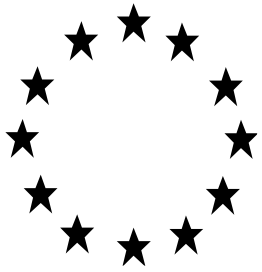
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



ACTIBIOL FOGGING PROFESIONAL

Product type 18

ETOFENPROX and PIPERONYL BUTOXIDE
as included in the Union list of approved active substances

Case Number in R4BP: BC-MM040875-23

Evaluating Competent Authority: SPAIN
Date: May 2024

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1 CONCLUSION

The biocidal product ACTIBIOL FOGGING PROFESIONAL is a ready to use (RTU) product intended to be applied by fog-equipment for indoor use at domestic and industrial premises (e.g. attics, false ceilings, garages, storage rooms, and rooms with low frequency of use).

The product is intended for application by professional users (e.g. PCO) who apply the product into the air space of the closed premise by thermal fogging or cold fogging treatment.

Physical-Chemical properties and Analytical Methods

ACTIBIOL FOGGING PROFESIONAL is a colourless liquid with mild odor. The mean relative density of the test item was 0.7671 ± 0.0002. The rest of the physical properties such as surface tension and viscosity are within specifications.

The results of the accelerated and long term stability studies showed that the product is stable when stored at 54°C ± 2°C for 14 days and at 20°C ± 2°C, for 24 months.

Based on the results obtained, a validity period of 24 months from the date of manufactured is proposed.

The biocidal product ACTIBIOL FOGGING PROFESIONAL contains 0.475 %w/w Etofenprox & 1.425 %w/w Piperonyl butoxide and given the nature of the formulation it is not considered explosive, oxidizing, highly flammable or auto-flammable. Therefore, there not be hazards associated with the physico-chemical properties of the product under normal conditions of use.

There are not substances of concern in the biocidal product, hence there are some substances different to the active substance that do not contribute to the product hazard classification with regard to physical chemical properties according to hazardous (Regulation (EC) No 1272/2008).

A validated analytical method is available for determining the concentration of Etofenprox and Piperonyl butoxide in the biocidal product according to SANCO/3030/99 REV.4.

Efficacy

ACTIBIOL FOGGING PROFESIONAL is a RTU product intended for use indoors by professionals for air-space treatments at the application rate of 0.262 mL/m^3. The application of the product must be performed by means of a cold or hot professional nebulizer which releases the product as a fog.

Direct efficacy after space treatment has been demonstrated with both cold and hot nebulization. The studies with hot nebulization have also probed the residual (surface) efficacy of the product after the space (air) treatment, up to 8 weeks. Studies with cold nebulization were not submitted.

The results of efficacy trials submitted have shown the effect of ACTIBIOL FOGGING PROFESIONAL against the following target organisms:

- *Blattella germanica* (German cockroaches)
- *Blatta orientalis* (Oriental cockroaches)
- *Sitophilus granaries* (wheat weevil)
- *Sitophilus oryzae* (lesser rice weevil)
- *Rhizopertha dominica* (lesser grain borer)
- *Oryzaephilus surinamensis* (sawtoothed grain beetle)
- *Tribolium confusum* (confused flour beetle)

Therefore, the label claims against these target organisms are acceptable. In addition, the generic claim "against crawling insects" is also acceptable.

Human health

There are one substance of concern in the biocidal product, which contributes to its classification with regard to human health hazards under Regulation (EC) No 1272/2008 (CLP Regulation).

The Spain Competent Authority has assessed the ED potential of the non-active substances in this biocidal product and has determined none of these non-active substances has an ED potential.

Finally, evaluating the exposure and characterizing the risk to human health of the biocidal products according to the pattern of use requested by the applicant, the conclusions for each scenario are:

Summary table risk assessment for human health			
Scenario	**Scenario**	**Conclusion**	**Exposed group**
1.	Load the fog-equipment with the ready-to-use product before the application.	A **safe** situation has been identified for loading the fog-equipment when the corresponding PPEs and RMMs are used.	Professional users
2.	Application of the end-product as space spray application (mist or thermal fog) in indoor areas	A **safe** situation has been identified for fogging application in indoor areas when the corresponding PPEs and RMMs are used.	Professional users
3.	Adult re-entering in the treated room for ventilation following application or equipment malfunction.	A **safe** situation has been identified for re-entering in treated areas when the corresponding PPEs and RMMs is used.	Professional users
Combined scenarios 1 + 2 + 3	Loading + Application + re-entry	A **safe** situation has been identified from the use biocide in indoor areas when the corresponding PPEs and RMMs is used.	Professional users
4.	Inhalation of volatilized residues	A **safe** situation has been identified for inhalation of volatilized residues.	General public
5.	Toddler playing on treated surfaces	A **safe** situation has been identified for toddler playing and/or crawling on treated surfaces when the corresponding instruction for use and RMMs are used.	General public (chronic)
6.	Adult re-entering in the treated room	A **safe** situation has been identified for re-entering in treated areas when the corresponding instruction for use and RMMs are used.	General public

Summary table risk assessment for human health			
Scenario	**Scenario**	**Conclusion**	**Exposed group**
7.	Laundering	A **safe** situation has been identified for adults laundering contaminated work clothing when the corresponding instruction for use and RMMs are used.	General public (chronic)
Combined scenarios 1 + 2 + 3 + 6 + 7	Loading + Application + Re-entring + laundering	A **safe** situation has been identified from the use biocide in indoor areas when the corresponding PPEs, instruction for use and RMMs are used.	General public (adult-chronic)

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

Additional information (only relevant in Spain):

Following the provisions of BPR art. 37(1), the Spanish Competent Authority (ES CA) will modify the conditions of the Authorisation of this biocidal product in the Spanish market in order to adapt the User categories to our national legal requirements (i.e. Royal Decree 830/2010).

The conclusions reached in this PAR are regarded as applicable to the Spanish category of **Trained Professionals**.

See more details in section 2.2.6.2.

Environment

The environmental risk assessment of the product ACTIBIOL FOGGING PROFESIONAL is based on the two active substances, etofenprox and PBO, and their environmentally relevant metabolites. Based on this risk assessment and on available data, no unacceptable risk to the environment has been identified for the product, when applied according to the intended uses.

Overall conclusion

According to the assessment performed for the biocidal product, the following uses are proposed for authorization, considering the appropriate risk mitigation measures indicated in the table below:

Uses	Target organisms	User categories	Authorised application rates	Use conditions: General risk mitigation measures
Use # 1 – Professionals – Hot fogging Use # 2 – Professionals – Cold fogging	Crawling insects including the following organisms: - *Blattella germanica*- adults and nymphs - *Blatta orientalis*– adults and nymphs - *Sitophilus granarius* - adults - *Sitophilus oryzae* - adults - *Rhizopertha dominica* - adults - *Oryzaephilus surinamensis* - adults - *Tribolium confusum* - adults	Professional (*)	Application rate: 0.262 mL/m^3 (space (air) treatment) 1 application per treatment Frequency: max. 1-2 times a year	Wash hands after handling the product and before eating, drinking and / or smoking. Avoid contact with eyes/skin. Avoid contact to treated surfaces/areas, in particular by children. Wear protective chemical resistant gloves meeting the requirements of EN 374 during product handling / application phase (glove material to be specified by the authorisation holder within the product information). Wear a protective coverall [type 6, EN 13034 or type 3, EN 14605 or type 4, EN 14605 or type 5, EN ISI 12982-1] during the re-entry phase. Do not (use/apply) directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock/pets. Routinely wash clothing and protective equipment to remove contaminants. Discard contaminated clothing and shoes that cannot be cleaned.

(*) The user category in Spain corresponds to **Trained Professional Users** according to Royal Decree 830/2010.

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)**
ACTIBIOL FOGGING PROFESSIONAL	Spain

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	QUÍMICA DE MUNGUÍA S.A.
	Address	Derio Bidea, 51 48100 Munguía (Vizcaya)
Authorisation number	ES-0032393-0000	
Date of the authorisation	13/05/2024	
Expiry date of the authorisation	13/05/2029	

2.1.1.3 Manufacturer(s) of the product

Name of manufacturer	QUÍMICA DE MUNGUÍA S.A.
Address of manufacturer	Derio Bidea, 51 48100 Munguía (Vizcaya, Spain)
Location of manufacturing sites	Derio Bidea, 51 48100 Munguía (Vizcaya, Spain).

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

Active substance	Etofenprox
Name of manufacturer	LKC Chem-Regs Ltd (Acting for Mitsui Chemicals Crop & Life Solutions, Inc. (Japan)) Ireland
Address of manufacturer	Marine House, Clanwilliam Place, Dublin 2,Dublin, Ireland
Location of manufacturing sites	Mitsui Chemicals Crop & Life Solutions, Inc. Omuta Works, 30 Asamuta-machi, Ohmuta-shi, Fukuoka 836-8610, Japan

Active substance	Piperonyl Butoxide Ultra
Name of manufacturer	ENDURA
Address of manufacturer	Viale Pietramellara, 5 40121 Bologna, Italy

Location of manufacturing sites	Endura S.p.A. Via Baiona, 107-111, 48123 Ravenna, Italy

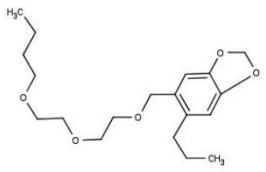
2.1.2 Product composition and formulation

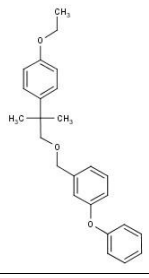
NB: the full composition of the product has been provided in the confidential annex.

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

Yes ☐
No ☒

2.1.2.1 Identity of the active substances

Main constituents	
ISO name	Piperonyl Butoxide
IUPAC or EC name	5-{[2-(2-butoxyethoxy) ethoxy]methyl}-6-propyl-1,3-benzodioxole
EC number	200-076-7
CAS number	51-03-6
Index number in Annex VI of CLP	
Minimum purity / content	940 g/Kg
Structural formula	$C_{19}H_{30}O_5$ 

Main constituents	
ISO name	Etofenprox
IUPAC or EC name	3-phenoxybenzyl-2-(4-ethoxyphenyl)-2-methylpropylether
EC number	407-980-2
CAS number	80844-07-1
Index number in Annex VI of CLP	604-091-00-3
Minimum purity / content	970 g/kg
Structural formula	$C_{25}H_{28}O_3$ 

2.1.2.2 Candidates for substitution

PBO is not considered an active substance candidate for substitution whilst Etofenprox is regarded as a candidate for substitution pursuant to Article 10(1)(d) of Regulation (EU) No 528/2012.

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 (%)
Etofenprox	1-ethoxy-4-{2-methyl-1-[(3-phenoxyphenyl)methoxy]propan-2-yl}benzene	Active substance	80844-07-1	407-980-2	0.475
PBO	2-(2-butoxyethoxy)ethyl 6-propylpiper-onyl ether (Piperonyl butoxide/PBO)	Active substance	51-03-6	200-076-7	1.425
Tetradecane	Tetradecan	Solvent	629-59-4	211-096-0	98.1

Note: For further details on full product composition please refer to the Confidential Annex to PAR

Etonfeprox

	AS content
Formulation recipe: Content of the AS used for the formulation of the BP (%)	0.475%
AS content in the BP to be indicated in the SPC (%)	0.475%
Minimum purity in the source of the AS (%)	97%
"Minimum[1] pure" AS content (%)	0.46%

Piperonyl butoxide (PBO)

	AS content
Formulation recipe: Content of the AS used for the formulation of the BP (%)	1.425%
AS content in the BP to be indicated in the SPC (%)	1.425%
Minimum purity in the source of the AS (%)	94%
"Minimum[2] pure" AS content (%)	1.34%

1 This is referring to the minimum purity specified for the AS source. However, it could be higher in some cases depending on the agreed tolerances in the AS manufacturing process.

2 Since this is referring to the minimum purity specified for the AS source. However, it could be higher in some cases depending on the agreed tolerances in the AS manufacturing process.

2.1.2.4 Information on technical equivalence

The active substance supplier, Mitsui Chemicals Crop & Life Solutions, Inc.. is the approved supplier of the Etofenprox active substance in accordance with Article 95 List of Regulation (EU) No 528/2012. Similarly, ENDURA S.p.A. is the only approved supplier of PBO in accordance with Article 95 List of Regulation (EU) No 528/2012. Therefore, these sources are not technically equivalent.

2.1.2.5 Information on the substance(s) of concern

According to the definition of a substance of concern laid down in the Guidance on the BPR Volume III Human Health- Assessment & Evaluation– Part B and C Risk Assessment (Version 4.0 December 2017), tetradecane has been identified as substance of concern for human health.
Please see the confidential annex to this PAR for further details.

2.1.2.6 Type of formulation

AL - any other liquid

2.1.3 Hazard and precautionary statements

Classification and labelling of the product according to the Regulation (EC) No 1272/2008

Classification	
Hazard category	Asp Tox 1 Lact Aquatic Acute 1 Aquatic Chronic 1
Hazard statement	H304, H362, H400, H410
Labelling	
Pictograms	GHS08, GHS09
Signal words	Danger
Hazard statements	H304:May be fatal if swallowed and enters airways. H362:May cause harm to breast-fed children. H410:Very toxic to aquatic life with long lasting effects. EUH066: 'Repeated exposure may cause skin dryness or cracking'.
Precautionary statements	P201: Obtain special instruction before use. P202: Do not handle until all safety precautions have been read and understood. P260: Do not breathe dust/fume/gas/mist/ vapours/spray. P263: Avoid contact during pregnancy/while nursing. P264: Wash…Thoroughly after handling. P270: Do not eat, drink or smoke when using this product. P273: Avoid release to the environment. P301+P310: IF SWALLOWED: Immediately call a POISON CENTER/ doctor/… P331: Do NOT induce vomiting.

	P308+P313: IF exposed or concerned: Get medical advice/attention. P391: Collect spillage. P405: Store locked up. P501: Dispose of contents/container as hazardous waste to a registered establishment or undertaking, in accordance with current regulations.

