	0.0017	0.003	0.0014					
$AREA_{i1}$ [m^2]	3210	3392	1290	1640					
$Qai\text{-}prescr_{i1,i2,i3}$ [kg]	0.096	0.102	0.039	0.049					
$Qnitrog\text{-}grass_{i1,4}$ [kg/yr]	2015	1813	1106	653					
$Qnitrog\text{-}arab_{i1,i4}$ [kg/yr]	13874	12483	7614	4500					
$Qphosph\text{-}grass_{i1,4}$ [kg/yr]	1235	1177	697	367					
$Qphosph\text{-}arab_{i1,i4}$ [kg/yr]	8508	4051	4818	8103	4803	2529	8395	5986	8395

- **Input parameters and intermediate output for calculating the local emission to soil (relevant for biocide type <u>i2=2; bloodsucking pests</u>)**

	Animal category (i1)								
Parameter	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**9**	
$F_{i1,i2,i3}$ (i4=manure/slurry) [-]	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	
Tbioc-int [-]	28	28	28	28	28	28	91	91	
Napp-bioc [-]	6	6	6	6	6	6	4	4	
$Qai_{i1,i2,i3,i4}$ [kg]	0.05	0.03	0.01	0.03	0.03	0.03	0.05	0.05	
$Napp\text{-}manure_{gr}$ [-]	1.9	1.9	1.9	1.9	1.9	1.9	1.0	1.0	
$Napp\text{-}bio_{manure\_ar2}$ [-]	6.0	6.0	6.0	6.0	6.0	6.0	2.3	2.3	
$Qai\text{-}grass_{i1,i2,i3,i4}$ [kg]	0.0921	0.0499	0.0185	0.0550	0.0627	0.0576	0.0482	0.0482	
$Qai\text{-}arab_{i1,i2,i3,i4}$ [kg]	0.2907	0.1575	0.0585	0.1737	0.1980	0.1818	0.1107	0.1107	
Parameter	**10**	**13**	**14**	**15**					
$F_{i1,i2,i3}$ (i4=manure/slurry) [-]	0.5	0.5	0.5	0.5					
Tbioc-int [-]	91	91	91	91					
Napp-bioc [-]	4	4	4	4					
$Qai_{i1,i2,i3,i4}$ [kg]	0.05	0.05	0.02	0.02					
$Napp\text{-}manure_{gr}$ [-]	1.0	1.0	1.0	1.0					
$Napp\text{-}bio_{manure\_ar2}$ [-]	2.3	2.3	2.3	2.3					

$Qai\text{-}grass_{i1,i2,i3,i4}$ [kg]	0.0482	0.0509	0.0194	0.0246					
$Qai\text{-}arab_{i1,i2,i3,i4}$ [kg]	0.1107	0.1170	0.0445	0.0566					

PEC calculations for Scenario 2:

The definitions of all relevant PEC values and the corresponding equations are presented below.

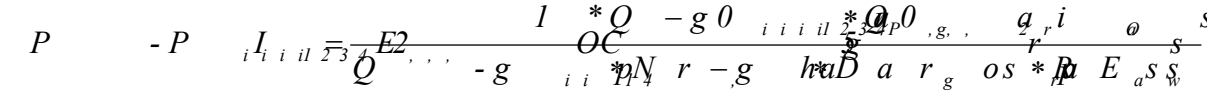
Initial concentration of the biocide (a.s.) in soil in the case of an immission standard for phosphate and land application on grassland – after one application and no degradation	PIECgrs-$P_2O_{5i1,i2,i3,i4}$	var.	[mg/kg_{ww}]
Initial concentration of the biocide (a.s.) in soil in the case of an immission standard for phosphate and land application on arable land	PIECarab-$P_2O_{5i1,i2,i3,i4}$	var.	[mg/kg_{ww}]
Initial concentration of the biocide (a.s.) in soil in the case of an immission standard for nitrogen and land application on grassland – after one application and no degradation	PIECgrs-$N_{i1,i2,i3,i4}$	var.	[mg/kg_{ww}]
Initial concentration of the biocide (a.s.) in soil in the case of an immission standard for nitrogen and land application on arable land	PIECarab-$N_{i1,i2,i3,i4}$	var.	[mg/kg_{ww}]
First order rate constant for degradation in bulk soil	$kdeg_{soil}$	6.2E-03	[1/d]
Fraction of active remaining in grassland soil after the last manure spreading event	$Fsoil_{grs}$	2.61	[-]
Initial concentration of the biocide (a.s.) in soil in the case of an immission standard for phosphate and land application on grassland – after the last of four manure application and degradation assumed	PIECgrs4_degr-$P_2O_{5i1,i2,i3,i4}$	var.	[mg/kg_{ww}]
Initial concentration of the biocide (a.s.) in soil in the case of an immission standard for nitrogen and land application on grassland – after the last of four manure	PIECgrs4_degr-$N_{i1,i2,i3,i4}$	var.	[mg/kg_{ww}]

application and degradation assumed			
Fraction of active remaining in arable soil after 10 year of manure application	$Fsoil_{arab\_10}$	1.12	[-]
Fraction of active remaining in grassland soil, 365 d after the first (of four) manure spreading events	$Fsoil_{grs2}$	0.28	[-]
Soil-water equilibrium partition coefficient	Ksoil-water	2290.5	[m^3/m^3]
Air-water partitioning coefficient	Kair-water	2.91E-05	[m^3/m^3]
Suspended-water equilibrium partition coefficient	Ksusp-water	1910	[m^3/m^3]
Initial concentration in grassland soil (after the last of four manure applications per year), after 10 years of manure application, taking degradation into account; based on phosphate immission standard	$PIECgrs_{10\_degr}$-$P_2O_{5i1,i2,i3,i4}$	var.	[mg/kg_{ww}]
Initial concentration in soil of arable land after 10 years of manure application, taking degradation into account; based on phosphate immission standard	$PIECarab_{10\_degr}$-$P_2O_{5i1,i2,i3,i4}$	var.	[mg/kg_{ww}]

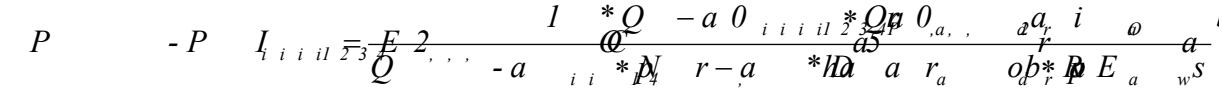
Initial concentration in grassland soil (after the last of four manure applications per year), after 10 years of manure application, taking degradation into account; based on nitrogen immission standard	$PIECgrs_{10\_degr}$-$N_{i1,i2,i3,i4}$	var.	[mg/kg_{ww}]
Initial concentration in soil of arable land after 10 years of manure application, taking degradation into account; based on nitrogen immission standard	$PIECarab_{10\_degr}$-$N_{i1,i2,i3,i4}$	var.	[mg/kg_{ww}]
Porewater/groundwater concentrations; grassland, based on phosphate immission standard	PIECgrs-gw-$P_2O_{5i1,i2,i3,i4}$	var.	[mg/L]

Porewater/groundwater concentrations; arable land, based on phosphate immission standard	PIECarab-gw-$P_2O_{5i1,i2,i3,i4}$	var.	[mg/L]
Porewater/groundwater concentrations; grassland, based on nitrogen immission standard	PIECgrs-gw-$N_{i1,i2,i3,i4}$	var.	[mg/L]
Porewater/groundwater concentrations; arable land, based on nitrogen immission standard	PIECarab-gw-$N_{i1,i2,i3,i4}$	var.	[mg/L]
Surface water concentrations; grassland, based on phosphate immission standard	PIECgrs-sw-$P_2O_{5i1,i2,i3,i4}$	var.	[mg/L]
Surface water concentrations; arable land, based on phosphate immission standard	PIECarab-sw-$P_2O_{5i1,i2,i3,i4}$	var.	[mg/L]
Surface water concentrations; grassland, based on nitrogen immission standard	PIECgrs-sw-$N_{i1,i2,i3,i4}$	var.	[mg/L]
Surface water concentrations; arable land, based on nitrogen immission standard	PIECarab-sw-$N_{i1,i2,i3,i4}$	var.	[mg/L]
Sediment concentrations; grassland, based on phosphate immission standard	PIECgrs-sed-$P_2O_{5i1,i2,i3,i4}$	var.	[mg/kg_{ww}]
Sediment concentrations; arable land, based on phosphate immission standard	PIECarab-sed-$P_2O_{5i1,i2,i3,i4}$	var.	[mg/kg_{ww}]
Sediment concentrations; grassland, based on nitrogen immission standard	PIECgrs-sed-$N_{i1,i2,i3,i4}$	var.	[mg/kg_{ww}]
Sediment concentrations; arable land, based on nitrogen immission standard	PIECarab-sed-$N_{i1,i2,i3,i4}$	var.	[mg/kg_{ww}]

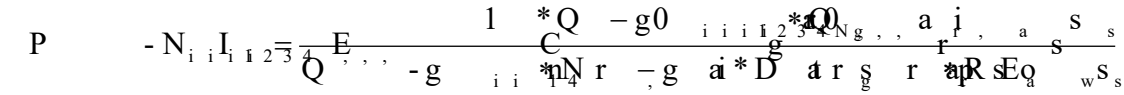
- **Concentration of the active ingredient in soil based on phosphorous or nitrogen immission standards for both grassland and arable land (one manure application):**



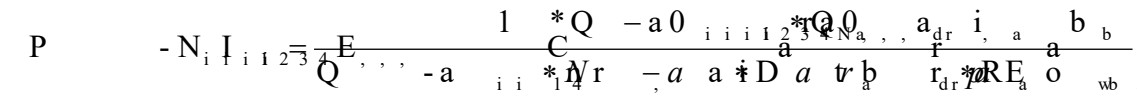
Eq. 15



Eq. 16

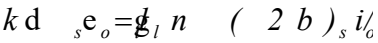


Eq. 17



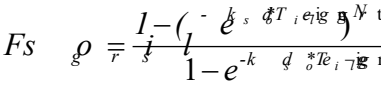
Eq. 18

Rate constant for biodegradation in soil:



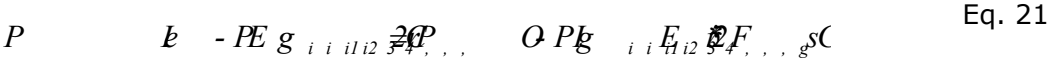
Eq. 19

Fraction of active remaining in grassland soil after the last (of four) manure spreading event:



Eq. 20

- **Concentration of the active ingredient in soil based on phosphorous or nitrogen immission standards for both grassland after the last (of four) manure application event, taking degradation into account.**



Eq. 21

Eq. 22

Fraction of active remaining in arable soil after 10 year of manure application:

$$Fs_{arable\_10} = \frac{1-(e^{-k_{soil}*T_{interval}})^{N_{applications}}}{1-e^{-k_{soil}*T_{interval}}}$$ Eq. 23

Fraction of active remaining in grassland soil, 365 d after the first (of four) manure spreading events:

$$Fs_{grassland\_365} = e^{-k_{soil}*T_{interval}*(N_{applications}-1)}$$ Eq. 24

Calculation of the air-water partitioning coefficient:

$$K_{air-water} = HLC/(R*T)$$ Eq. 25

Calculation of the soil-water partitioning coefficient:

$$K_{soil-water} = Fs_{soil}*K_{organic-water} + Fs_{air}*K_{air-water} + Fs_{water}*K_{water-water}$$ Eq.26

