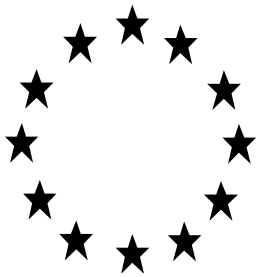
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

FINAL RISK ASSESSMENT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



PERTEX

Product type 18

Permethrin and Piperonyl Butoxide (PBO)

Case Number in R4BP: BC-JQ040667-19

Evaluating Competent Authority: Greece

Date: June 2021

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1 CONCLUSION

Conclusion for Physico-chemistry:

PERTEX is an Aqueous Microemulsion insecticide (PT 18), containing nominal (pure) active ingredient of 2.79 % w/w Permethrin and 0.05 % w/w Piperonyl Butoxide (PBO).

Its physicochemical properties are considered acceptable. A foaming issue was addressed with label implication and appropriate instructions for the preparation of the 2% solution of formulation PERTEX. For more information please refer to Table 2.2.2.

The product is not expected to have explosive or oxidising properties, nor to be self-heating or flammable; thus has no classification according to CLP criteria.

The product is stable for two years at ambient temperature when stored in HDPE or CoEx HDPE/EVOH packages (refer to acceptable accelerated and 2 years storage stability studies).

Acceptable analytical methods were provided for the determination of both active substances in the formulation.

Conclusion for Efficacy:

Several efficacy studies (laboratory, simulated use and field studies) were submitted for Pertex (aqueous microemulsion) containing permethrin 2.79 % and PBO 0.05%. Based on the results of the submitted efficacy studies, the product was effective when applied by professionals and trained professionals as:

- Surface treatment against ticks indoors by band application (Intended use 2).
- Surface treatment against ticks outdoors around building by band application (Intended use 4).
- Surface treatment against ticks indoors in animal houses/ shelters by band application (Intended use 6).

*Dose rate: 85.47 ml/ m^2 which corresponds to 1L for 11.7 m^2 of a 2 % solution v/v.

Equipment: low pump sprayer.

In the absence of a human or animal in the lab study to test tick biting behaviour before knock down and kill effect, the following limitation is proposed to be included in the PAR & SPC (specific instructions for use): "The product shall not be used in the presence of humans or animals. Humans and animals can re-enter into the treated area 24 hours after the product application".

The intended uses 1, 3 & 5 of the product, from an efficacy point of view, are not proposed to be authorized (for more details please refer to conclusion on efficacy of the product in 2.2.5.5. and 2.2.5.8).

Conclusion for Human Health:

Regarding health hazards the biocidal product PERTEX should be classified as a skin sensitizer category 1 (H317).

Regarding risk assessment, both the primary exposure of professional users and the secondary exposure of the general public do not entail unacceptable risks for human health.

Conclusion for Environment:

According to the environmental risk assessment, there is an acceptable risk for the STP, aquatic and terrestrial compartments for uses 1, 2, and 4 when following the label instructions of PERTEX ME.

USE 3 is NOT authorised (by guideline definition). Furthermore, there is an unacceptable risk for sediment dwelling organisms and for aquatic organisms in the Professional, Stable application, Flies scenario (scenario 5) when PERTEX ME is applied in grasslands, thus **USE 5 is NOT authorised in grasslands**. However, the use of PERTEX ME in arable lands is safe when it is ONLY applied in the animal sub-categories authorised, i.e., 1, 2, 3, 4, 5, 6, 7, 10, 13, 14, 15 (see Field of use, page 15).

For USE 6, there is an unacceptable risk for PERTEX ME to be used in animal housing when it is applied in the grasslands. However, an acceptable risk for PERTEX ME to be used in animal housing in arable lands, for non-target organisms, is demonstrated provided that label instructions are followed and PERTEX ME can **ONLY** be applied in the animal sub-categories authorised, i.e., 1, 2, 3, 4, 5, 6, 7, 10, 13, 14, 15 (see Field of use, page 17).

Strictly not to be used in stables/animal housings connected to a sewage treatment plant.

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)**
PERTEX	Greece

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Bleu Line S.r.l.
	Address	Via Virgilio, 28 - Z.I. Villanova 47122 Forlì (FC) Italy
Authorisation number		
Date of the authorisation		
Expiry date of the authorisation		

2.1.1.3 Manufacturer(s) of the products

Name of manufacturer	BLEU LINE S.r.l.
Address of manufacturer	Via Virgilio, 28, Z.I. Villanova 47122 Forlì (FC) Italy
Location of manufacturing sites	(1) BLEU LINE S.r.l, Via Tacito, 9, 20094 CORSICO (MI) Italy (2) FERBI S.r.l., viale 1° Maggio - C.da Ripoli, 64023 MOSCIANO S. ANGELO (TE) Italy (3) CHEMIA S.p.A., Via Statale, 327, 44047 DOSSO (FE) Italy

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

Active substance 1	Permethrin
Name of manufacturer	Tagros Chemicals India Private Ltd.
Namne of substance supplier according to art. 95	Limaru (acting for Tagros)
Address of manufacturer	No.72, Marshalls Road Jhaver Centre, IV floor, Rajah Annamalai Building Egmore Chennai 600008, India
Location of manufacturing sites	A-4/1&2, Sipcot Industrial Complex, Kudikadu, Cuddalore 607 005 Tamil Nadu

	India The address of the manufacturing plant for the active substance has been evaluated in the dossier for Permethrin PT18. The manufacturer of the active substance is the same.

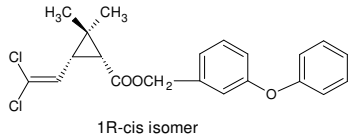
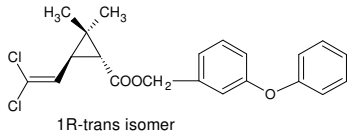
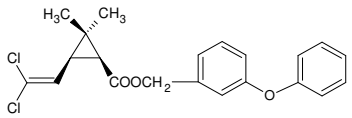
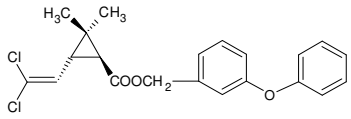
Active substance 2	Piperonyl Butoxide
Name of manufacturer	ENDURA S.P.A.
Address of manufacturer	Viale Pietramellara, 5 40121 Bologna Italy
Location of manufacturing sites	Via Baiona 107-111 48123 Ravenna Italy The address of the manufacturing plant for the active substance has been evaluated in the dossier for Piperonyl Butoxide PT18. The manufacturer of the active substance is the same. A statement on the postal code change of the manufacturing site is included in the IUCLID file.

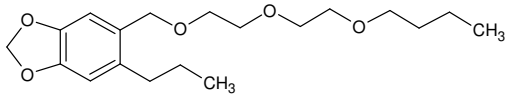
2.1.2 Product composition and formulation

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

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

Main constituents	
Active substance 1	
ISO name	Permethrin
IUPAC or EC name	(3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane-1-carboxylate
EC number	258-067-9
CAS number	52645-53-1
Index number in Annex VI of CLP	613-058-00-2
Minimum purity / content	93% w/w (ratio cis:trans 22-28:72-78) Permethrin is a reaction mass of four stereoisomers 1R-cis permethrin content = 5.0 – 10.0 % w/w 1S-cis permethrin content = 15.0 – 20.0 % w/w 1R-trans permethrin content = 45.0 – 55.0 % w/w 1S-trans permethrin content = 17.0 – 27.0 % w/w Content in the biocidal product: 3.0% w/w (technical) 2.79% w/w (pure, based on minimuim purity of 93% w/w)
Molecular formula	$C_{21}H_{20}Cl_2O_3$
Structural formula	 1R-cis isomer  1R-trans isomer  1S-cis isomer  1R-trans isomer
Molecular weight (g/mol)	391.29 g/mol
Active substance 2	
ISO name	Piperonyl Butoxide (PBO)
IUPAC or EC name	-[2-(2-butoxyethoxy)ethoxymethyl]-6-propyl-1,3-benzodioxole
EC number	200-076-7
CAS number	51-03-6
Index number in Annex VI of CLP	Not assigned
Minimum purity / content	94% w/w / 0.053 w/w (technical) - 0.05% w/w (pure, based on minimum purity of 94% w/w)
Molecular formula	$C_{19}H_{30}O_5$

Structural formula	
Molecular weight (g/mol)	338.43 g/mol

2.1.2.2 Candidate(s) for substitution

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

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

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

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (% w/w)**	**Content (g/L)****
Permethrin	(3-phenoxyphenyl) methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane-1-carboxylate	Active substance	52645-53-1	258-067-9	2.79* (pure) 3.0 (technical)	29.15 (pure) 31.34 (technical)
Piperonyl Butoxide (PBO)	-[2-(2-butoxyethoxy) ethoxymethyl]-6-propyl-1,3-benzodioxole	Active substance	51-03-6	200-076-7	0.05* (pure) 0.053 (technical)	0.52 (pure) 0.55 (technical)
Other components	Confidential information. Please refer to the confidential information annex at the end of the document				up to 100	Up to 1044.7

* based on minimum purity of 93% w/w and 94% w/w for permethrin and PBO respectively
** based on density of 1044.7 g/L at 20°C

2.1.2.4 Information on technical equivalence

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

The source of piperonyl butoxide in PERTEX biocidal formulation is Endura Spa, which supported PBO inclusion into Annex I of BPD. Thus, technical equivalence is not to be addressed.

2.1.2.5 Information on the substance(s) of concern

PERTEX contains no co-formulant that should be considered as a substance of concern (SoC). Please see the Confidential Annex for further details.

2.1.2.6 Type of formulation

ME – Aqueous Microemulsion

2.1.3 Hazard and precautionary statements

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

Classification	
Hazard category	Skin Sensitisation 1, Aquatic Acute 1, Aquatic Chronic 1
Hazard statement	H317: May cause an allergic skin reaction. H400: Very toxic to aquatic life H410: Very toxic to aquatic life with long lasting effects
Labelling	
Signal words	Warning
Hazard statements	H317: May cause an allergic skin reaction. H410: Very toxic to aquatic life with long lasting effects.
Precautionary statements	P101: If medical advice is needed, have product container or label at hand. P102: Keep out of reach of children. P261: Avoid breathing vapours and spray. P272: Contaminated work clothing should not be allowed out of the workplace. P273: Avoid release to the environment. P280: Wear protective gloves and protective clothing. P302+P352: IF ON SKIN: Wash with plenty of soap and water. P333+P313: If skin irritation or rash occurs: Get medical advice/attention. P362+P364: Take off contaminated clothing and wash it before reuse. P391: Collect spillage P501: Dispose of contents to collection points for hazardous or special waste.
Note	EUH401: To avoid risks to human health and the environment, comply with the instructions for use.

2.1.4 Authorised use(s)

2.1.4.1 Use description

Table 1. Use # 1 – Indoor – spraying on Flies **NOT AUTHORISED**

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	*Musca domestica* *Stomoxys calcitrans*
Field of use	Indoor Urban pest control (Domestic houses & Large/Industrial/ Commercial Buildings) in strictly dry cleaning areas
Application method(s)	Spraying as direct application
Application rate(s) and frequency	85.47 mL/m^2 correspond to 1 L for 11.7 m^2 of a 2% v/v dilution solution No limitation
Category(ies) of users	Trained professional Professional
Pack sizes and packaging material	Please see the relevant section.

2.1.4.2 Use-specific instructions for use

Apply through low pressure pump by direct application, with a final dilution of 2% v/v (2 L of concetrated product in 100 L of water).

1 L of product solution is indicated for about 11.7 m^2 of surface (85.47 mL/m^2).

Prepare the solution to be used, at the moment of use, add the concentrated product to the water (and not the water to the concentrated product) and mix the solution with a device (stirring rod) or shake gently for 15 sec before use in order to avoid the formation of foam.

The product **should only** be used in dry cleaning areas (for the domestic premises: cellars, attics, voids, crawl places, garages, while for the industrial premises-public buildings: commercial (industrial) warehouses that are NOT wet-cleaned and in rooms of electrical appliances).

2.1.4.3 Use-specific risk mitigation measures

During mixing/loading, perform the procedure on a floor covered with disposable plastic sheet.
Use disposable coveralls during application.
Perform dry cleaning of treated surfaces and adjacent floor.
Professionals: Wear protective coverall, protective gloves.

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

Refer to general direction of use

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

Refer to general direction of use

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

Refer to general direction of use

Table 2. Use # 2 – Surface treatment against ticks - Indoors

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	*Ixodes ricinus* adult
Field of use	Indoor Urban pest control (Domestic houses & Large/Industrial/ Commercial Buildings) in strictly dry cleaning areas
Application method(s)	Surface treatment by band application uniformly on the floor near the walls and on the walls at a maximum of 50 cm height with pump sprayer.
Application rate(s) and frequency	85.47 mL/ m^2 correspond to 1 L for 11.7 m^2 of a 2% v/v dilution solution Frequency of use: one application per month, if necessary
Category(ies) of users	Trained professional Professional
Pack sizes and packaging material	Please see the relevant section.

2.1.4.7 Use-specific instructions for use

Apply through low pressure pump to indoor porous and non-porous surface, with a final dilution of 2% v/v (2 L of concetrated product in 100 L of water) uniformly on the ground and on the walls at a maximum of 50 cm. 1 L of product solution is indicated for about 11.7 m^2 of surface (85.47 mL/m^2). Prepare the solution to be used, at the moment of use, add the concentrated product to the water (and not the water to the concentrated product) and mix the solution with a device (stirring rod) or shake gently for 15 sec before use in order to avoid the formation of foam. The product **should only** be used in dry cleaning areas (for the domestic premises: cellars, attics, voids, crawl places, garages, while for the industrial premises-public buildings: commercial (industrial) warehouses that are NOT wet-cleaned, and rooms of electrical appliances). The product shall not be used in the presence of humans or animals. Humans and animals can re-enter into the treated area 24 hours after the product application.

The product has no residual action against ticks and a single application does not protect humans and animals in case of re-infestation.

2.1.4.8 Use-specific risk mitigation measures

During mixing/loading, perform the procedure on a floor covered with disposable plastic sheet. Treated surfaces and adjacent floor shall be strictly dry cleaned. Professionals should wear protective coveralls and protective gloves.

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

Refer to general direction of use

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

Refer to general direction of use

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

Refer to general direction of use

Table 3. Use # 3 – Surface treatment against Tiger mosquitoes - Outdoors -**NOT AUTHORISED**

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	*Aedes albopictus* adult
Field of use	Outdoor
Application method(s)	Surface treatment on potted hedges in rural areas, covered with roof/tent.
Application rate(s) and frequency	85.47 mL/ m^2 correspond to 1 L for 11.7 m^2 of a 2% v/v dilution solution Frequency: 1 time per year
Category(ies) of users	Trained professional Professional
Pack sizes and packaging material	Please see the relevant section.

2.1.4.12 Use-specific instructions for use

Apply through low pressure pump on potted hedges in rural areas, covered with roof/tent, with a final dilution of 2% v/v (2 L of concetrated product in 100 L of water). 1 L of product solution is indicated for about 11.7 m^2 of surface (85.47 mL/).

Prepare the solution to be used, at the moment of use, add the concentrated pruduct to the water (and not the water to the concentrated product) and mix the solution with a device (stirring rod) or shake gently for 15 sec before use in order to avoid the formation of foam.

2.1.4.13 Use-specific risk mitigation measures

Apply only in area not directly connected with the STP.
Professionals: Wear protective coverall, protective gloves.

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

Refer to general direction of use

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

Refer to general direction of use

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

Refer to general direction of use

Table 4. Use # 4 – Surface treatment against ticks - Outdoors

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	*Ixodes ricinus* adult
Field of use	Outdoor, around buildings
Application method(s)	Surface treatment by band application uniformly on the floor near the walls and on the walls at a maximum of 50 cm height with pump sprayer.
Application rate(s) and frequency	85.47 mL/ m^2 correspond to 1 L for 11.7 m^2 of a 2% v/v dilution solution Frequency: 1 application per year
Category(ies) of users	Trained professional Professional
Pack sizes and packaging material	Please see the relevant section.

2.1.4.17 Use-specific instructions for use

Apply through low pressure pump around building, with a final dilution of 2% v/v (2 L of concetrated product in 100 L of water) uniformly on the ground and on the walls at a maximum of 50 cm.

1 L of product solution is indicated for about 11.7 m^2 of surface (85.47 mL/m2).

Prepare the solution to be used, at the moment of use, add the concentrated pruduct to the water (and not the water to the concentrated product) and mix the solution with a device (stirring rod) or shake gently for 15 sec before use in order to avoid the formation of foam. The product shall not be used in the presence of humans or animals. Humans and animals can re-enter into the treated area 24 hours after the product application. The product has no residual action against ticks and a single application does not protect humans and animals in case of re-infestation.

2.1.4.18 Use-specific risk mitigation measures

During mixing/loading, perform the procedure on a floor covered with disposable plastic sheet. Apply ONLY to roof-covered areas protected from flooding, rain fall or cleaning wash, where no release to sewer/STP is expected. Apply the product only during no rain events' Professionals should wear protective coveralls and protective gloves.

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

Refer to general direction of use

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

Refer to general direction of use

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

Refer to general direction of use

Table 5. Use # 5 –Rural Hygiene (Animal Houses/Shelters) – Flies- **NOT AUTHORISED**

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	*Musca domestica* *Stomoxys calcitrans*

Field of use	Indoors Rural Hygiene (Animal Houses/Shelters) With the frequency of 1 application per year the product can be used in the following animal house sub-categories: 1.Dairy cattle (housed during grazing season) 2.Beef cattle (housed during grazing season) 3.Veal calf 4.Sow-individual 5.Sow-group 6.Fattening pig 7.Laying hens in battery without treatment 10.Laying hens in compact battery cages 13.Laying hens in free range with grating floor 14.Parent broiler >18 weeks in free range with grating floor 15.Parent broiler in rearing with grating floor
Application method(s)	Spraying as direct application
Application rate(s) and frequency	85.47 mL/ m^2 correspond to 1 L for 11.7 m^2 of a 2% v/v dilution solution Frequency: 1 application per year
Category(ies) of users	Trained professional Professional
Pack sizes and packaging material	Please see the relevant section.

2.1.4.22 Use-specific instructions for use

Apply through low pressure pump by direct application, with a final dilution of 2% v/v (2 L of concetrated product in 100 L of water).

1 L of product solution is indicated for about 11.7 m^2 of surface (85.47 mL/m2).

Prepare the solution to be used, at the moment of use, add the concentrated pruduct to the water (and not the water to the concentrated product) and mix the solution with a device (stirring rod) or shake gently for 15 sec before use in order to avoid the formation of foam.

2.1.4.23 Use-specific risk mitigation measures

The product should be used without the presence of the animals or humans. Do not permit entrance of humans and animals in the treated area before 30 minutes.

Strictly NOT to be used in stables/animal housings connected to a sewage treatment plant (STP) and/or direct emissions to surface water cannot be prevented.

Only for application in animal housing (subcategories) authorised.

Professionals: Wear protective coverall, protective gloves

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

Refer to general direction of use

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

Refer to general direction of use

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

Refer to general direction of use

Table 6. Use # 6 – Rural Hygiene - Surface treatment against ticks in animal houses/ shelters – Indoors-

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	*Ixodes ricinus adult*
Field of use	Indoor Rural Hygiene (Animal Houses/Shelters) With the frequency of 1 application per year the product can be used in the following animal house sub-categories: 1.Dairy cattle (housed during grazing season) 2.Beef cattle (housed during grazing season) 3.Veal calf 4.Sow-individual 5.Sow-group 6.Fattening pig 7.Laying hens in battery without treatment 10.Laying hens in compact battery cages 13.Laying hens in free range with grating floor 14.Parent broiler >18 weeks in free range with grating floor 15.Parent broiler in rearing with grating floor
Application method(s)	Surface treatment by band application uniformly on the floor near the walls and on the walls at a maximum of 50 cm height with pump sprayer.
Application rate(s) and frequency	85.47 mL/m^2 correspond to 1 L for 11.7 m^2 of a 2% v/v dilution solution Frequency of use: one application per year
Category(ies) of users	Trained professional Professional
Pack sizes and packaging material	Please see the relevant section.

2.1.4.27 Use-specific instructions for use

Apply through low pressure pump to indoor porous and non-porous surface, with a final dilution of 2% v/v (2 L of concetrated product in 100 L of water) uniformly on the ground and on the walls at a maximum of 50 cm. 1 L of product solution is indicated for about 11.7 m^2 of surface (85.47 mL/m2).

Prepare the solution to be used, at the moment of use, add the concentrated product to the water (and not the water to the concentrated product) and mix the solution with a device (stirring rod) or shake gently for 15 sec before use in order to avoid the formation of foam.

The product shall not be used in the presence of humans or animals. Humans and animals can re-enter into the treated area 24 hours after the product application.

The product has no residual action against ticks and a single application does not protect humans and animals in case of re-infestation.

2.1.4.28 Use-specific risk mitigation measures

Strictly NOT to be used in stables/animal housings connected to a sewage treatment plant (STP) and/or direct emissions to surface water cannot be prevented.

Only for application in animal housing (subcategories) authorised.
Post product treatment, the manure produced in the treated animal housings is restricted for use only to arable lands (no grasslands).

Professionals should wear protective coveralls and protective gloves.

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

Refer to general direction of use

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

Refer to general direction of use

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

Refer to general direction of use

2.1.5 General directions for use

2.1.5.1 Instructions for use

Apply through low pressure pump to porous and non-porous surface, indoor and outdoor, with a final dilution of 2% v/v (2 L of concetrated product in 100 L of water).

1 L of product solution is indicated for about 11.7 m^2 of surface (85.47 mL/m^2).

Prepare the solution to be used, at the moment of use, add the concentrated product to the water (and not the water to the concentrated product) and mix the solution with a device (stirring rod) or shake gently for 15 sec before use in order to avoid the formation of foam.

When the product is applied indoors, it should be used in strictly NOT wet-cleaned areas (domestic premises: cellars, attics, voids, crawl places, garages; industrial premises-public buildings: commercial (industrial) warehouses that are NOT wet-cleaned, electrical appliances rooms).

For the outdoor uses, apply ONLY to roof-covered areas protected from flooding, rain fall or cleaning wash, where no release to sewer/STP is expected.

Strictly NOT to be used in stables/animal housings connected to a sewage treatment

plant (STP) and/or direct emissions to surface water cannot be prevented.

Do not use in a concentrated form.

Do not nebulizer in ambient air.

The product shall not be used in the presence of humans or animals. Humans and animals can re-enter into the treated area 24 hours after the product application.

The product has no residual action against ticks and a single application does not protect humans and animals in case of re-infestation.

Strategies for managing the development of resistance:

- Where possible, application treatments should be recommended to be combined with non-chemical measures.

- Product should always be used in accordance with label recommendations.

- Applications should always be made against the most susceptible stages in the pest life cycle.

- Where an extended period of control is required, treatments should be alternated with products with different modes of action.

- Levels of effectiveness should be monitored, and instances of reduced effectiveness should be investigated for possible evidence of resistance, noting that sanitary conditions and proximity of untreated refugia can contribute to the risk of re-infestation.

- In cases where label rates, correctly applied, fail to give the expected level of control and resistance is demonstrated, use of any product containing active substances with the same mode of action should cease.

- 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

During mixing/loading, perform the procedure on a floor covered with disposable plastic sheet.
Treated surfaces and adjacent floor shall be strictly dry cleaned.

The room must be sufficiently aerated before enter again.

After handling and in case of contamination wash thoroughly with soap and water.

Professionals should wear protective coveralls and protective gloves.

Move the animals away during the treatment.

Remove all food, feed and drinks from animal housing prior to biocidal treatment.

Remove any tool that may enter in contact with food/feedstuff during biocidal treatment.

Do not apply directly to surfaces and facilities likely to be in contact with food, feed, drinks and animals (surfaces where food is stored, prepared or consumed).

Cover all surfaces and facilities likely to be in contact with food, feed, drinks and animals before treatment to avoid any indirect contamination during nearby application.

Keep away from food/feed stuff, eating utensils or food/feed contact surfaces.

Clean the treated area before the re-entry of the animal.

The treated premises/room must not be accessible to pets, especially to cats due to high sensitivity to permethrin toxicity. Permethrin may be lethal to cats.

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

The product is very toxic to aquatic organisms with long lasting effects; can cause an allergic reaction due to permethrin.

Do not use in agriculture.

First aid instructions
IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.
IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.
IF ON SKIN: Take off contaminated clothing and wash it before reuse. Wash with plenty of soap and water.
If skin irritation or rash occurs: Get medical advice/attention.
IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Empty containers, unused product and other waste generated during the treatment, disposable plastic sheet and coveralls, 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.

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

Shelf life: 2 years

2.1.6 Other information

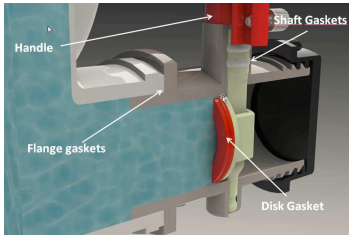
Not defined

2.1.7 Packaging of the biocidal product

Type of packaging	Size packaging	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 	50 ml	Diameter: 63,5 mm Height: 90,5 mm	Non transparent waterproof COEX (HDPE/EVOH)	HDPE screwcap.	Professional/ trained professional	Yes. Extrapolation can be made from bottle of 1000 g packaging size
	100 ml	Diameter: 63,5 mm Height: 90,5 mm				Yes. Extrapolation can be made from bottle of 1000 g packaging size
	150 ml	Diameter: 63,5 mm Height: 90,5 mm				Yes. Extrapolation can be made from bottle of 1000 g packaging size
	250 ml	Diameter: 62,5 mm Height: 126 mm				Yes. Extrapolation can be made from bottle of 1000 g packaging size
	500 ml	Diameter: 69 mm Height: 186 mm				Yes. Extrapolation can be made from bottle of 1000 g packaging size
	1000 ml	Diameter: 88,5 mm Height: 235 mm				**Yes. Based on data on storage stability test**

Type of packaging	Size packaging	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)
Jerrycan 	3 L	Lenght: 194 mm Width: 140 mm Height: 222 mm or Lenght: 193 mm Width: 112 mm Height: 255 mm	Non transparent waterproof HDPE	PE screwcap.	Professional/ trained professional	Yes. Extrapolation can be made from HDPE bottle of 1000 g packaging size as material of packaing is the same.
	5 L	Lenght: 190 mm Width: 153 mm Height: 268 mm				Yes. Extrapolation can be made from HDPE bottle of 1000 g packaging size as material of packaing is the same.
	10 L	Lenght: 235 mm Width: 196 mm Height: 323 mm				Yes. Extrapolation can be made from HDPE bottle of 1000 g packaging size as material of packaing is the same.
	20 L	Lenght: 296 mm Width: 246 mm Height: 380 mm				Yes. Extrapolation can be made from HDPE bottle of 1000 g packaging size as material of packaing is the same.
	25 L	Lenght: 296 mm Width: 246 mm Height: 445 mm				Yes. Extrapolation can be made from HDPE bottle of 1000 g packaging size as material of packaing is the same.

Type of packaging	Size packaging	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)
Drum 	200 L	Diameter: 581 mm height: 935 mm	Non transparent waterproof HDPE	PE screwcap.	Professional/ trained professional	Yes. Extrapolation can be made from HDPE bottle of 1000 g packaging size as material of packaing is the same.

Type of packaging	Size packaging	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)
Bulk  Closure: 	1000 L	Height: 1165 mm Base: 1000 x 1200 mm	Non transparent waterproof HDPE	Filling opening: 150 mm Closure: see image	Professional/ trained professional	Yes. Extrapolation can be made from HDPE bottle of 1000 g packaging size as material of packaing is the same.

All images are inserted for illustrative purposes. Colour can be different.

Conclusion on the packaging of the biocidal product
Accelerated storage stability test for 8 weeks at 40°C and 2 years shelf-life storage stability at ambient temperature demonstrated compatibility with the package materials HDPE and CoEx HDPE/EVOH (1L bottle). Extrapolation between different packaging size of the same material is acceptable. Therefore, the above mentioned proposed packagings are considered acceptable for commercial use.

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

The applicant Bleu line srl is not the owner of data on the active substances permethrin, as it is not the notifier which submitted the Annex II complete dossier to RMS Ireland.

The applicant Bleu line srl is not the owner of data on the active substance PBO as it is not the notifier which submitted the Annex II complete dossier to RMS Greece.

A full new product dossier was submitted by Bleu line srl in support of the product PERTEX containing permethrin and PBO, respectively.

A 10-year data protection (starting at the date of the registration in Greece) is claimed for the data submitted along with present dossier and summarised in the annex 3.1.

2.1.8.2 Access to documentation

The applicant Bleu line srl submit a letter of access by Limaru NV which cover the Annex II dossier of Tagros Chemicals India Ltd for all the data on the active substance permethrin in support for the registration of the product PERTEX containing permethrin.

The applicant Bleu line srl submit a letter of access by Endura Spa for all the data on the active substance PBO in support for the registration of the product PERTEX containing PBO.

2.2 ASSESSMENT OF THE BIOCIDAL PRODUCT

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

Table 7. Use # 1 – Indoor – spraying on Flies

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	*Musca domestica* *Stomoxys calcitrans*
Field of use	Indoor Urban pest control (Domestic houses & Large/Industrial/ Commercial Buildings) in dry cleaning areas
Application method(s)	Spraying as direct application
Application rate(s) and frequency	85.47 mL/m^2 correspond to 1 L for 11.7 m^2 of a 2% v/v dilution solution No limitation
Category(ies) of users	Trained professional Professional
Pack sizes and packaging material	Please see the relevant section.

Table 8. Use # 2 – Indoor spraying on tick

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	*Ixodes ricinus* adult
Field of use	Indoor Urban pest control (Domestic houses & Large/Industrial/ Commercial Buildings) in dry cleaning areas
Application method(s)	Spraying as general surface by narrow band application uniformly on the ground and on the walls at a maximum of 50 cm.
Application rate(s) and frequency	85.47 mL/ m^2 correspond to 1 L for 11.7 m^2 of a 2% v/v dilution solution No limitation
Category(ies) of users	Trained professional Professional

Pack sizes and packaging material	Please see the relevant section.

Table 9. Use # 3 – Outdoor – spraying on mosquitos insects

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	*Aedes albopictus* adult *Culex pipiens* adult
Field of use	Outdoor.
Application method(s)	Spraying on potted hedges in rural areas, covered with roof/tent.
Application rate(s) and frequency	85.47 mL/ m^2 correspond to 1 L for 11.7 m^2 of a 2% v/v dilution solution Frequency: 1 time per year
Category(ies) of users	Trained professional Professional
Pack sizes and packaging material	Please see the relevant section.

Table 10. Use # 4 – Outdoor – spraying tiks

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	*Ixodes ricinus* adult
Field of use	Outdoor, around building
Application method(s)	Spraying as general surface by narrow band application uniformly on the ground and on the walls at a maximum of 50 cm.
Application rate(s) and frequency	85.47 mL/ m^2 correspond to 1 L for 11.7 m^2 of a 2% v/v dilution solution Frequency: 1 time per year
Category(ies) of users	Trained professional Professional
Pack sizes and packaging material	Please see the relevant section.