2.1.4 Authorised use(s)

2.1.4.1 Use description

Table 2-1. **Use # 1 –Professionals – Hot fogging**

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods
Where relevant, an exact description of the authorised use	The biocide is a RTU liquid insecticide intended for air space treatment by hot fogging (thermonebulization) with residual (surface) activity up to 8 weeks post-treatment, to control the target insects in difficult-to-access indoor areas.
Target organism (including development stage)	Crawling insects including the following organisms: - *Blattella germanica* (German cockroaches) - adults and nymphs - *Blatta orientalis* (Oriental cockroaches) – adults and nymphs - *Sitophilus granarius* (wheat weevil) - adults - *Sitophilus oryzae* (lesser rice weevil) - adults - *Rhizopertha dominica* (lesser grain borer) - adults - *Oryzaephilus surinamensis* (sawtoothed grain beetle) - adults - *Tribolium confusum* (confused flour beetle) - adults
Field of use	Indoor use at domestic and industrial premises (e.g. attics, false ceilings, garages, storage rooms, and rooms with low frequency of use).
Application method(s)	Thermo-nebulizable insecticide for application by swing-fog type equipment for hot nebulization.
Application rate(s) and frequency	Application rate: 0.262 mL/m^3 air 1 application per treatment Frequency: max. 1-2 times a year
Category(ies) of users	Professionals (*)
Pack sizes and packaging material	Bottle, made of COEX, with 1 L of product Jerrycan, made of COEX, with 5 L and 20 L of product
(*) The user category in Spain corresponds to Trained Professional Users according to Royal Decree 830/2010.	

2.1.4.2 Use-specific instructions for use

Refer to general directions for use (section 2.1.5)

2.1.4.3 Use-specific risk mitigation measures

Refer to general directions for use (section 2.1.5)

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 directions for use (section 2.1.5)

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

Refer to general directions for use (section 2.1.5)

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 directions for use (section 2.1.5)

2.1.4.7 Use description

Table 2-2. **Use # 2 –Professionals – Cold fogging**

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods
Where relevant, an exact description of the authorised use	The biocide is a RTU liquid insecticide intended for air space treatment by cold fogging (nebulization), to control the target insects in difficult-to-access indoor areas.
Target organism (including development stage)	Crawling insects including the following: - *Blattella germanica* (German cockroaches) - adults and nymphs - *Blatta orientalis* (Oriental cockroaches) – adults and nymphs - *Sitophilus granarius* (wheat weevil) - adults - *Sitophilus oryzae* (lesser rice weevil) - adults - *Rhizopertha dominica* (lesser grain borer) - adults - *Oryzaephilus surinamensis* (sawtoothed grain beetle) - adults - *Tribolium confusum* (confused flour beetle) - adults

Field of use	Indoor use at domestic and industrial premises (e.g. attics, false ceilings, garages, storage rooms, and rooms with low frequency of use).
Application method(s)	Nebulizable insecticide for application by swing-fog type equipment for cold nebulization.
Application rate(s) and frequency	Application rate: 0.262 mL/m^3 air (space treatment) 1 application per treatment Frequency: max. 1-2 times a year
Category(ies) of users	Professionals (*)
Pack sizes and packaging material	Bottle, made of COEX, with 1 L of product Jerrycan, made of COEX, with 5 L and 20 L of product
(*) The user category in Spain corresponds to Trained Professional Users according to Royal Decree 830/2010.	

2.1.4.8 Use-specific instructions for use

Refer to general directions for use (section 2.1.5)

2.1.4.9 Use-specific risk mitigation measures

Refer to general directions for use (section 2.1.5)

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

Refer to general directions for use (section 2.1.5)

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

Refer to general directions for use (section 2.1.5)

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

Refer to general directions for use (section 2.1.5)

2.1.5 General directions for use

2.1.5.1 Instructions for use

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

The product must be used at indoor domestic and industrial premises such as attics, false ceilings, garages, storage rooms and rooms with low frequency of use by humans and

animals (pets).

The product is not intended for the treatment of pests on the stored products themselves.

The product must be used only indoors at confined spaces.

The treated premises must be closed and signposted in order to prevent the entry of people during the application.

Always that can be possible, treated premises must be ventilated before the re-entrance.

2.1.5.2 Risk mitigation measures

Wash hands after handling the product and before eating, drinking and / or smoking.

Avoid contact with eyes and skin.

Avoid contact to treated surfaces, in particular by children.

Wear protective chemical resistant gloves meeting the requirements of European Standard EN 374 during product handling and application phase (glove material to be specified by the authorisation holder within the product information).

Wear a protective coverall [type 6, EN 13034 or type 3, EN 14605 or type 4, EN 14605 or type 5, EN ISI 12982-1] during the re-entry phase.

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

Routinely wash clothing and protective equipment to remove contaminants.

Discard contaminated clothing and shoes that cannot be cleaned.

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

IF EXPOSED OR CONCERNED: Get medical advice/attention.

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

IF SWALLOWED: Do NOT induce vomiting.

If symptoms: Immediately call 112/ambulance for medical assistance.

If no symptoms: Call a POISON CENTRE or a doctor.

IF ON SKIN: Take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation occurs: Get medical advice.

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

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

2.1.5.4 Instructions for safe disposal of the product and its packaging

Empty containers, unused product, washing water, containers and other waste generated during application are considered hazardous waste.

Deposit packaging waste at the established collection points or deliver it to a registered hazardous waste operator as agreed with the extended producer responsibility system.

Deliver the other wastes to a registered establishment or undertaking for hazardous waste, in accordance with current regulations.

Code the waste according to Decision 2014/955/EU.

Do not release to soil, ground, surface water or any kind of sewer.

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

Protect from sunlight and frost.

Stay away from any source of ignition.

Store in the original package.

Keep out of reach of children.

2.1.6 Other information

Additional information (only relevant in Spain):

Following the provisions of BPR art. 37(1), the Spanish Competent Authority (ES CA) will modify the conditions of the Authorisation of this b.p. in the Spanish market in order to adapt the User categories to our national legal requirements (i.e. Royal Decree 830/2010 which stipulates the specific training and skills for Trained Professional users of biocides).

The conclusions reached in this PAR are regarded as applicable to the Spanish category of **Trained Professionals**, which is described as follows:

- *Trained Professional users* (TP): professionals whose daily work is related to the application of biocides (e.g. Pest Control Operators). They should have received specific training on the safe use of biocides including correct use of Personal Protection Equipment (PPE), and should have a formal professional certificate.

2.1.7 Packaging of the biocidal product

Type of packaging	Size/vol. 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	1 L	COEX	COEX	Professional	Yes
Jerrycan	5 L	COEX	COEX	Professional	Yes
Jerrycan	20 L	COEX	COEX	Professional	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

Data submitted in relation to product application. Please refer to a reference list included in confidential annex

2.1.8.2 Access to documentation

The applicant "QUIMICA DE MUNGUÍA S.A" supplies the Letters of Access (LoAs) for two active substances included in biocidal product submitted; Mitsui Chemicals Crop & Life Solutions, Inc.. as owner of data dossiers for Etofenprox active substance and ENDURA S.p.A. as owner of data dossier for PBO active substance.

2.2 Assessment of the biocidal product

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

Table 2.2.1-1 **Use # 1 – Professional use – Hot fogging concentrate (HN)**

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods
Where relevant, an exact description of the authorised use	Thermo-nebulizable insecticide to be applied by swing-fog type equipment.
Target organism (including development stage)	Insecticide of broad spectrum against all types of flying and / or crawling insects. Its efficacy is proved against: • *Sitophilus granarius* (wheat weevil) • *Sitophilus oryzae* (rice weevil) • *Rhizopertha dominica* (lesser grain borer) • *Oryzaephilus surinamensis* (saw-toothed beetle) • *Tribolium confusum* (flour beetle) • *Blattella germanica* (croton bug) • *Blatta orientalis* (water bugs)

Field of use	It is ready-to-use product to be applied by swing-fog equipments for indoor use at domestic and industrial premises (e.g. attics, false ceilings, garages, storage rooms, and low frequently rooms,...).
Application method(s)	The biocide is intended to be applied as hot-fogging concentrate (HN) or cold-fogging concentrate (KN) by swing-fog or fog-equipments on sealed premises where nobody must enter or stay during the treatment before the safety-time of 12 hours has been fulfilled.
Application rate(s) and frequency	Application rate: 1 mL/m^3 (1 litre is applied by thermonebulization at 1000 m^3)
Category(ies) of users	Professional
Pack sizes and packaging material	Please see the relevant section.

Table 2.3.1-2. **Use # 2 – Professional use – Cold fogging concentrate (KN)**

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods
Where relevant, an exact description of the authorised use	Cold fogging concentrate insecticide to be applied by fogging equipment.
Target organism (including development stage)	Insecticide of broad spectrum against all types of flying and / or crawling insects. Its efficacy is proved against: • *Sitophilus granarius* (wheat weevil) • *Sitophilus oryzae* (rice weevil) • *Rhizopertha dominica* (lesser grain borer) • *Oryzaephilus surinamensis* (saw-toothed beetle) • *Tribolium confusum* (flour beetle) • *Blattella germanica* (croton bug) • *Blatta orientalis* (water bugs)
Field of use	It is ready-to-use product to be applied by swing-fog equipments for indoor use at domestic and industrial premises (e.g. attics, false ceilings, garages, storage rooms, and low frequently rooms,...).
Application method(s)	The biocide is intended to be applied as hot-fogging concentrate (HN) or cold-fogging concentrate (KN) by swing-fog or fog-equipments on sealed premises where nobody must enter or stay during the treatment before the safety-time of 12 hours has been fulfilled.
Application rate(s) and frequency	Application rate: 1 mL/m^3 (1 litre is applied by thermonebulization at 1000 m^3)
Category(ies) of users	Professional
Pack sizes and packaging material	Please see the relevant section.

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual method	Etofenprox 0.53% w/w PBO 1.47% w/w Batch JC1218	Liquid	Study code: E18013.
Colour at 20 °C and 101.3 kPa	SOP Cambium: P.LB.F034	Etofenprox 0.53% w/w PBO 1.47% w/w Batch JC1218	Colorless liquid	Study code: E18013.
Odour at 20 °C and 101.3 kPa	SOP Cambium: P.LB.F034	Etofenprox 0.53% w/w PBO 1.47% w/w Batch JC1218	Mild odor	Study code: E18013.
Acidity / alkalinity	CIPAC Handbook J - MT 75.3 method (2000).	Etofenprox 0.53% w/w PBO 1.47% w/w Batch JC1218	<u>Before the accelerated storage procedure</u> The mean pH value of the **pure test item** was: **6.14 at 21.2 °C after 0 min.** **6.15 at 21.2 °C after 1 min.** <u>After the accelerated storage procedure</u> The mean pH value of the **pure test item** was: **6.26 at 21.0 °C after 0 min.** **6.25 at 21.0 °C after 1 min.** <u>After long term storage stability test:</u> The pH value of the sample after 12 months is 5.0 at 21.4 ºC The pH value of the sample after 24 months is 6.1 at 20.7 ºC <u>After low temperature stability test:</u> The pH value of the sample at 1% w/v after low	Study code: E18014. Study code: E18015. Study code: E20105

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
			temperature stability is 6.7 at 20.6 ºC.	
Relative density / bulk density	EEC A3, OECD 109, CIPAC MT3 and ISO 758.	Etofenprox 0.53% w/w PBO 1.47% w/w Batch JC1218	**D_{20}^{4} =** 0.7671 ± 0.0002	Study code: E18013.
Storage stability test – **accelerated storage**	CIPAC MT 46.3	Etofenprox 0.53% w/w PBO 1.47% w/w Batch JC1218	Temperature :54ºC ± 2ºC—14 days Packaging material: COEX bottle (commercial packaging) • Etofenprox $[C]_0$ = 0.53 % $[C]_f$ = 0.53 % $\Delta[C]$ = 0 % < 10% • PBO $[C]_0$ = 1.47 % $[C]_f$ = 1.47 % $\Delta[C]$ = 0 % < 10% There were no changes in the appearance and the whole packaging was intact, without any leaks after accelerated storage.	Study code: E18014.
Storage stability test – **long term storage at ambient temperature**	GIFAP Nr. 17	Etofenprox 0.475% w/w PBO 1.425% w/w	Temperature: 20 ºC ± 2 ºC---24 months Packaging material: COEX bottle (commercial packaging) 12 months: • <u>Etofenprox 12 months</u> $[C]_0$ = 0.475 % $[C]_f$ = 0.5021 % $\Delta[C]$ = 5.70 % < 10%	Study code: E18015

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
			• PBO 12 months $[C]_0$ = 1.425 % $[C]_f$ = 1.4565 % $\Delta[C]$ = 2.21 % < 10% • Etofenprox 24 months $[C]_0$ = 0.475 % $[C]_f$ = 0.4970 % $\Delta[C]$ = 4.63% < 10% • PBO 24 months $[C]_0$ = 1.425 % $[C]_f$ = 1.4126 % $\Delta[C]$ = -0.87 % < 10% The appeareance after 24 months of storage stability is a colourless liquid with mild odour. It can be concluded that the product is stable after storage at ambient temperature during 24 months.	
Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3	Etofenprox 0.475% w/w PBO 1.425% w/w	Temperature: 0 ºC ± 2 ºC ---7 days. Test item was totally frozen	Study code: E20105.
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	The product is stored in darkness at room temperature, so no effect of light is expected.			
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Please refer to storage stability test.			
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	Please refer to storage stability test.			

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
Wettability	Not applicable, the product is a liquid formulation.			
Suspensibility, spontaneity and dispersion stability	Not applicable, the product is a liquid formulation.			
Wet sieve analysis and dry sieve test	Not applicable, the product is a liquid formulation.			
Emulsifiability, re-emulsifiability and emulsion stability	Not applicable, the product is a liquid formulation.			
Disintegration time	Not applicable, the product is a liquid formulation.			
Particle size distribution	Not applicable, the product is a liquid formulation.			
Persistent foaming	Not applicable, the product is a liquid formulation.			
Flowability/Pourability/Dustability	Not applicable, the product is a liquid formulation.			
Burning rate — smoke generators	Not applicable, the product is a liquid formulation.			
Burning completeness — smoke generators	Not applicable, the product is a liquid formulation.			
Composition of smoke — smoke generators	Not applicable, the product is a liquid formulation.			
Spraying pattern — aerosols	The product is a liquid intended to be applied by fogging but no as an aerosol. Hence this property is not needed			
Physical compatibility	The product is not applied in combination with other products, so further studies are not needed.			
Chemical compatibility	The product is not applied in combination with other products, so further studies are not needed.			
Degree of dissolution and dilution stability	The product is not diluted before the application, it is a ready-to-use product to be applied by fogging, so further study is not needed.			
Surface tension	EEC A5 and OECD nr. 115	Etofenprox 0.475% w/w PBO 1.425% w/w	Value of the surface tension of the measurement 25.6 mN/m at 20.5 ºC. Since the obtained value is lower than 60 mN/m, the formulation should be considered a product with surfactant	Study code: E20105.
Viscosity	OECD 114, ISO 3104 and ISO 3105	Etofenprox 0.475% w/w PBO 1.425% w/w	The kinematic viscosity is 3.06 × 10^{-6} m^2/s or 3.06 cSt at 20 ºC. The kinematic viscosity is 2.11 × 10^{-6} m^2/s or 2.11 cSt at 40 ºC.	Study code: E18070.