Calculation of the suspended matter-water partitioning coefficient:

$$K_{susp.matter-water} = Fs_{susp.matter}*K_{organic-water} + Fs_{water}*K_{water-water}$$ Eq. 27

- **Concentration of the active ingredient in soil based on phosphorous or nitrogen immission standards for both grassland and arable land, after the last of four manure applications per year, after 10 consecutive years, taking degradation into account (equation corrected in the case of grassland, as agreed at the WG-I-2018, Janurary)**

$$PIEC_{grs10\_degr\text{-}P2O5_{i1,i2,13,14}} = PIEC_{grs4\_degr\text{-}P2O5_{i1,i2,i3,i4}} * (1-Fsoil_{grs}^{10})/(1-Fsoil_{grs})$$ Eq.28

$$PIEC_{arable10\_degr\text{-}P2O5_{i1,i2,13,14}} = PIEC_{arable4\_degr\text{-}P2O5_{i1,i2,i3,i4}} * (1-Fsoil_{arable}^{10})/(1-Fsoil_{arable})$$ Eq.29

$$PIEC_{grs10\_degr\text{-}N_{i1,i2,13,14}} = PIEC_{grs4\_degr\text{-}N_{i1,i2,i3,i4}} * (1-Fsoil_{grs}^{10})/(1-Fsoil_{grs})$$ Eq.30

$$PIEC_{arable10\_degr\text{-}N_{i1,i2,13,14}} = PIEC_{arable4\_degr\text{-}N_{i1,i2,i3,i4}} * (1-Fsoil_{arable}^{10})/(1-Fsoil_{arable})$$ Eq. 31

- **Concentrations in porewater/groundwater, derived from the concentrations in soil, after one manure application for arable and four manure application events for grassland, not taken degradation into account (applicable to both immission standards)**

$$P \quad -Ig \quad E\,w \quad \frac{P \quad C \quad I \quad *R \quad CH_w}{K_{s \quad -ow \quad i \quad d} *1 \quad t \quad e \quad 0_r} \qquad \text{Eq. 32}$$

- **Concentrations in surface water (applicable to both immission standards as well as grassland and arable land):**

$$P \quad -sI \quad =MP \quad -Gg \quad E\,w \quad CN/_{r \quad -d}D \qquad \text{Eq. 33}$$

- **Concentrations in sediment (applicable to both immission standards as well as grassland and arable land):**

$$P \quad -s \quad I=Re \quad E \quad -sd*11 \; GwE(\; 0 \quad KwC0 \quad s\,d0 \;) \qquad \text{Eq. 34}$$

- ✓ ***For biocide type i2=2; bloodsucking pests***
- ➢ **Initial concentration of alpha cypermethrin in soil, degradation NOT taken into account**

PEC in soil for arable land, 1 manure application/yr (i2=2 : bloodsucking pests)									
[mg/kg$_{ww}$]	Animal Category (i1)								
	1	2	3	4	5	6	7	9	
PIECarab-N$_{i1,i2,i3,i4}$	2.96E-03	1.43E-03	4.4825E-03	2.70E-03	3.08E-03	2.18E-03	3.8119E-04	4.25E-04	
PIECarab-P$_2$O$_{5i1,i2,i3,i4}$	5.24E-03	3.21E-03	3.7543E-03	1.72E-03	1.97E-03	1.63E-03	3.16E-04	3.47E-04	
	10	13	14	15					
PIECarab-N$_{i1,i2,i3,i4}$	4.25E-04	4.99E-04	3.11E-04	6.70E-04					
PIECarab-P$_2$O$_{5i1,i2,i3,i4}$	3.47E-04	3.85E-04	2.47E-04	5.96E-04					

PEC in soil for grassland after 1 manure application event, (i2=2 : bloodsucking pests)									
	1	2	3	4	5	6	7	9	
PIECgrs$_4$-N$_{i1,i2,i3,i4}$	2.59E-02	1.25E-02	3.91E-02	2.36E-02	2.69E-02	1.90E-02	4.57E-03	5.10E-03	
PIECgrs$_4$-P$_2$O$_{5i1,i2,i3,i4}$	5.91E-02	3.63E-02	4.24E-02	1.95E-02	2.22E-02	1.84E-02	4.89E-03	5.38E-03	
	10	13	14	15					
PIECgrs$_4$-N$_{i1,i2,i3,i4}$	5.10E-03	5.98E-03	3.73E-03	8.02E-03					

PIECgrs$_4$-P$_2$O$_{5i1,i2,i3,i4}$	5.38E-03	5.96E-03	3.83E-03	9.24E-03					

- **Considering degradation processes of alpha cypermethrin in soil, after 1-year application, taking degradation into account.**

PEC in soil for arable land after 1 manure application event, taking degradation into account (i2=2 : bloodsucking pests)									
[mg/kg$_{ww}$]	**Animal Category (i1)**								
	1	**2**	**3**	**4**	**5**	**6**	**7**	**9**	
PECarab$_{1_degr}$-N$_{i1,i2,i3,i4}$	2.96E-03	1.43E-03	4.48E-03	2.70E-03	3.08E-03	2.18E-03	3.81E-04	4.25E-04	
PECarab$_{1_degr}$-P$_2$O$_{5i1,i2,i3,i4}$	5.24E-03	3.21E-03	3.75E-03	1.73E-03	1.96E-03	1.63E-03	3.15E-04	3.47E-04	
	10	**13**	**14**	**15**					
PECarab$_{1_degr}$-N$_{i1,i2,i3,i4}$	4.25E-04	4.99E-04	3.11E-04	6.70E-04					
PECarab$_{1_degr}$-P$_2$O$_{5i1,i2,i3,i4}$	3.47E-04	3.85E-04	2.47E-04	5.96E-04					
PEC in soil for grassland after 1 manure application event, taking degradation into account (i2=2 : bloodsucking pests)									
	1	**2**	**3**	**4**	**5**	**6**	**7**	**9**	
PECgrs$_{4_degr}$-N$_{i1,i2,i3,i4}$	1.69E-02	8.15E-03	2.55E-02	1.54E-02	1.76E-02	1.24E-02	2.98E-03	3.33E-03	
PECgrs$_{4_degr}$-P$_2$O$_{5i1,i2,i3,i4}$	3.86E-02	2.37E-02	2.77E-02	1.27E-02	1.45E-02	1.20E-02	3.20E-03	3.51E-03	
	10	**13**	**14**	**15**					

PECgrs$_{4_degr}$-N$_{i1,i2,i3,i4}$	3.33E-03	3.91E-03	2.44E-03	5.24E-03					
PECgrs$_{4_degr}$-P$_2$O$_{5i1,i2,i3,i4}$	3.51E-03	3.90E-03	2.50E-03	6.04E-03					

- **Considering degradation processes of alpha cypermethrin in soil, after 10 consecutive years application**

PEC in soil for <u>arable</u> land, 1 manure application/yr. after 10 consecutive years, taking degradation into account (i2=2 : bloodsucking pests)									
[mg/kg$_{ww}$]	**Animal Category (i1)**								
	1	**2**	**3**	**4**	**5**	**6**	**7**	**9**	
PECarab$_{10_degr}$-N$_{i1,i2,i3,i4}$	3.31E-03	1.59E-03	5.00E-03	3.01E-03	3.44E-03	2.43E-03	4.25E-04	4.75E-04	
PECarab$_{10_degr}$-P$_2$O$_{5i1,i2,i3,i4}$	5.84E-03	3.59E-03	4.19E-03	1.92E-03	2.18E-03	1.82E-03	3.52E-04	3.87E-04	
	10	**13**	**14**	**15**					
PECarab$_{10_degr}$-N$_{i1,i2,i3,i4}$	4.75E-04	5.58E-04	3.48E-04	7.48E-04					
PECarab$_{10_degr}$-P$_2$O$_{5i1,i2,i3,i4}$	3.87E-04	4.30E-04	2.76E-04	6.65E-04					
PEC in soil for <u>grassland</u>, 1 manure application/yr. after 10 consecutive years, taking degradation into account (i2=2 : bloodsucking pests)									
	1	**2**	**3**	**4**	**5**	**6**	**7**	**9**	
PECgrs$_{10_degr}$-Ni1,i2,i3,i4	1.89E-02	9.10E-03	2.85E-02	1.72E-02	1.96E-02	1.39E-02	3.33E-03	3.72E-03	
PECgrs$_{10_degr}$-P2O5i1,i2,i3,i4	4.31E-02	2.65E-02	3.09E-02	1.42E-02	1.62E-02	1.34E-02	3.57E-03	3.92E-03	

	10	13	14	15					
PECgrs$_{10_degr}$-Ni1,i2,i3,i4	3.72E-03	4.37E-03	2.72E-03	5.85E-03					
PECgrs$_{10_degr}$-P2O5i1,i2,i3,i4	3.92E-03	4.35E-03	2.79E-03	6.74E-03					

- **Predicted Environmental Concentrations of alpha cypermethrin in <u>groundwater</u> (using PECsoil, after 10 coscecutive years manure application, PEC$_{10_degr}$, WG V, 2015, November & WG-I-2018, January)**

PEC in groundwater for <u>arable</u> and <u>grassland</u> (i2=2 : bloodsucking pests)									
[mg/L]	**Animal Category (i1)**								
	1	**2**	**3**	**4**	**5**	**6**	**7**	**9**	
PECgrs$_{10_degr}$-gw-N$_{i1,i2,i3,i4}$	1.40E-05	6.76E-06	2.12E-05	1.28E-05	1.46E-05	1.03E-05	2.47E-06	2.76E-06	
PECgrs$_{10_degr}$-gw- P$_2$O$_{5i1,i2,i3,i4}$	3.20E-05	1.96E-05	2.29E-05	1.06E-05	1.2E-05	9.98E-06	2.65E-06	2.91E-06	
PECars$_{10_degr}$-gw-N$_{i1,i2,i3,i4}$	2.46E-06	1.19E-06	3.71E-06	2.24E-06	2.55E-06	1.81E-06	3.16E-07	3.53E-07	
PECars$_{10_degr}$-gw- P$_2$O$_{5i1,i2,i3,i4}$	4.34E-06	2.66E-06	3.11E-06	1.43E-06	1.63E-06	1.35E-06	2.62E-07	2.87E-07	
	10	**13**	**14**	**15**					
PECgrs$_{10_degr}$-gw-N$_{i1,i2,i3,i4}$	2.76E-06	3.24E-06	2.02E-06	4.35E-06					

$PECgrs_{10\_degr}$-gw- $P_2O_{5i1,i2,i3,i4}$	2.91E-06	3.23E-06	2.07E-06	5E-06					
$PECars_{10\_degr}$-gw-$N_{i1,i2,i3,i4}$	3.53E-07	4.14E-07	2.58E-07	5.55E-07					
$PECars_{10\_degr}$-gw-$P_2O_{5i1,i2,i3,i4}$	2.87E-07	3.19E-07	2.05E-07	4.94E-07					

- **These values represent concentrations in porewater significantly below the current quality standard set at 0.1 µg l^{-1} by the EU Drinking Water Directive (98/83/EC).**

- **Predicted Environmental Concentrations of alpha cypermethrin in <u>surface water</u> (PECsoil, after 10 coscecutive years manure application, PEC_{10_degr} as an input)**