Table 11. Use # 5 –Rural Hygiene (Animal Houses/Shelters) – Flies

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	*Musca domestica* *Stomoxys calcitrans*
Field of use	Indoor Rural Hygiene (Animal Houses/Shelters)
Application method(s)	Spraying as direct application
Application rate(s) and frequency	85.47 mL/ m^2 correspond to 1 L for 11.7 m^2 of a 2% v/v dilution solution For frequency of use, see the use-specific mitigation measures
Category(ies) of users	Trained professional Professional
Pack sizes and packaging material	Please see the relevant section.

Table 12. Use # 6 –Rural Hygiene (Animal Houses/Shelters) – Tick

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	*Ixodes ricinus adult*
Field of use	Indoor Rural Hygiene (Animal Houses/Shelters)
Application method(s)	Spraying as general surface by narrow band application uniformly on the ground and on the walls at a maximum of 50 cm
Application rate(s) and frequency	85.47 mL/m^2 correspond to 1 L for 11.7 m^2 of a 2% v/v dilution solution For frequency of use, see the use-specific mitigation measures
Category(ies) of users	Trained professional Professional
Pack sizes and packaging material	Please see the relevant section.

2.2.2 Physical, chemical and technical properties

Test item PERTEX (Batch no. 2234/F and 2436/F) has been used for all the submitted expermental test. Composition of the formualtion „PERTEX" is reported in the confidential section.

Pertex is an Aqueous Microemulsion insecticide (PT 18). The formulation is a colorless liquid with characteristic odour. The pH of undiluted liquid is 6.4 at 20°C and has a relative density 1.0447 at 20°C. The product is surface active since its surface tension is 36.1 mN/m. It has a dynamic viscosity 497 mPa*s at 20°C. Foaming problem was indicating, since foam was 84.7 in 1 min, thus additional instructions for preparation of Pertex 2% solution were submitted and labelling was applied.

The product is stable during the accelerated storage stability test and 24 months at ambient temperature, using commercial packaging for storage condition tests.

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	GLP	Reference	Acceptability
Physical state at 20 °C and 101.3 kPa	EPA OPPTS 830.6302	PERTEX Batch no. 2234/F Purity: Permethrin 2.67 (pure) PBO 0.048 (pure)	Liquid	Y	[redacted], 2018, CH-010/2018	**Acceptable**
Colour at 20 °C and 101.3 kPa	EPA OPPTS 830.6303	PERTEX Batch no. 2234/F Purity: Permethrin 2.67 (pure) PBO 0.048 (pure)	colourless	Y	[redacted], 2018, CH-010/2018	**Acceptable**
Odour at 20 °C and 101.3 kPa	EPA OPPTS 830.6304	PERTEX Batch no. 2234/F Purity: Permethrin 2.67 (pure) PBO 0.048 (pure)	Characteristic odour	Y	[redacted], 2018, CH-010/2018	**Acceptable**
pH	CIPAC MT 75	PERTEX Batch no. 2234/F Purity: Permethrin 2.67	5.6 at 20 °C (Conc 1% w/v)	Y	[redacted], 2018, CH-010/2018	**Acceptable**

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	GLP	Reference	Acceptability
		(pure) PBO 0.048 (pure) PERTEX Batch no. 2436/F Purity: Permethrin 2.76 (pure) PBO 0.05 (pure)	6.4 at 20 °C (undiluted)	Y	[redacted], 2020, CH-0367/2020	
Relative density (pycnometer)	CIPAC MT 3.2 OECD 109 EU Method A.3	PERTEX Batch no. 2234/F Purity: Permethrin 2.67 (pure) PBO 0.048 (pure)	1.0447 g/mL at 20°C	Y	[redacted], 2018, CH-010/2018	**Acceptable**
Storage stability test – **accelerated storage**	CIPAC MT 46.3	PERTEX Batch no. 2234/F Purity: Permethrin 2.67 (pure) PBO 0.048 (pure)	After 8 weeks at 40°C, the test item stored in its commercial packaging (COEX HDPE/EVOH and HDPE bottle) did not show any significant difference in terms of active ingredients content, pH, aspect, emulsion characteristic and pourability, respect the initial conditions. Thus the test item can be considered thermically stable. Summary results are provided in the following table. Accelerated storage stability test has been performed at reduce temperature due to the potential thermal stability of permethrin. However, on the same batch, additional data on the active ingredients content after storage at 54°C for 2 weeks in HDPE bottle is available and provided below:	Y N	[redacted], 2018, CH-014/2018 [redacted], 2017, 17679/17, 17680/17 and 17681/17	**Acceptable**

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	GLP	Reference	Acceptability
			<table><tr><td></td><td>T 0</td><td>T 2 weeks</td></tr><tr><td>Permethrin</td><td>2.67% w/w</td><td>2.63% w/w</td></tr><tr><td>PBO</td><td>0.048 % w/w</td><td>0.047 % w/w</td></tr></table> Data confirms that both active substances are thermally stable, thus no restriction on storage condition is proposed. **<u>Relevant impurities</u>:** No data submitted for the determination of relevant impurities before and after storage in PERTEX formulation. No relevant impurities have been identified for Permethrin on April 2014 Assessment Report. The following ten relevant impurities have been reported for PBO in June 2016 BPC Opinion, January 2017 Assessment Report and September 2019 final updated Assessment Report: Safrole: max. content <0.004% w/w Dihydrosafrole: max. content <0.0085% w/w Dipiperonyl methane: max. content 1.95% w/w Dipiperonyl ether: max. content 0.9%w/w Isosafrole: max. content <0.004% w/w Methyl dihydrosafrole: max. content 0.5%w/w Piperonyl Butoxide-x (Piperonyl Butoxide homologue): max. content 0.47 % w/w			

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	GLP	Reference	Acceptability
			ortho-Piperonyl Butoxide (Piperonyl Butoxide homologue): max. content 0.51 % w/w N,N-dimethylformamide: max.content <0.04%w/w Dichloromethane: max. content <0.05% w/w <u>No methods have been submitted in the CAR for the determination of any of the proposed relevant impurities in the formulation.</u> The WG members concluded that since the relevant impurities (except methyl dihydrosafrole) are not formed during storage, the methods for monitoring the relevant impurities in the biocidal product are not required under the BPR. Regarding methyl dihydrosafrole based on WG III (May 2016), it was decided that a justification or storage stability data must be submitted to prove that relevant impurity methyl dihydrosafrole is not formed during storage in the formulation (final AR September 2019). A statement is available from the manufacturer that methyl dihydrosafrole it is not formed during storage ([redacted], 2018). The relevant justification is attached below:			

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	GLP	Reference	Acceptability
			 PBO SCJ-Methyl DHS statement AT04 **RefMS**: No further data are required based on the data presented above.			
Storage stability test – **long term storage at ambient temperature**	EPA OPPTS 830.6313	PERTEX Batch no. 2234/F Purity: Permethrin 2.67 (pure) PBO 0.048 (pure)	After two years at ambient temperature, the test item stored in its commercial packaging (COEX HDPE/EVOH and HDPE) did not show any significant difference respect the initial conditions. Thus a shelf life of 2 years is proposed. Summary results are provided in the following tables. **RefMS:** Regarding relevant impurities refer to comment above on accelerated study.	Y	[redacted], 2018, CH-015/2018	**Acceptable**
Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3	PERTEX Batch no. 2234/F Purity: Permethrin 2.67 (pure) PBO 0.048 (pure)	The sample, after 7 days at 0 ± 2°C, did not showed separation of solid or liquid and no changes in its physical state. Thus the test item can be considered stable at low temperature	Y	[redacted], 2018, CH-010/2018	**Acceptable**
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Justification for non-submission of data	-	The formulation is contained in a closed not transparent bottle and no exposure with light is expected during storage and uses, thus the test is not performed. Please refer to the section 2.1.7.	-	-	**Acceptable**
Effects on content of the active substance and	CIPAC MT 46.3	PERTEX Batch no. 2234/F Purity:	No change in active ingredient content after storage for 8 weeks at 40°C was observed.	Y	[redacted], 2018, CH-014/2018	**Acceptable**

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	GLP	Reference	Acceptability
technical characteristics of the biocidal product – **temperature and humidity**		Permethrin 2.67 (pure) PBO 0.048 (pure)	No change in active ingredient content after storage for 2 weeks at 54°C was observed.	N	[redacted], 2017, 17679/17, 17680/17 and 17681/17	
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	CIPAC MT 46.3	PERTEX Batch no. 2234/F Purity: Permethrin 2.67 (pure) PBO 0.048 (pure)	No effects on container material was observed after storage for 8 weeks at 40°C and after storage for two years at ambient temperature.	Y	[redacted], 2018, CH-014/2018 & [redacted], 2018, CH-015/2018	**Acceptable**
Wettability	Justification for non-submission of data	-	The study does not need to be conducted because the formulation is liquid	-	-	**-**
Suspensibility, spontaneity and dispersion stability	Justification for non-submission of data	-	The study does not need to be conducted because the formulation is liquid	-	-	**-**
Wet sieve analysis and dry sieve test	Justification for non-submission of data	-	The study does not need to be conducted because the formulation is liquid	-	-	**-**
Emulsifiability, re-emulsifiability and emulsion stability	CIPAC MT 36.3	PERTEX Batch no. 2234/F Purity: Permethrin 2.67 (pure) PBO 0.048 (pure)	Complete initial emulsification of the 2% dilution (0h). Complete re-emulsification after 24h	Y	[redacted], 2018, CH-010/2018	**Acceptable**

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	GLP	Reference	Acceptability
Disintegration time	Justification for non-submission of data	-	The study does not need to be conducted because the formulation is liquid	-	-	-
Particle size distribution, content of dust/fines, attrition, friability	Justification for non-submission of data	-	The study does not need to be conducted because the formulation is liquid	-	-	-
Persistent foaming	CIPAC MT 47.2	PERTEX Batch no. 2234/F Purity: Permethrin 2.67 (pure) PBO 0.048 (pure)	The persistent foaming determined at the highest use rate of 2.0 % v/v after 1 minutes is 84.7 mL. After 3 minutes is 84.7 mL and 80.0 mL after 12 minutes. As the foam is higher than the trigger value the following instruction for use is included in the label: "*Prepare the solution to be used, add the concentrated product to the water (and not the water to the concentrated product) and mix the solution with a device (stirring rod) or shake gently for 15 sec before use in order to avoid the formation of foam*" Please refer to the additional document submitted, where is it showed that applying this procedure, no foam is formed and a safe mixing and loading can be granted. **RefMS**: A document is available from the manufacturer with the suggested procedure for the preparation of Pertex 2% solution in order to avoid the formation of foam ([redacted]; 2020). The	Y N	[redacted], 2018, CH-010/2018 [redacted], 2020	**Acceptable.** Since the foaming is above the trigger value of 60 mL in 1 min, labelling should be applied: **"*Prepare the solution to be used, add the concentrated product to the water (and not the water to the concentrated product) and mix the solution with a device (stirring rod) or shake gently for 15 sec before use in order to avoid the formation of foam*".**

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	GLP	Reference	Acceptability
			relevant document is attached below:  Pertex_foam issue.pdf No further data are required based on the data presented above.			
Flowability/Pourability/Dustability	CIPAC MT 148	PERTEX Batch no. 2234/F Purity: Permethrin 2.67 (pure) PBO 0.048 (pure)	Residue: 2.30 % Rinsed residue: 0.24%	Y	[redacted], 2018, CH-010/2018	**Acceptable**
Burning rate — smoke generators	Justification for non-submission of data	-	The study does not need to be conducted because the formulation is liquid	-	-	-
Burning completeness — smoke generators	Justification for non-submission of data	-	The study does not need to be conducted because the formulation is liquid	-	-	-
Composition of smoke — smoke generators	Justification for non-submission of data	-	The study does not need to be conducted because the formulation is liquid	-	-	-
Spraying pattern — aerosols	Justification for non-submission of data	-	The study does not need to be conducted because the formulation is liquid	-	-	-
Physical compatibility	Justification for non-submission of data	-	The formulation is not expected to be used with other product, thus the test is not required.	-	-	-
Chemical compatibility	Justification for non-	-	The formulation is not expected to be used with other product, thus the test is not	-	-	-

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	GLP	Reference	Acceptability
	submission of data		required.			
Degree of dissolution and dilution stability	Justification for non-submission of data	-	The study does not need to be conducted because the formulation is liquid	-	-	-
Surface tension	EU Method A.5 OECD 115 (ring method)	PERTEX Batch no. 2234/F Purity: Permethrin 2.67 (pure) PBO 0.048 (pure)	Undiluted test item at 20°C: 36.1 mN/m 2% v/v water at 20°C: 38.6 mN/m.	Y	[redacted], 2018, CH-010/2018	**Acceptable** The product is surface active since its surface-tension is lower than 60 mN/m.
Viscosity	OECD Guideline 114 CIPAC MT 192 (rotasional viscometer)	PERTEX Batch no. 2234/F Purity: Permethrin 2.67 (pure) PBO 0.048 (pure)	Kinematic viscosity At 20°C: 476 cSt (mm^2/s) At 40°C: 169 cSt (mm^2/s) Dynamic viscosity At 20°C: 497 cP (mPa*s) At 40°C: 177 cP (mPa*s)	Y	[redacted], 2018, CH-010/2018	**Acceptable**

Detailed results of storage stability test for the HDPE COEX bottle

Property	**Method**	**Results before storage**	**Results after storage (8w at 40°C (CH-014/2018)**	**Results after storage (2y at room temperature (CH-015/2018)**
Permethrin (%)	No. 012/2018	2.70	2.68(+0.7% variation)	2.77 (+2.6% variation)
Cis-permethrin (%)	No. 012/2018	0.68	0.68 (+0% variation)	0.73 (+7.4% variation)
Trans-permethrin (%)	No. 012/2018	2.01	2.01 (+0% variation)	2.02 (+0.5% variation)
PBO (%)	No. 013/2018	0.050	0.051 (+2% variation)	0.052 (+ 4% variation)
Appearance	*EPA OPPTS 830.6302, 830.6303, 830.6304*	Colourless liquid with characteristic odour	Colourless liquid with characteristic odour	Colourless liquid with characteristic odour
pH	CIPAC MT 75.3 *OECD 122*	5.6 (1% w/v aqueous dilution)	5.6 (1% w/v aqueous dilution)	6.2 (1% w/v aqueous dilution) 5.8 (net item)
Emulsion characteristics and re-emulsification properties	CIPAC MT 36.3 and MT 18 (using Standard Water D)	Complete initial emulsification (0h) complete emulsification (24h) for both application rates	-	Complete initial emulsification (0h) complete emulsification (24h) for both application rates
Pourability	CIPAC MT 148	2.30 % as residue 0.24 % as rinsed residue	2.43 % as residue 0.24 % as rinsed residue	2.53 % as residue 0.24 % as rinsed residue
Stability of packaging	-	The container didn't present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena	The container didn't present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena	The container didn't present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena
Weight variation (%)	-	-	-0.02%	0.00%

Detailed results of storage stability test for the HDPE bottle

Property	Method	Results before storage	Results after storage (8w at 40°C (CH-014/2018)	Results after storage (2y at room temperature (CH-015/2018)
Permethrin (%)	No. 012/2018	2.70	2.72 (+0.7% variation)	2.78 (+2.9% variation)
Cis-permethrin (%)	No. 012/2018	0.68	0.68 (+0% variation)	0.73 (+7.4% variation)
Trans-permethrin (%)	No. 012/2018	2.01	2.04 (+1.5% variation)	2.02 (+0.5% variation)
PBO (%)	No. 013/2018	0.050	0.050 (+0% variation)	0.053 (+ 5.8 % variation)
Appearance	*EPA OPPTS 830.6302, 830.6303, 830.6304*	Colourless liquid with characteristic odour	White powder (microgranules) with characteristic odour	Colourless liquid with characteristic odour
pH	CIPAC MT 75.3 *OECD 122*	5.6 (1% w/v aqueous dilution) 6.4 (net item)*	-	4.7 (1% w/v aqueous dilution) 5.4 (net item)
Emulsion characteristics and re-emulsification properties	CIPAC MT 36.3 and MT 18 (using Standard Water D)	Complete initial emulsification (0h) complete emulsification (24h) for both application rates	-	Complete initial emulsification (0h) complete emulsification (24h) for both application rates
Stability of packaging	-	The container didn't present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena	The container didn't present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena	The container didn't present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena
Weight variation (%)	-	-	-0.02%	0.00%

*Study performed on different lot no. (Report no. CH0367/2020)

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

Physical-chemical properties:

The preparation is a colourless liquid with characteristic odour, containing 2.79 and 0.05 % w/w of permethrin and PBO, respectively. Its density is 1.0447 g/mL. When dispersed at 1% in water, it has a pH of 5.6 and 6.4 for neat formulation. The product is surface active since its surface tension is 36.1 mN/m. It has a dynamic viscosity 497 mPa*s at 20°C. Its emulsion characteristics and pourability are acceptable.

The persistent foaming is higher than the trigger value (84.7mL foam in 1 min), thus the following instruction for use is included in the label:**"Prepare the solution to be used, adding the concentrated product to the water (and not the water to the concentrated**

product) and mixing the solution (not shake) before using in order to avoid the formation of foam"

Storage stability:

There is no effect at high and low temperature on the stability of the formulation. After storage at 40°C for 8 weeks and after storage for 2 years at ambient temperature, the test item did not show any significant difference in terms of active ingredient content and technical characteristis, respect the initial conditions. Additional data on storage at 54°C for 2 weeks is available and show that the active ingredients content does not significantly change respect the initial conditions. Thus no limitation on the storage condition and a shelf life of 2 years are proposed.

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.

2.2.3 Physical hazards and respective characteristics

Test item PERTEX (Batch no. 2234/F and 2436/F) has been used for all the submitted expermental test. Composition of the formualtion „PERTEX" is reported in the confidential section.

The product is not expected to have explosive or oxidising properties, nor to be self-heating or flammable; thus has no classification according to CLP criteria.

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	GLP	Reference	Acceptability
Explosives	Manual of Tests and Criteria ST/SG/AC.10/11/Rev. 5 – Part III, Appendix 6, Section 3.	PERTEX Batch no. 2436/F Purity: Permethrin 2.76 (pure) PBO 0.05 (pure)	DCS screening: Total exothermic picks is 160.751 J/g, which is below the trigger value of 300 J/g. Thus the formulation is not candidate for classification as explosive.	N	[redacted], 2020, CH-0200/2020	**Acceptable**
Flammable gases	Justification for non-submission of data	-	The study does not need to be conducted because the formulation is liquid	-	-	**-**
Flammable aerosols	Justification for non-submission of data	-	The study does not need to be conducted because the formulation is not an aerosol	-	-	**-**
Oxidising gases	Justification for non-submission of data	-	The study does not need to be conducted because the formulation is liquid	-	-	**-**
Gases under pressure	Justification for non-submission of data	-	The study does not need to be conducted because the formulation is liquid	-	-	**-**
Flammable liquids	EU Method A.9	PERTEX Batch no. 2234/F Purity: Permethrin 2.67 (pure) PBO 0.048 (pure)	No typical flammability phenomena was observed up to 130°C. Thus the preparation is classified as non Flammable.	Y	[redacted], 2018, CH-010/2018	**Acceptable**
Flammable solids	Justification for non-submission of data	-	The study does not need to be conducted because the formulation is liquid	-	-	**-**

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	GLP	Reference	Acceptability
Self-reactive substances and mixtures	Manual of Tests and Criteria ST/SG/AC.10/11/Rev. 5 – Part III, Appendix 6, Section 3.	PERTEX Batch no. 2436/F Purity: Permethrin 2.76 (pure) PBO 0.05 (pure)	DCS screening: Total exothermic picks are 160.751 J/g, which is below the trigger value of 300 J/g. Thus the formulation is not candidate for classification as self-reactive.	N	[redacted], 2020, CH-0200/2020	**Acceptable**
Pyrophoric liquids	Justification for non-submission of data	-	The study does not need to be conducted because there are no chemicals groups present in the molecule which are associated with explosive or self-reactive properties and hence, the classification procedure does not need to be applied.	-	-	**-**
Pyrophoric solids	Justification for non-submission of data	-	The study does not need to be conducted because the formulation is liquid	-	-	**-**
Self-heating substances and mixtures	Justification for non-submission of data	-	The study does not need to be conducted because the formulation is liquid	-	-	**-**
Substances and mixtures which in contact with water emit flammable gases	Justification for non-submission of data	-	The study does not need to be conducted because none of the components is expected to emit flammable gases when they are in contact with water.	-	-	**-**

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	GLP	Reference	Acceptability
Oxidising liquids	Justification for non-submission of data	-	According to the UN Recommendations of the Transport of Dangerous Goods, Manual of Tests and Criteria, Section 34.4.1, UN Test O.1, Appendix 6, test is not required if the substance does not contain oxygen, fluorine or chlorine, or if these elements are present but bonded only to carbon or hydrogen. Based on the structural formula, none of the components does not contain fluorine or chlorine and the oxygen is bonded only to carbon or hydrogen. Thus test is not required and PERTEX should not be considered as oxidizer.	-	-	**Acceptable**
Oxidising solids	Justification for non-submission of data	-	The study does not need to be conducted because the formulation is liquid	-	-	**-**
Organic peroxides	Justification for non-submission of data	-	The study does not need to be conducted because none of the components does not fall under the definition of organic peroxides according to GHS and the relevant UN Manual tests and criteria.	-	-	**-**

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	GLP	Reference	Acceptability
Corrosive to metals	Justification for non-submission of data	-	None of the component are classified as corrosive to metals. No acidic or basic groups, halogens or substances form complexes with metals are present in the formulation. The pH of the undiluted product is neutral. Thus, according to the ECHA guidance, the test is not considered required and the formulation should not be classified as corrosive.	-	-	**Acceptable**
Auto-ignition temperatures of products (liquids and gases)	EU Method A.15 (closed cup method)	PERTEX Batch no. 2234/F Purity: Permethrin 2.67 (pure) PBO 0.048 (pure)	364°C	Y	[redacted], 2018, CH-010/2018	**Acceptable**
Relative self-ignition temperature for solids	Justification for non-submission of data	-	The study does not need to be conducted because the formulation is liquid	-	-	**-**
Dust explosion hazard	Justification for non-submission of data	-	The study does not need to be conducted because the formulation is liquid	-	-	**-**

Conclusion on the physical hazards and respective characteristics of the product
The safety relevant physico-chemical properties of the biocidal product have been evaluated.
The product is not expected to have explosive or oxidising properties, nor to be self-igniting or flammable.
The product is not classified according to ECHA Guidance on the Application of the CLP criteria Version 5.0 July 2017.

2.2.4 Methods for detection and identification

Permethrin
The methods for the analysis of permethirn residues in soil, air and water by HPLC-MS, have been acceptably validated and regarded to be sufficiently sensitive with respect to the levels of concern.
No analytical methods for the determination of residues of permethrin on body fluids and tissues are available as the molecule does not classify as toxic or highly toxic.
No analytical method are required for the determination of residue of permethrin in food/feed of plant/animal origin as the proposed used are not intend to be in contact with any food and feeding stuff.

A summary of all these methods is reported in the Assessment Report (AR) on Permethrin (PT 18) prepared by the RMS-Ireland (April 2014). Access to these data is granted to Blu Line S.r.l. by LIMARU NV, which covers the complete Tagros Chemicals India Ltd dossier.

PBO
The methods for the analysis of PBO residues in soil, air and water by HPLC-MS or GC-MS, have been acceptably validated and regarded to be sufficiently sensitive with respect to the levels of concern.
No analytical methods for the determination of residues of PBO on body fluids and tissues are available as the molecule does not classify as toxic or highly toxic.
No analytical method are required for the determination of residue of PBO in food/feed of plant/animal origin as the proposed used are not intend to be in contact with any food and feeding stuff.

A summary of all these methods is reported in the Assessment Report (AR) on PBO (PT 18) prepared by the RMS-Greece (January 2017). Access to these data is granted to Bleu Line S.r.l. by Endura S.p.A. LoA.

Analytical methods for soil									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Permethrin	HPLC-MS/MS	No information reported in the AR, April 2014						5.0 µg/kg	AR, April 2014
PBO	HPLC-MS	No information reported in the AR, January 2017						0.05 mg/kg	AR, January 2017

Analytical methods for air									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Permethrin	HPLC-MS/MS	No information reported in the AR, April 2014						5.00 µg/m^3 (Sumitomo) 0.1 µg/m^3 (Tagros)	AR, April 2014

Analytical methods for air								
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
PBO	GC-MS	No information reported in the AR, January 2017						5.83 µg/m^3	AR, January 2017

Analytical methods for drinking water								
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Permethrin	HPLC-MS/MS	No information reported in the AR, April 2014						0.05 µg/L	AR, April 2014
PBO	HPLC-MS/MS	No information reported in the AR, January 2017						0.1 µg/L	AR, January 2017

Analytical methods for ground water								
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Permethrin	HPLC-MS/MS	No information reported in the AR, April 2014						0.05 µg/L	AR, April 2014
PBO	HPLC-MS/MS	No information reported in the AR, January 2017						0.1 µg/L	AR, January 2017

Analytical methods for surface water								
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Permethrin	HPLC-MS/MS	No information reported in the AR, April 2014						0.05 µg/L	AR, April 2014
PBO	HPLC-MS/MS	No information reported in the AR, January 2017						0.1 µg/L	AR, January 2017

2.2.4.1 Formulation analysis

The identification and quantification of permethrin and PBO in the formulated product PERTEX (Batch no. 2234/F) is performed by HPLC/UV methods. The method meet the requirements provided by SANCO/3030/99 rev. 4. Validation data are summarized as follow.

Analytical methods for active ingredient in formulation									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**		**Repeatability (%)**		**Reference**
					Range	Mean	RSD	Horwits	
Permethrin	HPLC-UV	80 %, 100 % and 120 % of the nominal concentration of active ingredieng / 6	12.16 to 109.48 µg/mL r2 = 0.99988 Y=271858+2048 (n=5)	yes	99.41 – 101.72	100.3	1.13	2.31 at 2.70 % w/w	[redacted], 2018, CH-012/2018
Permethrin Cis isomer	HPLC-UV	80 %, 100 % and 120 % of the nominal concentration of active ingredieng / 6	4.80 to 43.19 µg/mL r2 = 0.99991 Y=269468-1220 (n=5)	Yes	97.78 – 100.23	98.9	1.19	2.84 at 0.68 % w/w	
Permethrin Trans isomer	HPLC-UV	80 %, 100 % and 120 % of the nominal concentration of active ingrediend / 6	7.37 to 66.29 µg/mL r2 = 0.99985 Y=273416+3268 (n=5)	Yes	99.28 – 102.06	100.6	2.01	2.41 at 2.01 % w/w	
PBO	HPLC-UV	80 %, 100 % and 120 % of the nominal concentration of active ingredieng / 6	30.47 to 71.09 µg/mL r2 = 0.99518 Y=53640+19415 (n=5)	Yes	99.90 – 109.84	105.5	1.86	4.20 at 0.050 % w/w	[redacted], 2018, CH-013/2018

- **PERMETHRIN**

Scope

This method (study CH-012/2018) is applicable to the quantitative determination of Permethrin active ingredient in PERTEX formulation samples. The method has been validated by the analysis of reference material and test item solution.

Principle of the method

The determination o fthe Permethrin is performedby HPLC, using an external standard and UV detection. The quantification of Permethrin is achieved by comparing each analytical standard peak area versus each active ingredient peak area in formulation. The validated method in study CH-012/2018 is able to separate each enantiomer with test solution (relevant chromatograms are available).

Preparation of the formulation solution
Using the analytical balance, weigh about 1100 mg of the test item 50.00 mL volumetric flask and make to volume with 2-propanol. Place the solution into ultrasonic bath for 5 minutes and then dilute the solution transferring 1.00 mL into 10.00 mL conical flask and making up to volume with eluent. Finally transfer an aliquot into a vial for the HPLC/UV analysis.

Chromatographic conditions
HPLC column: CHIRALPAK IB, 250 × 4.6 mm i.d., 5 µm
Detector: UV/Vis operating at 230 nm
Column temperature: 22°C
Eluent A: n-Heptane/tert-butyl methyl ether (98:2)
Isocratic: 100% of Eluent A
Eluent flow:1.00 mL/min
Volume of injection:10 µL
R. T. Permethrin Cis I : about 17.0 minutes
R. T. Permethrin Cis II : about 20.4 minutes
R. T. Permethrin Trans I : about 24.3 minutes
R. T. Permethrin Trans II : about 27.3 minutes
Total Analysis Time:40 minutes

Conclusions
The analitycial method tested was found to be validated according to the SANCO guideline, therefore it is considered acceptable for the determination of the active substance permethrin in the test material PERTEX.

cis:trans ratio: 25:75
*R:S (or S:R) ratio: cis isomer pair of 1.7 and trans isomer pair of 1.65

*The estimation of the ratio between R and S enantiomers which is widely used in practice to determine the enatio exess value (ee%) of chiral compound based on the HPLC peak area shown in chromatograms. Referring to two chromatogram, it can be calculated to have a R:S (or S:R) ratio of *cis* isomer pair of 1.7 and for *trans* pair of 1.65.

- **PBO**

Scope
This method (study CH-013/2018) is applicable to the quantitative determination of PBO active ingredient in PERTEX formulation samples. The method has been validated by the analysis of reference material and test item solution.

Principle of the method
The determination o fthe Permethrin is performedby HPLC, using an external standard and UV detection. The quantification of Piperonyl butoxide (PBO) is achieved by comparing the ratio of the reference material peak area versus Ethyl benzoate internal standard peak area and the same ratio determined for a sample containing a known amount of internal standard (relevant chromatograms are available).

Preparation of the formulation solution
Using the analytical balance, weigh about 1000 mg of the test item and add, using a volumetric pipette, 0.50 mL of the stock internal standard solution into a 10 mL conical flask. Add 9.5 mL of acetonitrile and place the solution into ultrasonic bath for 5 minutes. Finally transfer an aliquot into a vial for the HPLC/UV analysis.

Chromatographic conditions
HPLC column: Ascentis Phenyl, 250 × 4.6 mm i.d., 5 µm
Detector: UV/Vis operating at 251 nm
Column temperature: 23°C
Eluent A : Water
Eluent B : Acetonitrile

Eluent D : Phosphoric acid at 1% v/v
Gradient : from A:B:D: 20:70:10 to A:B:D: 0:90:10 in 25 minutes
from A:B:D: 0:90:10 to A:B:D: 20:70:10 in 1 minute
A:B:D: 20:70:10 for 4 minutes
Eluent flow:0.6 mL/min
Volume of injection:10 µL
R. T. Ethyl benzoate : about 8.1 minutes
R. T. Piperonyl butoxide : about 12.1 minutes
Total Analysis Time:30 minutes

Conclusions
The analitycial method tested was found to be validated according to the SANCO guideline, therefore it is considered acceptable for the determination of the active substance PBO in the test material PERTEX.

Conclusion on the methods for detection and identification of the product

Acceptable validated analytical methods are available for detection of permethrin and piperonyl butoxide in soil, air and water reported in the CAR documents for permethrin (Ireland, 2014) and piperonyl butoxide (Greece, 2017).