Conclusion on the physical, chemical and technical properties of the product
ACTIBIOL FOGGING PROFESIONAL is a colourless liquid with mild odor. The pH value of the product is 6.14 at 21.2ºC. The mean relative density of the test item was 0.7671 ± 0.0002. The kinematic viscosity of 3.06 × 10-6 m^2/s or 3.06 cSt at 20 ºC and 2.11 × 10-6 m^2/s or 2.11 cSt at 40 ºC. and a surface tension is 25.6 mN/m at 20.5 ºC. The results of the accelerated and long term stability studies showed that the product is stable when sotred at 54ºC ± 2ºC for 14 days and at 20°C ± 2°C, for 24 months. Under this conditions, the concentration of the active substances was within the specifications. The pH of the test item was considered stable during the stability procedure. There are no changes in the aspect of the solution or signs of deterioration in package proposed for commercialization. Based on the results obtained, a validity period of 24 months from the date of manufactured is proposed.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
Explosives	Manual of Tests and Criteria ST/SG/AC.10/11/Rev. 7	0.47 % w/w Etofenprox and 1.42 % w/w PBP Batch JC0923	The test item not present exothermic event up to 500° and therefore the test item is not a candidate for classification as a UN Class 1 explosive substance.	Study code: 23468-01C
Flammable gases	Not applicable. The study does not need to be conducted because the product is a liquid.			
Flammable aerosols	Not applicable. The study does not need to be conducted because the product is a liquid.			
Oxidising liquids	A.21	0.47 % w/w Etofenprox and 1.42 % w/w PBP Batch JC0923	The test item does not meet the criteria of oxidizing properties: the mean pressure rise of the mixture (12802 ms) is higher than the mean pressure rise time of a 1:1 mixture, by mass, of 65 % aqueous nitric acid and cellulose (3829 ms).	Study code: 23468-01C
Gases under pressure	Not applicable. The study does not need to be conducted because the product is a liquid.			
Flammable liquids	EEC A9 method, ASTM D93 1272/2008 SOP Cambium: P.LB.F004	Etofenprox 0.53% w/w PBO 1.47% w/w Batch JC1218	Flash point: > 100 ºC. The substance is not classified in any of the categories specified in EC Regulation No 1272/2008.	Study code: E18013.
Flammable solids	Not applicable. The study does not need to be conducted because the product is a liquid.			
Self-reactive substances and mixtures	There are no chemical 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. Therefore, this study is not necessary.			
Pyrophoric liquids	Not applicable. The experience in manufacture or handling shows that the product does not ignite spontaneously on coming into contact with air at normal temperatures. Therefore, this study is not need to be performed.			
Pyrophoric solids	Not applicable. The study does not need to be conducted because the product is a liquid.			
Self-heating substances and mixtures	Not applicable. There are no chemical 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. Therefore, this study is not necessary			
Substances and mixtures which in contact with water	Not applicable, ACTIBIOL FOGGING PROFESIONAL is a liquid, not intended to be applied with water, in addition there are no chemical groups present in the molecule which in contact with water are capable to emit flammable gases.			

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
emit flammable gases				
Organic peroxides	Not applicable (none of the ingredients contain a bivalent –O-O-structure)			
Corrosive to metals	ST/SG/AC.10/11/rev. 5 section 37.4	0.47 % w/w Etofenprox and 1.42 % w/w PBP Batch JC0923	Aluminium: The mass loss in totally dipped plate (%) is 0 %. Steel: The mass loss in totally dipped plate (%) is 0 %. So, the test item is considered non corrosive in Aluminium and in Steel	Study code: E23054
Auto-ignition temperatures of products (liquids and gases)	Official method: EEC A15 ASTM E 659 – 78 (2005) SOP Cambium: P.LB.F037	Etofenprox 0.53% w/w PBO 1.47% w/w Batch JC1218	Auto-ignition temperature is set at 221.2 ± 4.4 ºC at 753.5 mmHg**.**	Study code: E18013.
Relative self-ignition temperature for solids	Not applicable.The study does not need to be conducted because the product is a liquid.			
Dust explosion hazard	Not applicable.The study does not need to be conducted because the product is a liquid.			

Conclusion on the physical hazards and respective characteristics of the product
Regarding the physical hazards for the product ACTIBIOL FOGGING PROFESIONAL the **autoignition temperature** is **221.2 ± 4.4 ºC at 753.5 mmHg.** On the other hand, the **Flash point** of the product is **> 100.0 ºC**. The test item does not meet the criteria of **oxidizing properties**. The test item not present exothermic event up to 500° and therefore the test item is **not a candidate for classification as a UN Class 1 explosive substance.** ACTIBIOL FOGGIING PROFESSIONAL is considered **non corrosive.** Therefore the substance is not classified in any of the categories specified in Regulation (EC) No 1272/2008.

2.2.4 Methods for detection and identification

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Etofenprox	HPLC-DAD	Recovery rates at each spiking level: 96.7% at 0.0308 mg/ml; 98.1% at 0.0782 mg/ml.	Linearity inside the range of 0.0106 – 0.1062 mg/ml of Etofenprox due to a correlation coefficient of 0.9995.	The Rt of the reference item, and the test item, are similar. Not overlapping of peaks is observed. The interferences should not contribute in ± 3%	[95-105]	97.4	0.55	-	Ref. E18014.
PBO	HPLC-DAD	Recovery rates at each spiking level: 101.5% at 0.1251 mg/ml; 99.8% at 0.1658 mg/ml.	Linearity inside the range of 0.1088 – 0.2719 mg/ml of PBO due to a correlation coefficient of 0.9994.	The Rt of the reference item, and the test item, are similar. Not overlapping of peaks is observed. The interferences should not contribute in ± 3%	[97-103]	100.7	0.62	--	Ref. E18014.
Please refer to the active substance data for further methods.									

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

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

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

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

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

Analytical methods for monitoring of active substances and residues in food and feeding stuff									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Please refer to the active substance data for further methods									

Conclusion on the methods for detection and identification of the product
These analytical methods for determination of Etofenprox and PBO (active substances) were successfully validated according to SANCO/3030/99 REV.4.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

ACTIBIOL FOGGING PROFESIONAL is an insecticide (Product Type 18) intended to be used for air (space) treatment against crawling insects and other specific target insects in difficult-to-access areas.

The biocidal product is a nebulizable liquid, designed to be applied by hot o cold fogging by means of a swing-fog type equipment.

The product is intended to be used indoor by professional users in domestic and industrial premises (e.g. attics, false ceilings, garages, storage rooms, and rooms with low frequency of use).

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

ACTIBIOL FOGGING PROFESIONAL is intended to be used against crawling insects in order to control their infestation and protect the humans, their food and goods and also to avoid any nuisance that insects may cause to domestic animals (pets).

Note that this product is not intended for the treatment of pests on the stored products themselves.

The target insects are:

- *Blattella germanica* (German cockroaches) - adults and nymphs
- *Blatta orientalis* (Oriental cockroaches) – adults and nymphs
- *Sitophilus granarius* (wheat weevil) - adults
- *Sitophilus oryzae* (lesser rice weevil) - adults
- *Rhizopertha dominica* (lesser grain borer) - adults
- *Oryzaephilus surinamensis* (sawtoothed grain beetle) - adults
- *Tribolium confusum* (confused flour beetle) - adults

2.2.5.3 Effects on target organisms, including unacceptable suffering

ACTIBIOL FOGGING PROFESIONAL contains two active substances, i.e. Etofenprox and Piperonyl Butoxide.

Etofenprox is an insecticide whose efficacy has been contrasted along time against crawling insects, such as cockroaches. This a.s. produces knockdown and killing of the target organisms (CAR 2013).

Piperonyl Butoxide (PBO) is effective against the target organisms when present in products in combination with other active substances acting as insecticides, mainly pyrethrins and

synthetic pyrethroids, i.e. synergistic effect. This a.s. improves the killing and knockdown effect of the co-applied insecticide to the target organism (CAR 2017).

According to the literature, PBO is usually applied at a dose that on its own is sub-lethal to the target species. When PBO is applied in combination with a known toxicant (e.g. Etofenprox), the performance of the latter is enhanced at a rate that becomes lethal when on its own would be sub-lethal. Nevertheless, PBO on its own can exhibit some toxic effects, and hence at sub-lethal doses is likely to exert some stress on the insects.

2.2.5.4 Mode of action, including time delay

Etofenprox is an insecticide (pyrethroid) acting by direct contact and ingestion with a broad spectrum of action. It seems to act on sodium channels of the insect nervous system by disturbing the normal neurotransmittance (CAR 2013).

Piperonyl Butoxide is a contrasted synergist for insecticide formulations. The mode of action of PBO is complex. According to the literature, PBO stabilises the co-applied insecticide inside the insect body and potentiates more toxins to reach their target molecules. This result 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 PBO inhibits the oxidative and esterase-based metabolism (detoxification) 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 as Etofenprox (CAR 2017).

According to efficacy studies submitted in this dossier, ACTIBIOL FOGGING PROFESIONAL produces knockdown of the target insects after a 1 to 4 hours and mortality after 24h post-exposure.

2.2.5.5 Efficacy data

The following table summarise the efficacy studies with the product ACTIBIOL FOGGING PROFESIONAL submitted by the Applicant.

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Insecticide	PT 18	ACTIBIOL FOGGING PROFESIONAL	*Blattella germanica* (adults and nymphs) *Blatta orientalis* (adults and nymphs) *Sitophilus granaries* (adults) *Sitophilus oryzae* (adults) *Rhizopertha dominica* (adults) *Oryzaephilus surinamensis* (adults) *Tribolium confusum* (adults)	Laboratory tests (no-choice tests) C.E.B. method No. 135bis (1996)	**Space treatment (nebulization) trial** The treatment was done in a closed test chamber of 5 m long x 4 m wide x 3 m high (i.e. 60 m^3 or 20 m^2), with no ventilation. Appl. rate: 0.262 mL/m^3 (1 application). Type of application: **Cold** fogging using a professional nebulizer HURRICAND CYCLONE DYNA FOG (at medium rate of 14.2 L/hr). Standard original nozzles. 3-bar pressure. The device was placed on the floor in a corner with the nozzle aiming the centre of the test chamber. Knockdown (KD) (after 1 and 4 h) and mortality (M) (after 24 h) were recorded for the treated and untreated groups. Replicates: 4 for treated/untreated groups. Each replicate of treated groups consisted in 4 batches of 25 insects, two at 1.80 m height and two on the floor. Each batch was exposed in a glass jar with Teflon for 1 hour in the test chamber. Each replicate of untreated groups consisted in a batch of 25 insects, which was exposed in the center of test chamber.	**Space treatment direct efficacy** For all species: -KD (1 h): 100% -M (24 h): 100% Controls: KD (1h) 0%, M (24 h) ≤1% Since controls mortality is <10%, the trials are valid.	Report No 2314a-AF-LAB/0318R. 2018. Revised 2020.
Insecticide	PT 18	ACTIBIOL FOGGING PROFESIONAL	*Blattella germanica* (adults and nymphs)	Laboratory tests (no-choice tests)	The treatment was done in a closed test chamber of 5 m long x 4 m wide x 3 m high (i.e. 60 m^3 or 20 m^2), with no ventilation.	**Space treatment direct efficacy** For all species: -KD (1 h): 100%	Report No 2631-AFP-LAB/1220. 2021.

			Blatta orientalis (adults and nymphs) *Sitophilus granaries* (adults) *Sitophilus oryzae* (adults) *Rhizopertha dominica* (adults) *Oryzaephilus surinamensis* (adults) *Tribolium confusum* (adults)	(space treatment and residual efficacy) C.E.B. method No. 135bis (1996)	Appl. rate: 0.262 mL/m^3 (1 application of 15.7 mL in 60 m^3). Type of application: **Hot** fogging using a professional nebulizer IGEBA TF 34 (at rate of 9 L/hr). Standard original nozzles. 0.25-bar pressure. The device was placed on the floor in a corner with the nozzle aiming the centre of the test chamber. Knockdown (KD) (after 1 and 4 h) (only in space trial) and mortality (M) (after 24 h) were recorded for the treated and untreated groups. **<u>Space treatment (nebulization) trial (direct efficacy)</u>** Replicates: 4 for treated/untreated groups. Each replicate of treated groups consisted in 4 batches of 25 insects, two at 1.80 m height and two on the floor. Each batch was exposed in a glass jar with Teflon for 1 hour in the test chamber. Each replicate of untreated groups consisted in a batch of 25 insects, which was exposed in the center of test chamber to the nebulized product. **<u>Residual efficacy trial</u>** Tiles of 15x15 cm were exposed flat on the floor to the fog released during the space treatment test to check the residual efficacy of the product after ageing. The efficacy was evaluated at day 0 and after 8 weeks of storage on treated surfaces. The tests focused on 4 materials: - wood (pinewood), - wool (100% untreated sheep wool), - cotton fabric (100% cotton, 150 g/m^2), and, - ceramic tiles (non-porous side). Replicates: 4 for treated and control groups. Each replicate (25 insects) was exposed for 15 minutes to the treated (and untreated) surfaces, covered with a Petri dish.	-M (24 h): 100% Controls: M (24 h) 0% **<u>Residual efficacy trial</u>** -For porous and non-porous surfaces and all species: <u>Day 0:</u> -M (24 h): 100% Controls: M (24 h) 0% <u>Day 0 + 2 months</u> -M (24 h): 100% Controls: M (24 h) 0% Since controls mortality is <10%, the trials are valid.	Revised 2023.