PEC in surface water for <u>arable</u> and <u>grassland</u> (i2=2 : bloodsucking pests)									
[mg/L]	**Animal Category (i1)**								
	1	**2**	**3**	**4**	**5**	**6**	**7**	**9**	
$PECgrs\text{-}sw\text{-}N_{i1,i2,i3,i4}$	1.4E-06	6.76E-07	2.12E-06	1.28E-06	1.46E-06	1.03E-06	2.47E-07	2.76E-07	
$PECgrs\text{-}sw\text{-}P_2O_{5i1,i2,i3,i4}$	3.2E-06	1.96E-06	2.29E-06	1.06E-06	1.2E-06	9.98E-07	2.65E-07	2.91E-07	
$PECars\text{-}sw\text{-}N_{i1,i2,i3,i4}$	2.46E-07	1.19E-07	3.71E-07	2.24E-07	2.55E-07	1.81E-07	3.16E-08	3.53E-08	
$PECars\text{-}sw\text{-}P_2O_{5i1,i2,i3,i4}$	4.34E-07	2.66E-07	3.11E-07	1.43E-07	1.63E-07	1.35E-07	2.62E-08	2.87E-08	
	10	**13**	**14**	**15**					
$PECgrs\text{-}sw\text{-}N_{i1,i2,i3,i4}$	2.76E-07	3.24E-07	2.02E-07	4.35E-07					
$PECgrs\text{-}sw\text{-}P_2O_{5i1,i2,i3,i4}$	2.91E-07	3.23E-07	2.07E-07	5E-07					
$PECars\text{-}sw\text{-}N_{i1,i2,i3,i4}$	3.53E-08	4.14E-08	2.58E-08	5.55E-08					
$PECars\text{-}sw\text{-}P_2O_{5i1,i2,i3,i4}$	2.87E-08	3.19E-08	2.05E-08	4.94E-08					

- **Predicted Environmental Concentrations of alpha cypermethrin in <u>sediment</u> (PECsoil, after 10 coscecutive years manure application, PEC_{10_degr} as an input)**

PEC in sediment for <u>arable</u> and <u>grassland</u> (i2=2 : bloodsucking pests)									
[mg/kg$_{ww}$]	**Animal Category (i1)**								
	1	**2**	**3**	**4**	**5**	**6**	**7**	**9**	
PECgrs-sed-N$_{i1,i2,i3,i4}$	2.33E-03	1.12E-03	3.52E-03	2.12E-03	2.42E-03	1.71E-03	4.11E-04	4.58E-04	
PECgrs-sed-P$_2$O$_{5i1,i2,i3,i4}$	5.32E-03	3.26E-03	3.81E-03	1.75E-03	2.00E-03	1.66E-03	4.40E-04	4.83E-04	
PECars-sed-N$_{i1,i2,i3,i4}$	4.08E-04	1.97E-04	6.17E-04	3.72E-04	4.24E-04	3.00E-04	5.25E-05	5.86E-05	
PECars-sed-P$_2$O$_{5i1,i2,i3,i4}$	7.21E-04	4.42E-04	5.17E-04	2.38E-04	2.71E-04	2.25E-04	4.34E-05	4.77E-05	
	10	**13**	**14**	**15**					
PECgrs-sed-N$_{i1,i2,i3,i4}$	4.58E-04	5.38E-04	3.36E-04	7.22E-04					
PECgrs-sed-P$_2$O$_{5i1,i2,i3,i4}$	4.83E-04	5.36E-04	3.44E-04	8.31E-04					
PECars-sed-N$_{i1,i2,i3,i4}$	5.86E-05	6.88E-05	4.29E-05	9.22E-05					
PECars-sed-P$_2$O$_{5i1,i2,i3,i4}$	4.77E-05	5.30E-05	3.40E-05	8.21E-05					

Primary and secondary poisoning

Primary poisoning

Primary poisoning is not relevant for the foreseen use of Fendona 6 SC.

Secondary poisoning for Scenario 1

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

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

Where:

Variable/parameter (unit)	Symbol	Unit	Value	Source
Predicted Environmental Concentration in fish-eating predators	$PEC_{oral,\ fish\text{-}eating\ predator}$	[$mg.kg_{wet\ fish}^{-1}$]	2.39E-03	Output
Predicted Environmental Concentration in water	PEC_{water}	[$mg.L^{-1}$]	[1]	Input
Bioconcentration Factor for fish on wet weight basis	BCF_{fish}	[$L.kg_{wet\ fish}^{-1}$]	910[2]	Input
Biomagnification factor in fish	*BMF*	[-]	1[3]	Default

[1] PEC_{water} 2.63E-06 $mg.L^{-1}$ for Scenario 1
[2] According to alpha-cypermethrin CAR.
[3] According to alpha-cypermethrin CAR and Table 23 of ECHA Guidance on the BPR (Volume IV Environment –Version 2.0, October 2017)

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

Where:

Variable/parameter (unit)	Symbol	Unit	Value	Source
Predicted Environmental Concentration in earthworm-eating predators	$PEC_{oral,\ earthworm\text{-}eating\ predator}$	[$mg.kg_{wet\ earthworm}^{-1}$]	1.37E-03	Output
Concentration in earthworm on wet weight basis	$C_{earthworm}$	[$mg.kg_{wet\ earthworm}^{-1}$]	1.37E-03	Output
Bioconcentration Factor for earthworms on wet weight basis	$BCF_{earthworm}$	[$mg.kg_{wet\ earthworm}^{-1}$]	3796[1]	Input
Concentration in porewater	$C_{porewater}$	[$mg.L^{-1}$]	[2]	Input
Concentration in soil	C_{soil}	[$mg.kg_{wwt}^{-1}$]	[3]	Input
Fraction of gut loading in worm	F_{gut}	[$kg_{dwt}.kg_{wwt}^{-1}$]	0.1 [4]	Default
Conversion factor for soil concentration wet-dry weight soil	$CONV_{soil}$	[$kg_{wwt}.kg_{dwt}^{-1}$]	1.13 [4]	Default

[1] According to alpha- cypermethrin CAR.

[2] Worst case $PEC_{porewater}$ 3.86E-07 mg/L in Scenario 1.
[3] 180 days TWA PEC_{soil} 5.20E-04 mg/L in Scenario 1.
[4] Default values were obtained from ECHA Guidance on the BPR (October 2017)

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

Summary table on estimated theoretical exposition values (ETE) via food chain		
Scenario	***PEC*$_{oral,\ fish\text{-}eating\ predator}$**	***PEC*$_{oral,\ earthworm\text{-}eating\ predator}$**
1	2.39E-03	1.37E-03

Major change application

Secondary poisoning for Scenario 1: RMM, Fsim = 0.204%, large buildings only

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

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

Where:

Variable/parameter (unit)	**Symbol**	**Unit**	**Value**	**Source**
Predicted Environmental Concentration in fish-eating predators	$PEC_{oral,\ fish\text{-}eating\ predator}$	[$mg.kg_{wet\ fish}^{-1}$]	**2.98E-04**	Output
Predicted Environmental Concentration in water	PEC_{water}	[$mg.L^{-1}$]	[1]	Input
Bioconcentration Factor for fish on wet weight basis	BCF_{fish}	[$L.kg_{wet\ fish}^{-1}$]	910[2]	Input
Biomagnification factor in fish	*BMF*	[-]	1[3]	Default

[1] PEC_{water} **3.280E-07** $mg.L^{-1}$
[2] According to alpha-cypermethrin CAR.
[3] According to alpha-cypermethrin CAR and Table 23 of ECHA Guidance on the BPR (Volume IV Environment –Version 2.0, October 2017).

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

Where:

Variable/parameter (unit)	**Symbol**	**Unit**	**Value**	**Source**
Predicted Environmental Concentration in earthworm-eating predators	$PEC_{oral,\ earthworm\text{-}}$	[$mg.kg_{wet\ earthworm}^{-1}$]	**1.25E-04**	Output

	eating predator			
Bioconcentration Factor for earthworms on wet weight basis	$BCF_{earthworm}$	[$mg.kg_{wet\ earthworm}^{-1}$]	3796[1]	Input
Concentration in porewater	$C_{porewater}$	[$mg.L^{-1}$]	[2]	Input
Concentration in soil	C_{soil}	[$mg.kg_{wwt}^{-1}$]	[3]	Input
Fraction of gut loading in worm	F_{gut}	[$kg_{dwt}.kg_{wwt}^{-1}$]	0.1 [4]	Default
Conversion factor for soil concentration wet-dry weight soil	$CONV_{soil}$	[$kg_{wwt}.kg_{dwt}^{-1}$]	1.13 [4]	Default

[1] According to alpha- cypermethrin CAR.
[2] Worst case PECporewater **3.535E-08** mg/L
3 180 days TWA PECsoil **4.763E-05** mg/kg
[4] Default values were obtained from ECHA Guidance on the BPR (October 2017).

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

Summary table on estimated theoretical exposition values (ETE) via food chain for an Fsim of 0.204%		
Scenario	***PEC*$_{oral,\ fish\text{-}eating\ predator}$ *[mg/kg food]***	***PEC*$_{oral,\ earthworm\text{-}eating\ predator}$ *[mg/kg food]***
	RMM, large buildings only	**RMM, large buildings only**
1, RMM Fsim = 0.204%	**2.98E-04**	**1.25E-04**

Secondary poisoning for Scenario 2

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

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

Where:

Variable/parameter (unit)	Symbol	Unit	Value	Source
Predicted Environmental Concentration in fish-eating predators	$PEC_{oral,\ fish\text{-}eating\ predator}$	[$mg.kg_{wet\ fish}^{-1}$]	-	Output
Predicted Environmental Concentration in water	PEC_{water}	[$mg.L^{-1}$]	[1]	Input
Bioconcentration Factor for fish on wet weight basis	BCF_{fish}	[$L.kg_{wet\ fish}^{-1}$]	910[2]	Input
Biomagnification factor in fish	*BMF*	[-]	1[3]	Default

[1] PEC_{water} for worst case animal categories (i.e. 1,3, 5) in Scenario 2 for grassland based on nitrogen 10 years degradation. In particular, for bloodsucking pests: PECgrs10_degr-sw-N category 1 = 1.40E-06 mg/L, PECgrs10_degr-sw-N category 3 = 2.12E-06 mg/L, PECgrs10_degr-sw-N category 5 = 1.46E-06 mg/L.
[2] According to alpha-cypermethrin CAR.
[3] According to alpha-cypermethrin CAR and Table 23 of ECHA Guidance on the BPR (Volume IV Environment –Version 2.0, October 2017)

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

Where:

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

[1] According to alpha- cypermethrin CAR.
[2] $PEC_{porewater}$ for worst case animal categories (i.e. 1,3, 5) in Scenario 2 for grassland based on nitrogen 10 years degradation for bloodsucking pests. In particular: $PEC_{porewater}$ grs10degr- N category 1 = 1.40E-05 mg/L, $PEC_{porewater}$ grs10degr- N category 3 = 2.12E-05 mg/L, $PEC_{porewater}$ grs10degr- N category 5 = 1.46E-05 mg/L.
[3] PEC_{soil} for worst case animal categories (i.e. 1,3, 5) in Scenario 2 for grassland based on nitrogen 10 years degradation for bloodsucking pests. In particular: PEC_{soil} grs10degr- N category 1 = 1.89E-02 mg/L, PEC_{soil} grs10degr- N category 3 = 2.85E-02 mg/L, PEC_{soil} grs10degr- N category 5 = 1.96E-02 mg/L.
[4] Default values were obtained from ECHA Guidance on the BPR (October 2017)

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

Summary table on estimated theoretical exposition values (ETE) via food chain for both bloodsucking pests and flies		
Scenario 2	***PEC*$_{oral,\ fish\text{-}eating\ predator}$**	***PEC*$_{oral,\ earthworm\text{-}eating\ predator}$**
Animal category 1	1.27E-03	1.92E-03
Animal category 3	1.93E-03	2.90E-03
Animal category 5	1.32E-03	1.99E-03

2.2.8.3 Risk characterisation

Scenario 1:

Atmosphere

Conclusion:

No risk characterisation for air was conducted as exposure to air is considered negligible

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values	
	SimpleTreat v3.1
	PEC/PNEC$_{STP}$
Scenario 1	2.93E-07*

* Worst case PEC value used without mitigation measures.