The HPLC-UV analytical methods was found to be valid in terms of linearity, precision, accuracy in accordance with ECHA guidance, for the determination of permethrin and Piperonyl Butoxide, in PERTEX formulation. The analytical method for Permethrin is able to separate cis and trans isomers of permethrin.

Analytical methods for the determination of methyl dihydrosafrole, relevant impurity is not required since a waiving statement is provided. Please refer above on accelerated storage.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

PERTEX is an insecticide used indoors and outdoors, for surface treatment against ticks. All uses can be summarized as follow:

- Surface treatment against ticks indoors.
- Surface treatment against ticks outdoors, around building.
- Rural Hygiene - Surface treatment against ticks in animal houses/ shelters (indoors).

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

Efficacy of PERTEX has been determined in knock-down and killing activity against *Ixodes ricinus.*

2.2.5.3 Effects on target organisms, including unacceptable suffering

Efficacy of PERTEX has been determined by the observation of these effects:

- knock-down effect
- killing effect
- population reduction

2.2.5.4 Mode of action, including time delay

Permethrin

According to the permethrin's CAR, permethrin is a contact insecticide which causes convulsions, paralysis and ultimately death in target organisms. It is a type I axonic poison which exerts its effects by means of hyperexcitation of both the peripheral and central nervous systems of target insects. Its effects are characterised by progressive fine whole body tremor, exaggerated start response, uncoordinated muscle twitching and hyperexcitability. Permethrin also induces hepatic microsomal enzymes. Pyrethroids act on the insect nervous system by slowing action potential decay and thereby initiating repetitive discharges in motor and sensory axons. Electrophysiological studies have suggested that these phenomena result from modification of the gating kinetics of neuronal, voltage-sensitive Na channels. Single channel studies have been conducted which have shown that pyrethroids slow the kinetics of opening and closing of Na channels. Pyrethroids show high potency and selectivity for insects over mammals. The negative temperature dependence of pyrethroid action is partly responsible for the low mammalian toxicity of these compounds. Type 1 pyrethroids produce a distinct poisoning syndrome characterised by progressive fine whole body tremor, exaggerated start response, uncoordinated muscle twitching and hyperexcitability. The effects are generated largely by effects in the central nervous system. Permethrin also induces hepatic microsomal enzymes. It should also be noted that permethrin may also exhibit a mild contact repellent effect in conjunction with the insecticidal effect. This contact repellence effect is also common to other pyrethroid insecticides (such as deltamethrin, cypermethrin, esfenvalerate and lamda-cyhalothrin) and is known as the "hot-foot effect" and may be relevant for some arthropods. The repellent effect is dose related and for insecticidal products the repellent effect of permethrin is considered as a side effect, since the toxic response of the insect is a delayed kill (insecticidal) effect.

Piperonyl Butoxide

According to the PBO's CAR, its mode of action is complex. Piperonyl Butoxide stabilises the co-applied insecticide inside the insect body and potentiates more toxins to reach their target molecules. This results in an increased mortality of the target organism, and likewise, the same effect may be observed by using decreased amounts of insecticide, i.e. synergism. There is strong evidence from the literature, that Piperonyl Butoxide inhibits the oxidative and esterase-based metabolism (detoxyfication) of the co-applied insecticide.
Therefore, Piperonyl Butoxide delays the degradation of co-applied insecticidal substances and thereby prolongs the potential action of the compounds.

According to the literature Piperonyl Butoxide is usually applied at a dose that on its own is sublethal to the target species. When Piperonyl Butoxide is applied in combination with a known toxicant, the performance of the latter is enhanced at a rate that becomes lethal when on its own would be sublethal. Nevertheless, Piperonyl Butoxide on its own can exhibit some toxic effects, and hence at sublethal doses is likely to exert some stress on the insect.

2.2.5.5 Efficacy data

Experimental data on the efficacy of the biocidal product against target organism(s)					
Test substance	**Test organism**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Permethrin 2.79 gr PBO 0.05 gr (Microemulsion) (Pertex)	*Aedes albopictus* Development stage: Female adults Laboratory strain	Laboratory test	Laboratory conditions. No-choice test. The product is applied in different porous (marble tiles) and non-porous surfaces (ceramic tiles), which measured 20cm x 20cm, at a dose of 85.47 ml per 1m^2 of a 2 % solution with a micropipette and the product was then smeared on the whole surface with a plastic brush. Once the surfaces were dry 20 adult female mosquitoes were forced to stay in contact with the treated surfaces (under WHO cones) for 30 minutes the ones who were placed to the non porous surfaces and for 60 minutes the ones who were placed to the porous surfaces. The insects were then transferred to untreated healthy environment to observe knockdown and mortality up to 24 hours. Assessments of knockdown and/or killing effect were performed up to 30 minutes after exposure for the tests which conducted with non-porous surfaces and up to 60 minutes after exposure for the tests which conducted with porous surfaces. Mortality was recorded 24 hours later. The tests were conducted after treatment and repeated with the treated tiles stored for 1 week to measure the residual effect. Untreated control was included. 5 replicates were conducted.	In all types of surfaces (porous and non-porous) knock down was 100% in 10-20 minutes and mortality was 100% after 24 hours, for fresh and 1 week deposits. Mortality in untreated control: 0%.	[redacted], 2017 Report no. BLEPER290917 – 01 **Trial 1**
Permethrin 2.79 gr PBO 0.05 gr (Microemulsion) (Pertex)	*Culex pipiens* Development stage: Female adults Laboratory strain	Laboratory test	Laboratory conditions. No-choice test. The product is applied in different porous (marble tiles) and non-porous surfaces (ceramic tiles), which measured 20cm x 20cm , at a dose of 85.47 ml per 1m^2 of a 2 % solution with a micropipette and the product was then smeared on the whole surface with a plastic brush. Once the surfaces were dry 20 adult female mosquitoes were forced to stay in contact with the treated surfaces (under WHO	In all types of surfaces (porous and non-porous) knock down was 100% in 20-40 minutes and mortality was 100% after 24 hours. Mortality in untreated control: 0%.	[redacted], 2017 Report no. BLEPER290917 – 02 **Trial 2**

			cones) for 30 minutes the ones who were placed to the non porous surfaces and for 60 minutes the ones who were placed to the porous surfaces. The insects were then transferred to untreated healthy environment to observe knockdown and mortality up to 24 hours. Assessments of knockdown and/or killing effect were performed up to 30 minutes after exposure for the tests which conducted with non-porous surfaces and up to 60 minutes after exposure for the tests which conducted with porous surfaces. Mortality was recorded 24 hours later. Untreated control was included. 5 replicates were conducted.		
Permethrin 2.79 gr PBO 0.05 gr (Microemulsion) (Pertex)	*Ixodes ricinus* Development stage: Adults Laboratory strain	Laboratory test	Laboratory conditions. No-choice test. The product is applied in different porous (marble tiles) and non-porous surfaces (ceramic tiles), which measured 20cm x 20cm, at a dose of 85.47 ml per 1m^2 of a 2 % solution with a micropipette and the product was then smeared on the whole surface with a plastic brush. Once the surfaces were dry 10 adult ticks were forced to stay in contact with the treated surfaces (under transparent plastic cup) for 60 minutes. The ticks were then transferred to untreated healthy environment to observe knockdown and mortality up to 24 hours. Assessments of knockdown and/or killing effect were performed up to 60 minutes after exposure. Mortality was recorded 24 hours later. Untreated control was included. 5 replicates were conducted.	In all types of surfaces (porous and non-porous) knock down was 100% in 15 minutes and mortality was 100% after 24 hours. Mortality in untreated control: 0%.	[redacted], 2017 Report no. BLEPER290917 – 03 **Trial 3**
Permethrin 2.79 gr PBO 0.05 gr (Microemulsion) (Pertex)	*Musca domestica* Development stage: Adults Laboratory strain	Laboratory test	Laboratory conditions. Flies were inserted into small mono-use cylindrical cages made of 2mm-mesh mosquito net (5.5 cm diameter x 5.5 cm height). Each cage contained 10 adult insects and the cages were placed inside a drawn area on the floor of the test room (1 m^2). The product was applied spraying directly each cage from 20 cm at a dose of 85.47 ml per 1m^2 of a 2 % solution. Knockdown was recorded after the treatment up to 60 minutes. The flies were then transferred to untreated healthy environment to observe mortality up to 24 hours. 5 cages were used as treated	Product showed 100% knockdown 10 min after direct spray against the flies and 100% mortality 24 hours later. Mortality in the untreated control for all tests was 0%.	[redacted], 2017 Report no. BLEPER290917 – 04 **Trial 4**

			replications. Untreated control was used.		
Permethrin 2.79 gr PBO 0.05 gr (Microemulsion) (Pertex)	*Stomoxys calcitrans* Development stage: Adults Field collected	Laboratory test	Laboratory conditions. Flies were inserted into small mono-use cylindrical cages made of 2mm-mesh mosquito net (5.5 cm diameter x 5.5 cm height). Each cage contained 10 adult insects and the cages were placed inside a drawn area on the floor of the test room (1 m^2). The product was applied spraying directly each cage from 20 cm at a dose of 85.47 ml per 1m^2 of a 2 % solution. Knockdown was recorded after the treatment up to 60 minutes. The flies were then transferred to untreated healthy environment to observe mortality up to 24 hours. 5 cages were used as treated replications. Untreated control was used.	Product showed 100% knockdown 60 min after direct spray against the flies and 100% mortality 24 hours later. Mortality in the untreated control for all tests was 0%.	[redacted], 2017 Report no. BLEPER290917 – 05 **Trial 5**
Permethrin 2.79 gr PBO 0.05 gr (Microemulsion) (Pertex)	*Aedes albopictus* Development stage: Female adults Laboratory strain	Simulated test (outdoor)	The test was performed in 3 outdoor covered with roof areas (replications), each 40 m^2, of a hospital complex at South West of Padua City (Italy). The sites were far enough apart not to interfere with each other. Mosquitoes were inserted into cylindrical cages made of 2mm-mesh mosquito metallic net (5.5 cm diameter x 5.5 cm height). 3 cages, with 15 tiger mosquitoes each, were placed and hanged at different hights, no more than 180 cm from the ground. One cage was hanged on one of the walls of the area. The product was applied directly onto the caged mosquitoes spraying the area at a dose of 85.47 ml per 1m^2 of a 2 % solution. Knockdown was recorded after 10 minutes after the treatment. The mosquitoes were then transferred to the laboratory to observe mortality up to 24 hours. Untreated control was used.	Product showed 100% knockdown 10 min after direct spraying against the mosquitoes and 100% mortality 24 hours later. Mortality in the untreated control for all tests was 0%.	[redacted], 2018 Report no. BLEPER030818 – 01 **Trial 6**
Permethrin 2.79 gr PBO 0.05 gr (Microemulsion) (Pertex)	*Stomoxys calcitrans* *Musca domestica*	Field test (indoor)	The test was performed in 4 stables (replicaties) in Cavour and in Villafranca Piemonte (Torino). One stable was used for horses, the other two stables were used for sheep and goats. The stables were naturally infested with *Stomoxys calcitrans* and *Musca domestica.* Infestation was measured counting the insects resting on 4 spots, sized 1 m^2. The product was applied spraying different spots of the stable directly onto the insects where they were resting on surfaces at a dose of 85.47 ml per 1m^2 of a 2 % solution. The	The population reduction for *Stomoxys calcitrans* was 91.77% and for *Musca domestica* 90.35%, 24 hours after the treatment.	[redacted], 2020 Report no. BLEPER011020 **Trial 7**

			area was homogenously treated. During and after the treatment the stables were closed with nets to avoid flies go out or come in. Mortality was counted after 24 hours. 4 replication were conducted.		
Permethrin 2.79 gr PBO 0.05 gr (Microemulsion) (Pertex)	*Ixodes ricinus*	Field test (indoor & outdoor)	The indoor tests was performed in 3 stables (replicaties) and the 3 outdoor tests in a private house next to a stable, in a warehouse and in an outdoor area of a barn in Calalzo di Cadore (Italy). The areas were naturally infested with *Ixodes ricinus.* In both indoor and outdoor tests, infestation was measured counting the ticks climbing the walls on 4 spots, sized 1 m^2. The product was applied spraying the ground and the walls at a maximum of 50 cm height (band application), at a dose of 85.47 ml per 1m^2 of a 2 % solution. Mortality was counted after 24 hours. Untreated control was used.	<u>Outdoor treated areas</u> The population reduction for *Ixodes ricinus* was 98.85%, 24 hours after the treatment. control. In the untreated control population increased 4.67%. <u>Indoor treated areas</u> The population reduction for *Ixodes ricinus* was 98.97%, 24 hours after the treatment. control. In the untreated control population reduction was 4.27 %.	[redacted], 2018 Report no. BLEPER030818 – 03 **Trial 8**
Permethrin 2.79 gr PBO 0.05 gr (Microemulsion) (Pertex)	*Musca domestica* Development stage: Adults Laboratory strain	Simulated use test (outdoor)	The test was conducted in an abandoned farm in the countryside in Padua (Italy). Flies were inserted into small cylindrical cages made of 2mm-mesh mosquito net (5.5 cm diameter x 5.5 cm height). Each cage contained 10 adult insects and the cages were hunged in different heights (no more than 18/0 cm height), along a band 10 m long. The product was applied spraying the wall at a dose of 85.47 ml per 1m^2 of a 2 % solution, to cover a surface of 16 m^2. Knockdown was recorded after the treatment up to 60 minutes. The flies were then transferred to untreated healthy environment to observe mortality up to 24 hours. 10 cages were used as treated replications. Untreated control was used.	Product showed 100% knockdown 10 min after the treatment against the flies and 100% mortality 24 hours later. Mortality in the untreated control for all tests was 0%.	[redacted] 2018 Report no. BLEPER030818 – 03 **Trial 9**
Permethrin 2.79 gr PBO 0.05 gr (Microemulsion) (Pertex)	*Aedes albopictus* Development stage: Adults Laboratory strain & Wild population	Simulated use test & Field test	The study was performed in three outdoor areas infested by *Aedes albopictus*. The 3 sites (replications) were covered (protected by roofs). The sites were bordered by a wall (one side) and plants in pots (3 sides). In each area 4 cylindrical cages (diameter 5.5 cm x height 5.5 cm) containing 15 females were hung at different heights. Before the treatment, the mosquito population was measured using the Human Landing Teqnique. The number of landings was counted for 3	Product showed 100% knockdown 10 min after the treatment against the mosquitoes and 100% mortality 24 hours later. Mortality in the untreated control for all tests was 0%. The population reduction was 90.5%, 93.3%, 98.3% after 30 minutes, 1 hour and 2 hours respectively.	[redacted] 2020 Report no. P042-20 **Trial 10**

			minutes. After the positioning of the cages, the application was performed with a pump sprayer, at a dose of 85.47 ml per 1m^2 of a 2 % solution, to cover a surface of 28 m^2, from a distance of 50 cm, treating the plants and the walls where insects tend to rest, paying attention not to insist on the cages. Knockdown was recorded in the cages after the treatment. The mosquitoes were then transferred to untreated healthy environment to observe mortality up to 24 hours. The infestation reduction was measured by counting the landings for 3 minutes 30 minutes, 1 hour and 2 hours after treatment. 3 treated replications were performed. Untreated control was included.		

Conclusion on the efficacy of the product

Several efficacy studies (laboratory, simulated use and field studies) were submitted for Pertex (aqueous microemulsion) containing permethrin 2.79 % and PBO 0. 05%. Based on the results of the submitted efficacy studies, the product was effective when applied by professionals and trained professionals as:

- Surface treatment against ticks indoors by band application (Intended use 2).
- Surface treatment against ticks outdoors around building by band application (Intended use 4).
- Surface treatment against ticks indoors in animal houses/ shelters by band application (Intended use 6).

*Dose rate: 85.47 ml/ m^2 which corresponds to 1L for 11.7 m^2 of a 2 % solution v/v.

Equipment: low pump sprayer.

In the absence of a human or animal in the lab study to test tick biting behaviour before knock down and kill effect, the following limitation is proposed to be included in the PAR & SPC (specific instructions for use): “The product shall not be used in the presence of humans or animals. Humans and animals can re-enter into the treated area 24 hours after the product application”.

The intended uses 1 & 5 of Pertex [Direct application on flies (*Musca domestica & Stomoxys calcitrans*) indoors & in animal houses/ shelters, by professionals and trained professionals, from an efficacy point of view, are not acceptable as applied for by the applicant, for the following reasons:

<u>Intended use 5</u>

According to the guidance for products against flies in stables, a field study according to the directions for use is required. However, in the field trial 7 it seems that the product was not applied with the claimed application method. Considering the test method, the product was

applied onto the flies at rest, which means that the product acted also with the deposits onto the treated surfaces. The application method in the study reflects a direct treatment onto the flies and a general surface treatment, since the area was homogenously treated and the dead insects were counted 24 hours after, as clarified by the applicatnt. Thus, trial 7 does not support the label claim against flies through direct application using pump sprayer because the killing effect of the product in the study was due to the product deposit on the surfaces.

Intended use 1

According to the guidance, concerning the category of users "products used by professionals must have a high level of efficacy since the objective is to eradicate the infestation" and in terms of the claimed application method, i.e. direct spray onto the flies, "direct treatments involve application directly onto the insects, and are normally possible when the insects are visible and available to be sprayed". Hence, a high level of efficacy should be achieved by the use of the product according to the claimed application pattern. The eCA, has communicated to the applicant critical concerns about the practicability of the application and the level of efficacy after application by professionals in houses under real conditions, noting that in practice direct applications onto flying insects normally include space spray treatments using either aerosols or foggings consisting of low volume spray particle sizes (where the mist stays in the air space for some time), not the claimed low pressure sprays generating larger spray droplets. Due to the test design of the simulated use study with direct application onto caged flies, no safe conclusion can be drawn regarding efficacy of the product under real conditions where according to the claim a professional has to eliminate fly population by targeting free flying flies and flies at rest as well with a low pressure-coarse spray. It is also noted that in the field study the application of the product included direct treatment onto the insects and surface treatment as well, not only the claimed direct treatment.

The intended use 3 of the product [Surface treatment against mosquitoes (*Culex pipiens & Aedes albopictus*) outdoors, by professionals and trained professionals], from an efficacy point of view, is not acceptable as applied for by the applicant, for the following reasons: the submitted simulated use studies by [redacted] 2018 and by [redacted] 2020 against *Aedes albopictus* are not accepted and the product cannot be supported only by the lab studies. The study by [redacted] 2018 is not accepted because the product was applied directly onto caged mosquitoes. The simulated use test by [redacted] 2020 with caged tiger mosquitoes is not accepted due to unclear methodology description, and the fact that the application method does not comply with the claimed one. It is also noted that in order to support a general claim against mosquitoes, testing against *Culex* mosquitoes is required.

2.2.5.6 Occurrence of resistance and resistance management

Permethrin

Resistance has been reported for the use of Permethrin as a general insecticide in a wide variety of insects, especially in agricultural pests. The level of resistance is less than tenfold in some of the species but high levels of resistance have been observed for example in cockroaches (CAR, 2014). Because of the anticipated low level of selection pressure from the proposed uses (*i.e.* treatment of the whole sealed room rather than a spot treatment, avoiding insects to get used to it or escape from it), no specific strategy for management of the development of resistance is required.

The principles of strategies for managing the development of resistance are similar for permethrin as they are for other synthetic pyrethroids;

- Where possible, application treatments should be recommended to be combined with non-chemical measures

- Products should always be used in accordance with label recommendations
- Applications should always be made against the most susceptible stages in the pest life cycle
- Where an extended period of control is required, treatments should be alternated with products with different modes of action
- Levels of effectiveness should be monitored, and instances of reduced effectiveness should be investigated for possible evidence of resistance, noting that sanitary conditions and proximity of untreated refugia can contribute to the risk of re-infestation.
- in cases where label rates, correctly applied, fail to give the expected level of control and resistance is demonstrated, use of any product containing the same class of chemistry should cease.
- 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.

Piperonyl butoxide (PBO)
If PBO is used extensively in the field, in an effort to abrogate the effects of metabolic resistance, it is possible that resistance will occur to PBO itself.
Unlike other insecticides, the target of PBO is not a protein vital for continued life of the insect, but a protein that is conferring resistance. Therefore, to generate resistance to PBO the insect would have to produce a resistance mechanism to protect its resistance mechanism, rather than to protect a vital target.
That it could do so is not beyond belief, but the resulting phenotype of an insect generating such extreme metabolic resistance is likely to be extremely unfit.
PBO has been used extensively for many years as a tank mix in Australia and USA. Even so, there are scarce reports of resistance to the effects of this synergist. Only under extreme laboratory conditions, aimed to induce resistance by applying high doses, have strains of *Musca domestica* and *Plutella xylostella* been reported to develop some form of insensitivity to PBO, and even then the mechanisms were not characterised. Furthermore, when the heavy selection regime that had been used to select for this resistance was removed, the population reverted back to susceptibility within 5 generations, presumably due to heavy fitness costs associated with this insensitivity (1).

(1) Graham Moores. The Mode of Action of Piperonyl Butoxide and the Science of Insecticide Resistance. Endura S.p.A. 17 March 2009.

2.2.5.7 Known limitations

There are not limitations on efficacy of PERTEX. Underiderable and unintended side effects during the use of the product were not observed.

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 and outdoors by professionals and trained professionals.
The product is intended to be used against flies (*Musca domestica, Stomoxys calcitrans*) through direct application indoors and in animal houses/ shelters (Intended uses 1 & 5), as surface treatment against ticks (*Ixodes ricinus*) indoors, outdoors around building and in animal houses/ shelters (Intended uses 2, 4 & 6), and as surface treatment against mosquitos (*Aedes albopictus, Culex pipiens*) outdoors (Intended use 3).
*Dose rate: 85.47 ml/ m^2 which corresponds to 1L for 11.7 m^2 of a 2 % solution v/v.
Equipment: low pump sprayer.

The applicant, based on the efficacy evaluation, proposed the following rewording for the claimed application methods for the Intended uses 1 & 5 against flies:

- for the Intended use 1 "Apply the product spraying different spots of the room/large building directly onto the insects where they were resting on surface. Treat the area homogenously'' and
- for the Intended use 5 "Apply the product spraying different spots of the stable directly onto the insects where they were resting on surface. Treat the area homogenously''.

However, regarding efficacy, these are not acceptable because of the following reasons:

i) It is not clear for the users if the product is intended to be applied as a direct treatment onto the insects only (which is not acceptable as expalned in the pp 58-59), or as direct treatment onto the insects and as spot treatment, or as direct treatment onto the insects and as general surface treatment.
ii) No laboratory studies were submitted to support a general surface or a spot treatment.

Trials submitted by the applicant to substantiate label claims:

Intended Uses 1
Direct application on flies (*Musca domestica* & *Stomoxys calcitrans*) indoors, by professionals and trained professionals.
Intended Uses 5
Direct application on flies (*Musca domestica* & *Stomoxys calcitrans*) indoors in animal houses/ shelters, by professionals and trained professionals.

Trial 4
The results of the laboratory study by [redacted] 2017 show that Pertex was effective as a direct treatment at a dose 85.47 ml product/ m^2 (2% solution), on *Musca domestica* introduced to net cages. The product showed 100% knockdown 10 min after spraying the flies in the cages and 100% mortality 24 hours later.

Trial 5
The results of the laboratory study by [redacted] 2017 show that Pertex was effective as a direct treatment at a dose 85.47 ml product/ m^2 (2% solution), on *Stomoxys calcitrans* introduced to net cages. The product showed 96% knockdown 40 min after spraying the flies in the cages and 100% mortality 24 hours later.

Trial 7
The results of the field study by [redacted] 2018 show that Pertex was effective as a direct and surface treatment at a dose 85.47 ml product/ m^2 (2% solution), against *Stomoxys calcitrans* and *Musca domestica* when applied with pump spray indoors. The population reduction for *Stomoxys calcitrans* was 91.77% and for *Musca domestica* 90.35%, 24 hours after the treatment. Hence, this study does not support the claimed application method against flies, i.e. direct spray on flies.

Trial 9
The results of the simulated use test (in outdoor conditions) study by [redacted] 2018 show that Pertex was effective as a direct treatment, at a dose 85.47 ml product/ m^2 (2% solution), against *Musca domestica* introduced to disposable cages when applied with pump spray outdoors. The product showed 100% knockdown 10 min after spraying the flies in the cages and 100% mortality 24 hours later.

The intended uses 1 & 5 of Pertex, from an efficacy point of view, are not acceptable as applied for by the applicant, for the following reasons:

Intended use 5
According to the guidance, for products against flies in stables, a field study according to the directions for use is required. However, in the field trial 7 it seems that the product was not applied only with the claimed application method, i.e. direct application on flies. The product

was applied homogenously onto the flies at rest, and the dead insects were counted 24 hours after, as clarified by the applicant, which means that the product may have acted also with the deposits onto the treated surfaces. Hence, the application method in the study reflects a direct treatment onto the flies and a general surface treatment too.
The application method of the product in the field trial 7 does not comply with the claimed application method and therefore the study does not support efficacy of the product against flies in animal houses.

Intended use 1
According to the guidance, concerning the category of users "products used by professionals must have a high level of efficacy since the objective is to eradicate the infestation" and in terms of the claimed application method, i.e. direct spray onto the flies, "direct treatments involve application directly onto the insects, and are normally possible when the insects are visible and available to be sprayed". From the above-mentioned, a high level of efficacy is anticipated by the use of the product according to the claimed application pattern. The eCA, has critical concerns about the practicability and the level of efficacy of the claimed application by professionals in houses directly onto flies under real conditions, noting that in practice direct applications onto flying insects normally include space spray treatments using either aerosols or foggings consisting of low volume spray particle sizes (where the mist stays in the air space for some time), not the claimed low pressure sprays generating larger spray droplets. Due to the test design of the simulated use study with direct application onto caged flies, no safe conclusion can be drawn regarding efficacy of the product under real conditions where a professional has to eliminate fly population by targeting flies free flying or at rest with a low pressure-coarse spray. It is also noted that in the field study the application of the product included direct treatment onto the insects and surface treatment as well, not only the claimed direct treatment onto flies.

Intended Use 2
Surface treatment by narrow band application against ticks (*Ixodes ricinus*) indoors, by professionals and trained professionals.
Intended Use 4
Surface treatment by narrow band application against ticks (*Ixodes ricinus*) outdoors, around building, by professionals and trained professionals.
Intended Use 6
Surface treatment by narrow band application against ticks (*Ixodes ricinus*) indoors in animal houses/ shelters, by professionals and trained professionals.

Trial 3
The results of the laboratory study (non-coice test) by [redacted] 2018 show that Pertex was effective as surface treatment at a dose 85.47 ml product/ m^2 (2% solution), against ticks, providing 100% knockdown in 15 min and 100% mortality 24 hours after exposure of the insects to porous and non-porous surfaces.

Trial 8
The results of the field study by [redacted] 2018 show that Pertex was effective as a surface treatment by narrow band application, indoors and outdoors, against *Ixodes ricinus* at 85.47 ml product/ m^2 (2% solution). The population reduction for *Ixodes ricinus* was 98.85% for the tests indoors and 98.97% for the tests outdoors, 24 hours after the treatment.

Hence, the intended uses 2 & 4 & 6 of Pertex, from an efficacy point of view, are acceptable as applied for by the applicant, noting however the following:

- According to the guidance, an insecticide with knockdown and killing effect against ticks is normally considered to be sufficiently effective only if 100% knockdown and >95% killing effect are achieved before ticks start feeding. However, in the submitted lab study by [redacted] 2017 the product was not tested in the presence of a person or an arm or foot or

animal, as mentioned in the guidance, to evaluate if the knockdown and kill effect are achieved before ticks start feeding.
In the absence of a human or animal in the lab study to test tick biting behaviour before knock down and kill effect, the following limitation is proposed to be included in the PAR & SPC (specific instructions for use): "The product shall not be used in the presence of humans or animals. Humans and animals can re-enter into the treated area 24 hours after the product application".

- For consistency reasons, the application method for the intended uses 2, 4 & 6 against ticks are proposed to be "Surface treatment against ticks indoors", "Surface treatment against ticks outdoors" and "Rural Hygiene – Surface treatment against ticks in animal houses/ shelters (indoors)", respectively.

- Since the product did not tested for residual activity, we proposed the following instruction for use to be included in the PAR & SPC (specific instructions for use): " The product has no residual action against ticks and a single application does not protect humans and animals in case of re-infestation".

Intended Use 3
Surface treatment against mosquitoes (*Culex pipiens & Aedes albopictus*) outdoors, by professionals and trained professionals.

Trial 1
The results of the laboratory study (non-coice test) by [redacted] 2017 show that Pertex was effective as surface treatment at 85.47 ml product/ m^2 (2% solution), against *Aedes albopictus*, providing 100% knockdown in 10-20 min and 100% mortality 24 hours after exposure of the insects to fresh and 1-week aged porous and non-porous treated surfaces.

Trial 2
The results of the laboratory study (non-coice test) by [redacted] 2017 show that Pertex was effective as surface treatment at 85.47 ml product/ m^2 (2% solution), against *Culex pipiens*, providing 100% knockdown in 20-40 min and 100% mortality 24 hours after exposure of the insects to porous and non-porous treated surfaces.

Trial 6
According to the results of the simulated use study by [redacted] 2018 and clarifications provided by the applicant concerning the application method, the product was applied as a direct treatment onto caged *Aedes albopictus* mosquitoes, not as surface treatment as claimed. According to the results, the direct application of the product onto caged tiger mosquitoes at 85.47 ml product/ m^2 (2% solution), with pump spray outdoors in covered areas and resulted in 100% knockdown in 10 min and 100% mortality 24 in hours. However, this study is not accepted in support of the claimed application method against mosquitoes by surface treatment.

Trial 10
According to the test design of the simulated use study by [redacted] 2020 with caged *Aedes albopictus* mosquitoes outdoors "In the treated areas cages with *Aedes albopictus* mosquitoes were hung at different heights. After the positioning of the cages, the application was performed with a pump sprayer, at a dose of 85.47 ml per 1m^2 of a 2 % solution, to cover a surface of 28 m^2, from a distance of 50 cm, treating the plants and the walls where insects tend to rest, paying attention not to insist on the cages". According to the afore-mentioned description of the study design, it seems that the treatmement may included a direct spray onto the caged mosquitoes, not only a surface treatment as claimed, considering that the surface treatment was performed after the placement of the cages to the treated area. Also, it is not clear how the product acted onto the mosquitoes because it is not clarified where the cages were placed, i.e. attached or not on the treated surfaces, and how the insects came into

contact with the treated surfaces and exposed to the product considering that the application was performed after the placement of the cages to the treated area (which implies a surface teeatment and direct application onto the insects too).
Hence, the simulated use test with caged tiger mosquitoes is not accepted due to unclear methodology description, and the fact that the application method does not comply with the claimed one.

Hence, the intended use 3 of of the product [Surface treatment against mosquitoes (*Culex pipiens & Aedes albopictus*] outdoors, by professionals and trained professionals), from an efficacy point of view, is not acceptable as applied for by the applicant, since the submitted simulated use studies by [redacted] 2018 and by [redacted] 2020 against *Aedes albopictus* are not accepted and the efficacy of the product cannot be supported only by the lab studies. It is also noted that in order to support a general claim against mosquitoes, testing against *Culex* mosquitoes is required.