Insecticide	PT 18	ACTIBIOL FOGGING PROFESIONAL	*Sitophilus granaries* (adults) *Sitophilus oryzae* (adults) *Rhizopertha dominica* (adults) *Oryzaephilus surinamensis* (adults) *Tribolium confusum* (adults)	Simulated-use trials (space treatment, direct efficacy) (choice tests) C.E.B. method No. 135/159 (2007)	**<u>Space (nebulization) treatment trial (direct efficacy)</u>** The tests were conducted in a real empty storage premise of 15.70 m long x 8.80 m large x 5 m high (i.e. 138 m² and 691 m^3) with no ventilation. Insects had harbourages/crevices and food/water in the plastic boxes (choice tests). The floor (concrete), ceiling and walls (steel and wood) were covered by a plastic to avoid pollution between replicates. Appl. rate: 0.262 mL/m^3 (1 application of 181 mL in 691 m^3). Type of application: **Cold** fogging using a professional nebulizer HURRICAND CYCLONE DYNA FOG. The device was placed on the floor in a corner with the nozzle aiming the centre of the test chamber. Knockdown (KD) (after 1 and 4 h) and mortality (M) (after 24 h) were recorded for the treated and control groups. 5 replicates for treated/untreated groups. Each replicate of treated groups consisted in 4 batches of 25 insects, 2 at 1.80 m height and 2 on the floor in the test chamber. Each batch was exposed in a plastic box with harbourages/crevices and food/water covered by Teflon for 1 h (choice tests). Each replicate of untreated groups consisted in a batch of 25 insects, which was exposed in the center of test chamber.	**<u>Space treatment direct efficacy</u>** For all species: -KD (1 h): 100% -M (24 h): 100% Controls: -KD (1 h): 0% -M (24 h) ≤2% Since controls mortality is <5%, the trials are valid.	Report No 2314a-AF-SIM/0318R. 2018. Revised 2020.
Insecticide	PT 18	ACTIBIOL FOGGING PROFESIONAL	*Sitophilus granaries* (adults) *Sitophilus oryzae* (adults)	Simulated-use trials (space treatment, direct efficacy and surface spraying,	The tests were conducted in a real empty storage premise of 15.70 m long x 8.80 m large x 5 m high (i.e. 138 m² and 691 m^3) with no ventilation. Insects had harbourages/crevices and food/water in the plastic boxes (choice tests).	**<u>Space direct eff. trial</u>** For all species: -KD (1 h): 100% -M (24 h): 100% Controls: M (24 h) 0%	Report No 2631-AFP-SIM/1220. 2021. Revised 2023.

			Rhizopertha dominica (adults) *Oryzaephilus surinamensis* (adults) *Tribolium confusum* (adults)	residual efficacy) (choice tests) C.E.B. method No. 135/159 (2007)	The floor (concrete), ceiling and walls (steel and wood) were covered by a plastic to avoid pollution between replicates. Appl. rate: 0.262 mL/m^3 (1 application of 181 mL in 691 m^3) (72 seconds of spray). Type of application: **Hot** fogging using a professional nebulizer IGEBA TF 34 (at rate of 9 L/hr). Standard original nozzles. 0.25-bar pressure The device was placed on the floor in a corner with the nozzle aiming the centre of the test chamber. Knockdown (KD) (after 1 and 4 h) and mortality (M) (after 24 h) were recorded for the treated and control groups. **Space (nebulization) treatment trial (direct efficacy)** 5 replicates for treated/untreated groups. Each replicate of treated groups consisted in 4 batches of 25 insects, 2 at 1.80 m height and 2 on the floor in the test chamber. Each batch exposed to the product in a plastic box with harbourages/crevices and food/water covered by Teflon for 1 h (choice tests). Each replicate of untreated groups consisted in a batch of 25 insects, exposed in the center of test chamber. **Residual efficacy trial** Tiles of 15x15 cm were exposed flat on the floor to the fog released during the space treatment test to check the residual efficacy of the product after ageing. The efficacy was evaluated at day 0 and after 2 months of storage on 4 materials: - wood (pinewood), - wool (100% untreated sheep wool), - cotton fabric (100% cotton, 150 g/m^2), and, - ceramic tiles (non-porous side).	**Residual efficacy trial** For all species and surface types: Day 0: -KD (1h):100% -M (24h):100% Controls: M (24 h) 0% Day 0 + 2 months -KD (1h):100% -M (24h):100% Controls: M (24 h) 0% Since controls mortality is <5%, the trials are valid.	

					4 replicates for treated and control groups. Each replicate of 25 insects was exposed for 15 min to the treated (and untreated) surfaces, covered with a Petri dish. Since this is a no-choice test, it is considered a laboratory trial.		
Insecticide	PT 18	ACTIBIOL FOGGING PROFESIONAL	*Blatella germanica* *Blatta orientalis*	Field trials C.E.B. method 249.	The trials were conducted in May 2018 in France. The test was conducted in 5 locations (5 replicates) such as houses / bakeries / bars / restaurants with natural high cockroaches´ infestations (> 10 insects trapped overnight). 5 additional locations were used as controls. No details on exact locations. Two pre-counts were made at Day - 3 and Day – 1; the mean values gave the pre-treatment infestation levels. The selected objects corresponded to infestation level 2-4 (i.e. trapped 17-38 oriental; 40-182 German). The sticky traps were placed for 24 h in the premises, under the kitchen sink, near ovens, and in cabinets where the food was stored. 5 sticky traps were settled by site. Appl. rate: 0.262 mL/m^3 (1 application per site). Type of application: **Cold** fogging using a professional nebulizer HURRICAND CYCLONE DYNA FOG. The device was placed on the floor in a corner with the nozzle aiming the centre of the test chamber. The treated volumes ranged 54-142 m^3 (surfaces of 26-61 m^2). Assessments were carried out 24 h after the treatment. The efficacy was assessed by the percentage of population's reduction, relative to pre-treatment levels, determined with 24 h monitoring of sticky traps. Untreated sites were also monitored as controls.	<u>Population reduction:</u> <u>*-Blattella germanica:*</u> Treated sites after 24 h: 95.7% Untreated sites after 24 h: -3.1% <u>*-Blatta orientalis*</u> Treated sites after 24 h: 97.8% Untreated sites after 24 h: 1.3% Note: negative values mean that populations are increasing. Since controls proved an increase of populations or ≤15% reduction, the trials are valid.	Report No. 2314a-AF-FIELD/0318. 2018.

Insecticide	PT 18	ACTIBIOL FOGGING PROFESIONAL	*Blatella germanica* *Blatta orientalis*	Field trials C.E.B. method 249.	The trials were conducted in January 2021 in France. The test was conducted in 5 locations (5 replicates) such as houses / bakeries / bars / restaurants with natural high cockroaches´ infestations (> 10 insects trapped overnight). 5 additional locations were used as controls. No details on exact locations were given. Two pre-counts were made at Day - 3 and Day –1; the mean values gave the pre-treatment infestation levels. The selected objects corresponded to infestation level 2-5 (i.e. trapped 19-74 oriental; 43-302 German). The sticky traps were placed for 24 h in the premises, under the kitchen sink, near ovens, and in cabinets where the food was stored. 5 sticky traps were settled by site. Appl. rate: 0.262 mL/m^3 (1 application per site). Type of application: **Hot** fogging using a professional nebulizer IGEBA TF 34 (at rate of 9 L/hr). Standard original nozzles. 0.25-bar pressure The device was placed on the floor in a corner with the nozzle aiming the centre of the test chamber. The treated volumes ranged 55-204 m^3 (surfaces of 22-78 m^2). Assessments were carried out 1, 2, 4 & 8 weeks after the treatment. The efficacy was assessed by the percentage of population's reduction, relative to pre-treatment levels, determined with 24 h monitoring of sticky traps. Untreated sites were also monitored as controls.	<u>Population reduction:</u> <u>*-Blattella germanica:*</u> Treated sites after: 1 week: 92.6% 2 weeks: 96.1% 4 weeks: 98.1% 8 weeks: 97.3% Untreated sites after: 1 week: 8.7% 2 weeks: 7.5% 4 weeks: 0.8% 8 weeks: -2.2% <u>*-Blatta orientalis*</u> Treated sites after: 1 week: 92.7% 2 weeks: 97.7% 4 weeks: 98.4% 8 weeks: 97.6% Untreated sites after: 1 week: 2.6% 2 weeks: -5.9% 4 weeks: -1.7% 8 weeks: -2.6% Note: negative values mean that populations are increasing. Since controls proved an increase of populations or ≤15% reduction, the trials are valid.	Report No. 2631-AFP-FIELD/1220. 2021. Revised 2023.

Conclusion on the efficacy of the product

ES CA has assessed the efficacy studies submitted by the Applicant for authorisation of label claims of the RTU product ACTIBIOL FOGGING PROFESIONAL. Laboratory, simulated-use and field trials are available to demonstrate the efficacy of this insecticide.

The product is applied in a single application, by means of a swing-fog cold/hot nebulizer for (air) space treatment by nebulization (direct efficacy) at the application rate of 0.262 mL/m^3. In addition, residual efficacy with application by hot nebulization has also been tested.

For use against cockroaches, there are two laboratory studies and two field trials against *Blattella germanica* (German cockroach, adults and nymphs) and *Blatta orientalis* (Oriental cockroach, adults and nymphs). The product applied at the rate of 0.262 mL/m^3 resulted in 100% mortality after 24 h and 100% knockdown in 1 h after direct treatment (nebulization). The application with a hot nebulizer to assess the efficacy with residual treatment on porous and non-porous surfaces resulted in 100% mortality after 24 h, up to 8 weeks post-application. Controls mortality at 24 h was at most ≤1%, therefore the studies are valid. The field trials demonstrated that the product produces >90% mortality of insects (in 24 h) up to 8 weeks after treatment, relative to pre-treatment levels.
In conclusion, the product can be authorised against cockroaches for professional users. Since a small and a large species of cockroaches were tested (but population control is not claimed), the use against "crawling insects" can also be granted with this data package. Residual efficacy up to 8 weeks after treatment with hot nebulization can also be claimed.

For use against stored goods-attacking insects, there are two laboratory studies and two simulated-use trials with adults of *Sitophilus granarius* (wheat weevil), *Sitophilus oryzae* (lesser rice weevil), *Rhizopertha dominica* (lesser grain borer), *Oryzaephilus surinamensis* (sawtoothed grain beetle) and *Tribolium confusum* (confused flour beetle). The product applied at the rate of 0.262 mL/m^3 resulted in 100% mortality after 24 h and 100% knockdown in 1 h after direct treatment by hot/cold nebulization. The application with a hot nebulizer to assess the efficacy with residual treatment on porous and non-porous surfaces resulted in 100% mortality after 24 h, up to 8 weeks post-application. Controls mortality at 24 h was at most ≤2%, therefore the studies are valid.
In conclusion, the product can be authorised against *Sitophilus granarius* (wheat weevil), *Sitophilus oryzae* (lesser rice weevil), *Rhizopertha dominica* (lesser grain borer), *Oryzaephilus surinamensis* (sawtoothed grain beetle) and *Tribolium confusum* (confused flour beetle).

The applicant has also requested authorisation for the label claim against flying insects. However, the Guidance requires studies with flies, mosquitoes and wasps for use against flying insects. Since none of these species has been included in the studies, this label claim cannot be authorised.

2.2.5.6 Occurrence of resistance and resistance management

The literature search provided evidence of resistance to Etofenprox (CAR 2013), for several groups of insects, or more accurately of cross-resistance to pyrethroids. Resistance management strategies are therefore recommended.

For resistance management purposes, Etofenprox belongs to insecticide group 3A of the IRAC Mode of Action. Any insect population may contain individuals naturally resistant to Etofenprox and other group 3A insecticides. If these insecticides are used repeatedly, the resistant individuals may eventually dominate the pest insect population. These resistant insects may not be controlled by Etofenprox or by other group 3A insecticides.

In order to delay the development of resistance, specific strategies to prevent the development of resistance are outlined below:

- Avoid using ACTIBIOL FOGGING PROFESIONAL with other insecticides from the same chemical subgroup of Etofenprox or other active substance from the IRAC group 3A, such as pyrethroids.
- Alternate the use of ACTIBIOL FOGGING PROFESIONAL with products from other IRAC Mode of Action groups.
- Integrate other control measures such as chemical, cultural and biological, into insect control programs.

Regarding PBO, there are scarce reports of resistance to the effects of this synergist in the literature. Only under extreme laboratory conditions, aimed to induce resistance by applying high doses, in some strains of *Musca domestica* it has been reported some form of insensitivity to PBO, and even then mechanisms were not characterised. Furthermore, when the heavy selection regime that had been used to select for this resistance was removed, the population reverted to susceptibility within 5 generations (CAR 2017). Resistance management strategies are not recommended.

2.2.5.7 Known limitations

The Applicant reports that there are no known limitations.

2.2.5.8 Evaluation of the label claims

Please refer to `Conclusion on the efficacy of the product´, above.

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

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

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

ACTIBIOL FOGGING PROFESSIONAL contains two active substances, i.e Etofenprox (0.475%w/w) and Piperonyl butoxide (1.425%w/w).

No studies on the effects of ACTIBIOL FOGGING PROFESIONAL on human health have been submitted. However there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP). Therefore new studies with the biocidal product are scientifically not justified.

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	ACTIBIOL FOGGING PROFESIONAL is neither irritant nor corrosive to the skin.
Justification for the value/conclusion	None of the components of the product is classified for skin corrosion or irritation. Therefore, the product does not meet the criteria for classification for skin corrosion or irritation according to Regulation (EC) No 1272/2008. However, taking into account that tetradecane is labelled as EUH066, an appropriate labelling for skin dryness and cracking is indicated. In addition, according to harmonised classification and labelling of Piperonyl butoxide, supplemental hazard EUH066 "Repeated exposure may cause skin dryness or cracking" has been proposed.
Classification of the product according to CLP	Classification for skin corrosion or irritation is not required. Supplemental hazard statement EUH066: *"Repeated exposure may cause skin dryness or cracking"* is required.

Data waiving	
Information requirement	Skin corrosion/irritation study
Justification	The composition of the product is known. Testing on the product does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP). Synergistic effects between both active ingredients is expected. None of the ingredients are classified as skin irritant, so the product is not classified. Therefore, this study is not necessary.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	ACTIBIOL FOGGING PROFESIONAL is not classified as Eye Irritant.
Justification for the value/conclusion	According to harmonised classification and labelling of piperonyl butoxide, H319 "Causes serious eye irritation." has been proposed, but its concentration is below its generic classification limit. Therefore, the product does not meet the criteria for classification for eye irritation according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP	No classification for eye irritation is required.

Data waiving

Information requirement	Eye irritation study.
Justification	The composition of the product is known. Testing on the product does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP). Synergistic effects between both active ingredients is expected. None of the ingredients are classified as eye irritant, so the product is not classified. Therefore, this study is not necessary.

Respiratory tract irritation

Conclusion used in Risk Assessment – Respiratory tract irritation	
Value/conclusion	ACTIBIOL FOGGING PROFESSIONAL is not irritating to the respiratory tract.
Justification for the value/conclusion	Toxicological properties and classification of the biocidal product was deduced from the respective properties of the active substances and the co-formulant using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP).
Classification of the product according to CLP	No classification for respiratory tract irritation is required.