Conclusion:

In scenario 1, the microorganisms in STPs are not at risk. The PEC/PNEC ratios are far below 1.

Major change application

Sewage treatment plant (STP)

	Summary table on calculated PEC/PNEC values
	SimpleTreat v4
	PEC/PNEC$_{STP}$
	RMM, large buildings only **RMM, Fsim = 0.204%**
Scenario 1	**3.660E-08**

Conclusion:

In scenario 1, the microorganisms in STPs are not at risk. The PEC/PNEC ratios are far below 1.

Aquatic compartment

Summary table on calculated PEC/PNEC values		
	PEC/PNEC$_{water}$	**PEC/PNEC$_{sed}$ (EU agreed)**
SimpleTreat v3.1		
Scenario 1 Houses and buildings, Fsim=0.815%	5.48E-01*	**4.47E+00***

* Worst case PEC value used without mitigation measures.

Conclusion:

In the urban pest control scenario (scenario 1), aquatic organisms are not at risk. The PEC/PNEC ratios are below 1 and safe use is demonstrated.

Regarding sediment, the PEC/PNEC ratio for is above 1 for Scenario 1 with SimpleTreat v3.1 and for uses in both houses and buildings. Therefore, there is an unacceptable risk for sediment drewlling organisms for urban pest control scenario (scenario 1).

Major change application

Aquatic compartment

	Summary table on calculated PEC/PNEC values	
	PEC/PNEC$_{water}$	**PEC/PNECsed**
SimpleTreat v4	**RMM, large buildings only** **RMM, Fsim=0.204%**	**RMM, large buildings only** **RMM, Fsim=0.204%**
Scenario 1	**6.833E-02**	**5.573E-01**

Conclusion:

In the urban pest control scenario (scenario 1), aquatic organisms are not at risk. The PEC/PNEC ratio is below 1 and safe use is demonstrated.

Regarding sediment, the PEC/PNEC ratio is below 1**.** A safe use for sediment dwelling organisms for urban pest control scenario (scenario 1) can be shown.

Terrestrial compartment

Summary table on calculated PEC/PNEC values	
	SimpleTreat v3.1
Scenario 1	**PEC/PNEC$_{soil}$**
PEC$_{soil, 10}$ (0) * [mg/kg]	8.02E-04*

* Worst case PEC value without mitigation measures = immediately after the tenth application = Csludgesoil 10 (0)

Conclusion:

In scenario 1, soil organisms are not at risk. The PEC/PNEC ratios are far below 1.

Major change application

Terrestrial compartment

	Summary table on calculated PEC/PNEC values
	SimpleTreat v4
Scenario 1	**PEC/PNEC$_{soil}$**
	RMM, Large buildings only **RMM, Fsim = 0.204%**
PEC$_{soil, 10}$ (30) [mg/kg]	**8.149E-05**

Conclusion:

In scenario 1, soil organisms are not at risk. The PEC/PNEC ratios are below 1.

Groundwater

According to the on Guidance on the Biocidal Products Regulation, Volume IV Environment - Part B Risk Assessment (active substances), April 2015, the concentration in soil pore water is taken as an indication for potential groundwater levels. PECs in groundwater were calculated accordingly using equation 67 and 68 of this guidance document. As a first approach, neither transport nor dilution in deeper soil layers nor uptake by plants is taken into consideration.

Groundwater concentrations in the urban pest control scenario (scenario 1) are far below the drinking water limit of 0.1 µg/L.

Primary and secondary poisoning

Primary poisoning

Primary poisoning is not relevant for the foreseen use of Fendona 6 SC.

Secondary poisoning for Scenario 1

Summary table on secondary poisoning via the aquatic food chain					
Scenario	***PEC*oral, fish-eating predator**	**PNEC$_{birds}$[1]**	**PNEC$_{mammals}$ [2]**	**PEC/PNEC$_{birds}$**	**PEC/PNEC$_{mammals}$**
1	2.39E-03	5	2.67	4.79E-04	8.96E-04
Summary table on secondary poisoning via the terrestrial food chain					
Scenario	***PEC*oral, earthworm-eating predator**	**PNEC$_{birds}$[1]**	**PNEC$_{mammals}$ [2]**	**PEC/PNEC$_{birds}$**	**PEC/PNEC$_{mammals}$**
1	1.37E-03	5	2.67	2.74E-04	5.13E-04

[1] PNEC$_{bird}$ is 5 mg/kg food based on CAR of alpha- cypermethrin
[2] PNEC$_{mammal}$ is 2.67 mg/kg food based on CAR of alpha- cypermethrin

Conclusion:

In scenario 1, secondary poisoning of aquatic and terrestrial organisms does not result in a risk. The PEC/PNEC ratios are all below 1.

Major change application

Secondary poisoning for Scenario 1; **RMM Fsim = 0.204%, RMM large buildings only**

Summary table on secondary poisoning via the aquatic food chain					
Scenario	***PEC*oral, fish-eating predator***	**PNEC$_{birds}$[1]**	**PNEC$_{mammals}$ [2]**	**PEC/PNEC$_{birds}$**	**PEC/PNEC$_{mammals}$**
1	**2.98E-04**	5	2.67	**5.97E-05**	**1.12E-04**
Summary table on secondary poisoning via the terrestrial food chain					
Scenario	***PEC*oral, earthworm-eating predator***	**PNEC$_{birds}$[1]**	**PNEC$_{mammals}$ [2]**	**PEC/PNEC$_{birds}$**	**PEC/PNEC$_{mammals}$**
1	**1.25E-04**	5	2.67	**2.51E-05**	**4.70E-05**

*large buildings
[1] PNEC$_{bird}$ is 5 mg/kg food based on CAR of alpha- cypermethrin
[2] PNEC$_{mammal}$ is 2.67 mg/kg food based on CAR of alpha- cypermethrin

Conclusion:

In scenario 1, secondary poisoning of aquatic and terrestrial organisms does not result in a risk. The PEC/PNEC ratios are all below 1.

Scenario 2:

The risk assessment for Scenario 2 is performed, according to the Addendum to OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 14 (Agreed at the Environment Working Group V on November 26, 2015), with *PIEC*grs10_degr–*N*i1,i2,i3,i4 for terrestrial risk assessment, and with dividing *PIEC*grs10_degr–gw–*N*i1,i2,i3,i4 by a dilution factor of 10 for surface water. Therefore, calculations for arable land and calculations based on P_2O_5 are not presented.

Note: The risk assessment for flies is not presented since this use is not authrorised (see efficacy section)

Atmosphere

Conclusion:

No risk characterisation for air was conducted as exposure to air is considered negligible

Sewage treatment plant (STP)

Release from the facility drain to an STP and exposure of microorganisms in the STP was not considered for the use in rural hygiene as Fendona 6 SC must not be used in stables/animal housings connected to a sewage treatment plant.

Aquatic compartment

Scenario 2: Table on calculated PEC/PNEC values for the aquatic compartment (relevant for biocide type i2=2; bloodsucking pests); considering the route spraying in stables → manure → application of manure/slurry to soil						
Animal category (i1)						
	1	**2**	**3**	**4**	**5**	**6**
PEC/PNEC$_{water}$						
Grassland sw-$_{10\_degr}$-N	2.92E-01	1.41E-01	4.41E-01	2.66E-01	3.03E-01	2.15E-01
PEC/PNEC$_{sed}$ EU agreed						
Grassland sed-$_{10\_degr}$-N	**2.38E+0**	**1.15E+0**	**3.60E+0**	**2.17E+0**	**2.47E+0**	**1.75E+0**
	7	**9**	**10**	**13**	**14**	**15**
PEC/PNEC$_{water}$						
Grassland sw-$_{10\_degr}$-N	5.15E-02	5.75E-02	5.75E-02	6.75E-02	4.21E-02	9.05E-02
PEC/PNEC$_{sed}$ EU agreed						
Grassland sed-$_{10\_degr}$-N	4.20E-01	4.69E-01	4.69E-01	5.50E-01	3.43E-01	7.38E-01

Conclusion:

In scenario 2 (rural hygiene), aquatic organisms are not at risk for the exposure route spraying in stables=> manure => spreading manure / slurry on soil. However, for this exposure route, a risk to sediment dwelling organisms was identified when using the $PNEC_{sediment}$ EU agreed for 6 out of 12 animal subcategories. In conclusion, a safe use for sediment dwelling organisms is identified for animal subcategories 7, 9, 10, 13, 14, 15 (for explanation of animal subcatefories number see relevant table in page 181).

Terrestrial compartment

- ✓ **For biocide type i2=2; bloodsucking pests**
  - **Considering degradation processes of alpha cypermethrin in soil, after 10 consecutive years application**

PEC/PNEC in soil for grassland, 1 manure application/yr. after 10 consecutive years, taking degradation into account						
Animal category (i1)						
	1	**2**	**3**	**4**	**5**	**6**
Grassland-$_{10\_degr}$-N	2.14E-02	1.03E-02	3.23E-02	1.95E-02	2.22E-02	1.57E-02
	7	**9**	**10**	**13**	**14**	**15**
Grassland-$_{10\_degr}$-N	3.78E-03	4.21E-03	4.21E-03	4.95E-03	3.09E-03	6.64E-03

Conclusion:

In scenario 2, soil organisms are not at risk. The PEC/PNEC ratios are far below 1.

Groundwater

According to the on Guidance on the Biocidal Products Regulation, Volume IV Environment - Part B Risk Assessment (active substances), April 2015, the concentration in soil pore water is taken as an indication for potential groundwater levels. PECs in groundwater were calculated accordingly using equation 67 and 68 of this guidance document. As a first approach, neither transport nor dilution in deeper soil layers nor uptake by plants is taken into consideration.

Groundwater concentrations in scenario 2 (rural hygiene) are far below the drinking water limit of 0.1 µg/L.

Primary and secondary poisoning

Primary poisoning

Primary poisoning is not relevant for the foreseen use of Fendona 6 SC.