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.

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 biocidal products.

2.2.6 Risk assessment for human health

The current application is for PERTEX, a water based microemulsion (ME) formulation containing 3% w/w permethrin and 0.053% w/w piperonyl butoxide, for use both outdoor and indoor by professionals for the control of flying insects (flies and mosquitoes) and ticks (Product Type 18).

Indoor and outdoor uses by professionals are applied as dilution solution at 2% v/v (2 litres of concentrated product in 100 litres of water) as surface spray with a low pressure pump on porous and non porous surface, stables and hen-house.

The active substance permethrin was approved for use in biocidal products for product-type 18 in Regulation (EU) No 1090/2014 of 16 October 2014. Ireland acted as the Rapporteur Member State and the Assessment Report was finalised in the Standing Committee on Biocidal Products and published in April 2014.

The active substance piperonyl butoxide (PBO) was approved for use in biocidal products for product-type 18 in Regulation (EU) No 2016/2288 of 16 December 2016. Greece acted as the Rapporteur Member State and the Assessment Report was finalised in the Standing Committee on Biocidal Products and published in September 2019.

Acute toxicity studies with the product PERTEX are not available. The toxicological hazard assessment for the biocidal product relied on the information available for the individual components (please refer to the Confidential Annex of this PAR).

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

No new *in vitro* or animal studies are available.
No human data are available.

Conclusion used in Risk Assessment – Skin corrosion and irritation

Value/conclusion	No skin corrosion and irritation. In the absence of a specific study on skin corrosion and irritation, the classification for this endpoint of the biocidal product PERTEX has to be estimated by calculation method, in accordance with Regulation (EC) No 1272/2008. For the detailed assessment please refer to the Confidential Annex of the PAR.
Justification for the value/conclusion	The biocidal product PERTEX does not contain any ingredient classified as skin corrosive or irritant.
Classification of the product according to CLP Regulation	Not classified.

Eye irritation

No new *in vitro* or animal studies are available.
No human data are available.

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	No ocular irritant. In the absence of a specific study on eye irritation, the classification for this endpoint of the biocidal product PERTEX has to be estimated by calculation method, in accordance with Regulation (EC) No 1272/2008. For the detailed assessment please refer to the Confidential Annex of the PAR.
Justification for the value/conclusion	Piperonyl butoxide is classified as Eye Irrit. 2 with H319. However, the concentration of piperonyl butoxide in the biocidal product is below the generic concentration limit of 10%, set in Regulation (EC) No 1272/2008 and as such, classification for eye irritation is not triggered for the biocidal product. Please also refer to the Confidential Annex of the PAR.
Classification of the product according to CLP Regulation	Not classified.

Respiratory tract irritation

No data is available.
No human data is available.

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	Piperonyl butoxide is classified as STOT-SE 3 with H335 (see Assessment Report, Greece 2019). The concentration of piperonyl butoxide in the product is below the generic concentration limit of 20%, set in Regulation (EC) No 1272/2008 and as such, classification for respiratory track irritation is not triggered for the biocidal product. Please also refer to the Confidential Annex of the PAR.
Classification of the product according to CLP Regulation	Not classified.

Skin sensitization

No new animal studies are available.
No human data available.

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	In the absence of a specific study on skin sensitisation, the classification for this endpoint for the biocidal product PERTEX has to be estimated by calculation method.
Justification for the value/conclusion	The biocidal product PERTEX is classified a skin sensitizer considering that it contains 3% w/w permethrin, ingredient that is classified as H317 (Skin Sens. 1) under CLP Regulation. Please also refer to the Confidential Annex of the PAR.
Classification of the product according to CLP Regulation	Classified as H317 (Skin Sens. 1) under CLP Regulation.

Respiratory sensitization (ADS)

Data waiving	
Information requirement	No study is avalaible. There are currently no standard tests and no OECD test guidelines available for respiratory sensitisation and there is no testing requirement for this endpoint under the BPR.
Justification	Data waiving is acceptable. In the absence of a specific study, the respiratory sensitization of the biocidal product PERTEX has to be estimated by calculation method. Neither the active substance nor all the co-formulants are classified as respiratory sensitizers.
Classification of the product according to CLP	Not classified.

Acute toxicity

Acute toxicity by oral route

No new animal studies are available.
No human data available.

Value used in the Risk Assessment – Acute oral toxicity	
Value	No acute oral toxicity is available. In the absence of a specific study on acute oral toxicity, the classification for this endpoint of the biocidal product PERTEX has to be estimated by calculation method. For the detailed assessment please refer to the Confidential Annex of the PAR.
Justification for the selected value	The calculated oral ATE for the mixture is 16667 mg/kg bw/day and according to the rules laid down in Regulation (EC) No 1272/2008 is above the trigger value of 2000 mg/kg bw/day, hence the product does not require classification for acute oral toxicity, Category 4.
Classification of the product according to CLP Regulation	Not classified under CLP Regulation.

Acute toxicity by inhalation route

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	No study is avalaible. In the absence of a specific study, the acute inhalation toxicity of the biocidal product PERTEX has to be estimated by calculation method. For the detailed assessment please refer to the Confidential Annex of the PAR.
Justification for the selected value	The calculated inhalation ATE for the mixture is 50 mg/L and according to the rules laid down in Regulation (EC) No 1272/2008 is above the trigger value of 5 mg/L, hence the product does not require classification for acute inhalation toxicity, Category 4.
Classification of the product according to Regulation CLP	Not classified under CLP Regulation.

Acute toxicity by dermal route

No new animal studies are available.
No human data available.

Value used in the Risk Assessment – Acute dermal toxicity	
Value	No study is avalaible. In the absence of a specific study, the acute dermal toxicity of the biocidal product PERTEX has to be estimated by calculation method. For the detailed assessment please refer to the Confidential Annex of the PAR.
Justification for the selected value	It has to be considered that the biocidal product PERTEX does not contain any ingredient classified as acute dermal toxicity.
Classification of the product according to CLP Regulation	Not classified under CLP Regulation.

Additional information on the classification of the active substances

The current harmonised classification of permethrin (Acute Tox. 4, H302; Acute Tox. 4, H332; Skin Sensitization Cat. 1B, H317) has been used for the toxicological hazard assessment of the biocidal product PERTEX.

The classification of piperonyl butoxide has been recently discussed in RAC-53 (June 2020). The agreed classification (Eye irritation, Cat. 2, H319; STOT SE Cat. 3, H335; EUH066) has been used for the toxicological hazard assessment of the biocidal product PERTEX.

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption		
Substance	Permethrin	Piperonyl butoxide
Value(s)	70%	70%

Justification for the selected value(s)	In the absence of relevant dermal absorption data with PERTEX, the default value of 70% for organic solvent-based formulations containing ≤ 5% active substance has to be used for the risk assessment according to EFSA Guidance on Dermal Absorption, 2017 (EFSA Journal 2017;15(6):4873.

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

Available toxicological data relating to the non-active substances contained in PERTEX is provided in SDS attached to current submission.

The product does not contain any substances of concern. For further details please refer to the Confidential Annex of the PAR.

Available toxicological data relating to a mixture

The biocidal product PERTEX contains only one mixture: [redacted].

Available toxicological data relating to the mixture contained in PERTEX is provided in SDS attached to current submission. For further details please refer to the Confidential Annex of the PAR.

Other

No other relevant information available.

Screening non-active substance(s) for endocrine disrupting potential

The assessment of the endocrine-disrupting properties of the co-formulants in the biocidal product PERTEX has been performed according to the instructions described in the guidance document agreed in the Coordination Group (CG-34-2019-02 AP 16.5 e-consultation ED potential of co-formulants).

To assess the endocrine-disrupting (ED) potential of each co-formulant in the biocidal product, a step-wise approach was performed, which included screening of relevant databases and searching for freely available information in reliable literature sources.

The detailed assessment is presented in the Confidential Annex of the PAR.

Based on existing knowledge and available scientific information, there is no indication of concern regarding endocrine-disrupting properties of any of the co-formulants present in PERTEX. Therefore, the product is not considered an endocrine disruptor.

2.2.6.2 Exposure assessment

The product PERTEX is a water-based microemulsion (ME) formulation containing 3% w/w permethrin (CAS No. 52645-53-1) and 0.053% w/w piperonyl butoxide (CAS No. 51-03-6), as biocidal active substances (a.s.). The biocidal product is for use on both outdoor and indoor by professional and trained professional users for the control of flying insects (flies and mosquitoes) and ticks.

The product is applied as a surface spray with low pressure pump on porous and non-porous surfaces, stables, hen-house to control arthropods of hygienic-sanitary interest like stable fly, mosquitoes, ticks and so on. The product should be diluted and mixed before the use (do not shake).

The relevant paths of human exposure uses are fully described in Table 13.

The assessment of human exposure to the active substances permethrin and piperonyl butoxide resulting from the use of PERTEX follows the recommendations of the ECHA Biocides Human Health Exposure Methodology (2015), of the TNsG on Human Exposure (2002) and, where applicable, of the User Guidance (2002) as well as of the TNsG on Human Exposure (2007).

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

Table 13: relevant paths of human exposure to permethrin and piperonyl butoxide from the biocidal product PERTEX

Exposure path	Primary (direct) exposure			Secondary (indirect) exposure		
	Industrial use[1]	Professional use	Non-professional use	General public	Via environment[2]	Via food
Inhalation	No	Yes	No	Yes	Not relevant	Not relevant
Dermal	No	Yes	No	Yes	Not relevant	Not relevant
Oral	No	Not relevant	No	Yes (infants, toddlers)	Not relevant	Not relevant

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

[2] From TNsG on Human Exposure, 2007: "Exposure via the environment is an element of secondary exposure. It includes bystanders and consumers, including children, who are inadvertently exposed to biocides by inhalation of plumes drifting off-site and ingesting contaminated food." Those scenarios are not considered relevant in this case.

List of scenarios

Table 14: scenarios of intended uses of the biocidal product PERTEX			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
01	Mixing/loading & Application; Indoor	**Primary Exposure, direct** Spraying the biocidal product (diluted) – Domestic & Industrial buildings	Professionals
02	Mixing/loading & Application; Outdoor	**Primary Exposure, direct** Direct/Spot application (spraying) of the biocidal product (diluted) – around buildings	Professionals
03	Mixing/loading & Application; Indoor	**Primary Exposure, direct** Direct/Spot application (spraying) of the biocidal product (diluted) – Rural (Animal houses/Shelters)	Professionals
04	Post-application (indoor and outdoor)	**Primary exposure, indirect** Exposure *via* the dermal route (laundering their work clothes)	Professionals
05	Post-application (indoor and outdoor)	**Primary exposure, indirect** Exposure *via* the dermal route – cleaning of the spray equipment	Professionals
06	Post-application	**Secondary Exposure** Domestic: Exposure *via* inhalation, dermal and oral route	General public (adults, children, infants and toddlers)
07	Post-application	**Secondary Exposure** Rural-animal house/shelters: Exposure *via* inhalation and dermal route by accidental contamination from treated areas	General public (adults)

Table 15: scenarios of intended uses and application rates of the biocidal product PERTEX						
Scenario number	**Indoor / Outdoor**	**User**	**Type of application**	**Target pest**	**In-use dilution concentration (PERTEX)**	**In-use concentration (a.s)**
01, 03	Indoor	Professionals	Direct spraying (diluted)	Flying insects and ticks	2%	Permethrin 0.06% w/w PBO 0.00106% w/w
02	Outdoor	Professionals	Direct spraying (diluted)	Flying insects and ticks	2%	Permethrin 0.06% w/w PBO 0.00106% w/w

Industrial exposure

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

Professional direct exposure

Scenarios [01-02-03]

PERTEX is intented to be used by professionals indoors and outdoors. The recommended usage concentration of the spray solution is 2% v/v (equivalent to 2L of product in 100 litres of water).

For both indoor and outdoor uses PERTEX is applied to surfaces *via* a low pressure pump. A daily use is anticipated, with a median duration of application of 120 minutes several times per day (TNsG Chapter 3, p.110).

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

For the professional use, Scenarios 01, 02 & 03 are equivalent, as they all are assessed using Spraying model 1 while the application rate is the same for indoor and outdoor uses.

The models and calculations are presented in Annex 3.2 of the current document and the results are summarised below.

Scenarios [01, 02 & 03]

Description of Scenarios [01, 02, 03]

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]	70% for both active substances
	Inhalation rate[3]	1.25 m³/h
	Inhalation uptake	100%
	Concentration of a.s. in treatment solution[4]	Permethrin: 0.06% PBO: 0.00106%
	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%
	Respiratory protection	No

[1] no PPE, Tier 1 assessment, i.e. potential exposure
[2] EFSA Guidance on DermaL Absorption (2017) – default values
[3] 0.021 m³/min, HEEG Opinion 17, 2013
[4] 2% (2L product per 100 L water)
[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, professionals should wear suitable protective clothing (coveralls) and protective gloves. Nevertheless, a full assessment including a Tier 1 assessment has been performed for completeness. The resulting expected total systemic doses, including the total potential exposure (no PPE used) as well as the estimated uptake when protective clothing and gloves are used, are summarized in the tables below. The chosen model is applicable for surface/spot treatment by low pressure sprayers indoors and outdoors.

Please refer to Annex 3.2, Tables 1 & 2 for the detailed calculations.

Calculations for Scenarios [01, 02, 03]

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			
Permethrin					
Scenario [1], [2], [3]	1 / no PPE	0.0026	0.229	-	0.232
	2 / gloves, coated coverall	0.0026	0.0245	-	0.0271
Piperonyl butoxide					
Scenario [1], [2], [3]	1 / no PPE	0.000046	0.00405	-	0.0041
	2 / gloves, coated coverall	0.000046	0.00043	-	0.00048

Professional indirect exposure

Scenario [04]

Description of Scenario [04]
Adult professional – laundering work clothes at home Exposure to the product PERTEX can potentially occur *via* contact with the contaminated coveralls, during laundering 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 1 (TNsG Part 2, p.143). The indicative figure (75th percentile) is 11040 mg spray solution/day. It is also assumed that the coverall is washed weekly, after 5 days wear. Please refer to Annex 3.2 for the detailed calculations.

Calculations for Scenarios [04]

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			
Permethrin					
Scenario [04]	1 / no PPE	-	8.4×10^{-4}	-	8.4×10^{-4}
Piperonyl butoxide					
Scenario [04]	1 / no PPE	-	1.5×10^{-5}	-	1.5×10^{-5}

Scenario [05]

Description of Scenario [05]
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. Please refer to Annex 3.2 for the detailed calculations.

Calculations for Scenario [05]

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			
Permethrin					

Scenario [05]	1 / no PPE	-	7.7×10^{-6}	-	7.7×10^{-6}
Piperonyl butoxide					
Scenario [05]	1 / no PPE	-	1.4×10^{-7}	-	1.4×10^{-7}

Combined scenarios

The exposure estimates from the different routes of exposure (inhalation, dermal, oral) *per* scenario are added together to provide a total systemic (internal) dose and are provided in previous tables.

Non-professional exposure

Exposure for non-professional users is not foreseen since, the product is intended only for professional users.

Exposure of the general public

Bystanders are unlikely to be present during application of PERTEX or immediately after application by professional users. Children and adults are not expected to come into contact with treated surfaces; nevertheless, according to the intended uses in houses, schools and kindergartens, as a worst case it has been assumed that adult or children may be exposed to PERTEX after indoor application.

Secondary exposure in the domestic pest control exposure scenario for adult, children, infants and toddlers (chronic exposure) is possible *via* the dermal and the oral route.

Scenario [06]

Description of Scenario [06]
General public - Secondary exposure of infants, toddlers, children and adults.
Subsequent to the use of the biocidal product, secondary exposure of general public could occur in the residential environment. Secondary exposure is derived *via* inhalation, dermal and oral route (hand-to-mouth contact).
Inhalation exposure to volatilised residues of active substances is expected to occur for infants, toddlers, children and adults entering to treated areas.
Dermal exposure is expected to occur for the general public *via* direct contact to deposits of the biocides on the surface of contact after product application. Dermal exposure may occur to infants, toddlers and children crawling on floor or playing around treated surfaces for a significant time period and adults accidentally touching contaminated surfaces with their bare hands.
Oral exposure is relevant for infants and toddlers, that exhibit a great deal of hand-to-mouth contact. Therefore, a part of residues present on the hands will be dislodged by saliva and eventually ingested.
It is assumed that infants, toddlers and children would not be permitted to be present during the application operation and therefore, there would be no acute exposure. Secondary exposure for the general puclic occurs as long-term event and may be continuous (chronic exposure).

The models used for the secondary exposure assessment for the general public are summarized in the following table.

Overview of models used for secondary human health exposure assessment.		
Inhalation route	**Models**	**Population**
Vapours (volatilised residues)	HEEG opinion 13 - Assessment of inhalation exposure of volatilised biocidal active substances.	Infant Toddler Child Adult
Dermal route	**Model**	**Population**
Dermal contact with treated surfaces	ConsExpo Web, version 1.0.6 - RIVM Pest Control Products Fact Sheet, 2006 - Secondary exposure - Rubbing off.	Infant Toddler Child Adult
Oral route	**Model**	**Population**
Oral (hand-to-mouth contact)	ConsExpo Web, version 1.0.6 - RIVM Pest Control Products Fact Sheet, 2006 - Secondary exposure - Constant rate.	Infant Toddler

Assessment of Inhalation Exposure of Volatilised Biocidal Active Substances

Inhalation exposure of volatilised residues of active substances from surfaces after application of the product is expected to occur for infants, toddlers, children and adults entering to treated areas.

Volatization of permethrin and piperonyl butoxide is expected to be minimal due to low vapour pressure, low Henry's Law constant and high adsorption potential. However, the assessment of inhalation exposure of volatilised residues of active substances was performed for completeness reasons.

Tier-1 screening tool

As a Tier-1 screening tool whether inhalation exposure can be neglected or should be included into the risk assessment, the following screening test which is based on the toddler representing the worst case is proposed in HEEG Opinion 13 (Assessment of Inhalation Exposure of Volatilised Biocide Active Substance).

Let mw and vp denote the molecular weight (in g/mol) and the vapour pressure (in Pa). For toddler (based on an inhalation rate of 8 m^3/24 hr and body weight of 10 kg) and using an AEL in mg a.s./kg bw/d, if

$0.328 \times [(mw \times vp) / AEL_{long\text{-}term}] \leq 1$

then risk from inhalation exposure for the toddler is negligible, otherwise inhalation exposure should be included in the risk assessment. If the inhalation risk for the toddler is negligible, then the inhalation risk for the infant, child and for the adult can also be considered to be negligible.

Tier-1 screening tool has been applied for each active substance as detailed in the following table.

Screening tool of inhalation exposure of volatilised biocidal active substances					
Active substance	**MW (g/mol)**	**vp (Pa)**	**$AEL_{long\text{-}term}$ (mg/kg bw day)**	**0.328 × mw x vp/$AEL_{long\text{-}term}$**	**Result**

permethrin	391.29	2.155×10^{-6} (20°C)	0.05	0.0055	<1 risk from inhalation exposure for the toddler is negligible
piperonyl butoxide	338.43	1.33×10^{-5} (25°C)	0.2	0.0074	<1 risk from inhalation exposure for the toddler is negligible

As a result of the application of Tier-1 screening tool, the risk from the inhalation exposure for toddlers is negligible in long-term exposure. Therefore, the inhalation risk for the infants, the children and the adults is also considered negligible.

Dermal and oral exposure to residues on treated surfaces – infants, toddlers, children and adults.

Dermal exposure is expected to occur for the general public in the domestic area *via* direct contact to deposits of the biocides on the surface of contact after product application. Dermal exposure may occur to infants, toddlers and children crawling on floor or playing around treated surfaces for a significant time period and adults working around treated surfaces, thereby accidentally touching contaminated surfaces with their bare hands.

Oral exposure is relevant for infants and toddlers, that exhibit a great deal of hand-to-mouth contact. Therefore, residues present on the hands will be dislodged by saliva and eventually ingested. Oral exposure has been calculated using the assumption of Bremmer *et al*. (2002) that 10% of the amount ending up on the skin of the infant is taken up *via* hand-mouth contact. The hands form about 20% of the total uncovered skin and it is assumed that 50% of the product that ends up on the hands is taken in orally due to hand-mouth contact. This means that *via* hand-mouth contact 10% of the external dermal exposure is ingested. The ingestion rate can be calculated based on the assumption that from the total dermal exposure 10% is taken in orally due to hand-to-mouth contact (RIVM report 320005002/2006).

The models and the parameters used to calculate the secondary exposure assessment for the general public are described in detail in the following table, while the calculations are presented in the Annex 3.2 of this document.

Description of Scenario [06]		
Secondary dermal and oral exposure of the general public. The assessment of the dermal and oral exposure of the general public has been performed using ConsExpo Web, version 1.0.6. The parameters used were from the RIVM report 320005002/2006, Chapter 2, Spray applications, Targeted spot application, Exposure after application (p. 34-38).		
Parameter	**Value**	**Comments**
Exposed group	General public: infant, toddler, child, adult	-
Product database	Pest control products	-
Product category	Sprays	-
Product	Targetted spot	-
Scenario	Post-application (child)	-

Body weight	Infant: 8 kg Toddler: 10 kg Child: 23.9 kg Adult: 60 kg	HEEG Opinion "Default human factor values for use in exposure assessments of biocidal products".
Weight fraction substance	permetrhrin: 0.06%	Concentration of permethrin in the biocidal product.
	piperonyl butoxide: 0.00106%	Concentration of piperonyl butoxide in the biocidal product.
Dermal exposure		
Model	Direct product contact	-
Loading	Rubbing off	-
Exposure frequency	126 per year	Default value, as reported in RIVM report 320005002/2006: "Pest Control Products Fact Sheet" (p. 38).
Exposed area (palms and backs of both hands)	Infant: 196.8 cm^2 Toddler: 230.4 cm^2 Child: 427.8 cm^2 Adult: 820 cm^2	HEEG Opinion "Default human factor values for use in exposure assessments for biocidal products".
Transfer coefficient	Infant/toddler/child: 0.2 m^2/hr Adult: 0.78 m^2/hr	Recommendation no. 12 of the BPC Ad hoc Working Group on Human Exposure: "New default values for indoor Transfer Coefficient" (agreed at the Human Health Working Group V on 22 November 2016).
Dislodgeable amount	3.1 g/m^2	Default value, as reported in RIVM report 320005002/2006: "Pest Control Products Fact Sheet" (p. 38).
Contact time	60 min/day	Default value, as reported in RIVM report 320005002/2006: "Pest Control Products Fact Sheet" (p. 38).
Rubbed surface	2 m^2	Default value, as reported in RIVM report 320005002/2006: "Pest Control Products Fact Sheet" (p. 38).
Dermal absorption	70% for both active substances	Default dermal absorption value for both active substances, as proposed by EFSA Guidance on dermal absorption [EFSA Journal, 2017; 15(6): 4873] for organic solvent-based formulations containing ≤5% active substance.
Oral exposure: hand-to mouth contact		
Model	Direct product contact	-
Loading	Constant rate	-
Ingestion rate	1.03 mg/min (product)	Calculated as reported in RIVM report 320005002/2006: "Pest Control Products Fact Sheet" (p. 72).

		"The hands form about 20% of the total uncovered skin. It is assumed that 50% of the product that ends up on the hands is taken in orally due to hand-mouth contact. This means that via hand-mouth contact 10% of the external dermal exposure is ingested. The ingestion rate can be calculated based on the assumption that from the total dermal exposure 10% is taken in orally due to hand-mouth contact." Therefore, the ingestion rate for NEODUST is calculated as follows: transfer coefficient x dislodgeable amount x 10% = (0.2 m^2/hr x 3.1 g/m^2 x 1000 x 0.1) / 60 = 1.03 mg/min
Exposure time	60 min	Default value, as reported in RIVM report 320005002/2006: "Pest Control Products Fact Sheet" (p. 38).
Oral absorption	100% for both active substances	Assessment Reports of permethrin (Ireland, 2014) and piperonyl butoxide (Greece, 2019).

Calculations for Scenario [06]

Summary table: estimated secondary exposure of general public					
Scenario	**Active substance**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		mg/kg bw/day			
Scenario [06] Post application Infant	permethrin	-	3.3×10^{-2}	4.6×10^{-3}	**3.7×10^{-2}**
	piperonyl butoxide	-	5.8×10^{-4}	8.2×10^{-5}	**6.6×10^{-4}**
Scenario [06] Post application Toddler	permethrin	-	2.6×10^{-2}	3.7×10^{-3}	**3.0×10^{-2}**
	piperonyl butoxide	-	4.6×10^{-4}	6.6×10^{-5}	**5.3×10^{-4}**
Scenario [06] Post application Child	permethrin	-	1.1×10^{-2}	-	**1.1×10^{-2}**
	piperonyl butoxide	-	1.9×10^{-4}	-	**1.9×10^{-4}**
Scenario [06] Post application	permethrin	-	1.7×10^{-2}	-	**1.7×10^{-2}**

Adult	piperonyl butoxide	-	3.0×10^{-4}	-	**3.0×10^{-4}**

Combined scenarios

The exposure estimates from the different routes of exposure (inhalation, dermal, oral) *per* scenario are added together to provide a total systemic (internal) dose and are provided in previous tables.

Monitoring data

No monitoring data available.

Dietary exposure

The biocidal product PERTEX is also can be used as insecticide (product type 18) for control of flies and mosquitos insect and ticks by application to localised areas in animal shelters without the presence of the animal, so that the biocidal product does not come into contact with animals. The biocidal product PERTEX has to be applied when the animals are not present in the stables, therefore animals are not exposed directly to the biocidal product.

The intended uses of PERTEX are unlikely to cause a dietary risk to consumers. The biocidal product PERTEX will not get into contact with food, feed and livestock and will not leave residues in commodities for human or animal consumption.

Therefore, dietary exposure as result of use (i.e., food contamination and livestock exposure) can be excluded taking into account the following risk mitigation measures should be indicated on the label in order to avoid any accidental contamination on food/feedstuff from animal or vegetal origin such as:

- Evacuate animals prior to biocidal treatment
- Treatment of b.p should be away from areas of possible animal contact.
- Remove all food, feed and drinks from animal housing prior to biocidal treatment.
- Remove any tool that may enter in contact tith food/feedstuff during biocidal treatment.
- Do not apply directly to surfaces and facilities likely to be in contact with food, feed, drinks and animals (surfaces where food is stored, prepared or consumed)
- Cover all surfaces and facilities likely to be in contact with food, feed, drinks and animals before treatment to avoid any indirect contamination during nearby application
- Keep away from food/feed stuff, eating utensils or food/feed contact surfaces.
- Perform dry cleaning of treated surfaces and adjacent floor.
- Clean the treatead area before the re-entry of the animal.
- The treated premises/room must not be accessible to pets, especially to cats due to high sensitivity to permethrin toxicity. Permethrin may be lethal to cats..

Information of non-biocidal use of the active substance

The active substances permethrin and piperonyl butoxide are authorised for the use as biocides. Non-biocidal use foreseen.

Estimating Livestock Exposure to Active Substances used in Biocidal Products

Based on intended uses of the biocidal product, human exposure through residues in livestock is not foreseen and feeding and metabolism studies in livestock to permit evaluation of residues in food of animal origin are not required. Therefore, animal exposure and transfer to animal food commodities has not be investigated.

Nevertheless, to ensure that contact of the biocidal product with livestock is avoided for the use on stable and animal house, the following precautionary risk mitigation measures are proposed:

- "Move the animals away during the treatment"
- "The treatment premises/room must not accessible to pets"
- "Clean the treatead area before the re-entry of the animal"
- "Do not treat directly on the animal"

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

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

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

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

Aggregated exposure

Aggregated exposure (combined scenarios 01+04+05 or 02+04+05 or 03+04+05) has been assessed for the professional user who is exposed to the active substances permethrin and piperonyl butoxide during the application of the product (primary direct exposure – Scenario 01, 02, 03), during the laundering of the contaminated work clothes at home (primary indirect exposure – Scenario 04) and during the cleaning of the spraying equipment (primary indirect exposure – Scenario 05).

Summary of exposure assessment

Scenarios and values to be used in risk assessment				
Scenario Number / application	**Exposed Group (e.g. professionals, non-professionals, bystanders)**	**Active substance**	**Tier/PPE**	**Estimated total internal uptake (mg/kg bw/day)**
Scenarios [01, 02, 03] Application - Spraying	Professionals	Permethrin	1 / no PPE	**2.32×10^{-1}**
		Piperonyl butoxide		**4.1×10^{-3}**
Scenarios [01, 02, 03] Application - Spraying	Professionals	Permethrin	2 / gloves, coated coverall	**2.71×10^{-2}**
		Piperonyl butoxide		**4.8×10^{-4}**
Scenario [04]	Professionals	Permethrin	1 / no PPE	**8.4×10^{-4}**

Post application - laundering work clothes		Piperonyl butoxide		**1.5×10^{-5}**
Scenario [05] Post application - cleaning the equipment	Professionals	Permethrin	1 / no PPE	**7.7×10^{-6}**
		Piperonyl butoxide		**1.4×10^{-7}**
Scenario [06] Post application – Secondary exposure	General public Infants	Permethrin	1 / no PPE	**3.7×10^{-2}**
		Piperonyl butoxide		**6.6×10^{-4}**
Scenario [06] Post application – Secondary exposure	General public Toddlers	Permethrin	1 / no PPE	**3.0×10^{-2}**
		Piperonyl butoxide		**5.3×10^{-4}**
Scenario [06] Post application – Secondary exposure	General public Children	Permethrin	1 / no PPE	**1.1×10^{-2}**
		Piperonyl butoxide		**1.9×10^{-4}**
Scenario [06] Post application – Secondary exposure	General public Adults	Permethrin	1 / no PPE	**1.7×10^{-2}**
		Piperonyl butoxide		**3.0×10^{-4}**
Combined scenarios [01 + 04 + 05] or [02 + 04 + 05] or [03 + 04 + 05] Application & post-application	Adult professional user	Permethrin	2 / gloves, coated coverall	**2.795×10^{-2}**
		Piperonyl butoxide		**4.95×10^{-4}**

2.2.6.3 Risk characterisation for human health

The reference values for the active substances permethrin (Assessment report; Ireland, 2014) and piperonyl butoxide (Assessment report; Greece, 2019) that were used in risk characterisation for human health are described in the following tables.

Reference values for permethrin to be used in risk characterisation

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

The Assessment Report of permethrin (April 2014) provides AELs for short, medium and long-term exposure.

The 90-day inhalation rat study (Kumar, 2006) was deemed the most appropriate sub-chronic study to provide a NOAEL value that can be used to establish systemic $AEL_{acute\text{-}term}$. A NOAEL of 0.2201 mg/L was established in the study which corresponds to 59.46 mg/kg bw/day. Dividing

the NOAEL (59.46 mg/kg bw/day) by an overall assessment factor of 100, derives an ARfD or AEL_{acute} reference value of 0.5 mg/kg bw/day.

$AEL_{medium-term}$ or AOEL is derived from the dog 12-month study and it is estabilished at 0.05 mg/kg bw/day.