Data waiving	
Information requirement	Respiratory tract irritation data.
Justification	No experimental data on respiratory tract irritation of the biocidal product is available. However, the composition of the product is known and there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008. According to harmonised classification and labelling of piperonyl butoxide is classified as STOT SE 3; H335 "May cause respiratory irritation". However, since its concentration is below of 20% (point 3.8.3.4.5. of CLP Regulation), the biocidal product is not classified as STOT SE 3; H335.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	ACTIBIOL FOGGING PROFESIONAL is not a skin sensitizer
Justification for the value/conclusion	None of the components of the product is classified for skin sensitization. Therefore, the product does not meet the criteria for classification for skin sensitization according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP	No classification for skin sensitization is required.

Data waiving	
Information requirement	Skin sensitization study.
Justification	The composition of the product is known. Testing on the product does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP). Synergistic effects between both active ingredients is expected. None of the ingredients are classified as skin sensitizers, so the product is not classified. Therefore, this study is not necessary.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	ACTIBIOL FOGGING PROFESIONAL is not a respiratory sensitizer
Justification for the value/conclusion	None of the components of the product is classified for respiratory sensitization. Therefore, the product does not meet the criteria for classification for respiratory sensitization according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP	No classification for respiratory sensitization is required.

Data waiving	
Information requirement	Respiratory sensitization data
Justification	No data on respiratory sensitization have been submitted. However, the composition of the product is known and there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) Nº 1272/2008 (CLP Regulation). None of the ingredients are classified as respiratory sensitizers, so the product is not classified.

Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	ACTIBIOL FOGGING PROFESIONAL is not classified for acute oral toxicity
Justification for the selected value	None of the components of the product is classified for acute oral toxicity. Therefore, the product does not meet the criteria for classification for acute oral toxicity according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP	No classification for acute oral toxicity is required.

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

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	ACTIBIOL FOGGING PROFESIONAL is not classified for acute inhalation toxicity.
Justification for the selected value	None of the components of the product is classified for acute inhalation toxicity. Therefore, the product does not meet the criteria for classification for acute inhalation toxicity according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP	No classification for acute inhalation toxicity is required.

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

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	ACTIBIOL FOGGING PROFESIONAL is not classified for acute dermal toxicity
Justification for the selected value	None of the components of the product is classified for acute dermal toxicity. Therefore, the product does not meet the criteria for classification for acute dermal toxicity according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP	No classification for acute dermal toxicity is required.

Data waiving

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

Information on dermal absorption

There is no experimental data available on the dermal absorption of this formulation since no study has been conducted thus far. Although 16% and 4.8% are used as dermal absorption values for Etofenprox and PBO in their respective Assessment Reports, those formulations tested are differents to ACTIBIOL FOGGINGPROFESIONAL. Hence, the criteria for using the data of a similar formulation are not met. Therefore, a default value of 70% (formulation type: Organic solvent-based) should be used for products containing ≤ 5% of active substance (EFSA, 2017). Risk assessment calculations for human exposure have been made according to this value.

Value(s) used in the Risk Assessment – Dermal absorption		
Substances	Etofenprox	Piperonyl butoxide
Value(s)	70%	70%
Justification for the selected value(s)	According to EFSA Guidance on Dermal Absorption (EFSA Journal, 2017;15(6):4873), a default dermal absorption value of 70% may be applied.	

Data waiving	
Information requirement	Dermal absorption study
Justification	There is no experimental data available on the dermal absorption of ACTIBIOL FOGGING PROFESIONAL since no study has been conducted thus far. As a result, risk assessment calculations for human exposure have been made according to the EFSA guidance on dermal absorption (EFSA Journal, 2017;15(6):4873) using a default value of 70% dermal absorption for this product.

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

One substance of concern has been identified for human health. ACTIBIOL FOGGING PROFESIONAL contains 98.1% of tetradecane which is classified as Asp tox 1; H304 (May be fatal if swallowed and enters airways). EUH066 (Repeated exposure may cause skin dryness or cracking) is proposed, based on local skin effects and reactions that have been described for hydrocarbon solvents in accordance with the naming convention introduced by the Hydrocarbon Solvent Producers Association and its proposal on classification and labelling (HSPA 2017).

Available toxicological data relating to a mixture

Not applicable.

Other

Aspiration hazard

Value used in the Risk Assessment – Aspiration hazard	
Value/conclusion	Asp tox 1; H304
Justification	ACTIBIOL FOGGING PROFESINAL contains tetradecane which is a hydrocabon solvent classified as Asp tox 1; H304. Since its concentration is above of its generic concentration value of 10% and the kinematic viscosity measured at 40 ºC of the biocidal product is less than 20.5 mm^2/s, ACTIBIOL FOGGING PROFESIONAL must be classified in this category hazard.
Classification of the products according to CLP	ACTIBIOL FOGGING PROFESIONAL is classified as Asp tox 1; H304:*"May be fatal if swallowed and enters airways"*

Reproductive toxicity, additional category for effects on or via lactation (Lact.)

Value used in the Risk Assessment – Lact.	
Value/conclusion	Lact; H362
Justification	According to annex VI of CLP Regulation, etofenprox is classified as Lact; H362. No specific concentration limits are given for this ingredient in Annex VI of CLP, so the generic concentration limits of the CLP apply (≥ 0.3%). Since its concentration is above of its generic concentration value, it triggers the classification of the biocidal product.
Classification of the products according to CLP	ACTIBIOL FOGGING PROFESIONAL is classified as Lact H362: *"May cause harm to breast-fed children".*

ENDOCRINE DISRUPTING PROPERTIES

Since 7 June 2018, date when the Regulation (EU) No 2017/2100 came into force, endocrine disrupting properties assessment of active substance and co-formulants is mandatory according to the article 19 of BPR.

BPC opinion (June 2016) of BPO indicates *"Piperonyl Butoxide is not considered to have endocrine disrupting properties"*. However, piperonyl butoxide was placed in the CoRAP list to be evaluated by SE for potential endocrine disruptor. Finally it was removed from CoRAP prior to evaluation, considering that the main use of PBO is as a biocide and that the ED-criteria for biocides have been adopted recently, the further evaluation of the potential ED-properties of PBO could be handled in the renewal process under the biocides regulation. PBO was included in EU priority list in CAT2.

According to EPA's Endocrine Disruptor Screening Program (EDSP), PBO was included in The final EDSP List 1. The conclusion of the WoE evaluation is that PBO demonstrates no convincing evidence of potential interaction with the estrogen, androgen or thyroid pathways in mammals or wildlife. Therefore, based on weight of evidence considerations, mammalian

or wildlife EDSP Tier 2 testing is not recommended for PBO since there was no convincing evidence of potential interaction with the estrogen, androgen or thyroid pathways.

The Assessment Report (September 2013) of etonfenprox indicates *"There is no indication of endocrine potential of Etofenprox".* However, it has been included in ECHA's endocrine disruptor (ED) assessment list for discussion to ECHA's ED Expert Group

After reviewing the potential ED properties of co-formulants, ACTIBIOL FOGGING PROFESIONAL does contain any substances suspected of having endocrine disrupting properties.

Several sources were considered to check the potential endocrine disrupting properties of the co-formulants contained in the biocidal product.

For further details please refer to the Confidential Annex to this PAR.

2.2.6.2 Exposure assessment

General remarks

The assessment of occupational exposure towards etofenprox and PBO as insecticides are based on information provided by the Participants. In the absence of human exposure data, the exposure estimation to etofenprox and PBO are based on the selected models and default values from the Biocides Human Health Exposure Methodology (BHHEM 2015) along with HEEG recommendations and the Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation (Parts B+C) Version 4.0 December 2017.

If no appropriate models are available in the BHHEM, surrogate models are chosen and a justification is provided.

The proposed tiered approach for human exposure assessment is applied as follows. In several cases it is considered not to be appropriate to calculate a "reasonable worst case" exposure (Tier 1) according to the Guidelines. The dermal absorption of etofenprox and PBO in humans is well established as outlined above. Assuming no protection by the human skin (as proposed for Tier 1 estimates) is considered not to be reasonable. For all of the following calculations the established dermal absorption figure for humans is applied. Despite the fact that protective measures could be supposed to be carefully observed in a professional environment, a Tier 1 is proposed as a worst case. Then, personal protective equipment will be assumed to be worn as second scenario (Tier 2).

Where exposure is calculated based on empirical data (Biocides Human Health Exposure Methodology (BHHEM, 2015) along with HEEG recommendations), these data are applied in agreement with the recommendations given by the guidelines as follows: In case of continuous (chronic) exposure scenarios the typical exposure is calculated based on the 75%-ile of the data. The 95%-ile is considered to represent the typical case when recommended by applicable guidelines. Where 95%-iles are not given, the maximum values are used instead.

Additional information (only relevant in Spain):

Following the provisions of BPR art. 37(1), the Spanish Competent Authority (ES CA) will modify the conditions of the Authorisation of this b.p. in the Spanish market in order to adapt the User categories to our national legal requirements.
Royal Decree 830/2010 stipulates the specific training and skills for Trained Professional users of biocides. It follows that in Spain there are three User categories regarding the application of biocides, namely:

- *Trained Professional users* (TP): professionals whose daily work is related to the application of biocides (e.g. Pest Control Operators). They should have received specific training on the safe use of biocides including correct use of Personal Protection Equipment (PPE), and should have a formal professional certificate.
- *Professional users* (P): non-trained professionals which may use biocides in the context of their working activities, but not as a normal activity. It is unlikely that they have received specific training on the safe use of biocides. However it can be expected that they have some knowledge and skills on the handling of chemicals, according to the national legislation on occupational risks prevention, so that they are able to use correctly some kind of PPE if necessary.
- *Non-professional users* (NP) (General public): users of biocides in domestic areas in the context of their private life activities, who are not professionals.

The risk assessment performed in this PAR considers the user categories for application of b.p. as included in the Guidance documents, i.e. professionals and non-professionals. The exposure assessment is the same for professionals and trained professionals. The distinction between these professionals is based on expert judgment considering, among others, the hazard profile of the b.p., the kind of use applied for, the frequency of use, complexity of control measures or application methods, etc.

The conclusions reached in this PAR are regarded as applicable to the Spanish category of **Trained Professionals**, due to the complexity of the application method.

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

Summary table: relevant paths of human exposure							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Industrial use	**Professional use**	**Non-professional use**	**Industrial use**	**Professional use**	**General public**	**Via food**
Inhalation	n.a.	Yes	n.a.	n.a.	Yes	Yes	No
Dermal	n.a.	Yes	n.a.	n.a.	Yes	Yes	No
Oral	n.a.	No	n.a.	n.a.	No	Yes	No

n.a. not applicable

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

PRIMARY EXPOSURE

- Addition/formulation of biocidal product to prepare the end-product (formulation of biocidal product into end-use applications, Professional Users Exposure).

- Application of the product: Not relevant, the exposure during the application phase is unlikely. (Professional Users Exposure).
- Adult re-entering in the treated room (Professional Users Exposure).

SECONDARY EXPOSURE

- Inhalation exposure: inhalation of volatilized residues of active substances.
- Indirect exposure: exposure of consumers to materials or articles containing residues of biocide: toddler playing in a treated room, adult re-entering into a treated room, toddler playing in an area before the fog has disappeared, adult re-entering into an area before the fog has disappeared, persons laundering contaminated work clothing and dietary exposure to biocide residues (Consumer Indirect Exposure).

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
1.	Mixing and loading	**Primary exposure:** Load the fog-equipment with the ready-to-use product before the application.	Professionals
2.	Application	**Primary exposure:** Application of the end-product as space spray application (mist or thermal fog) in indoor areas.	Professionals
3.	Post-application	**Primary exposure:** Adult re-entering in the treated room for ventilation following application or equipment malfunction.	Professionals
4.	Post-application	**Secondary exposure:** Inhalation of volatilized residues	General public
5.	Post-application	**Secondary exposure:** Toddler after space spray treatment application in indoor areas	General public
6.	Post-application	**Secondary exposure:** Adult re-entering treated room	General public
7.	Post-application	**Secondary exposure:** Adult launders contaminated work clothing at home.	General public

Industrial exposure

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

Professional exposure

The product is intended to be applied by professional users (e.g. PCO) who apply the product into the air space of the closed premise by thermal fogging or cold fogging treatment. The treated premises must be sealed and nobody must enter in the premise during the treatment before the safety-time of 12 hours has been fulfilled according to the applicant's data. Therefore, the total exposure derived from the application is not only restricted to the handling phase (Scenario [1]), but also the likely exposure of the user when enters in the treated premise due to equipment malfunction and/or connect the ventilation system (in the case that it exists) is also regarded of concern and taken in account in the current assessment (Scenario [3]).

Scenario [1] – Mixing and loading

Description of Scenario [1]			
During this task, workers (e.g. PCO) discharge the liquid into the fog-equipment before the application. The scenario to be modelled is using mixing and loading model 7 "Pouring liquid into systems" according to the recommendation no. 7. The tasks described in this model most accurately apply to the above procedures. The mixing and loading phase is assumed to take 10 min/day. Inhalation exposure during automated transfer is considered negligible, because of low vapour pressure. In Tier 2 PPE (gloves) are considered.			
	Parameters	**Value / Units**	**Justification / Source**
Tier 1	Weight fraction of a.s.	0.475% (etofenprox) 1.425% (PBO)	Section 2.1.2.
	Body weight	60 kg	Recommendation no. 14, 2017
	Expected duration of actual exposure	10 minutes	Recommendation no. 7, 2015
	Hand exposure without gloves	101 mg/min	Recommendation no. 7, 2015
	Inhalation exposure	0.94 mg/min	Recommendation no. 7, 2015
	Dermal Absorption	70%	Guidance on Dermal Absorption (EFSA, 2017)
Tier 2	Hand exposure with gloves	1.01 mg/min	Recommendation no. 7, 2015

Calculations for Scenario [1]

Summary table: estimated exposure from professional uses [mg/kg bw/d]						
Exposure scenario	**Tier/ PPE**	**Active substance**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [1]	Tier 1 / no PPE	Etofenprox	1.55E-05	5.60E-02	--	5.60E-02
		PBO	4.65E-05	1.68E-01	--	1.68E-01
	Tier 2 / PPE	Etofenprox	1.55E-05	5.60E-04	--	5.75E-04
		PBO	4.65E-05	1.68E-03	--	1.73E-03

See more information in annex 3.2.