Secondary poisoning

Summary table on secondary poisoning via the aquatic food chain for both bloodsucking pests					
Scenario 2	***PEC*$_{oral,\ fish\text{-}eating\ predator}$**	**PNEC$_{birds}$[1]**	**PNEC$_{mammals}$ [2]**	**PEC/PNEC$_{birds}$**	**PEC/PNEC$_{mammals}$**
Animal cat 1	1.27E-03	5	2.67	2.55E-04	4.77E-04
Animal cat 3	1.93E-03	5	2.67	3.85E-04	7.22E-04
Animal cat 5	1.32E-03	5	2.67	2.65E-04	4.96E-04
Summary table on secondary poisoning via the terrestrial food chain for both bloodsucking pests					
Scenario 2	***PEC*$_{oral,\ earthworm\text{-}eating\ predator}$**	**PNEC$_{birds}$[1]**	**PNEC$_{mammals}$ [2]**	**PEC/PNEC$_{birds}$**	**PEC/PNEC$_{mammals}$**
Animal cat 1	1.92E-03	5	2.67	3.83E-04	7.17E-04
Animal cat 3	2.90E-03	5	2.67	5.79E-04	1.08E-03
Animal cat 5	1.99E-03	5	2.67	3.98E-04	7.46E-04

[1] $PNEC_{bird}$ is 5 mg/kg food based on CAR of alpha- cypermethrin
[2] $PNEC_{mammal}$ is 2.67 mg/kg food based on CAR of alpha- cypermethrin

Conclusion:

In scenario 2, secondary poisoning of aquatic and terrestrial organisms does not result in a risk. The PEC/PNEC ratios are all below 1.

Mixture toxicity

Mixture toxicity is not relevant as alpha-cypermethrin is the only a.i. in Fendona 6 SC and the b.p. does not contain any substance of concern for the environment.

Aggregated exposure (combined for relevant emission sources)

Aggregated exposure is not relevant since the a.s. is only used for PT 18 purposes.

Overall conclusion on the risk assessment for the environment of the product
• The risk assessment for **sewage treatment plants** indicates safe use for the b.p. regarding to scenario 1 – urban pest control. For scenario 2 this route was not considered as the product must not be used in animal shelters connected to an STP. • The risk assessment for **surface water** indicates safe use for the b.p. in the urban pest control scenario (scenario 1, STP exposure route) and in the rural hygiene scenario (scenario 2) for the exposure route spraying in stables => manure => spreading manure / slurry on soil. • The risk assessment **for sediment** indicates no safe use for the b.p. in the urban pest control scenario (scenario 1). In scenario 2 for the exposure route spraying in stables => manure => spreading manure / slurry on soil => run-off to surface water (sediment), a safe use for sediment dwelling organisms can be demonstrated for animal subcategories 7, 9, 10, 13, 14, 15 (for explanation of animal subcatefories number see relevant table in page 181). • For both scenarios, no risk for **soil** is identified. • For both scenarios, no risk for the **groundwater** is identified. • For both scenarios, no risk for the **secondary poisoning** is identified.

Major change application

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

- The risk assessment for **sewage treatment plants** indicates safe use for the b.p. regarding to scenario 1 – urban pest control.
- The risk assessment for **surface water** indicates safe use for the b.p. in the urban pest control scenario (scenario 1, STP exposure route).
- The risk assessment **for sediment** indicates a safe use for the b.p. in the urban pest control scenario (scenario 1) **considering a frequency of application of 1-2 applications per year and large buildings only as a risk mitigation measure.**
- For urban pest control scenario (scenario 1), no risk for **soil** is identified.
- For urban pest control scenario (scenario 1), no risk for the **groundwater** is identified.
- For urban pest control scenario (scenario 1), no risk for the **secondary poisoning** is identified.

2.2.9 Measures to protect man, animals and the environment

To protect man: The indirect exposure of PCOs and the general public, respectively, to alpha-cypermethrin in b.p. does not pose an unacceptable health risk when following the label instructions of the biocidal product. PCOs should use protective clothing and protective gloves. In the context of good practice the additional label phrase is proposed: 'Allow the applied solution to dry before re-entry into the treated areas by either humans or animals'. Please refer to the conclusions in section 2.6.3.

To protect animals: The exposure of livestock animals following treatment of surfaces in animal houses with Fendona 6 SC is considered safe with the additional label phrase: 'Allow the applied solution to dry before re-entry into the treated areas by either humans or animals'. No additional measures are required. Please refer to section 1.2.7.

To protect the environment: Remains of the product and spillage must be collected and not discharged to sewage system. The indoor treatment in urban areas is restricted to crack and crevices or limited suface areas. For rural hygiene the product must not be used in animal houses connected to sewage treatment plants. To protect the aquatic environment product must not be discharged to the sewage system. Please refer to the conclusions in section 1.2.8.3.

2.2.10 Assessment of a combination of biocidal products

This section is not relevant since Fendona 6 SC is not inteneded to be used in combination with other biocidal products.

2.2.11 Comparative assessment

No comparative assessment required.

3 ANNEXES

3.1 List of studies for the biocidal product

DATA REQUIREMENT: The List of Studies should be updated to include Study "Siebecker,2017, 2017/1099849".

Endpoint	Author	Year	Titel	Laboratory	Study No.	Data owner	Internal study no.	Protection claimed
Skin sensitisation	[redacted]	2008 a	Evaluation of skin sensitization in guinea pigs of the test substance FENDONA 6 SC	[redacted]	RE.428.0396.08	BASF S.A, Sao Paulo, SP, Brazil	2008/3002503	yes
Skin irritation / corrosion	[redacted]	2008 b	Evaluation of the primary dermal irritation in rabbits of the test substance FENDONA 6 SC	[redacted]	RE.413.0394.08	BASF S.A., Sao Paulo, SP, Brazil	2008/3002502	yes
Eye irritation	[redacted]	2008 c	Evaluation of Eye Irritation of the test substance FENDONA 6 SC in rabbits	[redacted]	RE.421.0395.08	BASF S.A, Sao Paulo, SP, Brazil	2008/3002523	yes
Analytical methods for the monitoring of residues in feeding stuff	Class T.,Bendig P., 2014		Validation of the BASF analytical method L0231/01 : Method for the determination of individual or co mbined diastereomeric forms of BAS 311 I (cis I, cis II (alpha-cypermethrin, BAS 310 I), trans III and trans IV) in animal matrices	PTRL Europe	428874	BASF SE	DocID 2013/1361967	yes
Acute toxicity: oral	[redacted]	2008 a	Evaluation of Acute Oral Toxicity in Rats of test substance FENDONA 6 SC	[redacted]	RE.409.0392.08	BASF S.A, Sao Paulo, SP, Brazil	2008/3002521	yes
Acute toxicity: dermal	[redacted]	2008 b	Evaluation of Acute Dermal Toxicity in Rats of test substance FENDONA 6 SC	[redacted]	RE.440.0393.08	BASF S.A, Sao Paulo, SP, Brazil	2008/3002522	yes

Endpoint	Author	Year	Titel	Laboratory	Study No.	Data owner	Internal study no.	Protection claimed
Efficacy data	Estany, D.	2016 a	Field trials to determine the efficacy of Fendona 6 SC against Blatella germanica	i2LResearch Southern Europe, Cornellà del Terri, Spain	15/166EE	BASF Pest Control Solutions, Cheadle Hulme, UK	DocID# 2016_1091548	yes
Efficacy data	Estany, D.	2016 b	Field trials to determine the efficacy of Fendona 6 SC against Blatella germanica	i2LResearch Southern Europe, Cornellà del Terri, Spain	15/166CC	BASF Pest Control Solutions, Cheadle Hulme, UK	DocID# 2016_1091543 with Addendum: DocID_2017_1119568	yes
Efficacy data	Estany, D.	2016 c	Field trial to determine the efficacy of Fendona 6SC against Blatta orientalis	i2LResearch Southern Europe, Cornellà del Terri, Spain	15/166CCC	BASF Pest Control Solutions, Cheadle Hulme, UK	DocID# 2016_1235738 with Addendum: DocID 2017/1123697	yes
Efficacy data	Estany, D.	2016 d	Field trial to determine the efficacy of Fendona 6SC against Blatta orientalis and Periplaneta americana	i2LResearch Southern Europe, Cornellà del Terri, Spain	15/166EEEE	BASF Pest Control Solutions, Cheadle Hulme, UK	DocID# 2016_1235740	yes
Efficacy data	Estany, D.	2016 e	Field trial to determine the efficacy of Fendona 6 SC against Stomoxys calcitrans	i2LResearch Southern Europe, Cornellà del Terri, Spain	15/166CCCC	BASF Pest Control Solutions, Cheadle Hulme, UK	DocID# 2016_1235742 with Addendum: DocID 2017/1121349	yes
Efficacy data	Estany, D.	2016 f	Field trial to determine the efficacy of Fendona 6 SC against Stomoxys calcitrans	i2LResearch Southern Europe, Cornellà del Terri, Spain	15/166EEEE	BASF Pest Control Solutions, Cheadle Hulme, UK	DocID# 2016_1235746	yes

Endpoint	Author	Year	Titel	Laboratory	Study No.	Data owner	Internal study no.	Protection claimed
Metabolism in livestock	[redacted]	2001	[trade name] insecticide (Alphacypermethrin - BAS 310 I): Magnitude of BAS 310 I residues in laying hen eggs, muscle, liver and abdominal fat after oral administration of BAS 310 I for 28 consecutive days	[redacted]	RES 00-052	BASF Agro Research, Princeton, NJ	AP00PT06	yes
Analytical methods	Frohn, D. and Singer, D.	2014	Supplement to CIPAC METHOD: ALPHA-CYPERMETHRIN 454 (APL0470/01 and APL0470/02) Additional Validation of the Analytical Method with respect to the formulation BAS 310 27 I as test item	BASF SE Crop Protection Ecology and Environmental Analytics, Speyerer Strasse 2, 67117 Limburgerhof, Germany	--	BASF SE	Doc ID# 2014/1298640	yes
Efficacy data	Gibson, D.	2016	Laboratory bioassay to determine the efficacy of Fendona 6 SC applied at 30 mg ai/m2 against pests	i2LResearch Ltd, Cardiff, UK	15/164	BASF Pest Control Solutions, Cheadle Hulme, UK	DocID# ~~2016_1089835~~ 2017_1119303	yes
Efficacy data	Gibson, D.	2016	Field trial to determine the efficacy of Fendona 6SC applied at 24 mg ai/m2 against black ants	i2LResearch Ltd, Cardiff, UK	15/166B	BASF Pest Control Solutions, Cheadle Hulme, UK	DocID# 2016_1100538	yes
Efficacy data	Gibson, D.	2016	Laboratory bioassay to determine the efficacy of Fendona 6 SC applied at 15 mg ai/m2 against pests	i2LResearch Ltd, Cardiff, UK	15/164	BASF Pest Control Solutions, Cheadle Hulme, UK	DocID# ~~2016_1089834~~ 2017_1118835	yes
Efficacy data	Gibson, D.	2016	Simulated use bioassay to determine the efficacy of Fendona 6 SC applied at 30 mg ai/m2 against pests	i2LResearch Ltd, Cardiff, UK	15/165	BASF Pest Control Solutions, Cheadle Hulme, UK	DocID# ~~2016_1089837~~ 2017_1119306	yes