The lowest NOAEL in key long-term carcinogenicity study was 50 mg/kg bw/day in the rat (McSheehy & Finn 1980). However, in the 12-month dog study (Kalinowski et al, 1982 (key)) a more conservative value was derived. In addition, the effects seen in the dog are those normally associated with pyrethroid toxicity. On this basis the $AEL_{long-term}$ has been set to 0.05 mg/kg bw/day.

Reference values for piperonyl butoxide to be used in risk characterisation

Reference	Study	NOAEL	AF	Correction for oral absorption	Value
AEL short term	developmental study rabbit	100 mg/kg bw/day	100	-	1 mg/kg bw/day
AEL medium term	1-year dietary study dog	16 mg/kg bw/day	100	100 %	0.2 mg/kg bw/day
AEL long term	1-year dietary study dog	16 mg/kg bw/day	100	100 %	0.2 mg/kg bw/day

The NOAEL derived from the 1-year dietary study in dogs is considered suitable for the medium-term AEL, long-term AEL.

In the rabbit teratology study, maternal body weight was decreased (4%) within the first day of dosing at the 200 mg/kg b.w./day. Thus, the NOAEL maternal of 100 mg/kg b.w./day from the rabbit teratology study was considered to be more relevant for the short-term AEL setting.

Based on the results of the ADME studies, an oral absorption value of 100% should be incorporated in the calculation of the AEL values.

The default assessment factor of 100 [10 (interspecies variation) x 10 (intraspecies variation)] is considered appropriate.

Risk for industrial users

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

Risk for professional/trained professional users

The risk characterisation for human health considers the primary exposure during the application of the product by professional users.

The product PERTEX may be used by professional/trained professional users both indoors and outdoors against arthropods of hygienic-sanitary interest and is a water-based microemulsion (ME) formulation containing 3% w/w permethrin and 0.053% piperonyl butoxide which is diluted and mixed prior to use.

The recommended usage concentration of the spray solution indoors and outdoor is 2% v/v (equivalent to 2L of concentrated product in 100 litres of water). For the indoor and outdoor use it is applied to surfaces *via* low pressure pump by professionals/trained professionals. The

application rate is the same for all the application scenarios; the product could be used against flies, stables flies and mosquitos on porous and non-porous surfaces, in indoor and outdoor, and against ticks and mites in infested stables and hen-house.

Regarding the primary exposure of professional users, based on the frequency of product applications the AEL $_{long\text{-}term}$ is used in the risk characterisation of exposure for professional users.

The risk characterisation for the application of the product by professionals is summarised in the table below.

Risk assessment results for human health, primary exposure					
Scenario	**Substance**	**Total uptake (mg/kg bw/d)**	**AEL long term (mg/kg bw/d)**	**HQ* (Exposure/ AEL)**	**Acceptable**
Scenario [01, 02, 03] Application Professionals Tier 1 / no PPE	permethrin	2.32×10^{-1}	0.05	**4.64**	**No**
	piperonyl butoxide	4.1×10^{-3}	0.2	**0.021**	**Yes**
Scenario [01, 02, 03] Application Professionals Tier 2 / gloves, coated coverall	permethrin	2.71×10^{-2}	0.05	**0.542**	**Yes**
	piperonyl butoxide	4.8×10^{-4}	0.2	**0.0024**	**Yes**
Scenario [04] Post application - laundering clothes Professionals Tier 1 / no PPE	permethrin	8.4×10^{-4}	0.05	**0.017**	**Yes**
	piperonyl butoxide	1.5×10^{-5}	0.2	**0.00008**	**Yes**
Scenario [05] Post application – cleaning equipment Professionals Tier 1 / no PPE	permethrin	7.7×10^{-6}	0.05	**0.00015**	**Yes**
	piperonyl butoxide	1.4×10^{-7}	0.2	**0.0000007**	**Yes**

* The Hazard Quotient (HQ) is defined as the ratio estimation of internal exposure/AEL.

Combined scenarios

The exposure estimates from the different routes of exposure (inhalation, dermal, oral) *per* scenario are added together to provide a total systemic (internal) dose.

Local effects

Considering that PERTEX is classified for Skin Sens. Cat. 1 (H317), the risk characterization for local effects is required only for the mixing & loading phase where the concentrate product is diluted up to the in-use concentrations according to the ECHA Guidance on the Biocidal Products Regulation, Volume III Human Health - Assessment & Evaluation (Parts B+C), Version 2.1 February 2017.

The qualitative risk assessment for the primary exposure of the professional user is presented in the following table.

Risk Characterisation for local effects: Primary exposure of professional users											
Hazard				**Exposure**				**Risk**			
Hazard Category	***effects in terms of C&L***	***additional relevant hazard information***	***PT***	***Who is exposed?***	***Tasks, uses, processes***	***Potential exposure route***	***Frequency and duration of potential exposure***	***Potential degree of exposure***	***Relevant RMM & PPE***	***Conclusion on risk***	***Uncertainties attached to conclusion may increase (↑) or decrease (↓) risk or both (↑↓)***
low	Skin Sens. 1, H317	-	18	Professionals	Mixing & loading phase: dilute product PERTEX	Skin (splashes, hand to eye transfer)	1-2/year; Few minutes or less per day	n.r.	• labelling as skin sensitisation • child proof closure • instructions for use minimizing exposure for professionals • substance/task appropriate gloves • skin coverage with appropriate barrier material based on potential for contact with the chemicals • washing of hands after use • regular cleaning of equipment and work area	Acceptable: +Reversible effect +professionals following instructions for use +experience expected +trained workers	Instructions for use and packaging as well as adherence to it, including washing of hands may vary (↑↓)

Conclusion

The ratio Exposure/AEL (HQ) for piperonyl butoxide is well below 1 for the professional user even without personal protective equipment.

However, the ratio Exposure/AEL (HQ) for permethrin is below 1 only for the professional user wearing gloves and coated coveralls.

Therefore, the risk for professionals appears acceptable for both the active substances contained in the biocidal product PERTEX only when professionals wear gloves and coated coveralls during product application.

Risk for the general public

The risk characterisation for human health considers also the secondary exposure of the general public after application of the biocidal product.

Subsequent to the use of the biocidal product, exposure to the general public is possible *via* the dermal and the oral route.

Dermal exposure may occur to infants, toddlers and children crawling on floor or playing around treated surfaces for a significant time period and adults accidentally touching contaminated surfaces with their bare hands.

Oral exposure is relevant for infants and toddlers, that exhibit a great deal of hand-to-mouth contact. Therefore, residues present on the hands will be dislodged by saliva and eventually ingested.

Regarding secondary exposure, the $AEL_{long\text{-}term}$ is used in the risk characterisation of exposure for the general public.

The risk characterisation for the general public is summarised in the table below.

Risk assessment results for human health, secondary exposure					
Scenario	**Substance**	**Total exposure (mg/kg bw/d)**	**AEL long term (mg/kg bw/d)**	**HQ* (Exposure/AEL)**	**Acceptable**
Scenario [06] Post-application Secondary exposure Infants	Permethrin	3.7×10^{-2}	0.05	**0.74**	**Yes**
	Piperonyl butoxide	6.6×10^{-4}	0.2	**0.0033**	**Yes**
Scenario [06] Post-application Secondary exposure Toddlers	Permethrin	3.0×10^{-2}	0.05	**0.6**	**Yes**
	Piperonyl butoxide	5.3×10^{-4}	0.2	**0.00265**	**Yes**
Scenario [06] Post-application Secondary exposure Children	Permethrin	1.1×10^{-2}	0.05	**0.22**	**Yes**
	Piperonyl butoxide	1.9×10^{-4}	0.2	**0.00095**	**Yes**
Scenario [06] Post-application Secondary exposure	Permethrin	1.7×10^{-2}	0.05	**0.34**	**Yes**
	Piperonyl butoxide	3.0×10^{-4}	0.2	**0.0015**	**Yes**

Adults					

* The Hazard Quotient (HQ) is defined as the ratio estimation of internal exposure/AEL.

Combined scenarios

The exposure estimates from the different routes of exposure (inhalation, dermal, oral) *per* scenario are added together to provide a total systemic (internal) dose.

Local effects

Taking into account that PERTEX is classified for Skin Sens. Cat. 1 (H317), a risk characterization for local effects for secondary exposure has been performed according to the ECHA Guidance on the Biocidal Products Regulation, Volume III Human Health - Assessment & Evaluation (Parts B+C), Version 2.1 February 2017 (p.247).

No risk is anticipated for the general public taking into account that any accidental exposure to the treated surfaces will be with the dried residues of the diluted product.

The qualitative risk assessment for secondary exposure for the product use is presented in the following table.

Risk Characterisation for local effects: Secondary exposure: general public										
Hazard				**Exposure**				***Risk***		
Hazard Category	***effects in terms of C&L***	***additional relevant hazard information***	***PT***	***Who is exposed?***	***Tasks, uses, processes***	***Potential exposure route***	***Frequency and duration of potential exposure***	***Potential degree of exposure***	***Relevant RMM (PPE not relevant)***	***Conclusion on risk***
Medium	Skin Sens. 1, H317	-	18	General public (adults, children, infants, pets)	Post application phase	Skin (Hands)	60 min/ day	Minimal exposure	• labelling as skin sensitization, instructions for use • child proof closure • packaging minimizing risk for exposure • Remove the product from surfaces where contact is more likely	Acceptable: - low degree of potential exposure

Conclusion

The ratio Exposure/AEL (HQ) for each active substance of the biocidal product PERTEX is well below 1. Therefore, secondary exposure to permethrin and piperonyl butoxide predicts an acceptable health risk for the general public from application of the biocidal product PERTEX.

Aggregated exposure

Aggregated exposure (combined scenarios 01+04+05 or 02+04+05 or 03+04+05) has been assessed for the professional user who is exposed to the active substances permethrin and piperonyl butoxide during the application of the product (primary direct exposure – Scenario 01, 02, 03), during the laundering of the contaminated work clothes at home (primary indirect exposure – Scenario 04) and during the cleaning of the spraying equipment (primary indirect exposure – Scenario 05).

The risk characterisation for the aggregated exposure of the adult professional user is summarised in the table below.

Risk assessment results for human health, aggregated exposure					
Scenario	**Substance**	**Total uptake (mg/kg bw/d)**	**AEL long term (mg/kg bw/d)**	**HQ* (Exposure/ AEL)**	**Acceptable**
Combined scenarios [01 + 04 + 05] or [02 + 04 + 05] or [03 + 04 + 05] Application & post-application Professionals	permethrin	2.795×10^{-2}	0.05	**0.559**	**Yes**
	piperonyl butoxide	4.95×10^{-4}	0.2	**0.00248**	**Yes**

* The Hazard Quotient (HQ) is defined as the ratio estimation of internal exposure/AEL.

Conclusion

The ratio Exposure/AEL (HQ) for each active substance of the biocidal product PERTEX is well below 1. Therefore, regarding aggregated exposure, the use of the biocidal product PERTEX is considered safe for the adult professional users, as the risk is acceptable for both active substances.

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

A risk characterisation from combined exposure to several active substances is relevant for the biocidal product PERTEX, as it contains two different active substances: permethrin and piperonyl butoxide.

Based on the ECHA BPR Guidance[1], a Tiered approach was implemented. According to the guidance, the "Tier 1" of this method is an intermediary step to verify risk acceptability for each substance used in the product. The calculations for this level were performed in the sections presented above. This step is to be followed by "Tier 2", which involves assessing the combined exposure to the substances of the biocidal product.

According to the ECHA guidance, the "Tier 1" step calculations must be undertaken in accordance with the methodology that is currently used for the assessment of products. Each active substance is assessed in terms of risks to primary and secondary exposure following all the scenarios which are relevant to the product use. The decision-making criterion for acceptability of risk remains as in the case of quantitative risk: the estimated level of exposure to each substance must be lower than its AEL. The Hazard Quotient which is defined by the ratio of internal exposure and AEL has to remain below 1.

Risk characterisation from combined exposure to permethrin and piperonyl butoxide has been calculated and results are reported in the previous sections named "*Risk for professional users*" and "*Risk for the general public*". The calculations presented above have shown acceptable risks (and hazard quotients) for all relevant scenarios for the active substances when considered separately (for details see above).

According to the ECHA Guidance on BPR, the "Tier 2" - level assessment of combined exposure to mixture is performed by concentration (dose) addition. This means that the effects of the active substances in the biocidal product are assumed to be concentration or dose-additive.

The Tier 2 assessment is performed with the same parameters as the first tier. The HQ for each substance is used to calculate a HI (Hazard Index) for the biocidal product according to the following method:

HI = Σ HQa.s.

The Hazard Quotient (HQ) is defined as the ratio estimation of internal exposure/AEL.

The HI is the sum of the HQs for each substance.

HI should be ≤1 to show an acceptable risk related to the use of the biocidal product.

Based on this approach, the additive risks from both active substances have been calculated for professional users (primary exposure) as well as for the general public (secondary exposure).

The risk characterisation for the additive effects of the primary exposure of professionals is summarised in the following table.

Combined risks from both active substances for professional users (additive effect)				
Scenario	**HQ permethrin**	**HQ piperonyl butoxide**	**HI product**	**Acceptable**
Scenario [01, 02, 03] Application Professionals Tier 2 / gloves,	0.542	0.0024	**0.544**	**Yes**

1 ECHA (2017) Guidance on the BPR: Volume III Human Health Assessment & Evaluation (Parts B+C) V2.1, ECHA-17-G-04-EN

coated coverall				
Scenario [04] Post application - laundering clothes Professionals Tier 1 / no PPE	0.017	0.00008	**0.0171**	**Yes**
Scenario [05] Post application – cleaning equipment Professionals Tier 1 / no PPE	0.00015	0.0000007	**0.000151**	**Yes**

Conclusion for additive effects of professional users

The simple addition of the AEL coverage (= hazard quotient, HQ) by both active substances leads to an HI (sum of HQs for the two active substances) which is below 1 for professional users. Therefore, combined additive risk calculations for the two active substances show acceptable risks for the primary exposure of professional users.

The risk characterisation for the additive effects of the secondary exposure of general public is summarised in the following table.

Combined risks from both active substances for general public (additive effect)				
Scenario	**HQ permethrin**	**HQ piperonyl butoxide**	**HI product**	**Acceptable**
Scenario [06] Post-application Secondary exposure Infants	0.74	0.0033	0.74	**Yes**
Scenario [06] Post-application Secondary exposure Toddlers	0.6	0.00265	0.6	**Yes**
Scenario [06] Post-application Secondary exposure Children	0.22	0.00095	0.22	**Yes**
Scenario [06] Post-application Secondary exposure Adults	0.34	0.0015	0.34	**Yes**

Conclusion for additive effects of the general public

The simple addition of the AEL coverage (= hazard quotient, HQ) by both active substances leads to an HI (sum of HQs for the three active substances) which is below 1

for all the exposed groups. Therefore, combined additive risk calculations for both active substances show acceptable risks for the secondary exposure of the general public.

The risk characterisation for the additive effects of the aggregated exposure of professional users is summarised in the following table.

Combined risks from both active substances for adult professional users (additive effect)				
Scenario	**HQ permethrin**	**HQ piperonyl butoxide**	**HI product**	**Acceptable**
Combined scenarios [01 + 04 + 05] or [02 + 04 + 05] or [03 + 04 + 05] Application & post-application Professionals	0.559	0.00248	0.56	**Yes**

Conclusion for the aggregated exposure of adult professional users

The simple addition of the AEL coverage (= hazard quotient, HQ) by both active substances leads to an HI (sum of HQs for the three active substances) which is below 1 for the aggegated exposure of the adult professional user .

Therefore, combined additive risk calculations for both active substances show acceptable risks for the adult professional user.

Risk for consumers via residues in food

The product PERTEX is not intended for the use on food neither directly nor in areas where food is stored. Moreover no transfer of active substance into foods as results of professional and/or industrial application is expected since the product is not applied by spraying or dusting such that food or feeding stuffs could be contaminated. Therefore, there is no requirement to assess risk to consumers via residues in food.

2.2.7 Risk assessment for animal health

As shown previsously, the product PERTEX should be unclassified with respect to toxicity, except for skin sensitisation (H317) and non-target species are not likely to be exposed in sufficient quantity to produce toxic effects. Thus no risk is envisaged for animal health.

2.2.8 Risk assessment for the environment

2.2.8.1 Effects assessment on the environment

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

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

Summary on PNEC used for the risk assessment							
Substance	**Surface water [$PNEC_{aquatic}$ (mg/L)]**	**Sediment [$PNEC_{sediment}$ (mg/kg wwt)]**	**STP microorganism [$PNEC_{STP}$ (mg/L)]**	**Soil [$PNEC_{soil}$ (mg/kg wwt)]**	**Birds [$PNEC_{oral, birds}$ (mg/kg diet)]**	**Mammals [$PNEC_{oral, mammals}$ (mg/kg diet)]**	**Reference**
Permethrin	4.7×10^{-7}	2.17×10^{-4}	0.00495	0.0876	16.7	120	AR, 2014
DCVA	0.015	0.055	Not relevant	4.6	Not relevant	Not relevant	AR, 2014
PBA	>0.01	0.042	Not relevant	1.44	Not relevant	Not relevant	AR, 2014
Piperonyl Butoxide (PBO)	0.00148	0.0004	2.89	0.0980	10	20	AR, 2017
Metabolite M-1	0.0028	-	Not relevant	0.0980	Not relevant	Not relevant	AR, 2017
Metabolite M-2	0.0033	-	Not relevant	0.0980	Not relevant	Not relevant	AR, 2017
Metabolite M-8	Not relevant	Not relevant	Not relevant	0.0980	Not relevant	Not relevant	AR, 2017
Metabolite M-12	0.0023	-	Not relevant	0.0980	10	20	AR, 2017
Metabolite EN 1-101/4	Not relevant	Not relevant	Not relevant	0.0980	Not relevant	Not relevant	AR, 2017

For risk assessment of permethrin only the active substance is considered to be ecotoxicologically relevant (worst case) since the metabolites are far less toxic to organisms than the parent compound.

In the AR, 2017 for PBO, the PEC/PNEC ratio for metabolites resulted lower than the ones for the active substance, therefore the risk of metabolites is considered covered by the risk assessment of the active substance.

Further Ecotoxicological studies

Data waiving	
Information requirement	Further ecotoxicological studies
Justification	Ecotoxicological studies on the formulation are generally not required for biocidal products as long as sufficient information can be extrapolated from the active substance. The ecotoxicological testing of the active substance permethrin and PBO were adequately covered in the AR (2014) and AR (2017), respectively and there are no other components in the PERTEX formulation which are of ecotoxicological relevance (confidential information, see Section B2.2), therefore no additional studies were performed and reference is made to the CAR, document IIA, section 4.2.

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

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

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

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

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

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

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

No data is available.

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

For the biocidal product PERTEX used as insecticide and acaricide, the following life cycle stages are identified:

1. Manufacturing of permethrin and PBO
2. Formulation of PERTEX

3. Intended Use of PERTEX

    a) Mixing and Loading of PERTEX

    b) Application of PERTEX

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

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

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

According to the "EU Evaluation Manual for the Authorisation of Biocidal Products; final version 1.0" emissions from active substance production and product formulation are considered less significant compared to emissions from the application phase, in service and waste phase of the product and these phases are not part of Regulation (EU) No 528/2012.
The formulation step is not covered by the ESD for PT 18; nevertheless it was no risk is identified for freshwater, air and agricultural soil compartments, provided that solid and liquid spills and cleaning waters are collected and dispose of as dangerous waste and all operations are conducted under aspiration and the collected emissions are treated before release to air.

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

PERTEX may be used by professionals both indoors and outdoors and it is a water based microemulsion (ME) formulation containing 2.79% w/w Permethrin and 0.05% PBO which is diluted prior to use. The recommended usage concentration of the spray solution indoors and outdoors is 2% v/v (equivalent to 2L of product in 100 litres of water).
For both the indoor and outdoor uses it is applied to surfaces via a low pressure pump.
In the ESD for PT18 it is generally assumed that insecticides used indoors will not directly reach the environmental compartments, but it is concluded that after the application of the insecticide, the cleaning step will lead the releases to waste water through wet cleaning methods.
For outdoor applications, it is assumed that the fate of the substance depends on the location of the treated structures, i.e. either in countryside or within a city. In urban area, insecticides will be washed with rain to the rainwater/sewer system and reach the sewage treatment plant (STP). Releases can then occur to the surface water from STP discharge, to agricultural soil from sludge application and eventually to groundwater. In rural area, losses will end up directly on unpaved soil and eventually to groundwater.
On this basis, the environmental exposure assessment has been performed for both active substances.
Nevertheless, the potential environmental exposure to metabolites should also be considered. Since no clear recommendations are available for metabolites at the time of writing, the chosen approach was to estimate the concentrations of relevant metabolites as a percentage of the concentrations of the parent compound permethrin and PBO. There are only minor differences between molecular weights of permethrin and PBO and its metabolites. Hence, correction based on the molecular weights was considered negligible.

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

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

Leaching behaviour (ADS)

No data is available.

Testing for distribution and dissipation in soil (ADS)

Data waiving	
Information requirement	No testing for distribution and dissipation in soil has been conducted on PERTEX.
Justification	The environmental fate and behaviour of the active substance permethrin and PBO have been adequately covered in the AR for the active susbtance (2014 and 2017, respectively), so reference is made to the said report, document IIA, section 4.1. Therefore, and in view of the low environmental exposure expected following the use of the formulation, testing for distribution and dissipation in the environment is not required.

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

Data waiving	
Information requirement	No testing for dissipation and distribution in water and sediment has been conducetd on PERTEX.
Justification	The environmental fate and behaviour of the active substance permethrin and PBO have been adequately covered in the AR for the active susbtance (2014 and 2017, respectively), so reference is made to the said report, document IIA, section 4.1. Therefore, and in view of the low environmental exposure expected following the use of the formulation, testing for distribution and dissipation in the environment is not required.

Testing for distribution and dissipation in air (ADS)

Data waiving	
Information requirement	No testing for dissipation and distribution in air has been conducted in PERTEX
Justification	The environmental fate and behaviour of the active substance permethrin and PBO have been adequately covered in the AR for the active susbtance (2014 and 2017, respectively), so reference is made to the said report, document IIA, section 4.1. Therefore, and in view of the low environmental exposure expected following the use of the formulation, testing for distribution and dissipation in the environment is not required.

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

No data required.

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

Not relevant

2.2.8.2 Exposure assessment

Pertex is a biocidal product of water based microemulsion formulation containing 3.0% w/w Permethrin and 0.053% w/w Piperonyl butoxide (% w/w technical grade active ingredients, TGAI). The product is intended to be used indoors (domestic houses & larger buildings) outdoors (rural areas) and in stables, only by professional users.

The environmental exposure assessment, where relevant, has been performed for both active substance permethrin and PBO and was conducted for the local scale only, as required for biocidal products. The risk of their metabolites is considered covered by the risk assessment of the active substances. As the metabolites of permethrin are far less toxic to organisms than the parent compound (worst case), exposure assessment was only presented for the active substance. Moreover, in the AR, 2017 for PBO, the PEC/PNEC ratio for metabolites resulted lower than the ones for the active substance.

General information

Assessed PT	PT 18
Assessed scenarios	**Scenario 1:** Use # 1 Indoor application for professional user- flies **Scenario 2:** Use # 2 Indoor application for professional user- ticks **Scenario 3:** Use # 3 – Outdoor application for professional user-flies, mosquitoes **Scenario 4:** Use # 4 – Outdoor application for professional user-ticks **Scenario 5:** Use # 5 – Stable application for professional user-flies **Scenario 6:** Use # 6 – Stable application for professional user-ticks
ESD(s) used	ESD for PT18 (2008): Series on Emission Scenario Documents Number 18 , Emissions Scenario Document for insecticides, acaricides and products to control other arthropods for household and professional uses ENV/JM/MONO(2008)14). ESD for PT18 (2006): OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 14, Emission Scenario Document for Insecticides for Stables and Manure Storage Systems, 25-Jan-2006, ENV/JM/MONO(2006)
Approach	**Scenario 1 to 6:** Average consumption
Distribution in the	Calculated based on Guidance on the Biocidal Products

environment	Regulation. Volume IV Environment - Assessment and Evaluation (Parts B + C). Version v.2.0. October 2017. Technical Agreements for Biocides (TAB) Version 2.0, August 2018) & (TAB ENV v.2.1, December 2019)
Groundwater simulation	YES
Confidential Annexes	No.
Life cycle steps assessed	**Scenarios 1 to 6**: Production: No, Formulation: No, Use: Yes, Service life: No
Remarks	The surface spray scenario was used from the ESD. It was adapted accordingly for the intended use 4, outdoors, as no specific emission scenario was available.

Compared to emissions from the application event (considered worst case for the risk assessment), emissions from the product formulation and service phase of the product are considered less relevant, as reported in "Guidance on the Biocidal Products Regulation, Volume IV Environment – Part B Risk Assessment, version 1.0".

Emission estimation

General aspects for the emission calculations

The product is diluted prior to use. The product is always sold as concentrated solution needing dilution. The recommended usage concentration of the spray solution indoors and outdoors is 2% v/v. It is applied to surfaces via a low pressure pump.

After indoor use of an insecticide product, STP is regarded as the unique point source of direct active ingredients emissions to environmental compartments per day. Emissions need to be calculated for the preparation (mixing/loading) step, the application step, and the cleaning step, through wet cleaning procedure.

As explained in the OECD ESD PT 18, during the cleaning step, two cases are considered:

- cleaning events resulting only in emissions to waste: 100% of the surfaces are cleaned by vacuum/broom (F_w = 1, F_{ww} = 0) and the clothes of the operator are disposable ($F_{applicator, w}$ = 1, $F_{applicator, ww}$ = 0),
- cleaning events resulting only in emissions to waste water: 100% of the surfaces are washable (F_{ww} = 1, F_w = 0) and the clothes of the operator are washed ($F_{applicator, ww}$ = 1, $F_{applicator, w}$ = 0).

Exposure assessment is assessed case by case, based on the different scenarios, considering the field of use, as claimed by the applicant, the product application by only professional users and where possible the application of strict Risk Mitigation Measures.

The input parameters for the EUSES calculation are based on the Assessment Report for the Inclusion of active substance permethrin and PBO in Annex I or IA to Directive 98/8/EC (Product Type 18) (AR, 2014 and AR, 2017, respectively for permethrin and PBO).

Emmision estimation for Scenario 1 & 2

Scenario 1 & 2 considers professional use for application indoors against flies and ticks in limited areas, which are declared as strictly 'not wet-cleaned'. Those areas are for the domestic premises: cellars, attics, voids, crawl places, garages, while for the industrial premises-public buildings: commercial (industrial) warehouses that are not wet-cleaned and rooms of electrical appliances. Thus, emissions during the cleaning step are not relevant, as those areas are considered restricted to dry cleaning, i.e., areas not allowing wet-cleaning procedures.
Further, as the product is applied by a professional user, two RMM are eligible to eliminate any emissions while mixing/loading and applicator application step, i.e., the covering of the floor with a plastic disposable sheet & the use of disposable coveralls during preparation/application by the user.

Therefore, for the intented use 1 & 2 of this product, of limited 'field of use', by a professional user, emissions to the STP are not foreseen, as the areas are under a 'non-wet cleaning' status, and RMM are eligible to eliminate any other exposure. All Mitigation Measures are strictly noted in the product label instructions.

Emmision estimation Scenario 3

Scenario 3 considers an outdoor application by professional user against mosquitoes, spraying on potted hedges in rural areas, with the scope to protect the outside area from the mosquitoes and not to prevent the entrance of mosquitoes to the building. This Scenario is by definition out of the concept of the current ESD for outdoor uses against mosquitoes meant 'to treat walls or entrance borders in order to prevent the entrance of mosquitoes in the buildings'', therefore no scenarios can be adapted for the intented Use under the current PT18 outdoor use guidances.

Emmision estimation Scenario 4
Scenario 4 considers an outdoor, rural, spraying application against ticks by a professional user. For this application there is not a relevant scenario available for outdoor uses. The scenario for crawling insects (chemical barrier, treating foundation and band of soil around the building) has been adapted.

The scenario was assessed under the following RMM: (1) the mixing/loading step is considered negligible under the RMM of preparing the product in a paved space where a plastic disposable sheet will be used by the applicator (professional user), (2) wash-off the treated surface by rainfall is also considered negligible following that the product will be used (one application per year) strictly in a non-rainy day.

Risk Mitigation Meausures are clearly stated in the product label instructions.

Under the above considerations, the input parameters for calculating the local emission of permethrin & piperonyl butoxide arising from outdoor use of Pertex, **against ticks,** are reported in the table below. For the treated area concentrations in the soil volume distant of 0.5m from the wall, which receive deposition, run off and direct application are calculated. Local concentration of the active substances in the countryside are only presented for the treated area, as the worst case emission values are from the treated zone.

Input	Value	Unit	Remarks
Scenario 4: Outdoor (domestic houses and larger buildings), general surface spraying application, for professional users against **ticks**			
General			
Fraction of **permethrin** in the product	3	%	Technical grade active ingredient (TGAI).
Fraction of **piperonyl butoxide** in the product	0.053	%	Technical grade active ingredient (TGAI).
Application method	Scenario for crawling insects (chemical barrier, treating foundation and band of soil around the building)		
Location of treated area	Rural area		
Quantity of product applied	1.7858	g/m^2	Total amount per application in domestic houses
Application			
Area of foundation treated per day, standard house	25	m^2/d	As reported in ESD, p140
Area of foundation treated per day, larger buildings	125	m^2/d	
Area of soil treated per day, standard house	26	m^2/d	
Area of soil treated per day, larger buildings	126	m^2/d	
Fraction emitted to soil during outdoor foundation spray application against crawling inscects	0.3	-	
Fraction emitted to soil during outdoor ground spray application	0.99	-	
Soil volume for deposition and application at 0.5 m (treated) standard house	13	-	
Soil volume for deposition and application at 0.5 m (treated) larger building	63	m^3/d	
Frequency of product use	2.04E-03	%	claimed by the applicant, 1 application per year

Calculations for Scenario 4, after the Equations 47 & 48 of ESD

Resulting local emission to soil and foundations (direct emissions) of permethrin & PBO		
Compartment	**Local emission [kg/d]**	**Remarks**
Soil standard house, treated area	1.379E-03	**Espray soil of permethrin**

Resulting local emission to soil and foundations (direct emissions) of permethrin & PBO		
Compartment	**Local emission [kg/d]**	**Remarks**
Soil larger building, treated area	6.682E-03	**Espray soil of permethrin**
Soil standard house, treated area	2.436E-05	**Espray soil of PBO**
Soil large building, treated area	1.181E-04	**Espray soil of PBO**
Foundations, standard house, treated area	4.018E-04	**Espray foundation of permethrin**
Foundations, larger building, treated area	2.009E-03	**Espray foundation of permethrin**
Foundations, standard house, treated area	7.099E-06	**Espray foundation of PBO**
Foundations, larger building, treated area	3.549E-05	**Espray foundation of PBO**

Emmision estimation Scenario 5 & 6

The input parameter used for the environmental exposure assessment for professional use in 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. The treated area in the stables, taken as the worst case scenario, Tier I, used for calculations, is the total default area of the housing (floor, walls and ceiling) plus the slatted areas and other areas.