Further information and considerations on scenario [1]
According to the criteria of the Regulation (EC) No 1272/2008, the biocidal product is proposed to be classified as causing skin dryness (EUH066). Therefore, a qualitative assessment of local effects will be performed in Section C.1 according to Guidance on the BPR Volume III Human Health- Assessment & Evaluation– Part B and C Risk Assessment (Version 4.0 December 2017).

Scenario [2] – Application as a space spray as a mist or thermal fog

Description of Scenario [2]
The biocide is intended to be applied as hot/cold-fogging concentrate (HN/KN) by fog-equipments on sealed premises where nobody must enter or stay during the treatment before the safety-time of 12 hours has been fulfilled according to the applicant's data. The biocidal product will spray after activation, generating fog and releasing the active substances in to the room atmosphere. Directly after activation, the room will be left and closed during the application. Therefore, exposure is very unlikely for both, inhaled and dermal uptake if the user is informed accordingly in the instructions of use.

Calculations for Scenario [2]
Not necessary. No risk of exposure since the treatment itself is performed in the absence of the user and during most of the time that aerosol droplets may still be present in the room the user is absent.

Further information and considerations on scenario [2]
According to the criteria of the Regulation (EC) No 1272/2008, the biocidal product is proposed to be classified as causing skin dryness (EUH066). Therefore, a qualitative assessment of local effects will be performed in Section C.1 according to Guidance on the BPR Volume III Human Health- Assessment & Evaluation– Part B and C Risk Assessment (Version 4.0 December 2017).

Scenario [3] – Post-Application of the biocidal product (re-entry period in the treated room).

Description of Scenario [2]
The biocidal product is ready to use product to be applied by swing-fog equipments for indoor use at domestic and industrial premises (e.g. attics, false ceilings, garages, storage rooms, and low frequently rooms,...) but not intended to be applied on facilities where there is a constant presence and continued of children (e.g. play areas of children, nurseries, children's schools,…). According to information from the Applicant: 1. no access of persons to the treated area is permitted during treatment. 2. The treated premises must be sealed and signposted in order to avoid the entry of anybody in the premise during the treatment. 3. Let the product act for at least 12 hours. Therefore, primary exposure is expected only at re-entry for ventilation following application and/or equipment malfunction during application phase. The exposure is derived via inhalation and dermal route. Dermal exposure may occur for professional user via direct contact to deposits of the biocide on the surface of contact, e.g. opening windows or doors at re-entry following application. Inhalation exposure may occur for professional

user via direct contact with airborne droplets of the biocide, e.g. re-entry for equipment malfunction.
The default scenario « Fogging and misting models 2 & 3 » to assess dermal and inhalation exposure during the application phase from the Recommendation no. 6 is used.

The model assumes that:

1. exposure is deemed throughout an entire work day, with 60 min devoted to fogging, a minimum requirement according to HEAdhoc recommendation no. 6.
2. Workers are peripatetic and much time is spent travelling to treatment sites and surveying.

To our case, a task duration of 15 min is deemed as worst case where it is assumed that the worker spends a quarter of its time doing post-application tasks within of the work shift.

	Parameters	**Value / Units**	**Justification / Source**
Tier 1	Weight fraction of a.s.	0.475% (etofenprox) 1.425% (PBO)	Section 2.1.2.
	Body weight	60 kg	Recommendation 14, 2017
	Task Duration	15 min	Expert judgement.
	Dermal exposure		
	Indicative dermal exposure, Body	21.8 mg/min	Recommendation 6, 2020
	Indicative dermal exposure Hand deposition – without protective gloves	33 mg/min	Recommendation 6, 2020
	Dermal Absorption	70 %	Guidance on Dermal Absorption (EFSA, 2017)
	Inhalation exposure		
	Respiration volume	1.25 m^3 air/hour	Recommendation 14, 2017
	Inhalation exposure	70.2 mg/m^3	Recommendation 6, 2020
	Inhalation absorption	100%	Default value.
Tier 2	PPE (coated coverall)	20% penetration	HEEG Opinion 9
	Indicative dermal exposure Hand deposition – with protective gloves	0.33 mg/min	Recommendation 6, 2020

Calculations for Scenario [3]

Summary table: estimated exposure from professional uses						
Exposure scenario	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake [mg/kg bw/d]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated oral uptake [mg/kg bw/d]**	**Estimated total uptake [mg/kg bw/d]**
Scenario [3]	Tier 1 / no PPE	Etofenprox	1.74E-03	4.56E-02	-	4.73E-02
		PBO	5.21E-03	1.37E-01	-	1.42E-01

Summary table: estimated exposure from professional uses						
Exposure scenario	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake [mg/kg bw/d]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated oral uptake [mg/kg bw/d]**	**Estimated total uptake [mg/kg bw/d]**
	Tier 2 / PPE	Etofenprox	1.74E-04	3.90E-03	-	5.64E-03
		PBO	5.21E-03	1.17E-02	-	1.69E-02

See more information in annex 3.2.

Further information and considerations on scenarios [3]
According to the criteria of the Regulation (EC) No 1272/2008, the biocidal product is proposed to be classified as causing skin dryness (EUH066). Therefore, a qualitative assessment of local effects will be performed in Section C.1 according to Guidance on the BPR Volume III Human Health- Assessment & Evaluation– Part B and C Risk Assessment (Version 4.0 December 2017).

Combined scenarios

Summary table: estimated exposure from professional uses						
Exposure scenario	**Tier/PPE**	**Active substance**	**Estimated inhalation uptake [mg/kg bw/d]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated oral uptake [mg/kg bw/d]**	**Estimated total uptake [mg/kg bw/d]**
Scenario [1, 2, 3]	Tier 1 / no PPE	Etofenprox	1.75E-03	1.02E-01	--	1.03E-01
		PBO	1.75E-03	4.46E-03	--	6.21E-03
	Tier 2 / PPEs	Etofenprox	5.26E-03	3.05E-01	--	3.10E-01
		PBO	5.26E-03	1.34E-02	--	1.86E-02

See more information in annex 3.2.

Non-Professionals

The exposure is not foreseen. The product is only to be used by professional users.

Exposure of the general public

Secondary exposure will occur when persons stay in rooms during operation of the one-shot aerosol cartridge. In addition, the active substances may end up on the floor and/or become attached to other materials. Persons, who get in contact (e.g. adults/toddlers playing/crawling on the floor) might be exposed particularly dermally and orally via hand-to-mouth contact.

Scenario [4] - Inhalation of volatilized residues

Description of Scenario [4]			
Professional and general public may be exposed to volatilised residues from etofenprox and PBO residues will vaporise and could be available for inhalation by people present in the room. However, based on the document, HEEG opinion 13 on Assessment of Inhalation Exposure of volatilised biocide active substance, it might not be necessary to calculate the exposure to volatilised residues: - For etofenprox: $$\mathbf{0.328} \times \frac{\mathbf{376.5} \times \mathbf{8.13E{-}07}}{\mathbf{0.011}} = \mathbf{9.13E-03} \leq 1$$ - For PBO: $$\mathbf{0.328} \times \frac{\mathbf{338.43} \times \mathbf{1.33{-}05}}{\mathbf{0.2}} = \mathbf{7.38E-03} \leq 1$$ The result of this equation is lower than 1 for active substances. The exposure to volatilised residues indoor can be considered negligible for workers and general public for the biocidal product according to the assessment of effects on human health conclusions.		
	Parameters	**Value / Units**	**Justification / Source**
Tier 1	Weight fraction of a.s.	0.475% (etofenprox) 1.425% (PBO)	Section 2.1.2.
	Body weight: Adult Child Toddler Infant	 60 kg 23.9 kg 10 kg 8 kg	Recommendation no. 14, 2017.
	Inhalation rate: Adult Child Toddler Infant	 16 m^3/24h 12 m^3/24h 8 m^3/24h 5.4 m^3/24h	Recommendation no. 14, 2017.
	Vapour pressure (Vp)	8.13E-07 Pa (etofenprox) 1.33E-05 Pa (PBO)	CAR/AR (AT, 2013) CAR/AR (EL, 2017)
	Molecular weight (Mw):	376.5 g/mol (etofenprox) 338.43 g/mol (PBO)	CAR/AR (AT, 2013) CAR/AR (EL, 2017)
	Gas constant (R)	8.31451 $J.mol^{-1}.K^{-1}$	HEEG opinion no. 13
	Temperature (T)	298 K	HEEG opinion no. 13

Calculations for Scenario [4]
No calculations are needed. No exposure is foreseen.

Further information and considerations on scenario [4]
According to the criteria of the Regulation (EC) No 1272/2008, the biocidal product is proposed to be classified as causing skin dryness (EUH066). Therefore, a qualitative assessment of local effects will be performed in Section C.1 according to Guidance on the BPR Volume III Human Health- Assessment & Evaluation– Part B and C Risk Assessment (Version 4.0 December 2017).

Scenario 5 - Toddler playing in a treated room

Description of Scenario [5]

Secondary exposure as a result of use of a.s. may occur via the dermal route (transfer of surface bound residues to the skin) and by inhalation (while aerosol particles settle during the acute phase of the secondary exposure). However, inhalation exposure (secondary) as a result of use of a.s. in the biocidal product is considered to be negligible since:

- Bystanders are kept out of the treatment areas until spray aerosols have dispersed or dust have settled.,
- Vapour pressure of a.s. is low (8.13E-07 Pa @ 25ºC, 2.11E-05 Pa @ 25ºC; according to Council Directive 1999/13/EC, a substance should be considered volatile when the vapour pressure >0.01 kPa at 20ºC).

Thus, secondary exposure of a.s. is considered predominantly via the dermal route (transfer of surface bound residues to the skin).
The transfer of residues to the skin depends on:

- The intensity of contact with surfaces which can be described by a generic transfer coefficient (cm^2/hour).
- The amount of transferable residues presents on the surface (mg a.s./cm^2).
- The exposure duration (hours per day).

The relevant default values given in the Recommendation no. 12 of the BPC Ad hoc Working Group on Human Exposure – 'New default values for indoor Transfer Coefficient' are presented below:

- Transfer Coefficient (TC): 2000 cm^2/hour
- Exposure period (EP): 1 hour per day

To calculate the amount of surface transferable residues in the absence of specific data the TNsG propose a default value of 30% of the residues present on the surface. Thus regarding transfer efficiency of surface residues the following figures apply for Aquapy:

- - Hard surfaces: 30 % of the surface residues

For the toddler one might in addition consider oral exposure via hand to mouth transfer. The TNsG propose to assume in a tier 1 approach that 10% of the total amount of product that ends up on the skin of the toddler is taken in orally by hand to mouth contact (= 10% of the hand exposure).

These data are included in Tier 1, for Tier 2 a deposition value of 10% was used for the fraction of active substance emitted to floor (based on Emission Scenario Document for PT18) and the dislodgeable residue can be refined taking into account the US EPA Residential SOPs (2012), where, after the revision of complete datasets for some chemicals, it is concluded in table 7-9 that the dislodgeable residue for PBO in hard surfaces is 5% (75^{th} percentile) and for chemicals that do not have chemical-specific data available (e.g. etofenprox, propan-2-ol), the recommended screening level point estimates for use in post-application dermal exposure assessments is 8% for hard surfaces. In addition, the oral exposure is calculated based on the assumption that 40% of the palms will be in contact with the product (recommendation no. 5 - 2015), 10% of dermal load will be ingested by hand-to-mouth transfer (ConsExpo) and 57% of the product will be extracted by saliva (US EPA Residential SOPs - 2012).

Tier 1	**Parameters**	**Value / Units**	**Justification / Source**
	Weight fraction of a.s.	0.475% (etofenprox) 1.425% (PBO)	Section 2.1.2.
	Maximum application rate	0.262 mL BP/m^3	Applicant's data (section B.2)
	Density	0.7671 g/mL	Applicant's data (section B.2)

	Room height	3.48 m	Applicant's data (section B.2)
	Area treated (deposition rate)	100%	Worst case
	Surface residues	3.32E-04 mg etopenfrox/cm^2 9.96E-04 mg PBO/cm^2	Calculated value.
	Body weight	10 kg	Recommendation no. 14, 2017
	Dermal exposure		
	Transfer coefficient	2000 cm^2/h	Recommendation no. 12, 2016
	Surface transferable residues	30%	BHHEM, 2015.
	Exposure period	1h/day	BHHEM, 2015.
	Dermal Absorption	70 %	Guidance on Dermal Absorption (EFSA, 2017)
	Oral exposure		
	Transferable fraction from hand to mouth	10 %	TNsG
	Oral absorption	100 %	Default value.
Tier 2	Area treated (deposition rate)	10%	Section 2.2.8 (ESD No. 18)
	Surface residues	3.32E-05 mg etopenfrox/cm^2 9.96E-05 mg PBO/cm^2	Calculated value.
	Dermal exposure		
	Surface transferable residues	8% (etofenprox) 5% (PBO)	US EPA Residential SOPs - 2012
	Oral exposure		
	Proportion of palms of hand in contact	40%	Recommendation no. 5, 2015.
	Fraction of Pesticide Extracted by Saliva	57%	US EPA Residential SOPs - 2012

Calculations for Scenario [5]

Summary table: systemic exposure from general public						
Exposure scenario	**Tier**	**Active substance**	**Estimated inhalation uptake [mg/kg bw/d]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated oral uptake [mg/kg bw/d]**	**Estimated total uptake [mg/kg bw/d]**
Scenario [5]	Tier 1	Etofenprox	--	1.39E-02	5.97E-04	1.45E-02
		PBO	--	4.18E-02	1.79E-03	4.36E-02
	Tier 2	Etofenprox	--	3.72E-04	3.63E-06	3.75E-04
		PBO	--	6.97E-04	4.54E-04	1.15E-03

See more information in annex 3.2.

Further information and considerations on scenario [5]

According to the criteria of the Regulation (EC) No 1272/2008, the biocidal product is proposed to be classified as causing skin dryness (EUH066). Therefore, a qualitative assessment of local effects will be performed in Section C.1 according to Guidance on the BPR Volume III Human Health- Assessment & Evaluation– Part B and C Risk Assessment (Version 4.0 December 2017).