Endpoint	Author	Year	Titel	Laboratory	Study No.	Data owner	Internal study no.	Protection claimed
Efficacy data	Gibson, D.	2016	Simulated use bioassay to determine the efficacy of Fendona 6 SC applied at 15 mg ai/m2 against pests	i2LResearch Ltd, Cardiff, UK	15/165	BASF Pest Control Solutions, Cheadle Hulme, UK	DocID# ~~2016_1089836~~ 2017/1119573	yes
Efficacy data	Gibson D.	2016	Simulated use bioassay to determine the efficacy of Fendona 1.5 SC and Fendona 6 SC applied as a residual spray against cockroaches	i2LResearch Ltd, Cardiff, UK	15/366	BASF Pest Control Solutions, Cheadle Hulme, UK	DocID# ~~2016_1136390~~ 2017/1119575	yes
Efficacy data	Gibson, D.	2016	Field trial to determine the efficacy of Fendona 6SC apllied at 15 mg ai/m2 against black ants	i2LResearch Ltd, Cardiff, UK	15/166C	BASF Pest Control Solutions, Cheadle Hulme, UK	DocID# 2016_1235734	yes
Efficacy data	Gibson, D.	2016	Field trial to determine the efficacy of Fendona 6SC apllied at 15 mg ai/m2 against black ants	i2LResearch Ltd, Cardiff, UK	15/166D	BASF Pest Control Solutions, Cheadle Hulme, UK	DocID# 2016_1235736	yes
Sediment toxicity	[redacted]	2016 a	Chronic toxicity of BAS 310 27 I (active ingredient alpha-cypermethrin; BAS 310 I) to the non-biting midge Chironomus riparius – exposed via spiked sediment	[redacted]	S15-04450	BASF SE, Ludwigshafen, Germany	741161; DocID 2015/1107650	yes
Sediment toxicity	[redacted]	2016 b	Report Amendment No. 1 to Study S15-04450	[redacted]	S15-04450	BASF SE, Ludwigshafen, Germany	741161; DocID 2016/1085281	yes
Sediment toxicity	[redacted]	2016 c	Chronic toxicity of BAS 310 22 I (active ingredient alpha-cypermethrin; BAS 310 I) to the non-biting midge Chironomus riparius – exposed via spiked sediment	[redacted]	S15-04449	BASF SE, Ludwigshafen, Germany	741163; DocID 2015/1107651	yes

Endpoint	Author	Year	Titel	Laboratory	Study No.	Data owner	Internal study no.	Protection claimed
Sediment toxicity	[redacted]	2016 d	Report Amendment No. 1 to Study S15-04449	[redacted]	S15-04449	BASF SE, Ludwigshafen, Germany	741163; DocID 2016/1085280	yes
Metabolism in livestock	[redacted]	2003	[trade name] Insecticide (Alphacypermethrin, CL 900049, BAS 310 I): Magnitude of Alphacypermethrin Residues in the Milk and Edible Tissues of Dairy Cattle Following Oral Administration for Twenty-Eight (28) Consecutive Days	[redacted]	RES 01-008	BASF Agro Research, Princeton, NJ	AP00PT01	yes
Density Technical characteristics of the biocidal product Flammability Appearance/ physical state/colour pH Surface tension Viscosity Storage stability and reactivity towards container material	Kaestel, R.	2003	Final report: Physical and chemical properties of BAS 310 27 I	BASF SE, BASF Agricultural Center Limburgerhof, Crop Protection Division, Ecology and Environmental Analytics, PO Box 120, 67114 Limburgerhof, Germany	168625_1	BASF SE - Agrarzentrum, Limburgerhof, Germany	DocID 2003/1018885	yes
Storage stability and reactivity towards container material	Kroehl, T.	2012	alpha-Cypermethrin 15 g/L SC - chemical and physical stability of formula BAS 310 22 I when stored for up to 3 years at 23°c in commercial packs	BASF SE, BASF Agricultural Center Limburgerhof, Crop Protection Division, Ecology and Environmental Analytics, PO Box 120, 67114	338463-1	BASF SE - Agrarzentrum, Limburgerhof, Germany	DocID# 2011/1269168	yes

Endpoint	Author	Year	Titel	Laboratory	Study No.	Data owner	Internal study no.	Protection claimed
				Limburgerhof, Germany				
Storage stability and reactivity towards container material	Kroehl, T.	2015	Statement on 3 year shelf-life	BASF SE Crop Protection, Product Search and Development	--	BASF SE - Agrarzentrum, Limburgerhof, Germany	DocID# 2015/1169392	yes
Viscosity, Persistent Foaming and Suspensibility, low temp stability, reactivity to container material	Kroehl, T	2015a	Data on Viscosity, Persistent Foaming and Suspensibility	BASF SE, BASF Agricultural Center Limburgerhof, Germany	783533_1	BASF	DocID 2015_1204787	yes
Efficacy data	Loakes, S.	2011	Laboratory bioassay to determine the residual efficacy of formulations BAS 310 27 I and BAS 310 08 I against bed bugs, Cimex lectularius, cat fleas, Ctenocephalides felis and Indian meal moths, Plodia interpunctella	i2LResearch Ltd, Cardiff, UK	11/131	BASF Pest Control Solutions, Cheshire, UK	DocID# 2011_1292613	yes
Explosivenes s Auto flammability	Löffler, U.	2003	Evaluation of physical and chemical properties according to directive 98/69/EC, Annex A9-A17	BASF Aktiengesellschaft GTC/S-L511, Ludwigshafen	SIK-Nr. 03/1649	BASF AG	DocID# 2003_1023335	yes
Oxidising properties	Löhr	2009	Evaluation of physical and chemical properties according to directive 94/37/EC (67/548/EC Annex V)	BASF SE, GTC/S-L511, Ludwigshafen	09/0544	BASF SE	DocID# 2009_1046735	yes
Efficacy data	Lüpkes, K.-H.	2011	Residual efficacy as well as efficacy of still wet surfaces on various surfaces with product Fendona 15 SC / Littac 15 SC against House flies Musca domestica, Stable flies Stomoxys	BioGenius GmbH, Bergisch Gladbach, Germany	BIO065a-11	BASF, Limburgerhof, Germany	DocID# 2011_1291553	yes

Endpoint	Author	Year	Titel	Laboratory	Study No.	Data owner	Internal study no.	Protection claimed
			calcitrans and Litter beetles Alphitobius diaperinus					
Acute toxicity: inhalation	[redacted]	2004	BAS 310 27 I - Acute inhalation toxicity study in Wistar rats 4-hour liquid aerosol exposure	[redacted]	13I0412/037014	BASF AG, Ludwigshafen/Rhein, Germany	2004/1027687	yes
Efficacy data	Miller, P.F. & Peters, B.	1988 a	Trial to investigate efficacy of Fendona and Cislin 10 against Black House Ants	School of Biological & Biomedical Sciences, University of Technology, Sydney, Australia	R3W8	BASF	DocID# 1988_8000003	yes
Efficacy data	Miller, P.F. & Peters, B.	1988 b	Report on the efficacy of Fendona and Cislin 10 against Periplaneta sp (American and Australian Cockroach)	School of Biological & Biomedical Sciences, University of Technology, Sydney, Australia		BASF	DocID# 1988_8000001	yes
Efficacy data	Miller, P.F. & Peters, B.	1989	Trial to investigate efficacy of Fendona and Cislin 10 against Coastal Brown Ants	School of Biological & Biomedical Sciences, University of Technology, Sydney, Australia	R35W8	BASF	DocID# 1989_8000001	yes
Dermal absorption	[redacted]	2016	Report 14C-BAS 310 I (alpha-Cypermethrin) in BAS 310 27 I Study of penetration through human skin in vitro	[redacted]	10B0440/03B028	BASF SE, Ludwigshafen, Germany	AP study ID 806752; Doc ID 2016/1030367	yes
Analytical methods for the monitoring of residues in feeding stuff	Schernikau N.	2014	Independent laboratory validation of the BASF analytical method L0231/01: Determination of individual or combined diastereomeric forms of BAS 311 I (Cis I, Cis II (Alpha-Cypermethrin, BAS 310 I), trans III and trans IV) in animal matrices	Eurofins Agrosciences Services	S14-03796	BASF SE	DocID 2014/1145882	yes

Endpoint	Author	Year	Titel	Laboratory	Study No.	Data owner	Internal study no.	Protection claimed
Viscocity	Seibecker, M	2017	Additional information on the rotational viscosity determination which was described in the accelerated study 168631_1	BASF SE, Agricultural Center Limburgerhof, Germany	168631_1 Additional information document	BASF	DocID 2017_1099849	yes
Corrosive to metals	Titz	2019	Laboratory Corrosion Test of BAS 310 27 I, DocID 2019/1000541, to Classify Corrosive Substances of Class 8 in Accordance with the UN Recommendations on the Transport of Dangerous Goods.	BASF SE	Report: 219.1111 TBOl	BASF SE	?	yes

Major change application

The following efficacy studies have been included with the major change application to support the claimed species listed under Use # 1.

Endpoint	Author	Year	Title	Laboratory	Study No.	Data owner	Internal study no.	Protection claimed
Efficacy data	Serrano, B.	2012	Field testing of the efficacy of an insecticidal product to control German cockroaches: BAS 310 27 I – FENDONA SC – 15 and 30 mg a.s./m²	T.E.C. Laboratory, France	1468b/0911	BASF	DocID: 2019/1068358	yes
Efficacy data	Gibson, D.	2019	Bridging study to determine the efficacy of Fendona 6 SC applied as a residual spray against cockroaches (mortality end-point determination)	i2LResearch Ltd, UK	19/011	BASF	DocID: 2019/1068356	yes
Efficacy data	Gibson, D.	2019	Simulated use bioassay to determine the efficacy of Fendona 6 SC (BAS 310 27 I) applied as a residual surface spray against Mosquitoes, *Culex quinquefasciatus*, and Houseflies,	i2LResearch Ltd, UK	19/014	BASF	DocID: 2019/1057848	yes

Endpoint	Author	Year	Title	Laboratory	Study No.	Data owner	Internal study no.	Protection claimed
			Musca domestica (mortality end-point determination)					
Efficacy data	Lupkes, K.H.	2012	Residual efficacy of product Fendona 6 SC against German cockroaches (*Blattella germanica*), Cat fleas (*Ctenocephalides felis*) and Bed bugs (*Cimex lectularius*). Report number: BIO010a-12	BioGenius GmbH Biology, Germany	M04314	BASF	DocID: 2019/ 1068334	yes
Efficacy data	Lupkes, K.H.	2019	Statement on test report BioGenius BIO010a-12	BioGenius GmbH Biology, Germany	N/A	BASF	DocID: 2019/ 1068074	Yes

3.2 Output tables from exposure assessment tools

Table 1. Calculations of primary exposure of trained professionals (PCOs) to alpha-cypermethrin resulting from low-pressure insecticide application of Fendona in the rural hygiene scenario at 30 mg a.s./m² (spraying model 1 from TNsG on human exposure, with additional details from HSE survey EH74/3).