Since the product PERTEX must be applied in animal houses not connected to STP, calculations are only presented for i1 = 1-7, 10, 13-15 animal sub-categories, (which according to ENV 168 these sub-categories are not connected to STP and do not give rise to emission of waste water), for i2 = 1 (Insecticide (adulticide) against flies and i2=2 against bloodsucking insects (ticks). 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 scenario that leads to the highest emissions and therefore covers the other animal categories as worst case is "Veal Calves" (number 3 according to the OECD ESD for PT18).

In the following table (Table 2.2.8.2-6) the input parameters used to calculate the soil concentration after manure application for the worst-case animal category i1 = 3 (veal calves) are presented.

Parameter	**PERTEX**
Type of Housing	Veal calves (3 OECD ESD for PT18)
Application	Spraying
Manure	Slurry
Nitrogen emission standard (EU)	170 kg/ha (grassland and arable land)
Phosphate emission standard (EU)	110 kg/ha (grassland) 85 kg/ha (arable land)
Treated area per housing	Tier I: 650m² (default wall+ceiling+ floor area)
Amount of product prescribed to be used per m2 (Qprod-uins)	1.7858 g/m^2
Manure storage interval, arable land	212 days
Manure storage interval, grassland	53 days
No. of biocide applications in 1 year	1
Biocide application interval (Tbioc-int)	212 days
Fraction of active gradient release (Fmanure/slurry)	0.5

<u>Calculations for Scenario 5 & 6: Applications in Animal Husbandry Areas</u>

Concentration of the active ingredient in soil based on phosphorous or nitrogen immission standards for both grassland (four manure applications) and arable land (one manure application):

$$PIECgrs\ -\ P2O5_{i1,i2,i3,i4} = \frac{100 * Qai - grass_{i1,i2,i3,i4} * Q_{P2O5,\,grassland}}{Qphosph\ -\ grass_{i1,i4} * Napp - grass * DEPTH_{grassland} * RHOsoil_{wet}}$$

$$PIECarab\ -\ P2O5_{i1,i2,i3,i4} = \frac{100 * Qai - arab_{i1,i2,i3,i4} * Q_{P2O5,arable\_land}}{Qphosph\ -\ arab_{i1,i4} * Napp - arab * DEPTH_{arable\_land} * RHOsoil_{wet}}$$

$$\text{PIECgrs - N}_{i1,i2,i3,i4} = \frac{100 * \text{Qai} - \text{grass}_{i1,i2,i3,i4} * \text{Q}_{\text{N,grassland}}}{\text{Qnitrog - grass}_{i1,i4} * \text{Napp} - \text{grass} * \text{DEPTH}_{\text{grassland}} * \text{RHOsoil}_{\text{wet}}}$$

$$\text{PIECarab - N}_{i1,i2,i3,i4} = \frac{100 * \text{Qai} - \text{arab}_{i1,i2,i3,i4} * \text{Q}_{\text{N,arable\_land}}}{\text{Qnitrog - arab}_{i1,i4} * Napp - arab * \text{DEPTH}_{\text{arable\_land}} * \text{RHOsoil}_{\text{wet}}}$$

Rate constant for biodegradation in soil:

$$k\text{deg}_{soil} = ln(2)/DT50bio_{soil}$$

Fraction of active remaining in grassland soil after the last (of four) manure spreading event:

$$Fsoil_{grs} = \frac{1-(e^{-kdeg_{soil} * Tgr-\text{int}})^{Napp_{grass}}}{1-e^{-kdeg_{soil} * Tgr-\text{int}}}$$

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.

$$PIECgrs4\_agr\text{-}P2O5_{i1i2i3i4} = PIECgrs\text{-}P2O5_{i1i2i3i4} * Fsoil_{grs}$$

$$PIECgrs4\_agr\text{-}N_{i1i2i3i4} = PIECgrs\text{-}N_{i1i2i3i4} * Fsoil_{grs}$$

Fraction of active remaining in arable soil after 10 year of manure application:

$$Fsoil_{arab\_10} = \frac{1-(e^{-kdeg_{soil} * Tar-\text{int},10})^{Napp_{arab,10}}}{1-e^{-kdeg_{soil} * Tar-\text{int},10}}$$

Fraction of active remaining in grassland soil, 365 d after the last (of four) manure spreading events:

$$Fsoil_{grs2} = e^{-kdeg_{soil} * Tgr-\text{int}_{no\_manure}}$$

Calculation of the air-water partitioning coefficient:

$$Kair - water = Henry / (R * Temp\_air - wat)$$

Calculation of the soil-water partitioning coefficient:

$$Ksoil-water = Fair * Kair-water + Fwater_{soil} + Fsolid_{soil} * RHOsolid * Kpsoil * 1000$$

Calculation of the suspended matter-water partitioning coefficient:

$$Ksusp-water = Fwater_{susp} + Fsolid_{susp} * RHOsolid * Kpsusp * 1000$$

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)

$$PIECgrs_{10\_degr} - N_{i1,i2,i3,i4} - PIECgrs_{4\_degr} - N_{i1,i2,i3,i4} \cdot \frac{1 - Fsoil_{grs2}^{10}}{1 - Fsoil_{grs2}}$$

$$PIECarab_{10\_degr} - P2O5_{i1i2i3i4} = PIECarab - P2O5_{i1i2i3i4} * Fsoil_{arab\_10}$$

$$PIECarab_{10\_degr} - N_{i1i2i3i4} = PIECarab - N_{i1i2i3i4} * Fsoil_{arab\_10}$$

Concentrations in porewater/groundwater, derived from the concentrations in soil, PIECgrs10_degr-Ni1,i2,13,14 using TGD equations for equilibrium partitioning.

$$PIEC - gw = \frac{PIECsoil * RHOsoil_{wet}}{K_{soil-water} * 1000}$$

Concentrations in surface water (applicable to both immission standards as well as grassland and arable land):

$$PIEC - sw = PIEC - gw / DILUTIO_{run-off}$$

Concentrations in sediment (applicable to both immission standards as well as grassland and arable land):

$$PIEC - sed = PIEC - sw * 1000 * (Ksus - water / RHOs\ usp)$$

Fate and distribution in exposed environmental compartments

Fate and distribution of active substances in exposed environmental compartments were estimated using the Guidance on the Biocidal Products Regulation, Volume IV Environment -Assessment & Evaluation, Part B+C, Version 2.0 (October 2017).

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
Scenario 1 & 2	No	No	No	No	No	No	No	No	No
~~Scenario 3~~	~~No~~	~~No~~	~~No~~	~~No~~	~~No~~	~~No~~	~~No~~	~~No~~	~~No~~
Scenario 4	No	No	No	No	No	No	Yes	Yes	No
Scenario 5 & 6	No	No	No	No	No	No	Yes	Yes	No

For Scenario 5 & 6
* Exposure can occur via the route usage in animal houses → application of slurry/manure to soil → runoff to surface water / leaching to groundwater.
** In some animal categories, STP are directly exposed. However, for PERTEX 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.

Input parameters (only set values) for calculating the fate and distribution in the environment for permethrin			
Input	Value	Unit	Remarks
Molecular weight	391.29		
Melting point	35	°C	
Boiling point	305	°C	
Vapour pressure (at 20°C)	2.155E-6	Pa	
Water solubility (at 20°C)	0.00495	mg/l	
Log Octanol/water partition coefficient	4.67	Log 10	
Organic carbon/water partition coefficient (Koc)	26930	l/kg	arithmetic mean, n=10
Henry's Law Constant (at 20°C)	4.6E-3	Pa/m3/mol	
Biodegradability	*Not Ready biodegradable*		
DT_{50} for degradation in soil	106	d (at 12ºC)	geometric mean, n=5
DT_{50} for degradation in air	0.701	d	geometric mean, n=5

Input parameters (only set values) for calculating the fate and distribution in the environment for PBO

Input	Value	Unit	Remarks
Molecular weight	338.43		
Melting point	<-10	°C	
Boiling point	203	°C	
Vapour pressure (at 25°C)	2.53E-06	Pa	
Water solubility (at 20°C and pH 7.01)	28.9	mg/l	
Log Octanol/water partition coefficient	4.8	Log 10	
Organic carbon/water partition coefficient (Koc)	2506.5	l/kg	ENV_7.2 WG2019, e-consultation _new end points
Henry's Law Constant (at 20°C)	1.648E-04	Pa/m3/mol	
Biodegradability	*Not readily biodegradable*		
DT_{50} for degradation in soil (at 12ºC)	58.3	d	geometric mean, n=4
DT_{50} for degradation in air	3.597	hrs	

Calculated PEC values for Permethrin & PBO for Indoor (1 & 2) and Outdoor (4) scenarios

Summary table on calculated PEC values								
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**$PEC_{seawater}$**	**PEC_{seased}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**
	[mg/L]	[mg/l]	[mg/kg_{wwt}]	[mg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[mg/l]	[mg/m^3]
Permethrin								
Scenario 1 & 2	0	0	0	Not relevant	Not relevant	0	0	0
Scenario 4 – Standard house, treated area	0	0	0	Not relevant	Not relevant	**8.06E-02**	**1.70E-04**	0
Scenario 4 – Large building treated area	0	0	0	Not relevant	Not relevant	**8.12E-02**	**1.71E-04**	0

Summary table on calculated PEC values								
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**$PEC_{seawater}$**	**PEC_{seased}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**
	[mg/L]	[mg/l]	[mg/kg_{wwt}]	[mg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[mg/l]	[mg/m^3]
PBO								
Scenario 1 & 2	0	0	0	Not relevant	Not relevant	0	0	0
Scenario 4 – Standard house, treated area	0	0	0	Not relevant	Not relevant	**1.42E-03**	**3.21E-05**	0
Scenario 4 – Large building, treated area	0	0	0	Not relevant	Not relevant	**1.434E-03**	**3.233E-05**	0

Calculated PEC values for permethrin & PBO for the Scenarios 5 & 6: *Applications in Animal Husbandry Areas*

The input values contained in the Table above were used in the calculations.

For soil, the calculation of initial environmental concentrations (PIECs) assumes application of slurry/manure onto arable and grassland soils without taking biodegradation of Permethrin and PBO into account in the first instance. According to the ESD, manure is applied to arable soil (1 application/year) and to grassland (4 applications/year). Therefore, potential concentrations of *the active substances* are estimated for the soil compartment (arable land and grassland).

The predicted soil concentration, after 10 years of consecutive manure/slurry applications, PIEC10_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). For grassland, the relevant soil concentration used for risk assessment is based on four manure application events per year, ten consecutive years, and considering degradation in soil ($PIEC\text{grs}_{10\text{-degr}}\text{–}N_{i1,i2,i3,i4}$/ $PIEC\text{grs}_{10\text{-degr}}\text{–}P2O5_{i1,i2,i3,i4}$). For arable land, ten consecutive years with one manure application event per year and degradation in soil is considered ($PIEC\text{ars}_{10\text{-degr}}\text{–}N_{i1,i2,i3,i4}$ / $PIEC\text{ars}_{10\text{-degr}}\text{–}P2O5_{i1,i2,i3,i4}$).

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 (PECground water) was calculated considering

degradation processes in soil after 10 consecutive years of manure application, i.e., PIEC10degr 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.

PECsurface water and PECsediment were calculated for the route of exposure of permethrin and PBO via slurry/manure to soil and subsequent run-off to surface water (incl. sediment).

PECsurface water was derived by diluting the PECgroundwater by a factor of 10 (OECD ESD No. 14).

Ksoilwater for groundwater and surface water calculations were taken as 808.1 m^3/m^3 (for permethrin), and 75.395 for PBO.

PECsediment was calculated according to equation 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 permethrin of 26930 L/kg, and 2506.5 L/kg of PBO to calculate a suspended matter-water partitioning coefficient (Ksusp-water) of 674.15 m^3/m^3 for permethrin, while 63.562 m^3/m^3 for PBO.

PEC values were calculated based on both immission standard for N and P for soil, whereas for groundwater, surface water and sediment, immission based on N are only presented in the exposure assessment.

The scenario that leads to the highest emissions and therefore covers all the other animal categories as worst case is "Veal Calves" (number 3 according to the OECD ESD for PT18).

The product label states, 'Do not use in animal housings where exposure to a STP and/ or direct emission to surface water cannot be prevented'', thus poultry housings connected to the sewer was excluded for the risk assessment. Subsequent calculated PEC values for STP route are therefore not required.

The $PIEC_{soil}$ concentrations were calculated for all the animal categories, excluding the animal housings connected to STP, and are presented below**.**

Scenario 5 – Permethrin

- ✓ ***For biocide type i2=1; flies***
- ➢ **Initial concentration of permethrin in soil, degradation NOT taken into account**

PEC in soil for arable land, 1 manure application											
[mg/kg$_{ww}$]	**Animal Category (i1)**										
	1	**2**	**3**	**4**	**5**	**6**	**7**	**10**	**13**	**14**	**15**
PIECarab-N$_{i1,i2,i3,i4}$	4.2786E-04	2.2812E-04	6.3517E-04	3.5584E-04	4.5359E-04	2.9229E-04	9.5111E-05	1.0615E-04	1.9540E-04	1.0550E-04	2.2310E-04
PIECarab-P$_2$O$_{5i1,i2,i3,i4}$	7.5564E-04	5.1244E-04	5.3199E-04	2.2714E-04	2.8955E-04	2.1875E-04	7.8739E-05	8.6542E-05	1.5051E-04	8.3613E-05	1.9847E-04

PEC in soil for grassland after 4 manure application events											
[mg/kg$_{ww}$]	**Animal Category (i1)**										
	1	**2**	**3**	**4**	**5**	**6**	**7**	**10**	**13**	**14**	**15**
PIECgrs$_4$-N$_{i1,i2,i3,i4}$	1.179E-02	6.284E-03	1.750E-02	9.802E-03	1.250E-02	8.052E-03	2.620E-03	2.924E-03	5.383E-03	2.906E-03	6.146E-03
PIECgrs$_4$-P$_2$O$_{5i1,i2,i3,i4}$	2.694E-02	1.827E-02	1.896E-02	8.098E-03	1.032E-02	7.798E-03	2.807E-03	3.085E-03	5.366E-03	2.981E-03	7.075E-03

- **Considering degradation processes of permethrin 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											
[mg/kg$_{ww}$]	**Animal Category (i1)**										
	1	**2**	**3**	**4**	**5**	**6**	**7**	**10**	**13**	**14**	**15**
PECarab$_{1_degr}$-N$_{i1,i2,i3,i4}$	4.2786E-04	2.2812E-04	6.3517E-04	3.5584E-04	4.5359E-04	2.9229E-04	9.5111E-05	1.0615E-04	1.9540E-04	1.0550E-04	2.2310E-04
PECarab$_{1_degr}$-P$_2$O$_{5i1,i2,i3,i4}$	7.5564E-04	5.1244E-04	5.3199E-04	2.2714E-04	2.8955E-04	2.1875E-04	7.8739E-05	8.6542E-05	1.5051E-04	8.3613E-05	1.9847E-04

PEC in soil for grassland after 4 manure application event, taking degradation into account											
[mg/kg$_{ww}$]	**Animal Category (i1)**										
	1	**2**	**3**	**4**	**5**	**6**	**7**	**10**	**13**	**14**	**15**
PECgrs$_{4_degr}$-N$_{i1,i2,i3,i4}$	7.558E-03	4.030E-03	1.122E-02	6.286E-03	8.013E-03	5.164E-03	1.680E-03	1.875E-03	3.452E-03	1.864E-03	3.941E-03
PECgrs$_{4_degr}$-P$_2$O$_{5i1,i2,i3,i4}$	1.728E-02	1.172E-02	1.216E-02	5.193E-03	6.619E-03	5.001E-03	1.800E-03	1.978E-03	3.441E-03	1.912E-03	4.537E-03

- **Considering degradation processes of permethrin in soil, after 10 consecutive years application**

PEC in soil for arable land, 1 manure application/yr after 10 consecutive years, taking degradation into account											
[mg/kg$_{ww}$]	**Animal Category (i1)**										
	1	**2**	**3**	**4**	**5**	**6**	**7**	**10**	**13**	**14**	**15**
PECarab$_{10_degr}$-N$_{i1,i2,i3,i4}$	4.7171E-04	2.5149E-04	7.0027E-04	3.9230E-04	5.0008E-04	3.2225E-04	1.0486E-04	1.1702E-04	2.1543E-04	1.1631E-04	2.4597E-04
PECarab$_{10_degr}$-P$_2$O$_{5i1,i2,i3,i4}$	8.3309E-04	5.6496E-04	5.8651E-04	2.5042E-04	3.1922E-04	2.4117E-04	8.6809E-05	9.5412E-05	1.6594E-04	9.2182E-05	2.1882E-04

PEC in soil for grassland, 4 manure application/yr. after 10 consecutive years, taking degradation into account											
[mg/kg$_{ww}$]	**Animal Category (i1)**										
	1	**2**	**3**	**4**	**5**	**6**	**7**	**10**	**13**	**14**	**15**
PECgrs$_{10_degr}$-Ni1,i2,i3,i4	8.337E-03	4.445E-03	1.238E-02	6.934E-03	8.838E-03	5.695E-03	1.853E-03	2.068E-03	3.807E-03	2.056E-03	4.347E-03
PECgrs$_{10_degr}$-P2O5i1,i2,i3,i4	1.905E-02	1.292E-02	1.341E-02	5.728E-03	7.301E-03	5.516E-03	1.986E-03	2.182E-03	3.795E-03	2.108E-03	5.005E-03

- **Predicted Environmental Concentrations of permethrin in groundwater (using PECsoil, after 10 consecutive years manure application, PEC$_{10_degr}$, WG V, 2015, November & WG-I-2018, January)**

PEC in groundwater for arable and grassland											
[mg/kg$_{ww}$]	Animal Category (i1)										
	1	2	3	4	5	6	7	10	13	14	15
PECgrs$_{10_degr}$-gw-N$_{i1,i2,i3,i4}$	1.75E-05	9.33E-06	2.60E-05	1.46E-05	1.86E-05	1.20E-05	3.89E-06	4.34E-06	8.00E-06	4.32E-06	9.13E-06
PECgrs$_{10_degr}$-gw-P$_2$O$_{5i1,i2,i3,i4}$	4.00E-05	2.71E-05	2.82E-05	1.20E-05	1.53E-05	1.16E-05	4.17E-06	4.58E-06	7.97E-06	4.43E-06	1.05E-05
PECars$_{10_degr}$-gw-N$_{i1,i2,i3,i4}$	9.9234E-07	5.2907E-07	1.4731E-06	8.2529E-07	1.0520E-06	6.7791E-07	2.2059E-07	2.4618E-07	4.5320E-07	2.4468E-07	5.1744E-07
PECars$_{10_degr}$-gw-P$_2$O$_{5i1,i2,i3,i4}$	1.7526E-06	1.1885E-06	1.2338E-06	5.2682E-07	6.7155E-07	5.0735E-07	1.8262E-07	2.0072E-07	3.4908E-07	1.9392E-07	4.6032E-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 permethrin in surface water (PECsoil, after 10 consecutive years manure application, PEC$_{10_degr}$ as an input)**

PEC in surface water for grassland

[mg/kg$_{ww}$]	Animal Category (i1)										
	1	**2**	**3**	**4**	**5**	**6**	**7**	**10**	**13**	**14**	**15**
PECgrs-sw-N$_{i1,i2,i3,i4}$	1.75077E-06	9.33432E-07	2.59906E-06	1.45605E-06	1.85607E-06	1.19604E-06	3.89186E-07	4.3434E-07	7.99571E-07	4.3169E-07	9.12921E-07
PECgrs-sw-P$_2$O$_{5i1,i2,i3,i4}$	4.00146E-06	2.71361E-06	2.8171E-06	1.20283E-06	1.53327E-06	1.15839E-06	4.16958E-07	4.58278E-07	7.97029E-07	4.42766E-07	1.05101E-06

PEC in surface water for arable lands											
[mg/kg$_{ww}$]	Animal Category (i1)										
	1	**2**	**3**	**4**	**5**	**6**	**7**	**10**	**13**	**14**	**15**
PECars-sw-N$_{i1,i2,i3,i4}$	9.9234E-08	5.2907E-08	1.4731E-07	8.2529E-08	1.0520E-07	6.7791E-08	2.2059E-08	2.4618E-08	4.5320E-08	2.4468E-08	5.1744E-08
PECars-sw-P$_2$O$_{5i1,i2,i3,i4}$	1.7526E-07	1.1885E-07	1.2338E-07	5.2682E-08	6.7155E-08	5.0735E-08	1.8262E-08	2.0072E-08	3.4908E-08	1.9392E-08	4.6032E-08

- **Predicted Environmental Concentrations of permethrin in sediment (PECsoil, after 10 coscecutive years manure application, PEC$_{10_degr}$ as an input)**

PEC in sediment for grassland

[mg/kg$_{ww}$]	Animal Category (i1)										
	1	**2**	**3**	**4**	**5**	**6**	**7**	**10**	**13**	**14**	**15**
PECgrs-sed-N$_{i1,i2,i3,i4}$	1.03E-03	5.47E-04	1.52E-03	8.54E-04	1.09E-03	7.01E-04	2.28E-04	2.55E-04	4.69E-04	2.53E-04	5.35E-04
PECgrs-sed-P$_2$O$_{5i1,i2,i3,i4}$	2.35E-03	1.59E-03	1.65E-03	7.05E-04	8.99E-04	6.79E-04	2.44E-04	2.69E-04	4.67E-04	2.60E-04	6.16E-04

PEC in sediment for arable lands

[mg/kg$_{ww}$]	Animal Category (i1)										
	1	**2**	**3**	**4**	**5**	**6**	**7**	**10**	**13**	**14**	**15**
PECars-sed-N$_{i1,i2,i3,i4}$	5.82E-05	3.10E-05	8.64E-05	4.84E-05	6.17E-05	3.97E-05	1.29E-05	1.44E-05	2.66E-05	1.43E-05	3.03E-05
PECars-sed-P$_2$O$_{5i1,i2,i3,i4}$	1.03E-04	6.97E-05	7.23E-05	3.09E-05	3.94E-05	2.97E-05	1.07E-05	1.18E-05	2.05E-05	1.14E-05	2.70E-05

Scenario 5 - PBO

- ✓ ***For biocide type i2=1; flies***
- ➢ **Initial concentration of PBO in soil, degradation NOT taken into account**

PEC in soil for arable land, 1 manure application											
[mg/kg$_{ww}$]	**Animal Category (i1)**										
	1	**2**	**3**	**4**	**5**	**6**	**7**	**10**	**13**	**14**	**15**
PIECarab-N$_{i1,i2,i3,i4}$	7.5589E-06	4.0300E-06	1.1221E-05	6.2864E-06	8.0135E-06	5.1638E-06	1.6803E-06	1.8752E-06	3.4521E-06	1.8638E-06	3.9415E-06
PIECarab-P$_2$O$_{5i1,i2,i3,i4}$	1.3350E-05	9.0532E-06	9.3984E-06	4.0129E-06	5.1153E-06	3.8646E-06	1.3911E-06	1.5289E-06	2.6591E-06	1.4772E-06	3.5064E-06

PEC in soil for grassland after 4 manure application events											
[mg/kg$_{ww}$]	**Animal Category (i1)**										
	1	**2**	**3**	**4**	**5**	**6**	**7**	**10**	**13**	**14**	**15**
PIECgrs$_4$-N$_{i1,i2,i3,i4}$	2.082E-04	1.110E-04	3.091E-04	1.732E-04	2.207E-04	1.422E-04	4.629E-05	5.166E-05	9.510E-05	5.134E-05	1.086E-04
PIECgrs$_4$-P$_2$O$_{5i1,i2,i3,i4}$	4.759E-04	3.227E-04	3.350E-04	1.431E-04	1.824E-04	1.378E-04	4.959E-05	5.450E-05	9.479E-05	5.266E-05	1.250E-04

- **Considering degradation processes of PBO 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											
[mg/kg$_{ww}$]	**Animal Category (i1)**										
	1	**2**	**3**	**4**	**5**	**6**	**7**	**10**	**13**	**14**	**15**

$PECarab_{1\_degr}$-$N_{i1,i2,i3,i4}$	7.5589E-06	4.0300E-06	1.1221E-05	6.2864E-06	8.0135E-06	5.1638E-06	1.6803E-06	1.8752E-06	3.4521E-06	1.8638E-06	3.9415E-06
$PECarab_{1\_degr}$-$P_2O_{5i1,i2,i3,i4}$	1.3350E-05	9.0532E-06	9.3984E-06	4.0129E-06	5.1153E-06	3.8646E-06	1.3911E-06	1.5289E-06	2.6591E-06	1.4772E-06	3.5064E-06

PEC in soil for grassland after 4 manure application event, taking degradation into account											
[mg/kg_{ww}]	**Animal Category (i1)**										
	1	**2**	**3**	**4**	**5**	**6**	**7**	**10**	**13**	**14**	**15**
$PECgrs_{4\_degr}$-$N_{i1,i2,i3,i4}$	1.024E-04	5.460E-05	1.520E-04	8.516E-05	1.086E-04	6.995E-05	2.276E-05	2.540E-05	4.677E-05	2.525E-05	5.340E-05
$PECgrs_{4\_degr}$-$P_2O_{5i1,i2,i3,i4}$	2.340E-04	1.587E-04	1.648E-04	7.035E-05	8.968E-05	6.775E-05	2.439E-05	2.680E-05	4.662E-05	2.590E-05	6.147E-05

- **Considering degradation processes of PBO in soil, after 10 consecutive years application**

PEC in soil for arable land, 1 manure application/yr after 10 consecutive years, taking degradation into account											
[mg/kg_{ww}]	**Animal Category (i1)**										
	1	**2**	**3**	**4**	**5**	**6**	**7**	**10**	**13**	**14**	**15**
$PECarab_{10\_degr}$-$N_{i1,i2,i3,i4}$	7.6587E-06	4.0833E-06	1.1370E-05	6.3695E-06	8.1194E-06	5.2321E-06	1.7025E-06	1.9000E-06	3.4977E-06	1.8884E-06	3.9936E-06
$PECarab_{10\_degr}$	1.3526E-05	9.1728E-06	9.5226E-06	4.0659E-06	5.1829E-06	3.9157E-06	1.4094E-06	1.5491E-06	2.6942E-06	1.4967E-06	3.5527E-06

-$P_2O_{5i1,i2,i3,i4}$											

PEC in soil for <u>grassland</u>, 4 manure application/yr. after 10 consecutive years, taking degradation into account											
[mg/kg_{ww}]	**Animal Category (i1)**										
	1	**2**	**3**	**4**	**5**	**6**	**7**	**10**	**13**	**14**	**15**
$PECgrs_{10\_degr-Ni1,i2,i3,i4}$	1.129E-04	6.022E-05	1.677E-04	9.393E-05	1.197E-04	7.716E-05	2.511E-05	2.802E-05	5.158E-05	2.785E-05	5.890E-05
$PECgrs_{10\_degr-P2O5i1,i2,i3,i4}$	2.581E-04	1.751E-04	1.817E-04	7.760E-05	9.892E-05	7.473E-05	2.690E-05	2.956E-05	5.142E-05	2.856E-05	6.780E-05

- **Predicted Environmental Concentrations of PBO in <u>groundwater</u> (using PECsoil, after 10 consecutive 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>											
[mg/kg_{ww}]	**Animal Category (i1)**										
	1	**2**	**3**	**4**	**5**	**6**	**7**	**10**	**13**	**14**	**15**
$PECgrs_{10\_degr-gw-Ni1,i2,i3,i4}$	2.37E-07	1.26E-07	3.52E-07	1.97E-07	2.51E-07	1.62E-07	5.27E-08	5.88E-08	1.08E-07	5.85E-08	1.24E-07
$PECgrs_{10\_degr-gw-P2O5i1,i2,i3,i4}$	5.42E-07	3.68E-07	3.82E-07	1.63E-07	2.08E-07	1.57E-07	5.65E-08	6.21E-08	1.08E-07	6.00E-08	1.42E-07

$PECars_{10\_degr}$-gw-$N_{i1,i2,i3,i4}$	1.6112E-08	8.5900E-09	2.3918E-08	1.3399E-08	1.7081E-08	1.1007E-08	3.5815E-09	3.9971E-09	7.3581E-09	3.9727E-09	8.4013E-09
$PECars_{10\_degr}$-gw-$P_2O_{5i1,i2,i3,i4}$	2.8455E-08	1.9297E-08	2.0033E-08	8.5534E-09	1.0903E-08	8.2374E-09	2.9650E-09	3.2589E-09	5.6678E-09	3.1486E-09	7.4738E-09

- **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 PBO in <u>surface water</u> (PECsoil, after 10 consecutive years manure application, PEC_{10_degr}**

as an input)

PEC in surface water for <u>grassland</u>											
[mg/kg_{ww}]	**Animal Category (i1)**										
	1	**2**	**3**	**4**	**5**	**6**	**7**	**10**	**13**	**14**	**15**
PECgrs-sw-$N_{i1,i2,i3,i4}$	2.3719E-08	1.26459E-08	3.52114E-08	1.97262E-08	2.51455E-08	1.62036E-08	5.27259E-09	5.88432E-09	1.08324E-08	5.84842E-09	1.2368E-08
PECgrs-sw-$P_2O_{5i1,i2,i3,i4}$	5.42107E-08	3.67633E-08	3.81654E-08	1.62956E-08	2.07724E-08	1.56935E-08	5.64884E-09	6.20863E-09	1.07979E-08	5.99847E-09	1.42388E-08

PEC in surface water for <u>arable lands</u>	
[mg/kg_{ww}]	**Animal Category (i1)**

	1	2	3	4	5	6	7	10	13	14	15
PECars-sw-$N_{i1,i2,i3,i4}$	1.6112E-09	8.5900E-10	2.3918E-09	1.3399E-09	1.7081E-09	1.1007E-09	3.5815E-10	3.9971E-10	7.3581E-10	3.9727E-10	8.4013E-10
PECars-sw-$P_2O_{5i1,i2,i3,i4}$	2.8455E-09	1.9297E-09	2.0033E-09	8.5534E-10	1.0903E-09	8.2374E-10	2.9650E-10	3.2589E-10	5.6678E-10	3.1486E-10	7.4738E-10

- **Predicted Environmental Concentrations of PBO in <u>sediment</u> (PECsoil, after 10 coscecutive years manure application, PEC_{10_degr}**

as an input)

PEC in sediment for <u>grassland</u>											
[mg/kg_{ww}]	**Animal Category (i1)**										
	1	**2**	**3**	**4**	**5**	**6**	**7**	**10**	**13**	**14**	**15**
PECgrs-sed-$N_{i1,i2,i3,i4}$	1.39E-05	7.41E-06	2.06E-05	1.16E-05	1.47E-05	9.50E-06	3.09E-06	3.45E-06	6.35E-06	3.43E-06	7.25E-06
PECgrs-sed-$P_2O_{5i1,i2,i3,i4}$	3.18E-05	2.16E-05	2.24E-05	9.55E-06	1.22E-05	9.20E-06	3.31E-06	3.64E-06	6.33E-06	3.52E-06	8.35E-06