Scenario 6 - Adult re-entering into a treated room

Description of Scenario [6]			
For completeness the total secondary exposure of an adult person is expected to be less compared to the exposure of a toddler. Assuming a transfer coefficient of 7800 cm^2/h (a default value used by Recommendation no. 12, 2016) and a body weight of 60 kg the dermal exposure of an adult person crawling across treated hard surface (space spray-type treatment) for 1 h will be estimated as follows:			
Tier 1	**Parameters**	**Value / Units**	**Justification / Source**
	Weight fraction of a.s.	0.475% (etofenprox) 1.425% (PBO)	Section 2.1.2.
	Maximum application rate	0.262 mL BP/m^3	Applicant's data (section B.2)
	Density	0.7671 g/mL	Applicant's data (section B.2)
	Room height	3.48 m	Applicant's data (section B.2)
	Area treated (deposition rate)	100%	Worst case
	Surface residues	3.32E-04 mg etopenfrox/cm^2 9.96E-04 mg PBO/cm^2	Calculated value.
	Body weight	60 kg	Recommendation no. 14, 2017
	Dermal exposure		
	Transfer coefficient	7800 cm^2/h	Recommendation no. 12, 2016
	Surface transferable residues	30%	BHHEM, 2015.
	Exposure period	1h/day	TNsG
	Dermal Absorption	70 %	Guidance on Dermal Absorption (EFSA, 2017)
	Oral exposure		
	Transferable fraction of b.p. from hand to mouth (i.e. from two fingers only)	4 %	TNsG June 2002, Part 2 – page 274.
	Oral absorption	100 %	Default value.
Tier 2	Area treated (deposition rate)	10%	Section 2.2.8 (ESD No. 18)
	Surface residues	3.32E-05 mg etopenfrox/cm^2	Calculated value.

		9.96E-05 mg PBO/cm^2	
	Dermal exposure		
	Surface transferable residues	8% (etofenprox) 5% (PBO)	US EPA Residential SOPs - 2012
	Oral exposure		
	Proportion of palms of hand in contact	40%	Recommendation no. 5, 2015.
	Fraction of Pesticide Extracted by Saliva	57%	US EPA Residential SOPs - 2012

Calculations for Scenario [6]

Summary table: systemic exposure from general public						
Exposure scenario	**Tier**	**Active substance**	**Estimated inhalation uptake [mg/kg bw/d]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated oral uptake [mg/kg bw/d]**	**Estimated total uptake [mg/kg bw/d]**
Scenario [6]	Tier 1	Etofenprox	--	9.06E-03	1.55E-04	9.21E-03
		PBO	--	2.72E-02	4.66E-04	2.76E-02
	Tier 2	Etofenprox	--	2.42E-03	9.44E-06	2.43E-03
		PBO	--	4.53E-03	1.77E-05	4.55E-03

See more information in annex 3.2.

Scenario [7] – Laundering work clothes

Description of Scenario [7]			
Exposure to product can occur when washing contaminated work clothes. Persons at risk are adults professionals. The exposure is considered acute intermediary, as it does not occur on a daily basis but may be longer-term. In general, this approach assumes that the washing is carried out in a domestic automatic washing machine, therefore, the exposure will be dermally through the hands, from handling the contaminated clothes before and during the introduction of the clothes in the washing machine. Laundering is considered to be after a five-day work week, hence the total amount of product on work clothes is assumed to be five times the daily contamination associated with the application method used and it is assumed that the clothing to be washed is a coverall worn by a professional. The contamination of clothes is based on the re-entry of professional in the treated room during the application from which the tier that shows safe use is tier 2 where PPEs are worn. It is assumed that applicator wear regular clothes which, according to HEEG opinion 9, have a Default Protection Factor of 50%.			
	Parameters	**Value / Units**	**Justification / Source**

Description of Scenario [7]			
Tier 1	Weight fraction of a.s.	0.475% (etofenprox) 1.425% (PBO)	Section 2.1.2.
	Body weight	60 kg	Recommendation no. 14, 2017
	Dermal exposure		
	Indicative value from model	130.8 mg/d	Re-entry during fooging by professionals
	Surface medium-sized coverall	22700 cm^2	Estimated parameter usually accepted
	Regular clothes penetration	50 %	HEEG Opinion 9 (2010)
	Dermal Absorption	70% (etofenprox) 70% (PBO)	Guidance on Dermal Absorption (EFSA, 2017)
	Skin surface area in contact	820 cm^2	For an adult, the total area of both hands (front and back) is 820 cm^2 (Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure Default human factor values for use in exposure assessments for biocidal products (revision of HEEG opinion 17 agreed at the Human Health Working Group III on 12 June 2017))
	Transfer coefficient	30 %	BHHEM, 2015 - Cotton, knitwear, plastic, wood Dried fluid - wet hand

Calculations for Scenario [7]

Summary table: estimated exposure from professional uses						
Exposure scenario	**Tier**	**Active substance**	**Estimated inhalation uptake [mg/kg bw/d]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated oral uptake [mg/kg bw/d]**	**Estimated total uptake [mg/kg bw/d]**
Scenario [7]	Tier 1	Etofenprox	--	3.93E-04	--	3.93E-04
		PBO	--	1.18E-03	--	1.18E-03

See more information in annex 3.2.

Further information and considerations on scenario [7]

According to the criteria of the Regulation (EC) No 1272/2008, the biocidal product is proposed to be classified as causing skin dryness (EUH066). Therefore, a qualitative assessment of local effects will be performed in Section C.1 according to Guidance on the

BPR Volume III Human Health- Assessment & Evaluation– Part B and C Risk Assessment (Version 4.0 December 2017).

Combined scenarios for adults

Summary table: estimated exposure from professional uses						
Exposure scenario	**Tier**	**Active substance**	**Estimated inhalation uptake [mg/kg bw/d]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated oral uptake [mg/kg bw/d]**	**Estimated total uptake [mg/kg bw/d]**
Scenario [1, 2, 3, 6, 7]	Tier 2 (scenarios 1, 2 & 3) + Tier 2 (scenario 6) + Tier 1 (scenario 7)	Etofenprox	2.44E-02	2.44E-02	2.44E-02	2.44E-02
		PBO	2.44E-02	2.44E-02	2.44E-02	2.44E-02

See more information in annex 3.2.

Monitoring data

No monitoring studies have been developed by the applicant as they are not considered needed.

Dietary exposure

No dietary exposure is foreseen because the product is not intended to be applied on places related with food, drinking water or livestock. In addition, the product is not intended to be used in presence of human or animals and the treated facilities must be sealed during the application until the safety time has been fulfilled.

Information of non-biocidal use of the active substances

ETOFENPROX

Summary table of other (non-biocidal) uses			
	Sector of use	**Intended use**	**Reference value(s)**
1.	Plant protection products	COMMISSION IMPLEMENTING REGULATION (EU) No 2021/1449 of 3 September 2021 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 2-phenylphenol (including its salts such as the sodium salt), 8-hydroxyquinoline, amidosulfuron, bifenox, chlormequat, chlorotoluron, clofentezine, clomazone, cypermethrin, daminozide, deltamethrin, dicamba, difenoconazole, diflufenican, dimethachlor, **etofenprox**, fenoxaprop-P, fenpropidin, fludioxonil, flufenacet, fosthiazate,	(1)

		indoxacarb, lenacil, MCPA, MCPB, nicosulfuron, paraffin oils, paraffin oil, penconazole, picloram, propaquizafop, prosulfocarb, quizalofop-P-ethyl, quizalofop-P-tefuryl, sulphur, tetraconazole, tri-allate, triflusulfuron and tritosulfuron	

(1). COMMISSION REGULATION (EU) No 2021/590 of 12 April 2021 amending Annexes II and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for aclonifen, boscalid, cow milk, **etofenprox**, ferric pyrophosphate, L-cysteine, lambda-cyhalothrin, maleic hydrazide, mefentrifluconazole, sodium 5-nitroguaiacolate, sodium o-nitrophenolate, sodium p-nitrophenolate and triclopyr in or on certain products

Piperonyl butoxide/PBO

Summary table of other (non-biocidal) uses			
	Sector of use	**Intended use**	**Reference value(s)**
1.	Plant protection products	Not yet assessed at EU level	Not Applicable
2.	Veterinary use	NO ENTRY For topical use only.	No MRL required (1)
3.	Cosmetics Ingredients	Skin protecting	Not Applicable

(1) COMMISSION REGULATION (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin.

Estimating Livestock Exposure to Active Substances used in Biocidal Products

The product is not intended to be applied in presence of animals nor animal housing. Therefore, no livestock exposure is regarded necessary.

According to Guidance on the BPR: Volume III Parts B+C Version 4.0 December 2017, 5. Guidance on Estimating Livestock Exposure to Biocidal Active Substances, the following risk mitigation measures are required and added to PAR:

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

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

The product is not intended to be applied into foods nor places where food and feed can be stored. Then no transfer estimation of Etofenprox and PBO into foods is considered necessary.

According to Guidance on the BPR: Volume III Parts B+C Version 4.0 December 2017, 5. Guidance on Estimating Transfer of Biocidal Active Substances into Foods – Professional Uses, the following risk mitigation measures are added to PAR required:

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

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

The product is not intended to be applied by non-professional users.

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

Exposure resulting from the production and formulation of the active substances and of the biocidal product are not considered, here as they are out of scope of the Biocide Regulation. Active substances are manufactured outside of EU.

During the product and formulation of the biocidal product, human are not exposed to the product residues as the process is automated and the operator is segregated from the product source. Therefore, no risk assessment is needed at this regard. Moreover, all the steps of the manufacturing process at QUIMUNSA manufacturing plants are performed according to the instructions given in the Directive 98/24/EC - risks related to chemical agents at work.

Once the product is applied, no recovery is possible and disposal of the empty can must be done according to the authority waste regulations.

Aggregated exposure

In a regular case, the user only applies one treatment per day as PT18. Hence, no aggregated exposure is foreseeable for the user and no aggregated exposure should be taken into account in the Human risk assessment.

2.2.6.3 Risk characterisation for human health

The risk characterisation is conducted at a first stage for each active substance by comparison of human exposure and the toxicity using the Acceptable Exposure Limit (AEL) approach in which the exposure estimates are compared with the systemic reference values that were determined by dividing the relevant N(L)OAEL (mg/kg/day) by an overall Assessment Factor (AF). Risks are considered acceptable if the systemic exposure/AEL ratio is < 1. None of the active substance is regarded susceptible to cause site of contact toxicity, reference values and a risk characterisation for local effects are not required.

ETOFENPROX: Reference values to be used in Risk Characterisation (taken from Etofenprox's AR)

Reference	**Study**	**NOAEL (LOAEL)**	**AF[1]**	**Correction for oral absorption**	**Value (mg/kg bw/d)**
AELshort-term	Rat developmental neurotoxicity feeding study	28.4 mg/kg bw day	100	0.3	0.085
AELmedium-term	Rat subchronic feeding study	20 mg/kg bw day	100	0.3	0.06

AELlong-term	Rat 2-year feeding study	3.7 mg/kg bw day	100	0.3	0.011
ARfD	-	-	-	-	-
ADI	-	-	-	-	-

[1] The default assessment factor of 100 is obtained from [10 (interspecies variation) x 10 (intraspecies variation)] which is considered appropriate by the active substances' AR.

PIPERONYL BUTOXIDE: Reference values to be used in Risk Characterisation (taken from PBO's AR)

Reference	**Study**	**NOAEL (LOAEL)**	**AF[1]**	**Correction for oral absorption**	**Value (mg/kg bw/d)**
AELshort-term	developmental rabbit	100 mg/Kg bw/day	100	-	1
AELmedium-term	1-year dietary dog	16 mg/kg b.w./day	100	-	0.2
AELlong-term	1-year dietary dog	16 mg/kg b.w./day	100	-	0.2
ARfD	Not set. Not required.				
ADI	1-year dietary dog	16 mg/kg b.w./day	100	-	0.2

[1] Assuming 100 oral absorption. The default assessment factor of 100 is obtained from [10 (interspecies variation) x 10 (intraspecies variation)] which is considered appropriate by the active substances' AR.

Maximum residue limits or equivalent

Due that the product ACTIBIOL FOGGING PROFESIONAL is not intended to be applied on facilities where food/ feed or animals can be stored or placed, no MRL is established for the product. In addition, no MRL is also regarded for any of the active substances in the respective AR, because none of them are considered to be used at food/feed stored commodities.

2.2.6.3.1 Risk for industrial users

No risk exposure is foreseen because the product is not intended to be used by industrial users.

2.2.6.3.2 Risk for professional users

The exposure assessment for professional operators is evaluated under the comparison with the proposed $AEL_{long\text{-}term}$ for each active substance as a Risk Characterization Ratio (RCR). If this quotient is above to the trigger value of 100% it will mean an unacceptable risk exposure for human. RCRs have been calculated for each scenario, firstly for each active substance and subsequent for the entire formulation.

Systemic effects

Task/ Scenario	Tier / PPE	Active substance	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
1. M&L	Tier 1 / no PPEs	Etofenprox	3.7	0.011	5.60E-02	509	**No**
		PBO	16	0.2	1.68E-01	84.0	Yes
	Tier 2 / PPE	Etofenprox	3.7	0.011	5.75E-04	5.23	Yes
		PBO	16	0.2	1.73E-03	0.86	Yes
2. Application	Tier 1 / no PPEs	Etofenprox	3.7	0.011	Negligible		Yes
		PBO	16	0.2	Negligible		Yes
3. Post-application	Tier 1 / no PPEs	Etofenprox	3.7	0.011	4.73E-02	430	**No**
		PBO	16	0.2	1.42E-01	71	Yes
	Tier 2 / PPEs	Etofenprox	3.7	0.011	5.64E-03	51	Yes
		PBO	16	0.2	1.69E-02	8	Yes

No unacceptable risk has been identified for different tasks considered when workers wear protective gloves for Scenario 1 and protective gloves and coated coverall for Scenario 3.

Combined scenarios

Scenarios combined	Tier / PPE	Active substance	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
1 + 2 + 3	Tier 1 / no PPEs	Etofenprox	3.7	0.011	1.03E-01	939	**No**
		PBO	16	0.2	3.10E-01	155	**No**
	Tier 2 / PPEs	Etofenprox	3.7	0.011	6.21E-03	56	Yes
		PBO	16	0.2	1.86E-02	9	Yes

No unacceptable risk has been identified for combined tasks considered when workers wear protective gloves and coated coverall.

Local effects

According to the criteria of the Regulation (EC) No 1272/2008, the biocide is proposed to be labelled with EUH066 (repeated exposure may cause dryness or cracking). Therefore, the qualitative assessment of local effects is performed in this section.