	Tier 1	Tier 2	
	Unprotected	**Protected (PPE)**	**Protected (PPE/RPE)**
	Low-pressure (1-3 bar) insecticide spraying (total 120 min)		
Dermal mix/load/apply			
Potential dermal exposure	92 mg/min	92 mg/min	92 mg/min
Product on clothing (over 120 min)	11 040 mg	11 040 mg	11 040 mg
Penetration(1)	100 %	20%	20%
Product on skin	11 040 mg	2 208 mg	2 208 mg
Potential hand exposure	181 mg/min	10.7 mg/min	10.7 mg/min
Hand exposure (2) (3)	21 720 mg	1 284 mg	1 284 mg
Total product on skin	32 760 mg	3 492 mg	3 492 mg
0.06 % alpha-cypermethrin in application solution	19.66 mg	2.10 mg	2.10 mg
Dermal uptake	5%	5%	5%
Dose via skin	0.98 mg	0.11 mg	0.11 mg
Dermal body dose per day	0.0164 mg/kg bw/d	0.0018 mg/kg bw/d	0.0018 mg/kg bw/d
Inhalation mix/load/apply			
Aerial concentration	104 mg/m³	104 mg/m³	104 mg/m³
Inhaled volume (over 120 min)	2.5 m³	2.5 m³	2.5 m³
RPE protection factor	–	–	90%
Inhaled amount of product	260 mg	260 mg	26.0 mg
0.06 % alpha-cypermethrin in application solution	0.156 mg	0.156 mg	0.016 mg
Inhalation uptake	100%	100%	100%
Dose via inhalation (a.s.)	0.156 mg	0.156 mg	0.016 mg
Inhalative body dose per day	0.0026 mg/kg bw	0.0026 mg/kg bw	0.00027 mg/kg bw
Systemic dose (summary of routes)	**0.0190 mg/kg bw/d**	**0.0044 mg/kg bw/d**	**0.0021 mg/kg bw/d**

(1) 80% protection factor for coated coverall for PT18 according to ECHA Biocides Human Health Exposure Methodology (p. 156)

(2) Maximum (due to only five values) and median of outer glove exposure from HSE EH74/3, Table 4 for worst case and normal case, respectively, at Tier 1 (unprotected)

(3) 75th percentile and median of inside glove exposure from HSE EH74/3 for worst case and normal case, respectively, at Tier 2 (protected)

Table 2: Calculations of primary exposure of consumers (non-professionals) to alpha-cypermethrin after mixing and loading resulting from low-pressure insecticide application of Fendona in the rural hygiene scenario at 30 mg a.s./m² (worst case) according to Mixing and loading Model 2, non-professionals, TNsG p.134; HSL 2001 and Mixing and loading Model 3, professionals, TNsG p.135; EUROPOEM

	Tier 1
	Potential Exposure
	Worst case
	Low-pressure (1-3 bar) insecticide spraying (total 7 min)
Dermal mixing/loading	
Product on bare hands and forearms per event	12.8 mg
Penetration (1)	100 %
Total product on skin	12.8 mg
6% alpha-cypermethrin in concentrate	0.768 mg
Dermal uptake	1%
A.s. dose via skin	0.0077
Dermal body dose a.s. per application	1.28×10^{-4} mg/kg bw/d
Inhalation mixing/loading	
Default EUROPOEM	0.1 mg/kg a.s.
6% alpha-cypermethrin in concentrate	0.006 mg
Inhalation uptake	100%
A.s. dose via inhalation	0.006 mg
Inhalative body dose a.s. per day	1×10^{-4} mg/kg bw/d
Systemic dose (summary of routes)	**2.28×10^{-4} mg/kg bw/d**

(1) HEEG opinion 9, 2010: Non-professionals wearing long sleeved shirt and trousers or skirt with shoes – no gloves worn. Hand exposure is always 100%. Long sleeved shirt would result in 50% penetration for forearms, however individual exposure to forearms cannot be retrieved from the available data (TNsG 2002, p.134). Therefore 100% exposure to forearms is considered worst case.

Table 3. Calculations of primary exposure of consumers (non-professionals) to alpha-cypermethrin after application resulting from low-pressure insecticide application of Fendona in the rural hygiene scenario at 30 mg a.s./m² according to application via hand-held trigger spray (Consumer spraying and dusting model 2 TNsG part 2, p 197, hand-held trigger spray)

	Tier 1	Tier 2
	Potential Exposure	**Wearing long sleeved shirt and trousers**
Low-pressure (1-3 bar) insecticide spraying (total 7 min)		
Dermal application		
Potential dermal exposure hands and forearms	36.1 mg/min	36.1 mg/min
Product on hands and forearms (100% (1), over 7 min)	252.7 mg	252.7 mg
Potential dermal exposure leg, feet & face	9.7 mg/min	9.7 mg/min
Product on leg, feet & face (over 7 min)	67.9 mg	67.9 mg
Penetration (1)	100 %	50%
Total product on leg, feet & face	67.9 mg	33.95 mg
Total product on skin	320.6 mg	286.6 mg
0.06% alpha-cypermethrin in application solution	0.1924 mg	0.172 mg
Dermal uptake	5%	5%
A.s. dose via skin	0.0096 mg	0.0086 mg
Dermal body dose a.s. per application	1.6×10^{-4} mg/kg bw/d	1.4×10^{-4} mg/kg bw/d
Inhalation application		
Aerial concentration	10.5 mg/m³	10.5 mg/m³
Inhaled volume (over 7 min)	0.146 m³	0.146 m³
Inhaled amount of product	1.53 mg	1.53 mg
0.06% alpha-cypermethrin in application solution	9.2×10^{-4} mg	9.2×10^{-4} mg
Inhalation uptake	100%	100%
A.s. dose via inhalation	9.2×10^{-4} mg	9.2×10^{-4} mg
Inhalative body dose a.s. per day	1.5×10^{-5} mg/kg bw/d	1.5×10^{-5} mg/kg bw/d
Systemic dose (summary of routes)	**1.75×10^{-4} mg/kg bw/d**	**1.55×10^{-4} mg/kg bw/d**

(1) HEEG opinion 9, 2010: Non-professionals wearing long sleeved shirt and trousers or skirt with shoes – no gloves worn. Hand exposure is always 100%. Long sleeved shirt would result in 50% penetration for forearms, however individual exposure to forearms cannot be retrieved from the available data (TNsG 2002, p.134). Therefore 100% exposure to forearms is considered worst case. Penetration to leg and feet is 50% considering consumers wear trouser with shoes. For exposure to face 50% penetration are considered due to no individual data for face exposure is available. However considering forearm exposure is much higher than exposure to face and that forearm exposure has been considered 100% penetration, the assumption on 50% penetration via face is considered acceptable.

Table 4: Calculation of acute exposure to alpha-cypermethrin via skin contact with Fendona-treated surfaces in the rural pest control scenario

Parameter	Definition	Value
Dislodgeable fraction formulation [mg/cm²]*	DF	0.53
Applied a.s. in formulation	M	0.06%
Hand Surface [cm²]	HS	410
Hand contamination	HC	100%
Dermal load [mg a.s.]	DL = DF x M x HS x HC	1.3×10^{-1}
Dermal absorption	DA	5 %
Body weight [kg]	BW	60.0
Systemic dose via skin [mg/kg bw/d]	I_{dermal} = DL × DA × BW^{-1}	1.09×10^{-4}

** based on TNsG part 2, p. 261 (Defaults for non-professional use and residential exposure to biocides), where the dislodgeable fraction formulation is calculated from the emission formulation rate of 0.65 g/sec, the use duration of 600 sec., a dislodgeable fraction of 30% and a surface area of 22 m².*

Table 5: Calculation of acute exposure to alpha-cypermethrin via skin contact with Fendona-treated surfaces in the crack and crevice application scenario (urban exposure scenario)

Parameter	Definition	Value
Dislodgeable fraction formulation [mg/cm²]*	DF	1.16
Applied a.s. in formulation	M	0.03%
Hand Surface [cm²]	HS	410
Hand contamination	HC	100%
Dermal load [mg a.s.]	DL = DF x M x HS x HC	0.14
Dermal absorption	DA	5 %
Body weight [kg]	BW	60.0
Systemic dose via skin [mg/kg bw/d]	I_{dermal} = DE × DA × BW^{-1}	1.2×10^{-4}

* *based on Pest control ConsExpo Factsheet.*

Table 6: Calculation of acute exposure to alpha-cypermethrin via skin contact with Fendona-treated surfaces in the crack and crevice application scenario (domestic exposure scenario)

Parameter	Definition	Values			
		Adults	**Children**	**Toddlers**	**Infants**
Dislodgeable fraction formulation [mg/cm²]*	DF	1.16	1.16	1.16	1.16
Applied a.s. in formulation	M	0.03%	0.03%	0.03%	0.03%
Hand Surface [cm²]	HS	410	427.8	230.4	196.8
Hand contamination	HC	100%	100%	100%	100%
Dermal load [mg a.s.]	DL = DF x M x HS x HC	0.14	0.15	0.08	0.068
Dermal absorption	DA	5%	5%	5%	5%
Body weight [kg]	BW	60	23.9	10	8
Systemic dose via skin [mg/kg bw/d]	I_{dermal} = DL × DA × BW^{-1}	1.2×10^{-4}	3.1×10^{-4}	4×10^{-4}	4.2×10^{-4}

** Based on Pest control ConsExpo Factsheet*.

Table 7: Calculation of the systemic dose exposure of infants via HTM contact (oral exposure).

Parameter	Definition	Values	
		Toddlers	**Infants**
Dislodgeable fraction formulation [mg/cm²]*	DF	1.16	1.16
Applied a.s. in formulation	M	0.03%	0.03%
Hand surface area [%]	SA	20%	20%
Dermal load [mg a.s.]	DL = DF x M x SA	6.96×10^{-5}	6.96×10^{-5}
Efficiency of removal by saliva from skin	RE	50%	50%
Transfer coefficient [cm^2/h]	TC	2000	2000
Body weight [kg]	BW	10	8
Oral exposure [mg/kg bw/d]	E_{oral} = DL × SA × RE × F × BW^{-1}	6.96×10^{-3}	8.7×10^{-3}
Oral absorption rate	AR_{oral}	0.45	0.45
Systemic oral dose [mg/kg bw/d]	I_{oral} = E_{oral} × AR_{oral}	3.1×10^{-3}	3.9×10^{-3}

Table 8: Calculated MRLs, HRs and STMRs for alpha-cypermethrin and input values for risk assessments

Groups and examples of individual products to which the MRLs apply	[mg/kg]	Cypermethrin MRLs (Reg. (EU) No 626/2017) [mg/kg]
Swine		
Muscle	0.051	2
Fat tissue	0.16	2
Liver	0.051	0.2
Kidney	0.051	0.2
Edible offals	0.051	0.2
Bovine		
Muscle	0.051	2
Fat tissue	0.064	2
Liver	0.051	0.2
Kidney	0.051	0.2
Edible offals	0.051	0.2
Poultry		
Muscle	0.051	0.1
Fat tissue	0.051	0.1
Liver	0.051	0.052
Kidney	0.051	0.052
Edible offals	0.051	0.052
Cattle		
Milk	0.011	0.05
Chicken		
Birds eggs	0.011	0.052

1 Indicates lower limit of detection
2 Indicated lower limit of analytical determination

Table 9: Dietary risk assessment using the EMA standard food basket and EU MRLs (Reg. (EU) No 626/2017) or residue levels derived from feeding studies as input parameters

Species	Commodity	Cypermethrin MRLs (Reg. (EU) No 626/2017) [mg/kg]	Consumption via EMA food basket [kg/person]	Residue consumed [mg/person]
Ruminants	Milk	0.05	1.5	0.075
	Meat	2	0.3	0.6
	Fat	2	0.05	0.1
	Liver	0.2	0.1	0.02
	Kidney	0.2	0.05	0.01

ADI		Total TMDI:	0.805
0.015	mg/kg bw	% ADI:	89.4%
0.9	mg/person (60 kg bw)		

Species	Commodity	Cypermethrin MRLs (Reg. (EU) No 626/2017) [mg/kg]	Consumption via EMA food basket [kg/person]	Residue consumed [mg/person]
Pigs	Meat	2	0.3	0.6
	Fat	2	0.05	0.1
	Liver	0.2	0.1	0.02
	Kidney	0.2	0.05	0.01

ADI		Total TMDI:	0.73
0.015	mg/kg bw	% ADI:	81.1%
0.9	mg/person (60 kg bw)		