PEC in sediment for <u>arable lands</u>	
[mg/kg_{ww}]	**Animal Category (i1)**

	1	2	3	4	5	6	7	10	13	14	15
PECars-sed-$N_{i1,i2,i3,i4}$	9.44E-07	5.04E-07	1.40E-06	7.86E-07	1.00E-06	6.45E-07	2.10E-07	2.34E-07	4.31E-07	2.33E-07	4.92E-07
PECars-sed-$P_2O_{5i1,i2,i3,i4}$	1.67E-06	1.13E-06	1.17E-06	5.01E-07	6.39E-07	4.83E-07	1.74E-07	1.91E-07	3.32E-07	1.85E-07	4.38E-07

Scenario 6 – Permethrin

- ✓ ***For biocide type i2=2; ticks***
- ➢ **Initial concentration of permethrin in soil, degradation NOT taken into account**

PEC in soil for arable land, 1 manure application											
[mg/kg_{ww}]	**Animal Category (i1)**										
	1	**2**	**3**	**4**	**5**	**6**	**7**	**10**	**13**	**14**	**15**
PIECarab-$N_{i1,i2,i3,i4}$	8.2754E-04	3.9920E-04	1.2511E-03	7.5468E-04	8.6026E-04	6.0869E-04	2.7755E-04	3.0975E-04	3.6378E-04	2.2682E-04	4.8785E-04
PIECarab-$P_2O_{5i1,i2,i3,i4}$	1.4615E-03	8.9677E-04	1.0479E-03	4.8174E-04	5.4914E-04	4.5554E-04	2.2977E-04	2.5255E-04	2.8021E-04	1.7977E-04	4.3400E-04

PEC in soil for grassland after 4 manure application events	
[mg/kg_{ww}]	**Animal Category (i1)**

	1	2	3	4	5	6	7	10	13	14	15
$PIECgrs_{4}$-$N_{i1,i2,i3,i4}$	2.280E-02	1.100E-02	3.446E-02	2.079E-02	2.370E-02	1.677E-02	7.646E-03	8.533E-03	1.002E-02	6.248E-03	1.344E-02
$PIECgrs_{4}$-$P_2O_{5i1,i2,i3,i4}$	5.210E-02	3.197E-02	3.736E-02	1.717E-02	1.958E-02	1.624E-02	8.191E-03	9.003E-03	9.989E-03	6.409E-03	1.547E-02

- **Considering degradation processes of permethrin 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											
[mg/kg_{ww}]	**Animal Category (i1)**										
	1	**2**	**3**	**4**	**5**	**6**	**7**	**10**	**13**	**14**	**15**
$PECarab_{1\_degr}$-$N_{i1,i2,i3,i4}$	8.2754E-04	3.9920E-04	1.2511E-03	7.5468E-04	8.6026E-04	6.0869E-04	2.7755E-04	3.0975E-04	3.6378E-04	2.2682E-04	4.8785E-04
$PECarab_{1\_degr}$-$P_2O_{5i1,i2,i3,i4}$	1.4615E-03	8.9677E-04	1.0479E-03	4.8174E-04	5.4914E-04	4.5554E-04	2.2977E-04	2.5255E-04	2.8021E-04	1.7977E-04	4.3400E-04

PEC in soil for grassland after 4 manure application event, taking degradation into account											
[mg/kg_{ww}]	**Animal Category (i1)**										
	1	**2**	**3**	**4**	**5**	**6**	**7**	**10**	**13**	**14**	**15**
$PECgrs_{4\_degr}$-$N_{i1,i2,i3,i4}$	1.462E-02	7.052E-03	2.210E-02	1.333E-02	1.520E-02	1.075E-02	4.903E-03	5.472E-03	6.426E-03	4.007E-03	8.618E-03

$PECgrs_{4\_degr}$-$P_2O_{5i1,i2,i3,i4}$	3.341E-02	2.050E-02	2.396E-02	1.101E-02	1.255E-02	1.041E-02	5.253E-03	5.774E-03	6.406E-03	4.110E-03	9.922E-03

- **Considering degradation processes of permethrin 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											
[mg/kg$_{ww}$]	**Animal Category (i1)**										
	1	**2**	**3**	**4**	**5**	**6**	**7**	**10**	**13**	**14**	**15**
$PECarab_{10\_degr}$-$N_{i1,i2,i3,i4}$	9.1235E-04	4.4012E-04	1.3793E-03	8.3203E-04	9.4843E-04	6.7107E-04	3.0600E-04	3.4150E-04	4.0106E-04	2.5007E-04	5.3785E-04
$PECarab_{10\_degr}$-$P_2O_{5i1,i2,i3,i4}$	1.6113E-03	9.8868E-04	1.1552E-03	5.3112E-04	6.0542E-04	5.0223E-04	2.5332E-04	2.7843E-04	3.0893E-04	1.9819E-04	4.7848E-04

PEC in soil for <u>grassland</u>, 4 manure application/yr. after 10 consecutive years, taking degradation into account											
[mg/kg$_{ww}$]	**Animal Category (i1)**										
	1	**2**	**3**	**4**	**5**	**6**	**7**	**10**	**13**	**14**	**15**
$PECgrs_{10\_degr}$-Ni1,i2,i3,i4	1.612E-02	7.779E-03	2.438E-02	1.471E-02	1.676E-02	1.186E-02	5.408E-03	6.036E-03	7.088E-03	4.420E-03	9.506E-03
$PECgrs_{10\_degr}$-P2O5i1,i2,i3,i4	3.685E-02	2.261E-02	2.642E-02	1.215E-02	1.385E-02	1.149E-02	5.794E-03	6.368E-03	7.066E-03	4.533E-03	1.094E-02

- **Predicted Environmental Concentrations of permethrin in <u>groundwater</u> (using PECsoil, after 10 consecutive 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>											
[mg/kg_{ww}]	**Animal Category (i1)**										
	1	**2**	**3**	**4**	**5**	**6**	**7**	**10**	**13**	**14**	**15**
$PECgrs_{10\_degr}$-gw-$N_{i1,i2,i3,i4}$	3.39E-05	1.63E-05	5.12E-05	3.09E-05	3.52E-05	2.49E-05	1.14E-05	1.27E-05	1.49E-05	9.28E-06	2.00E-05
$PECgrs_{10\_degr}$-gw- $P_2O_{5i1,i2,i3,i4}$	7.74E-05	4.75E-05	5.55E-05	2.55E-05	2.91E-05	2.41E-05	1.22E-05	1.34E-05	1.48E-05	9.52E-06	2.30E-05
$PECars_{10\_degr}$-gw-$N_{i1,i2,i3,i4}$	1.9193E-06	9.2587E-07	2.9017E-06	1.7503E-06	1.9952E-06	1.4117E-06	6.4372E-07	7.1841E-07	8.4371E-07	5.2607E-07	1.1315E-06
$PECars_{10\_degr}$-gw- $P_2O_{5i1,i2,i3,i4}$	3.3897E-06	2.0799E-06	2.4303E-06	1.1173E-06	1.2736E-06	1.0565E-06	5.3292E-07	5.8573E-07	6.4989E-07	4.1693E-07	1.0066E-06

- **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 permethrin in <u>surface water</u> (PECsoil, after 10 consecutive years manure application, PEC_{10_degr}**

as an input)

PEC in surface water for <u>grassland</u>											
[mg/kg$_{ww}$]	**Animal Category (i1)**										
	1	**2**	**3**	**4**	**5**	**6**	**7**	**10**	**13**	**14**	**15**
PECgrs-sw-$N_{i1,i2,i3,i4}$	3.38622E-06	1.63351E-06	5.11937E-06	3.08811E-06	3.52013E-06	2.49072E-06	1.13571E-06	1.26748E-06	1.48855E-06	9.28133E-07	1.99625E-06
PECgrs-sw-$P_2O_{5i1,i2,i3,i4}$	7.73935E-06	4.74882E-06	5.54884E-06	2.55105E-06	2.90793E-06	2.41231E-06	1.21676E-06	1.33734E-06	1.48382E-06	9.51946E-07	2.29821E-06

PEC in surface water for <u>arable lands</u>											
[mg/kg$_{ww}$]	**Animal Category (i1)**										
	1	**2**	**3**	**4**	**5**	**6**	**7**	**10**	**13**	**14**	**15**
PECars-sw-$N_{i1,i2,i3,i4}$	1.9193E-07	9.2587E-08	2.9017E-07	1.7503E-07	1.9952E-07	1.4117E-07	6.4372E-08	7.1841E-08	8.4371E-08	5.2607E-08	1.1315E-07
PECars-sw-$P_2O_{5i1,i2,i3,i4}$	3.3897E-07	2.0799E-07	2.4303E-07	1.1173E-07	1.2736E-07	1.0565E-07	5.3292E-08	5.8573E-08	6.4989E-08	4.1693E-08	1.0066E-07

- **Predicted Environmental Concentrations of permethrin in <u>sediment</u> (PECsoil, after 10 coscecutive years manure application, PEC_{10_degr}**

as an input)

PEC in sediment for <u>grassland</u>											
[mg/kg$_{ww}$]	**Animal Category (i1)**										
	1	**2**	**3**	**4**	**5**	**6**	**7**	**10**	**13**	**14**	**15**
PECgrs-sed-$N_{i1,i2,i3,i4}$	1.99E-03	9.58E-04	3.00E-03	1.81E-03	2.06E-03	1.46E-03	6.66E-04	7.43E-04	8.73E-04	5.44E-04	1.17E-03
PECgrs-sed-$P_2O_{5i1,i2,i3,i4}$	4.54E-03	2.78E-03	3.25E-03	1.50E-03	1.70E-03	1.41E-03	7.13E-04	7.84E-04	8.70E-04	5.58E-04	1.35E-03

PEC in sediment for <u>arable lands</u>											
[mg/kg$_{ww}$]	**Animal Category (i1)**										
	1	**2**	**3**	**4**	**5**	**6**	**7**	**10**	**13**	**14**	**15**
PECars-sed-$N_{i1,i2,i3,i4}$	1.13E-04	5.43E-05	1.70E-04	1.03E-04	1.17E-04	8.28E-05	3.77E-05	4.21E-05	4.95E-05	3.08E-05	6.63E-05
PECars-sed-$P_2O_{5i1,i2,i3,i4}$	1.99E-04	1.22E-04	1.42E-04	6.55E-05	7.47E-05	6.19E-05	3.12E-05	3.43E-05	3.81E-05	2.44E-05	5.90E-05

Scenario 6 - PBO

- ✓ ***For biocide type i2=2; ticks***
- ➢ **Initial concentration of PBO in soil, degradation NOT taken into account**

PEC in soil for arable land, 1 manure application											
[mg/kg$_{ww}$]	**Animal Category (i1)**										
	1	**2**	**3**	**4**	**5**	**6**	**7**	**10**	**13**	**14**	**15**
PIECarab-N$_{i1,i2,i3,i4}$	1.4620E-05	7.0526E-06	2.2103E-05	1.3333E-05	1.5198E-05	1.0754E-05	4.9034E-06	5.4723E-06	6.4267E-06	4.0072E-06	8.6187E-06
PIECarab-P$_2$O$_{5i1,i2,i3,i4}$	2.5820E-05	1.5843E-05	1.8512E-05	8.5108E-06	9.7015E-06	8.0479E-06	4.0594E-06	4.4616E-06	4.9503E-06	3.1759E-06	7.6673E-06

PEC in soil for grassland after 4 manure application events											
[mg/kg$_{ww}$]	**Animal Category (i1)**										
	1	**2**	**3**	**4**	**5**	**6**	**7**	**10**	**13**	**14**	**15**
PIECgrs$_4$-N$_{i1,i2,i3,i4}$	4.027E-04	1.943E-04	6.089E-04	3.673E-04	4.187E-04	2.962E-04	1.351E-04	1.507E-04	1.770E-04	1.104E-04	2.374E-04
PIECgrs$_4$-P$_2$O$_{5i1,i2,i3,i4}$	9.205E-04	5.648E-04	6.599E-04	3.034E-04	3.458E-04	2.869E-04	1.447E-04	1.591E-04	1.765E-04	1.132E-04	2.733E-04

- ➢ **Considering degradation processes of PBO 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											
[mg/kg$_{ww}$]	**Animal Category (i1)**										
	1	**2**	**3**	**4**	**5**	**6**	**7**	**10**	**13**	**14**	**15**
PECarab$_{1_degr-N_{i1,i2,i3,i4}}$	1.4620E-05	7.0526E-06	2.2103E-05	1.3333E-05	1.5198E-05	1.0754E-05	4.9034E-06	5.4723E-06	6.4267E-06	4.0072E-06	8.6187E-06
PECarab$_{1_degr-P_2O_{5i1,i2,i3,i4}}$	2.5820E-05	1.5843E-05	1.8512E-05	8.5108E-06	9.7015E-06	8.0479E-06	4.0594E-06	4.4616E-06	4.9503E-06	3.1759E-06	7.6673E-06

PEC in soil for grassland after 4 manure application event, taking degradation into account											
[mg/kg$_{ww}$]	**Animal Category (i1)**										
	1	**2**	**3**	**4**	**5**	**6**	**7**	**10**	**13**	**14**	**15**
PECgrs$_{4_degr-N_{i1,i2,i3,i4}}$	1.981E-04	9.554E-05	2.994E-04	1.806E-04	2.059E-04	1.457E-04	6.643E-05	7.413E-05	8.706E-05	5.429E-05	1.168E-04
PECgrs$_{4_degr-P_2O_{5i1,i2,i3,i4}}$	4.527E-04	2.778E-04	3.245E-04	1.492E-04	1.701E-04	1.411E-04	7.117E-05	7.822E-05	8.679E-05	5.568E-05	1.344E-04

- **Considering degradation processes of PBO in soil, after 10 consecutive years application**

PEC in soil for arable land, 1 manure application/yr after 10 consecutive years, taking degradation into account

[mg/kg$_{ww}$]	Animal Category (i1)										
	1	**2**	**3**	**4**	**5**	**6**	**7**	**10**	**13**	**14**	**15**
PECarab$_{10_degr}$-N$_{i1,i2,i3,i4}$	1.4813E-05	7.1458E-06	2.2395E-05	1.3509E-05	1.5399E-05	1.0896E-05	4.9682E-06	5.5446E-06	6.5117E-06	4.0601E-06	8.7326E-06
PECarab$_{10_degr}$-P$_2$O$_{5i1,i2,i3,i4}$	2.6161E-05	1.6052E-05	1.8757E-05	8.6233E-06	9.8296E-06	8.1543E-06	4.1130E-06	4.5206E-06	5.0157E-06	3.2179E-06	7.7686E-06

PEC in soil for grassland, 4 manure application/yr. after 10 consecutive years, taking degradation into account											
[mg/kg$_{ww}$]	Animal Category (i1)										
	1	**2**	**3**	**4**	**5**	**6**	**7**	**10**	**13**	**14**	**15**
PECgrs$_{10_degr}$-Ni1,i2,i3,i4	2.185E-04	1.054E-04	3.303E-04	1.992E-04	2.271E-04	1.607E-04	7.327E-05	8.177E-05	9.603E-05	5.988E-05	1.288E-04
PECgrs$_{10_degr}$-P2O5i1,i2,i3,i4	4.993E-04	3.064E-04	3.580E-04	1.646E-04	1.876E-04	1.556E-04	7.850E-05	8.628E-05	9.573E-05	6.141E-05	1.483E-04

- **Predicted Environmental Concentrations of PBO in groundwater (using PECsoil, after 10 consecutive years manure application, PEC$_{10_degr}$, WG V, 2015, November & WG-I-2018, January)**

PEC in groundwater for arable and grassland	
[mg/kg$_{ww}$]	**Animal Category (i1)**

	1	2	3	4	5	6	7	10	13	14	15
$PECgrs_{10\_degr}$-gw-$N_{i1,i2,i3,i4}$	4.59E-07	2.21E-07	6.94E-07	4.18E-07	4.77E-07	3.37E-07	1.54E-07	1.72E-07	2.02E-07	1.26E-07	2.70E-07
$PECgrs_{10\_degr}$-gw-$P_2O_{5i1,i2,i3,i4}$	1.05E-06	6.43E-07	7.52E-07	3.46E-07	3.94E-07	3.27E-07	1.65E-07	1.81E-07	2.01E-07	1.29E-07	3.11E-07
$PECars_{10\_degr}$-gw-$N_{i1,i2,i3,i4}$	3.1162E-08	1.5033E-08	4.7112E-08	2.8419E-08	3.2394E-08	2.2921E-08	1.0452E-08	1.1664E-08	1.3699E-08	8.5413E-09	1.8371E-08
$PECars_{10\_degr}$-gw-$P_2O_{5i1,i2,i3,i4}$	5.5035E-08	3.3769E-08	3.9458E-08	1.8141E-08	2.0679E-08	1.7154E-08	8.6525E-09	9.5100E-09	1.0552E-08	6.7694E-09	1.6343E-08

- **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 PBO in <u>surface water</u> (PECsoil, after 10 consecutive years manure application, PEC_{10_degr} as an input)**

PEC in surface water for <u>grassland</u>											
[mg/kg_{ww}]	**Animal Category (i1)**										
	1	**2**	**3**	**4**	**5**	**6**	**7**	**10**	**13**	**14**	**15**

PECgrs-sw-$N_{i1,i2,i3,i4}$	4.58757E-08	2.21303E-08	6.93559E-08	4.18369E-08	4.76898E-08	3.37436E-08	1.53864E-08	1.71715E-08	2.01665E-08	1.25741E-08	2.70447E-08
PECgrs-sw-$P_2O_{5i1,i2,i3,i4}$	1.04851E-07	6.43357E-08	7.51743E-08	3.45609E-08	3.93959E-08	3.26813E-08	1.64843E-08	1.81179E-08	2.01024E-08	1.28967E-08	3.11355E-08

PEC in surface water for arable lands											
[mg/kg$_{ww}$]	**Animal Category (i1)**										
	1	**2**	**3**	**4**	**5**	**6**	**7**	**10**	**13**	**14**	**15**
PECars-sw-$N_{i1,i2,i3,i4}$	3.1162E-09	1.5033E-09	4.7112E-09	2.8419E-09	3.2394E-09	2.2921E-09	1.0452E-09	1.1664E-09	1.3699E-09	8.5413E-10	1.8371E-09
PECars-sw-$P_2O_{5i1,i2,i3,i4}$	5.5035E-09	3.3769E-09	3.9458E-09	1.8141E-09	2.0679E-09	1.7154E-09	8.6525E-10	9.5100E-10	1.0552E-09	6.7694E-10	1.6343E-09

- **Predicted Environmental Concentrations of PBO in sediment (PECsoil, after 10 coscecutive years manure application, PEC_{10_degr} as an input)**

PEC in sediment for grassland											
[mg/kg$_{ww}$]	**Animal Category (i1)**										
	1	**2**	**3**	**4**	**5**	**6**	**7**	**10**	**13**	**14**	**15**

PECgrs-sed-$N_{i1,i2,i3,i4}$	2.69E-05	1.30E-05	4.07E-05	2.45E-05	2.80E-05	1.98E-05	9.02E-06	1.01E-05	1.18E-05	7.37E-06	1.59E-05
PECgrs-sed-$P_2O_{5i1,i2,i3,i4}$	6.15E-05	3.77E-05	4.41E-05	2.03E-05	2.31E-05	1.92E-05	9.66E-06	1.06E-05	1.18E-05	7.56E-06	1.83E-05

PEC in sediment for arable lands											
[mg/kg_{ww}]	**Animal Category (i1)**										
	1	**2**	**3**	**4**	**5**	**6**	**7**	**10**	**13**	**14**	**15**
PECars-sed-$N_{i1,i2,i3,i4}$	1.83E-06	8.81E-07	2.76E-06	1.67E-06	1.90E-06	1.34E-06	6.13E-07	6.84E-07	8.03E-07	5.01E-07	1.08E-06
PECars-sed-$P_2O_{5i1,i2,i3,i4}$	3.23E-06	1.98E-06	2.31E-06	1.06E-06	1.21E-06	1.01E-06	5.07E-07	5.57E-07	6.19E-07	3.97E-07	9.58E-07

Primary and secondary poisoning

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

Secondary poisoning

The log octanol/water partition coefficient of permethrin and PBO (4.67 and 4.8, respectively) are abore the trigged value of 3 suggesting that the two substances may have significant potential for bioconcentration in both aquatic and terrestrial biota.

Permethrin:
An experimentally BCF of 500 - 570 L/kg in fish (AR, 2014) and 15108 L/kg in earthwormare available for permethrin

PBO:
The aquatic bioaccumulation potential of Piperonyl Butoxide was experimentally investigated using the Bluegill sunfish *Lepomis macrochirus* (1992; A7.4.3.3). The kinetic (mean) BCF values in edible, non-edible and whole fish were calculated to be 99, 450 and 290 L/kg. The bioaccumulation potential of Piperonyl Butoxide in terrestrial organisms was predicted by using the relationship of Jager (1998) since no experimentally derived earthworm bioconcentration data were available. The earthworm bioconcentration factor ($BCF_{earthworm}$) was estimated to be 757 mg/kg. As regards metabolite M-12, the bioaccumulation potential in both aquatic (fish) and terrestrial (earthworms) organisms was predicted by using the equations developed by Veith et al. (1979) and Jager (1998), respectively. The fish and earthworm BCF values were estimated to be 89.5 L/kg and 15.8 mg/kg, respectively.

BCF used in the assessment are summarized in the table below.

Summary table of Bioconcentration Factor (BCF)		
	BCF_{fish}	**$BCF_{earthworm}$**
	[L/kgwwt]	[L/kgwwt]
Permethrin	570	15108
PBO	290 (whole fish)	757

In the EUSES calculations for secondary poisoning the PECregional is added to the PEClocal assuming that 50% of the food is sourced from the local environment and 50% from the regional environment. According to the TGD, the foraging area of fish-eating predators may be very large and therefore using the PEClocal may lead to an overestimation of the risk, especially as biodegradation in surface water is not taken into account.

PECregional may have the opposite effect. It has therefore been decided that a scenario where 50% of the diet comes from a local area and 50% of the diet comes from a regional area is the most appropriate for the assessment. As the PECregional is not calculated for the biocide assessment, the PEClocal divided by two was used for the calculation.

For the assessment of secondary poisoning in the aquatic food chain (water → fish → predator) the concentration of contaminant in food (fish) of fish-eating predators

(PECoralpredator) is calculated from the PEC for surface water, the measured BCF for fish and the biomagnification factor (BMF) according to the following formula

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

For the assessment of secondary poisoning in the terrestrial food chain (soil → worm → predator) the exposure of the predators may be affected by the amount of substance that is in the soil, since birds and mammals consume worms with their gut contents and the gut of earthworms can contain substantial amounts of soil. The $PEC_{oral,predator}$ is calculated as:

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

Where F_{gut}=0.1 kg_{dwt}/kg_{wwt} and $CONV_{soil}$= 1.13 kg_{wwt}/kg_{dwt}

For scenario 4 the worst case PECoral is reported. For scenarios 5 and 6 (Stable application for professional user for flies and ticks respectively) the worst-case subcategory was considered for "Veal calves".

Summary table on estimated theoretical exposition values (ETE) via food chain

Scenario	$PEC_{oral,\ fish\text{-}eating\ predator}$	$PEC_{oral,\ earthworm\text{-}eating\ predator}$
Scenario 1a	-	-
Scenario 2a	-	-
Scenario 4a – standard house, treated area	-	2.57E+00
Scenario 4a – large building, treated area	-	2.59E+00
Scenario 5a - arable land	8.397E-05	2.23E-02
Scenario 5a - grassland	1.481E-03	3.94E-01
Scenario 6a - arable land	1.654E-04	4.40E-02
Scenario 6a - grassland	2.918E-03	7.76E-01
Scenario 1b	-	-
Scenario 2b	-	-
Scenario 4b – standard house, treated area	-	2.44E-02
Scenario 4b – large building, treated area	-	2.46E-02
Scenario 5b - arable land	6.936E-07	1.93E-05
Scenario 5b - grassland	1.021E-05	2.84E-04

Scenario 6b - arable land	1.366E-06	3.79E-05
Scenario 6b - grassland	2.011E-05	5.59E-04

2.2.8.3 Risk characterisation

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

Atmosphere

Conclusion:

The low vapour pressure (Pure) and Henry's Law constant of the active substance permethrin (K = 4.6E-03 Pa m3 mol-1) and PBO (K = 1.68E-04) indicate that there will be negligible loss of permethrin and PBO to the atmosphere.

Sewage treatment plant (STP)

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

Summary table on calculated PEC/PNEC values	
	$PEC/PNEC_{STP}$
permethrin	
Scenario 1a	0
Scenario 2a	0
Scenario 4a (standard house and large building, treated area)	0
PBO	
Scenario 1b	0
Scenario 2b	0
Scenario 4b (standard house and large building, treated area)	0

Conclusion: According to the obtained PEC/PNEC ratio, the use of PERTEX is safe for the microorganisms involved in biodegradation processes in the STP, since the ratio between the predicted environmental concentration and the predicted no-effect concentration is zero for all scenarios.

Aquatic compartment

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

Summary table on calculated PEC/PNEC values				
	$PEC/PNEC_{water}$	**$PEC/PNEC_{sed}$**	**$PEC/PNEC_{seawater}$**	**$PEC/PNEC_{seased}$**
permethrin				
Scenario 1a	0	0	Not relevant	Not relevant
Scenario 2a	0	0	Not relevant	Not relevant
Scenario 4a (standard house and large building, treated area)	0	0	Not relevant	Not relevant
PBO				
Scenario 1b	0	0	Not relevant	Not relevant
Scenario 2b	0	0	Not relevant	Not relevant
Scenario 4b (standard house and large building, treated area)	0	0	Not relevant	Not relevant

Conclusion for surface water:

According to the obtained PEC/PNEC ratio, the combined use of PERTEX is safe for the aquatic environment, since the $PEC_{sw}/PNEC_{sw}$ ratio is zero.

Conclusion for sediment:
According to the obtained PEC/PNEC ratio, the use of PERTEX is safe for the sediment drewlling organisms, since the $PEC_{sed}/PNEC_{sed}$ ratio is zero.

Terrestrial compartment

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

Calculated PEC/PNEC values	
	$PEC/PNEC_{soil}$

Calculated PEC/PNEC values	
	PEC/PNEC$_{soil}$
permethrin	
Scenario 1a	0
Scenario 2a	0
Scenario 4a – standard house, treated area	9.20E-01
Scenario 4a – large building, treated area	9.26E-01
PBO	
Scenario 1b	0
Scenario 2b	0
Scenario 4b – standard house, treated area	1.45E-02
Scenario 4b – large building, treated area	1.46E-02

Conclusion: According to the obtained PEC/PNEC ratio, the use of PERTEX is safe for the soil compartment, since the $PEC_{soil}/PNEC_{soil}$ ratio is lower than 1.

Groundwater

Conclusion: For scenario 4, in large buildings, the PECgw for permethrin is slightly higher than the trigger value for drinking water of 0.1 μg/L. As a second tier, a refinement of the ground water assessment has been carried out using FOCUS PEARL. The application rate of the product of 1.79 g/m^2 has been considered. The application rate used in the assessment with FOCUS PEARL was converted in g/ha corresponding to 0.537 kg/ha of permethrin. The assessmnent was carried out for the grass (alfalfa) crop for all the scenarios.

Input parameters for Tier II

Molar mass (g/mol)	391.29
Saturated vapor pressure (Pa)	2.155E-6
Solubility in water (mg/L)	0.00495
Kom (L/kg)	15620
Half-life (d)	106
Dosage (kg/ha)	0.537
Date	01 January
Crop	Grass

PECgw for all scenarios resulted lower than 0.0001 mg/L

Scenario 5a – permethrin (arable land)

Category- subcategory	Index i1	PEC/ PNECsoil	PEC/ PNECsw	PEC/ PNECsed
Dairy cattle	1	5.385E-03	2.107E-01	2.681E-01
Beef cattle	2	2.871E-03	1.123E-01	1.429E-01
Veal calf	3	7.994E-03	3.128E-01	3.980E-01
Sow-individual	4	4.478E-03	1.752E-01	2.230E-01
Sow-group	5	5.709E-03	2.234E-01	2.842E-01
Fattening pig	6	3.679E-03	1.439E-01	1.831E-01
Laying hen-battery (no treatment)	7	1.197E-03	4.683E-02	5.959E-02
Laying hen – compact	10	1.336E-03	5.227E-02	6.651E-02
laying hen - free range grating floor	13	2.459E-03	9.622E-02	1.224E-01
parent broiler. free range grating floor	14	1.328E-03	5.195E-02	6.610E-02
parent broiler. rearing. grating floor	15	2.808E-03	1.099E-01	1.398E-01

Scenario 5a – permethrin (grassland)

Category- subcategory	Index i1	PEC/ PNECsoil	PEC/ PNECsw	PEC/ PNECsed
Dairy cattle	1	9.517E-02	**3.717E+00**	**4.730E+00**
Beef cattle	2	5.074E-02	**1.982E+00**	**2.522E+00**
Veal calf	3	1.413E-01	**5.518E+00**	**7.021E+00**
Sow-individual	4	7.915E-02	**3.091E+00**	**3.933E+00**
Sow-group	5	1.009E-01	**3.941E+00**	**5.014E+00**
Fattening pig	6	6.502E-02	**2.539E+00**	**3.231E+00**
Laying hen-battery (no treatment)	7	2.116E-02	8.263E-01	**1.051E+00**
Laying hen – compact	10	2.361E-02	9.222E-01	**1.173E+00**
laying hen - free range grating floor	13	4.346E-02	**1.698E+00**	**2.160E+00**
parent broiler. free range grating floor	14	2.347E-02	9.165E-01	**1.166E+00**
parent broiler. rearing. grating floor	15	4.963E-02	**1.938E+00**	**2.466E+00**

Scenario 5b – PBO (arable land)

Category- subcategory	Index i1	PEC/ PNECsoil	PEC/ PNECsw	PEC/P NECsed
Dairy cattle	1	7.815E-05	1.089E-06	2.361E-03
Beef cattle	2	4.167E-05	5.804E-07	1.259E-03
Veal calf	3	1.160E-04	1.616E-06	3.505E-03
Sow-individual	4	6.499E-05	9.054E-07	1.964E-03
Sow-group	5	8.285E-05	1.154E-06	2.503E-03
Fattening pig	6	5.339E-05	7.437E-07	1.613E-03

Laying hen-battery (no treatment)	7	1.737E-05	2.420E-07	5.249E-04
Laying hen – compact	10	1.939E-05	2.701E-07	5.858E-04
laying hen - free range grating floor	13	3.569E-05	4.972E-07	1.078E-03
parent broiler. free range grating floor	14	1.927E-05	2.684E-07	5.822E-04
parent broiler. rearing. grating floor	15	4.075E-05	5.677E-07	1.231E-03

Scenario 5b – PBO (grassland)

Category- subcategory	Index i1	PEC/ PNECsoil	PEC/ PNECsw	PEC/P NECsed
Dairy cattle	1	1.153E-03	1.603E-05	3.476E-02
Beef cattle	2	6.145E-04	8.545E-06	1.853E-02
Veal calf	3	1.711E-03	2.379E-05	5.160E-02
Sow-individual	4	9.585E-04	1.333E-05	2.891E-02
Sow-group	5	1.222E-03	1.699E-05	3.685E-02
Fattening pig	6	7.873E-04	1.095E-05	2.375E-02
Laying hen-battery (no treatment)	7	2.562E-04	3.563E-06	7.727E-03
Laying hen – compact	10	2.859E-04	3.976E-06	8.624E-03
laying hen - free range grating floor	13	5.264E-04	7.319E-06	1.588E-02
parent broiler. free range grating floor	14	2.842E-04	3.952E-06	8.571E-03
parent broiler. rearing. grating floor	15	6.010E-04	8.357E-06	1.813E-02

Conclusion: According to the obtained PEC/PNEC ratio, the use of PERTEX **is not safe in grasslands** for the scenario 5 (Stable application for professional user-flies). However its use is safe in arable lands.

Scenario 6a – permethrin (arable land)

Category- subcategory	Index i1	PEC/ PNECsoil	PEC/ PNECsw	PEC/ PNECsed
Dairy cattle	1	1.041E-02	4.075E-01	5.185E-01
Beef cattle	2	5.024E-03	1.966E-01	2.501E-01
Veal calf	3	1.575E-02	6.161E-01	7.839E-01
Sow-individual	4	9.498E-03	3.716E-01	4.729E-01
Sow-group	5	1.083E-02	4.236E-01	5.390E-01
Fattening pig	6	7.661E-03	2.997E-01	3.814E-01
Laying hen-battery (no treatment)	7	3.493E-03	1.367E-01	1.739E-01
Laying hen – compact	10	3.898E-03	1.525E-01	1.941E-01
laying hen - free range grating floor	13	4.578E-03	1.791E-01	2.279E-01
parent broiler. free range grating floor	14	2.855E-03	1.117E-01	1.421E-01
parent broiler. rearing. grating floor	15	6.140E-03	2.402E-01	3.057E-01

Scenario 6a – permethrin (grassland)

Category- subcategory	Index i1	PEC/ PNECsoil	PEC/ PNECsw	PEC/ PNECsed
Dairy cattle	1	1.841E-01	**7.189E+00**	**9.148E+00**
Beef cattle	2	8.880E-02	**3.468E+00**	**4.413E+00**
Veal calf	3	2.783E-01	**1.087E+01**	**1.383E+01**
Sow-individual	4	1.679E-01	**6.557E+00**	**8.342E+00**
Sow-group	5	1.914E-01	**7.474E+00**	**9.510E+00**
Fattening pig	6	1.354E-01	**5.288E+00**	**6.729E+00**
Laying hen-battery (no treatment)	7	6.174E-02	**2.411E+00**	**3.068E+00**
Laying hen – compact	10	6.890E-02	**2.691E+00**	**3.424E+00**
laying hen - free range grating floor	13	8.092E-02	**3.160E+00**	**4.021E+00**
parent broiler. free range grating floor	14	5.045E-02	**1.971E+00**	**2.507E+00**
parent broiler. rearing. grating floor	15	1.085E-01	**4.238E+00**	**5.393E+00**

Scenario 6b - PBO (arable land)

Category- subcategory	Index i1	PEC/ PNECsoil	PEC/ PNECsw	PEC/ PNECsed
Dairy cattle	1	1.512E-04	2.106E-06	4.567E-03
Beef cattle	2	7.292E-05	1.016E-06	2.203E-03
Veal calf	3	2.285E-04	3.183E-06	6.904E-03
Sow-individual	4	1.378E-04	1.920E-06	4.165E-03
Sow-group	5	1.571E-04	2.189E-06	4.748E-03
Fattening pig	6	1.112E-04	1.549E-06	3.359E-03
Laying hen-battery (no treatment)	7	5.070E-05	7.062E-07	1.532E-03
Laying hen – compact	10	5.658E-05	7.881E-07	1.709E-03
laying hen - free range grating floor	13	6.645E-05	9.256E-07	2.008E-03
parent broiler. free range grating floor	14	4.143E-05	5.771E-07	1.252E-03
parent broiler. rearing. grating floor	15	8.911E-05	1.241E-06	2.692E-03

Scenario 6b – PBO (grassland)

Category- subcategory	Index i1	PEC/ PNECsoil	PEC/ PNECsw	PEC/P NECsed
Dairy cattle	1	2.229E-03	3.100E-05	6.723E-02
Beef cattle	2	1.075E-03	1.495E-05	3.243E-02
Veal calf	3	3.370E-03	4.686E-05	1.016E-01
Sow-individual	4	2.033E-03	2.827E-05	6.131E-02

Sow-group	5	2.317E-03	3.222E-05	6.989E-02
Fattening pig	6	1.640E-03	2.280E-05	4.945E-02
Laying hen-battery (no treatment)	7	7.476E-04	1.040E-05	2.255E-02
Laying hen – compact	10	8.344E-04	1.160E-05	2.517E-02
laying hen - free range grating floor	13	9.799E-04	1.363E-05	2.956E-02
parent broiler. free range grating floor	14	6.110E-04	8.496E-06	1.843E-02
parent broiler. rearing. grating floor	15	1.314E-03	1.827E-05	3.964E-02

Conclusion: According to the obtained PEC/PNEC ratio, the use of PERTEX is safe for the scenario 6 (Stable application for professional user-ticks) only in arable lands for all stable subcategories. Regarding the grasslands, the use of PERTEX **is not safe** for the scenario 6.

Primary and secondary poisoning

Primary poisoning

Not relevant

Secondary poisoning

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

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

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

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

Summary table on secondary poisoning via the aquatic food chain					
Scenario	***$PEC_{oral,\ fish\text{-}eating\ predator}$***	**$PNEC_{bird}$**	**$PNEC_{mammals}$**	**PEC/ $PNEC_{birds}$**	**PEC/ $PNEC_{mammals}$**
permethrin					
Scenario 1a	-	16.7	120	-	-
Scenario 2a	-	16.7	120	-	-
Scenario 4a – standard house, treated area	-	16.7	120	-	-

Summary table on secondary poisoning via the aquatic food chain					
Scenario	***PEC*$_{oral,\ fish\text{-}eating\ predator}$**	**PNEC$_{bird}$**	**PNEC$_{mammals}$**	**PEC/ PNEC$_{birds}$**	**PEC/ PNEC$_{mammals}$**
Scenario 4a – large building, treated area	-	16.7	120	-	-
Scenario 5a - arable land	8.397E-05	16.7	120	5.028E-06	6.997E-07
Scenario 5a - grassland	1.481E-03	16.7	120	8.871E-05	1.235E-05
Scenario 6a - arable land	1.654E-04	16.7	120	9.904E-06	1.378E-06
Scenario 6a - grassland	2.918E-03	16.7	120	1.747E-04	2.432E-05
PBO					
Scenario 1b	-	10	20	-	-
Scenario 2b	-	10	20	-	-
Scenario 4b – standard house, treated area	6.936E-07	10	20	6.936E-08	3.4681E-08
Scenario 4b – large building, treated area	1.021E-05	10	20	1.021E-06	5.1057E-07
Scenario 5b - arable land	1.366E-06	10	20	1.366E-07	6.8312E-08
Scenario 5b – grassland	2.011E-05	10	20	2.011E-06	1.0057E-06
Scenario 6b - arable land	6.936E-07	10	20	6.936E-08	3.4681E-08
Scenario 6b - grassland	1.021E-05	10	20	1.021E-06	5.1057E-07
Summary table on secondary poisoning via the terrestrial food chain					
Scenario	***PEC*$_{oral,\ earthworm\text{-}eating\ predator}$**	**PNEC$_{birds}$[1]**	**PNEC$_{mammals}$ [2]**	**PEC/ PNEC$_{birds}$**	**PEC/ PNEC$_{mammals}$**
permethrin					
Scenario 1a	-	16.7	120	-	-
Scenario 2a	-	16.7	120	-	-
Scenario 4a – standard house, treated area	2.57E+00	16.7	120	1.54E-01	2.14E-02

Summary table on secondary poisoning via the aquatic food chain					
Scenario	***PEC*$_{oral,\ fish\text{-}eating\ predator}$**	**PNEC$_{bird}$**	**PNEC$_{mammals}$**	**PEC/ PNEC$_{birds}$**	**PEC/ PNEC$_{mammals}$**
Scenario 4a – large building, treated area	2.59E+00	16.7	120	1.55E-01	2.16E-02
Scenario 5a - arable land	2.23E-02	16.7	120	1.34E-03	1.86E-04
Scenario 5a - grassland	3.94E-01	16.7	120	2.36E-02	3.28E-03
Scenario 6a - arable land	4.40E-02	16.7	120	2.63E-03	3.66E-04
Scenario 6a - grassland	7.76E-01	16.7	120	4.65E-02	6.47E-03
PBO					
Scenario 1b	-	10	20	-	-
Scenario 2b	-	10	20	-	-
Scenario 4b – standard house, treated area	2.44E-02	10	20	2.44E-03	1.22E-03
Scenario 4b – large building, treated area	2.46E-02	10	20	2.46E-03	1.23E-03
Scenario 5b - arable land	1.93E-05	10	20	1.93E-06	9.63E-07
Scenario 5b – grassland	2.84E-04	10	20	2.84E-05	1.42E-05
Scenario 6b - arable land	3.79E-05	10	20	3.79E-06	1.90E-06
Scenario 6b - grassland	5.59E-04	10	20	5.59E-05	2.79E-05

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

Mixture toxicity

As a first tier PEC/PNEC ratio for permethrin and PBO were summarized:

$PEC/PNEC_{mixture}=PEC/PNEC_{permethrin}+PEC/PNEC_{PBO}$

Summary table of calculated ΣPEC/PNEC values						
	ΣPEC/ $PNEC_{soil}$	**ΣPEC$_{gw}$***	**ΣPEC/ $PNEC_{earthworms\text{-}eating\ birds}$**	**ΣPEC/ $PNEC_{earthworms\text{-}eating\ mammals}$**	**ΣPEC/ $PNEC_{fish\text{-}eating\ birds}$**	**ΣPEC/ $PNEC_{fish\text{-}eating\ mammals}$**
Scenario 4 – standard house, treated area	9.20E-01	2.02E-04	1.56E-01	2.26E-02	-	-
Scenario 4 – large building, treated area	9.27E-01	2.03E-04	1.57E-01	2.28E-02	-	-
Stable	2.82E-01	5.19E-05	4.65E-02	6.49E-03	1.767E-04	2.532E-05

*PECgw for PBO are reported, considering that PECgw for permethrin have been calculated lower than 0.001 μg/L with PEARL.

Conclusion: PEC/PNEC value for mixture toxicity are below the trigger of 1 for soil and secondary poisoning.

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

Atmosphere
The low vapour pressure (Pure) and Henry's Law constant of the active substance permethrin (K = 4.6E-03 Pa m3 mol-1) and PBO (K = 1.68E-04) indicate that there will be negligible loss of permethrin and PBO to the atmosphere. According to these results, an accumulation of permethrin and PBO in the air is not expected, thus risk characterization is not necessary.

STP compartment
There is no concern for microorganisms involved in biodegradation processes in the STP when following the label instructions of PERTEX ME.

Aquatic compartment
There is no concern for aquatic organisms when following the label instructions of PERTEX ME.

Terrestrial compartment
The risk characterization for terrestrial compartment is carried out. After the indended use scenario the PEC/PNEC ratio are below 1, indicating a safe use when following the label instructions of PERTEX ME.

Groundwater
The predicted groundwater concentrations, for all assessed scenarios for both active substances are < 0.1 µg/L (or 1E-04 mg/L), the maximum permissible concentration by directive 2006/18/EC. Therefore the risk to the groundwater environment for the uses of permethrin and PBO in the product is acceptable.

Primary and secondary poisoning compartment
The risk characterization for primary and secordary poisoing compartment is carried out. After the indended use scenario the PEC/PNEC ratio are below 1, indicating a safe use when following the label instructions of PERTEX ME.

Mixture toxicity
The risk characterization from mixture toxicity is carried out. After the intended use scenario the ∑PEC/PNEC for the relevant compartments are below 1, indicating a safe use when following the label instructions of PERTEX ME.

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

- There is an unacceptable risk for sediment dwelling organisms and for aquatic organisms in the "Stable application for professional user-flies" scenario when PERTEX ME is applied in grasslands and thus **USE 5 is NOT authorised in grasslands.** However, the risk in arable lands is acceptable.
- There is an unacceptable risk for PERTEX ME to be used in animal housing (scenario 6) when it s applied in the grasslands.
- There is an acceptable risk for PERTEX ME to be used in animal housing (scenario 6) when it can **ONLY** be applied in the following animal subcategories in arable lands:

i1	Type of housing	
1	Cattle	Dairy cattle
2		Beef cattle
3		Veal calves
4	Pigs	Sows-indivinduals
5		Sows-groups
6		Fattening pigs
7	Poultry	Battery, No treatment, Laying hens
10		Battery, Compact, Laying hens
13		Free range, Grating floor, Laying hens
14		Free range, Grating floor, Parent broilers
15		Free range, Grating floor, Parent broilers in rearing

Strictly **NOT to be used** in stables/animal housings connected to a sewage treatment plant (STP).

2.2.9 Measures to protect man, animals and the environment

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

2.2.10 Assessment of a combination of biocidal products

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

2.2.11 Comparative assessment

Not relevant

3 ANNEXES

3.1 List of studies for the biocidal product (family)

Author(s)	Year	Title Company Report No. Source (where different from company)	Vertebrate study Y/N	Owner
[redacted]	2018	PERTEX: Determination of the Physico-chemical Properties Report no. CH-010/2018 ChemServcie Srl - Controlli e Ricerche	N	BLEU LINE S.r.l.
[redacted]	2018	PERTEX: Determination of the Accelerated Storage Stability And Corrosion Characteristics Report no. CH-014/2018 ChemServcie Srl - Controlli e Ricerche	N	BLEU LINE S.r.l.
[redacted]	2020	PERTEX: Two Years Storage Stability and Corrosion Characteristics Report no. CH-015/2018 ChemServcie Srl - Controlli e Ricerche	N	BLEU LINE S.r.l.
[redacted]	2018	PERTEX: Validation of the Analytical Method for the Determination of Permethrin Active Ingredient Content Report no. CH-012/2018 ChemServcie Srl - Controlli e Ricerche	N	BLEU LINE S.r.l.
[redacted]	2018	PERTEX: Validation of the Analytical Method for the Determination of Piperonyl butoxide Active Ingredient Content Report no. CH-013/2018 ChemServcie Srl - Controlli e Ricerche	N	BLEU LINE S.r.l.
[redacted]	2017	EVALUATION OF THE EFFICACY OF "PERTEX" AGAINST AEDES ALBOPICTUS (FORCED CONTACT TEST ON POROUS AND NON-POROUS SURFACE) Report no. BLEPER290917 -01 Entostudio s.n.c.	N	BLEU LINE S.r.l.
[redacted]	2017	EVALUATION OF THE EFFICACY OF "PERTEX" AGAINST CULEX PIPIENS (FORCED CONTACT TEST ON POROUS AND NON-POROUS SURFACE) Report no. BLEPER290917 -02 Entostudio s.n.c.	N	BLEU LINE S.r.l.

Author(s)	Year	Title Company Report No. Source (where different from company)	Vertebrate study Y/N	Owner
[redacted]	2017	EVALUATION OF THE EFFICACY OF "PERTEX" AGAINST IXODES RICINUS (FORCED CONTACT TEST ON POROUS AND NON-POROUS SURFACE) Report no. BLEPER290917 -03 Entostudio s.n.c.	N	BLEU LINE S.r.l.
[redacted]	2017	EVALUATION OF THE EFFICACY OF "PERTEX" AGAINST MUSCA DOMESTICA (DIRECT APPLICATION) Report no. BLEPER290917 -04 Entostudio s.n.c.	N	BLEU LINE S.r.l.
[redacted]	2017	EVALUATION OF THE EFFICACY OF "PERTEX" AGAINST STOMOXYS CALCITRANS (DIRECT APPLICATION) Report no. BLEPER290917 -05 Entostudio s.n.c.	N	BLEU LINE S.r.l.
[redacted]	2018	EVALUATION OF THE INSECTICIDAL EFFICACY OF "PERTEX" AGAINST AEDES ALBOPICTUS (FIELD TEST) Report no. BLEPER030 818 - 01 Entostudio s.n.c.	N	BLEU LINE S.r.l.
[redacted]	2018	EVALUATION OF THE EFFICACY OF "PERTEX" AGAINST IXODES RICINUS INDOOR & OUTDOOR (FIELD TEST) Report no. BLEPER030 818 - 03 Entostudio s.n.c.	N	BLEU LINE S.r.l.
[redacted]	2018	EVALUATION OF THE EFFICACY OF "PERTEX" AGAINST MUSCA DOMESTICA (OUTDOOR FIELD TEST) Report no. BLEPER030 818 - 04 Entostudio s.n.c.	N	BLEU LINE S.r.l.
[redacted]	~~2018~~	~~EVALUATION OF THE EFFICACY OF "PERTEX" AGAINST STOMOXYS CALCITRANS AND MUSCA DOMESTICA (FIELD TEST)~~ ~~Report no. BLEPER030 818 - 02~~ ~~Entostudio s.n.c.~~	~~N~~	~~BLEU LINE S.r.l.~~
[redacted]	2020	PERTEX: Determination of the pH value Report no. CH-0367/2020 ChemServcie Srl - Controlli e Ricerche	N	BLEU LINE S.r.l.
[redacted]	2020	PERTEX: Determination of the Explosive properties by preliminary Differential Scanning Calorimetry (DSC) analysis Report no. CH-0200/2020 ChemServcie Srl - Controlli e Ricerche	N	BLEU LINE S.r.l.

Author(s)	Year	Title Company Report No. Source (where different from company)	Vertebrate study Y/N	Owner
[redacted]	2017	Accelerated Storage Stability Test at 54°C ±2°C of Pertex, A Ready to Use Insectidice Based on Permethrin and Piperonylbutoxide Report no. 17679/17, 17680/17 and 17681/17 Bucciarelli Laboratori srl	N	BLEU LINE S.r.l.
[redacted]	2020	EVALUATION OF THE INSECTICIDAL EFFICACY OF "PERTEX" AGAINST Aedes albopictus (FIELD TEST) Report no. P042-20 Entostudio s.n.c.	N	BLEU LINE S.r.l.
[redacted]	2020	EFFICACY EVALUATION OF "PERTEX" AGAINST Stomoxys calcitrans AND Musca domestica (FIELD TEST) Report no. BLEPER011020 Entostudio s.n.c.	N	BLEU LINE S.r.l.

3.2 Models used and exposure calculations

3.2.1 Human exposure Scenarios [01, 02, 03] – Permethrin

Table 1. Calculations of primary exposure of professionals to permethrin resulting from low-pressure insecticide application of PERTEX (spraying model 1 from TNsG on human exposure, with additional details from HSE survey EH74/3).

	Tier 1	**Tier 2**
	Unprotected	**Protected (PPE)**
Dermal mix/load/apply		
Potential dermal exposure	92 mg/min	92 mg/min
Product on clothing (over 120 min)	11 040 mg	11 040 mg
Penetration(1)	100 %	20%
Product on skin	11 040 mg	2 208 mg
Potential hand exposure	181 mg/min	10.7 mg/min
Hand exposure (2) (3)	21 720 mg	1 284 mg
Total product on skin	32 760 mg	3 492 mg
0.06 % permethrin in application solution	19.66 mg	2.10 mg
Dermal uptake	70%	70%
Dose via skin	13.76 mg	1.47 mg
Dermal body dose per day	0.229 mg/kg bw/d	0.0245 mg/kg bw/d
Inhalation mix/load/apply		
Aerial concentration	104 mg/m³	104 mg/m³
Inhaled volume (over 120 min)	2.5 m³	2.5 m³
RPE protection factor	–	–
Inhaled amount of product	260 mg	260 mg
0.06 % permethrin in application solution	0.156 mg	0.156 mg
Inhalation uptake	100%	100%
Dose via inhalation (a.s.)	0.156 mg	0.156 mg
Inhalative body dose per day	0.0026 mg/kg bw	0.0026 mg/kg bw
Systemic dose (summary of routes)	**0.232 mg/kg bw/d**	**0.0271 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)

3.2.2 Human exposure Scenarios [01, 02, 03] – Piperonyl butoxide

Table 2. Calculations of primary exposure of professionals to Piperonyl butoxide resulting from low-pressure insecticide application of PERTEX (spraying model 1 from TNsG on human exposure, with additional details from HSE survey EH74/3).

	Tier 1	**Tier 2**
	Unprotected	**Protected (PPE)**
Dermal mix/load/apply		
Potential dermal exposure	92 mg/min	92 mg/min
Product on clothing (over 120 min)	11 040 mg	11 040 mg
Penetration(1)	100 %	20%
Product on skin	11 040 mg	2 208 mg
Potential hand exposure	181 mg/min	10.7 mg/min
Hand exposure (2) (3)	21 720 mg	1 284 mg
Total product on skin	32 760 mg	3 492 mg
0.00106 % PBO in application solution	0.347 mg	0.037 mg
Dermal uptake	70%	70%
Dose via skin	0.243 mg	0.0259 mg
Dermal body dose per day	0.00405 mg/kg bw/d	0.00043 mg/kg bw/d
Inhalation mix/load/apply		
Aerial concentration	104 mg/m³	104 mg/m³
Inhaled volume (over 120 min)	2.5 m³	2.5 m³
RPE protection factor	–	–
Inhaled amount of product	260 mg	260 mg
0.00106 % PBO in application solution	0.00276 mg	0.00276 mg
Inhalation uptake	100%	100%
Dose via inhalation (a.s.)	0.00276 mg	0.00276 mg
Inhalative body dose per day	0.000046 mg/kg bw	0.000046 mg/kg bw
Systemic dose (summary of routes)	**0.0041 mg/kg bw/d**	**0.00048 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)

3.2.3 Human exposure Scenario [04] - Permethrin

Adult professional – cleaning work clothes at home
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. It is assumed that the coverall is washed weekly, after 5 days wear.

With an a.s. concentration in the spray solution of 0.06%, the potential contamination is 6.6 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 × 6.6 mg a.s./day = 33 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 1.46 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 70% is assumed for permethrin. 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
= (0.00146 mg a.s./cm² × 820 cm² x 0.3 × 0.7) / 60 kg bw
= 4.2 x 10^{-3} mg/kg bw/week
= 8.4 x 10^{-4} mg/kg bw/d

Exposed Population	**Route and Exposure Levels [mg/kg bw/d]***
	Cleaning work clothes at home
Adults	8.4 x 10^{-4} mg/kg bw/d

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

3.2.4 Human exposure – Scenario [04] – Piperonyl Butoxide

Adult professional – cleaning work clothes at home
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. It is assumed that the coverall is washed weekly, after 5 days wear.

With an a.s. concentration in the spray solution of 0.00106%, the potential contamination is 0.12 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 × 0.12 mg a.s./day = 0.585 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 2.6 x 10^{-5} 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 70% is assumed for PBO. 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
= (0.000026 mg a.s./cm² × 820 cm² x 0.3 × 0.7) / 60 kg bw
= 7.4 x 10^{-5} mg/kg bw/week

= 1.5 x 10^{-5} mg/kg bw/d

Exposed Population	**Route and Exposure Levels [mg/kg bw/d]***
	Cleaning work clothes at home
Adults	1.5 x 10^{-5} mg/kg bw/d

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

3.2.5 Human exposure – Scenario [05] - Permethrin

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 (70%)	0.00066 0.7
Total systemic exposure to a.s. *via* dermal exposure (mg a.s./person/day)	0.000462
Total systemic exposure to a.s. for a 60 kg adult (mg a.s./kg bw/day)	7.7 X 10^{-6}

3.2.6 Human exposure – Scenario [05] - Piperonyl Butoxide

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 0.00106%)] skin penetration (70%)	1.17 X 10^{-5} 0.7
Total systemic exposure to a.s. *via* dermal exposure (mg a.s./person/day)	8.2 X 10^{-6}
Total systemic exposure to a.s. for a 60 kg adult (mg a.s./kg bw/day)	1.4 X 10^{-7}

3.2.7 Human exposure – Scenario [06]

Secondary exposure - General public – dermal and oral exposure to residues on treated surfaces after spot application

Results for Scenario [06] – Secondary exposure of infants - Permethrin

Dermal

Dermal load	–	
External event dose	4.7×10^{-2}	mg/kg bw
External dose on day of exposure	4.7×10^{-2}	mg/kg bw
Internal event dose	3.3×10^{-2}	mg/kg bw
Internal dose on day of exposure	3.3×10^{-2}	mg/kg bw/day
Internal year average dose	1.1×10^{-2}	mg/kg bw/day

Oral

External event dose	4.6×10^{-3}	mg/kg bw
External dose on day of exposure	4.6×10^{-3}	mg/kg bw
Internal event dose	4.6×10^{-3}	mg/kg bw
Internal dose on day of exposure	4.6×10^{-3}	mg/kg bw/day
Internal year average dose	1.6×10^{-3}	mg/kg bw/day

Integrated

Internal event dose	3.7×10^{-2}	mg/kg bw
Internal dose on day of exposure	3.7×10^{-2}	mg/kg bw/day
Internal year average dose	1.3×10^{-2}	mg/kg bw/day

Results for Scenario [06] – Secondary exposure of toddlers - Permethrin

Dermal

Dermal load	–	
External event dose	3.7×10^{-2}	mg/kg bw
External dose on day of exposure	3.7×10^{-2}	mg/kg bw
Internal event dose	2.6×10^{-2}	mg/kg bw
Internal dose on day of exposure	2.6×10^{-2}	mg/kg bw/day
Internal year average dose	9.0×10^{-3}	mg/kg bw/day

Oral

External event dose	3.7×10^{-3}	mg/kg bw
External dose on day of exposure	3.7×10^{-3}	mg/kg bw
Internal event dose	3.7×10^{-3}	mg/kg bw
Internal dose on day of exposure	3.7×10^{-3}	mg/kg bw/day
Internal year average dose	1.3×10^{-3}	mg/kg bw/day

Integrated

Internal event dose	3.0×10^{-2}	mg/kg bw
Internal dose on day of exposure	3.0×10^{-2}	mg/kg bw/day
Internal year average dose	1.0×10^{-2}	mg/kg bw/day

Results for Scenario [06] – Secondary exposure of children - Permethrin

Dermal

Dermal load	–	
External event dose	1.6×10^{-2}	mg/kg bw
External dose on day of exposure	1.6×10^{-2}	mg/kg bw
Internal event dose	1.1×10^{-2}	mg/kg bw
Internal dose on day of exposure	1.1×10^{-2}	mg/kg bw/day
Internal year average dose	3.8×10^{-3}	mg/kg bw/day

Integrated

Internal event dose	1.1×10^{-2}	mg/kg bw
Internal dose on day of exposure	1.1×10^{-2}	mg/kg bw/day
Internal year average dose	3.8×10^{-3}	mg/kg bw/day

Results for Scenario [06] – Secondary exposure of adults – Permethrin

Dermal

Dermal load	–	
External event dose	2.4×10^{-2}	mg/kg bw
External dose on day of exposure	2.4×10^{-2}	mg/kg bw
Internal event dose	1.7×10^{-2}	mg/kg bw
Internal dose on day of exposure	1.7×10^{-2}	mg/kg bw/day
Internal year average dose	5.8×10^{-3}	mg/kg bw/day

Integrated

Internal event dose	1.7×10^{-2}	mg/kg bw
Internal dose on day of exposure	1.7×10^{-2}	mg/kg bw/day
Internal year average dose	5.8×10^{-3}	mg/kg bw/day

Results for Scenario [06] – Secondary exposure of infants – Piperonyl butoxide

Dermal

Dermal load	–	
External event dose	8.2×10^{-4}	mg/kg bw
External dose on day of exposure	8.2×10^{-4}	mg/kg bw
Internal event dose	5.8×10^{-4}	mg/kg bw
Internal dose on day of exposure	5.8×10^{-4}	mg/kg bw/day
Internal year average dose	2.0×10^{-4}	mg/kg bw/day

Oral

External event dose	8.2×10^{-5}	mg/kg bw
External dose on day of exposure	8.2×10^{-5}	mg/kg bw
Internal event dose	8.2×10^{-5}	mg/kg bw
Internal dose on day of exposure	8.2×10^{-5}	mg/kg bw/day
Internal year average dose	2.8×10^{-5}	mg/kg bw/day

Integrated

Internal event dose	6.6×10^{-4}	mg/kg bw
Internal dose on day of exposure	6.6×10^{-4}	mg/kg bw/day
Internal year average dose	2.3×10^{-4}	mg/kg bw/day

Results for Scenario [06] – Secondary exposure of toddlers – Piperonyl butoxide

Dermal

Dermal load	–	
External event dose	6.6×10^{-4}	mg/kg bw
External dose on day of exposure	6.6×10^{-4}	mg/kg bw
Internal event dose	4.6×10^{-4}	mg/kg bw
Internal dose on day of exposure	4.6×10^{-4}	mg/kg bw/day
Internal year average dose	1.6×10^{-4}	mg/kg bw/day

Oral

External event dose	6.6×10^{-5}	mg/kg bw
External dose on day of exposure	6.6×10^{-5}	mg/kg bw
Internal event dose	6.6×10^{-5}	mg/kg bw
Internal dose on day of exposure	6.6×10^{-5}	mg/kg bw/day
Internal year average dose	2.3×10^{-5}	mg/kg bw/day

Integrated

Internal event dose	5.3×10^{-4}	mg/kg bw
Internal dose on day of exposure	5.3×10^{-4}	mg/kg bw/day
Internal year average dose	1.8×10^{-4}	mg/kg bw/day

Results for Scenario [06] – Secondary exposure of children – Piperonyl butoxide

Dermal

Dermal load	–	
External event dose	2.7×10^{-4}	mg/kg bw
External dose on day of exposure	2.7×10^{-4}	mg/kg bw
Internal event dose	1.9×10^{-4}	mg/kg bw
Internal dose on day of exposure	1.9×10^{-4}	mg/kg bw/day
Internal year average dose	6.6×10^{-5}	mg/kg bw/day

Integrated

Internal event dose	1.9×10^{-4}	mg/kg bw
Internal dose on day of exposure	1.9×10^{-4}	mg/kg bw/day
Internal year average dose	6.6×10^{-5}	mg/kg bw/day

Results for Scenario [06] – Secondary exposure of adults – Piperonyl butoxide

Dermal

Dermal load	–	
External event dose	4.3×10^{-4}	mg/kg bw
External dose on day of exposure	4.3×10^{-4}	mg/kg bw
Internal event dose	3.0×10^{-4}	mg/kg bw
Internal dose on day of exposure	3.0×10^{-4}	mg/kg bw/day
Internal year average dose	1.0×10^{-4}	mg/kg bw/day

Integrated

Internal event dose	3.0×10^{-4}	mg/kg bw
Internal dose on day of exposure	3.0×10^{-4}	mg/kg bw/day
Internal year average dose	1.0×10^{-4}	mg/kg bw/day

3.2.8 Emission Environmental exposure calculation

Not required.

3.3 New information on the active substance

None.

3.4 Residue behaviour

Not required.

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

Not required, please refer to the IUCLID file.

3.6 Confidential annex

See separate document.

3.7 Other

No other information required.