Species	Commodity	Cypermethrin MRLs (Reg. (EU) No 626/2017) [mg/kg]	Consumption via EMA food basket [kg/person]	Residue consumed [mg/person]
Poultry	Egg	0.05	0.1	0.005
	Meat	0.1	0.3	0.03
	Fat	0.1	0.05	0.005
	Liver	0.05	0.1	0.005
	Kidney	0.05	0.05	0.0025

ADI		Total TMDI:	0.0475
0.015	mg/kg bw	% ADI:	5.3%
0.9	mg/person (60 kg bw)		

Species	Commodity	Cypermethrin MRLs (Reg. (EU) No 626/2017) [mg/kg]	Consumption via EMA food basket [kg/person]	Residue consumed [mg/person]
Ruminants	Milk	0.05	1.5	0.075
	Meat	2	0.3	0.6
	Fat	2	0.05	0.1
	Liver	0.2	0.1	0.02
	Kidney	0.2	0.05	0.01

ADI		Total TMDI:	0.805
0.015	mg/kg bw	% ADI:	89.4%
0.9	mg/person (60 kg bw)		

Species	Commodity	Cypermethrin MRLs (Reg. (EU) No 626/2017) [mg/kg]	Consumption via EMA food basket [kg/person]	Residue consumed [mg/person]
Pigs	Meat	2	0.3	0.6
	Fat	2	0.05	0.1
	Liver	0.2	0.1	0.02
	Kidney	0.2	0.05	0.01

ADI		Total TMDI:	0.73
0.015	mg/kg bw	% ADI:	81.1%
0.9	mg/person (60 kg bw)		

Species	Commodity	Cypermethrin MRLs (Reg. (EU) No 626/2017) [mg/kg]	Consumption via EMA food basket [kg/person]	Residue consumed [mg/person]
Poultry	Egg	0.05	0.1	0.005
	Meat	0.1	0.3	0.03
	Fat	0.1	0.05	0.005
	Liver	0.05	0.1	0.005
	Kidney	0.05	0.05	0.0025

ADI		Total TMDI:	0.0475
0.015	mg/kg bw	% ADI:	5.3%
0.9	mg/person (60 kg bw)		

Table 10: TMDI calculation for alpha-cypermethrin with PRIMo Model (Rev 2.0) using MRLs for the biocide uses submitted in this dossier

Alpha-cypermethrin			
Status of the active substance:	**Listed**	Code no.	
LOQ (mg/kg bw):	0.01 / 0.05	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0.015**	ARfD (mg/kg bw):	**0.04**
Source of ADI:	**EU**	Source of ARfD:	**EU**
Year of evaluation:	**2004**	Year of evaluation:	**2004**

Prepare workbook for refined calculations

Undo refined calculations

The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity the highest national MRL was identified (proposed temporary MRL = pTMRL).
The pTMRLs have been submitted to EFSA in September 2006.

Chronic risk assessment

TMDI (range) in % of ADI minimum - maximum	
	48
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)
48.1	NL child	20.8	Swine: Meat	15.9	Bovine: Meat	9.8	Milk and cream,	
41.5	ES child	18.9	Bovine: Meat	16.5	Swine: Meat	4.2	Milk and cream,	
36.3	FR toddler	17.9	Bovine: Meat	13.2	Milk and cream,	4.4	Swine: Meat	
35.0	WHO regional European diet	16.8	Swine: Meat	14.1	Bovine: Meat	1.6	Swine: Fat free of lean meat	
29.8	WHO Cluster diet F	15.4	Swine: Meat	12.0	Bovine: Meat	1.3	Milk and cream,	
25.4	WHO Cluster diet B	11.0	Bovine: Meat	10.3	Swine: Meat	1.1	Milk and cream,	
24.6	NL general	12.3	Swine: Meat	9.4	Bovine: Meat	2.2	Milk and cream,	
22.4	ES adult	10.0	Bovine: Meat	9.5	Swine: Meat	1.7	Milk and cream,	
21.5	WHO cluster diet E	9.4	Bovine: Meat	7.8	Swine: Meat	2.3	Swine: Fat free of lean meat	
19.6	LT adult	12.9	Swine: Meat	3.4	Bovine: Meat	1.7	Swine: Fat free of lean meat	
17.6	FR infant	8.6	Milk and cream,	7.7	Bovine: Meat	0.9	Swine: Meat	
15.6	DE child	5.8	Swine: Meat	4.8	Milk and cream,	4.5	Bovine: Meat	
13.5	UK Infant	12.9	Milk and cream,	0.4	Birds' eggs	0.1	Bovine: Liver	
13.4	WHO cluster diet D	8.0	Bovine: Meat	1.8	Swine: Meat	1.7	Milk and cream,	
12.9	IE adult	5.4	Bovine: Meat	5.3	Swine: Meat	0.9	Milk and cream,	
11.8	FR all population	6.7	Bovine: Meat	3.9	Swine: Meat	0.9	Milk and cream,	
9.4	DK adult	7.4	Bovine: Meat	1.8	Milk and cream,	0.1	Birds' eggs	
7.2	UK Toddler	6.9	Milk and cream,	0.3	Birds' eggs	0.0	Bovine: Liver	
4.7	DK child	4.2	Milk and cream,	0.3	Birds' eggs	0.2	Bovine: Liver	
4.4	SE general population 90th percentile	4.1	Milk and cream,	0.3	Birds' eggs		FRUIT (FRESH OR FROZEN)	
2.0	FI adult	1.9	Milk and cream,	0.1	Birds' eggs		FRUIT (FRESH OR FROZEN)	
1.2	UK vegetarian	1.1	Milk and cream,	0.1	Birds' eggs	0.0	Poultry: Meat	
1.1	UK Adult	1.0	Milk and cream,	0.1	Birds' eggs	0.0	Other bovine products	
	IT adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	IT adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	IT adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	IT adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Alpha-cypermethrin is unlikely to present a public health concern.

Table 11: TMDI calculation for alpha-cypermethrin with PRIMo Model (rev 2.0) using residues levels as derived from the animal feeding studies for the biocide uses submitted in this dossier

Alpha-cypermethrin			
Status of the active substance:	**Listed**	Code no.	
LOQ (mg/kg bw):	0.01 / 0.05	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0.015**	ARfD (mg/kg bw):	**0.04**
Source of ADI:	**EU**	Source of ARfD:	**EU**
Year of evaluation:	**2004**	Year of evaluation:	**2004**

Prepare workbook for refined calculations

Undo refined calculations

The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity the highest national MRL was identified (proposed temporary MRL = pTMRL).
The pTMRLs have been submitted to EFSA in September 2006.

Chronic risk assessment

TMDI (range) in % of ADI
minimum - maximum
4.0

No of diets exceeding ADI: ---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)
3.6	FR toddler	2.6	Milk and cream,	0.4	Bovine: Meat	0.3	Poultry: Meat	
3.3	NL child	2.0	Milk and cream,	0.5	Swine: Meat	0.4	Bovine: Meat	
2.7	UK Infant	2.6	Milk and cream,	0.1	Birds' eggs	0.0	Bovine: Liver	
2.3	ES child	0.8	Milk and cream,	0.5	Bovine: Meat	0.4	Poultry: Meat	
2.2	FR infant	1.7	Milk and cream,	0.2	Bovine: Meat	0.2	Poultry: Meat	
1.7	WHO regional European diet	0.4	Swine: Meat	0.4	Bovine: Meat	0.3	Milk and cream,	
1.5	DE child	1.0	Milk and cream,	0.2	Poultry: Meat	0.1	Swine: Meat	
1.4	UK Toddler	1.4	Milk and cream,	0.1	Birds' eggs	0.0	Bovine: Liver	
1.3	WHO Cluster diet B	0.3	Poultry: Meat	0.3	Bovine: Meat	0.3	Swine: Meat	
1.3	WHO cluster diet E	0.3	Poultry: Meat	0.2	Bovine: Meat	0.2	Milk and cream,	
1.2	WHO Cluster diet F	0.4	Swine: Meat	0.3	Bovine: Meat	0.3	Milk and cream,	
1.2	NL general	0.4	Milk and cream,	0.3	Swine: Meat	0.2	Bovine: Meat	
1.1	ES adult	0.3	Milk and cream,	0.2	Bovine: Meat	0.2	Swine: Meat	
0.9	LT adult	0.3	Swine: Meat	0.3	Milk and cream,	0.1	Swine: Fat free of lean meat	
0.9	DK child	0.8	Milk and cream,	0.1	Birds' eggs	0.0	Bovine: Liver	
0.9	WHO cluster diet D	0.3	Milk and cream,	0.2	Bovine: Meat	0.1	Poultry: Meat	
0.9	SE general population 90th percentile	0.8	Milk and cream,	0.1	Birds' eggs		FRUIT (FRESH OR FROZEN)	
0.9	IE adult	0.2	Other swine products	0.2	Milk and cream,	0.1	Bovine: Meat	
0.7	FR all population	0.2	Poultry: Meat	0.2	Milk and cream,	0.2	Bovine: Meat	
0.6	DK adult	0.4	Milk and cream,	0.2	Bovine: Meat	0.0	Birds' eggs	
0.4	FI adult	0.4	Milk and cream,	0.0	Birds' eggs		FRUIT (FRESH OR FROZEN)	
0.3	UK vegetarian	0.2	Milk and cream,	0.0	Birds' eggs	0.0	Poultry: Meat	
0.2	UK Adult	0.2	Milk and cream,	0.0	Birds' eggs	0.0	Other bovine products	
	IT adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	IT adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	IT adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	IT adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Alpha-cypermethrin is unlikely to present a public health concern.

Table 12: IESTRI calculation for the biocide uses

Acute risk assessment /children						Acute risk assessment / adults / general population					
The acute risk assessment is based on the ARfD.											
For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.											
In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used. In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variabilty factor of 3.											
Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100 % of the ARfD.											
Unprocessed commodities	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):**		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):**		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		---
	IESTI 1	*)	**)	**IESTI 2**	*)	**)	**IESTI 1**	*)	**)	**IESTI 2**	*)	**)
	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
	63.9	Bovine: Meat	2 / -	63.9	Bovine: Meat	2 / -	29.8	Bovine: Meat	2 / -	29.8	Bovine: Meat	2 / -
	42.4	Swine: Meat	2 / -	42.4	Swine: Meat	2 / -	25.0	Swine: Meat	2 / -	25.0	Swine: Meat	2 / -
	15.5	Milk and milk products:	0.05 / -	15.5	Milk and milk	0.05 / -	7.8	Goat: Meat	2 / -	7.8	Goat: Meat	2 / -
	10.3	Bovine: Fat	2 / -	10.3	Bovine: Fat	2 / -	7.1	Swine: Fat free of	2 / -	7.1	Swine: Fat free of lean meat	2 / -
	6.3	Swine: Fat free of lean	2 / -	6.3	Swine: Fat free of	2 / -	3.3	Bovine: Fat	2 / -	3.3	Bovine: Fat	2 / -

3.3 New information on the active substance

Not available

3.4 Residue behaviour

Not relevant

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

Not applicable. IUCLID file is available.

3.6 Confidential annex

See sepate file.

3.7 Study summaries of Chrionomus riparius spiked sediment studies with Fendona 6 SC and Fendona 1.5 SC

Chronic toxicity of BAS 310 27 I to Chir

Chronic toxicity of BAS 310 22 I to Chir