Primary Exposure / Professional use

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**
Low	Causes skin dryness (EUH066)	Concentration of 0.475% etofenprox and 1.425% PBO	18	Professional users	Remove the one-shot aerosol cartridge from their packaging, place onto the floor before and press the valve Application of the end-product as space spray application (mist or thermal fog) in indoor areas Post-Application of the biocidal product (re-entry period in the treated room)	Skin RT	More than few minutes but equal to or less than few hours per day	0.475% etofenprox and 1.425% PBO	**Measures to control exposure, such as:** **Technics** - Minimisation of manual phases/work tasks, - Minimisation of splashes and spills; - Avoidance of contact with contaminated tools and objects; - Regular cleaning of equipment and work area; **Organisation** -Management /supervision in place to check that the RMMs in place are being used correctly and OCs followed; - Training for staff on good practice. - Good standard of personal hygiene **<u>Personal protective equipment</u>** - Face shield; - Substance/task appropriate gloves; - protection coverall (EN 13034, 13962, 14605 or 943 according to pattern of exposure)	Acceptable: + Reversible effect. + Experience expected + Professionals following instructions for use;

Qualitative risk assessment

The biocidal product has been allocated to the "Low" hazard category according to the classification as causing skin dryness (EUH066) in the hazard categories proposed in the Guidance for Human Health Risk Assessment & evaluation (Volume III – Part B + C).

Use of the product in the proposed manner (detailed in scenarios 1, 2 & 3) is considered acceptable if the RMM, which have to be used for protection from the skin dryness potential of the fogged product, are described as follows.

Exposure controls

Personal protective equipment:
- Face shield;
- Substance/task appropriate gloves;
- protection coverall (EN 13034, 13962, 14605 or 943 according to pattern of exposure)

Respiratory protection is not considered necessary when loading in adequately ventilated areas. Further, airborne particles are not expected to be formed during loading operations. However, where ventilation is inadequate a suitable substance/task appropriate respirator is considered necessary.

Organisation:

- General safety and hygiene measures:

Do not inhale gases/vapours/aerosols. Avoid contact with the skin, eyes and clothing. Handle in accordance with good industrial hygiene and safety practice. Wearing of closed work clothing is recommended. When using, do not eat, drink or smoke. Hands and/or face should be washed before breaks and at the end of the shift. At the end of the shift the skin should be cleaned and skin-care agents applied. Gloves must be inspected regularly and prior to each use. Replace if necessary (e.g., pinhole leaks).

Conclusion

The estimated systemic exposure to etofenprox and PBO is below the reference value during load the fog-equipment when the professional worker is wearing protective gloves and RMMs for low hazard class chemicals are implemented for minimise exposure or possible health effects from local exposure.

During application no risk of exposure is foreseen since the treatment itself is performed in the absence of the user and during most of the time that aerosol droplets may still be present in the room the user is absent.

Finally, during re-entry period in the treated room, for ventilation following application and/or equipment malfunction during application phase, the professional worker's exposure to etofenprox and PBO is estimated to be below the $AEL_{long\text{-}term}$ and therefore acceptable when the professional worker is wearing protective gloves and coated coverall. In addition, RMMs for low hazard class chemicals are implemented in order to prevent any contact with the end-product.

Therefore, to prevent any potential risk by its use, the following IfU/RMMs should be included in the label:

- *The product must be used only indoors at confined spaces.*
- *The treated premises must be closed and signposted in order to prevent the entry of people during their application.*
- *Wear protective chemical resistant gloves meeting the requirements of European Standard EN 374 during product handling / re-entry phase (glove material to be specified by the authorisation holder within the product information).*
- *Wear a protective coverall [type 6, EN 13034 or type 3, EN 14605 or type 4, EN 14605 or type 5, EN ISI 12982-1] during re-entry phase.*
- *Avoid contact with eyes/skin.*
- *Always that can be possible, treated premises must be ventilated thoroughly before the re-entrance.*
- *Wash hands after handling the product and before eating, drinking and / or smoking.*

2.2.6.3.3 Risk for non-professional users

The product is not intended to be applied by non-professional users hence, it is not necessary assessed.

2.2.6.3.4 Risk for the general public

Systemic effects

Task/ Scenario	Tier	Active substance	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
4. Inhalation of Volatilised Residues	Tier 1	Etofenprox	3.7	0.011	Negligible		Yes
		PBO	16	0.2	Negligible		Yes
5. Toddlers playing/crawling on treated surfaces	Tier 1	Etofenprox	3.7	0.011	1.45E-02	132	**No**
		PBO	16	0.2	4.36E-02	22	Yes
	Tier 2	Etofenprox	3.7	0.011	3.75E-04	3.41	Yes
		PBO	16	0.2	1.15E-03	0.58	Yes
6. Adults playing/crawling on treated surfaces	Tier 1	Etofenprox	3.7	0.011	9.21E-03	84	Yes
		PBO	16	0.2	2.76E-02	14	Yes
	Tier 2	Etofenprox	3.7	0.011	2.43E-03	22	Yes
		PBO	16	0.2	4.55E-03	2	Yes
7. Laundering working clothes	Tier 1	Etofenprox	3.7	0.011	3.93E-04	4	Yes
		PBO	16	0.2	1.18E-03	0.59	Yes

After the Scenario 5 has been refined (Tier 2), no unacceptable risk has been identified for different tasks considered.

Combined scenarios

Scenarios combined	Tier	Active substance	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
1 + 2 + 3 + 6 + 7	Tier 2 [1, 2 & 3] Tier 2 [6] Tier 1 [7]	Etofenprox	3.7	0.011	9.03E-03	82	Yes
		PBO	16	0.2	2.44E-02	12	Yes

After the Scenario 6 has been refined (Tier 2), unacceptable risk has been identified for combined tasks considered.

Local effects

According to the criteria of the Regulation (EC) No 1272/2008, the biocide is proposed to be labelled with EUH066 (repeated exposure may cause dryness or cracking). Therefore, the qualitative assessment of local effects is performed in this section.

Qualitative risk assessment

The biocidal product has been allocated to the "Low" hazard category according to the classification as causing skin dryness (EUH066) in the hazard categories proposed in the Guidance for Human Health Risk Assessment & evaluation (Volume III – Part B + C).

Use of the product in the proposed manner (detailed in scenarios 3, 4, 5 & 6) is considered acceptable if the RMM, which have to be used for protection from the skin dryness potential of the fog product, are described as follows.

Exposure controls

Risk mitigation measures:

- Labelling.
- Instructions for use that minimise exposure or possible health effects.

Conclusion

Based on the results obtained in the risk assessment, the exposure of general public results in level of exposure less than the relevant reference values for systemic exposure after refinement of the scenarios 5 & 6.

Moreover, exposure should be controlled through risk mitigation measures: labelling, instructions for use that minimise exposure or possible health effects in case of local exposure.

Therefore, to prevent any potential risk by its use, the following IfU/RMMs should be included in the label:

- *Avoid contact to treated surfaces/areas, in particular by children.*
- *Always read the label or leaflet before use and follow all the instructions provided.*

2.2.6.3.5 Risk for consumers via residues in food

As it was mentioned before in the section of dietary exposure, ACTIBIOL FOGGING PROFESIONAL is not intended to be applied on places where food/feed can be stored so exposure to residues over food or feeding stuff is not foreseen and must always be avoided.

In addition, to prevent any potential risk by its use, the following RMMs are included:

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

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

Cumulative risk assessment is performed according to Guidance on the BPR: Volume III, Assessment & Evaluation (Parts B+C), Version 2.1 – February 2017, (pp 261 & Appendix 4.7, pp 293).

Preliminary step:

Piperonyl butoxide
The mode of action of Piperonyl Butoxide is complex. According to the literature, 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.

Etofenprox
Etofenprox is an insecticide acting by direct contact and ingestion. It acts on sodium channels of the insect nervous system by disturbing the normal neurotransmittance.

Given their mode of action we can assume that there is indication of synergy within active substances.

A summary of systemic exposures for the scenarios assessed are shown in section 2.2.6.2.

TIER 1 and TIER 2:

Tier 1 is an intermediary step to verify risk acceptability for each active ingredient used in the product, as currently performed. It is followed by Tier 2, which involves assessing the combined exposure to the substances of the mixture/biocidal product.

For the toxicological section, primary exposure of professionals has been considered and exposure estimations were compared to the chronic AEL for etofenprox and PBO. Secondary exposure for adults/toddlers was performed according to long term scenarios using chronic AEL.

Results of Tier 1 / 2 assessments are shown in the following table.

Primary exposure: Professional, chronic exposure

M&L without PPE	etofenprox	PBO	conclusion

Tier 1	509 %AEL	84 %AEL	Not Acceptable
Tier 2	5.09	0.84	Not acceptable
	HI = 5.93		
M&L with PPE	**etofenprox**	**PBO**	**conclusion**
Tier 1	5.23 %AEL	0.83 %AEL	Acceptable
Tier 2	5.23E-02	8.30E-03	Acceptable
	HI = 6.06E-02		
Application by fogging	**etofenprox**	**PBO**	**conclusion**
Tier 1	Negligible	Negligible	Acceptable
Tier 2	Negligible	Negligible	Acceptable
	HI = 0.00		
Post-application without PPEs	**etofenprox**	**PBO**	**conclusion**
Tier 1	430 %AEL	71 %AEL	Not acceptable
Tier 2	4.30	0.71	Not acceptable
	HI = 5.01		
Post-application with PPEs	**etofenprox**	**PBO**	**conclusion**
Tier 1	51 %AEL	8 %AEL	Acceptable
Tier 2	0.51	0.08	Acceptable
	HI = 0.59		
M&L + Application + Post-application without PPE	**etofenprox**	**PBO**	**conclusion**
Tier 1	939 %AEL	155 %AEL	Not acceptable
Tier 2	9.39	1.55	Not acceptable
	HI = 10.94		
M&L + Application + Post-application with PPE	**etofenprox**	**PBO**	**conclusion**
Tier 1	56 %AEL	9 %AEL	Acceptable
Tier 2	0.56	0.09	Acceptable
	HI = 0.65		

Indirect exposure: adult, chronic exposure

Inhalation of Volatilized Residues	**etofenprox**	**PBO**	**conclusion**
Tier 1	Negligible	Negligible	Acceptable
Tier 2	Negligible	Negligible	Acceptable
	HI = 0.00		
Adults playing/crawling on treated surfaces refined	**etofenprox**	**PBO**	**conclusion**
Tier 1	22 %AEL	2 %AEL	Acceptable
Tier 2	0.22	0.02	Acceptable
	HI = 0.24		

Indirect exposure: toddler, chronic exposure

Toddlers playing/crawling on treated surfaces refined	etofenprox	PBO	conclusion
Tier 1	3.41 %AEL	0.58 %AEL	Acceptable
Tier 2	0.0341	0.0058	Acceptable
	HI = 0.04		

Indirect exposure: adult, chronic exposure

Laundering working clothes	etofenprox	PBO	conclusion
Tier 1	17 %AEL	2.8 %AEL	Acceptable
Tier 2	0.17	0.028	Acceptable
	HI = 0.20		

Combined exposure: adult, chronic exposure

M&L + Application + Post-Application with PPE + Adults playing/crawling on treated surfaces refined	etofenprox	PBO	conclusion
Tier 1	82 %AEL	12 %AEL	Acceptable
Tier 2	0.82	0.12	Acceptable
	HI = 0.94		

Conclusion:

For (trained) professional use:

TIER I: Risk assessment is not acceptable for each substance individually in the product without PPE but is acceptable with gloves and coated coverall for all tasks and combined tasks studied.

TIER 2: Mixture Risk assessment is not acceptable in T2 without PPE but is acceptable with gloves and coated coverall for all tasks and combined tasks studied.

For the indirect exposure:

TIER I: Risk assessment is acceptable for each substance individually in the product after refining.

TIER 2: Mixture risk assessment is acceptable in T2 after refining.

For all combined task exposure:

TIER I: Risk assessment is acceptable for each substance individually for all combined tasks studied.

TIER 2: Mixture Risk assessment is also acceptable in T2.

Therefore, no unacceptable risk has been identified for all tasks considered when workers wear protective gloves and coated coverall.

2.2.7 Risk assessment for animal health

ACTIBIOL FOGGING PROFESIONAL is not intended to be used against any vertebrate animal. It is specified to be only used against insects indoors at sealed premises without the presence of food/feed, animals or human, then when it is applied indoor no risk for the animal is likely.

In addition, to prevent any potential risk by its use, the following RMMs are included:

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

2.2.8 Risk assessment for the environment

The current environmental risk assessment of ACTIBIOL FOGGING PROFESIONAL is based on both active substances data published on each respective CAR. According to product's formulation no substance of concern is deemed for environment. Hence, the environmental risk assessment is focused in Etofenprox and its relevant metabolites for the environment (α-CO and 4'-OH) and PBO and its relevant metabolites for the environment (M1, M2, M8, M12 and EN 1-101/4).

Intended use	Categories of user	Field of use	Type of application	Scope of use	Target animal
#1	Trained Professional	Indoor	Hot Fogging	Difficult-to-access areas and rarely used rooms at household and industrial premises	Crawling insects
#2	Trained Professional	Indoor	Cold Fogging	Difficult-to-access areas and rarely used rooms at household and industrial premises	Crawling insects

For all the uses, the rate of application is:

- Hot/Cold 262 mL/ 1000 m^3 (density of 0.7671 g/ml -> 0.2 g product /m^3)

So, taking into account the active substance concentration, the following application rates are deemed for the active substances:

	Etofenprox	PBO
Hot/Cold Fogging	9.55E-07 kg/m^3	2.85E-06 kg/m^3

Risk assessment for the environment has been performed according requirements and approaches of Biocidal Products Regulation (BPR) (EU) No 528/2012. Moreover, the assessment has been performed following ECHA Guidance on the BPR: Volume IV

Environment, Assessment & Evaluation (Parts B+C), Version 2.0, October 2017.

2.2.8.1 Effects assessment on the environment

Etofenprox is regarded as hydrolytically stable at environment and it was not shown to be readily biodegradable in the aquatic compartment. With regard to the formation of metabolites in aquatic systems, two major metabolites – α–CO and 4'-OH– were detected in the CAR at significant concentrations (i.e. >10 %) in the water-sediment degradation study. Maximum formation of α–CO reached 63.5% in water and did not exceed 21.4% for the 4'OH in sediment.

On the other hand, Piperonyl Butoxide is hydrolytically stable in solution in the dark at 25°C at pH 5, 7 and 9 and its half-life under these conditions is greater than 500 days. According to OECD 301 B, PBO is classified as not readily biodegradable. Five major PBO's metabolites are considered of concern for the environment. Hence, the ecotoxicological properties of Piperonyl Butoxide major aquatic/sediment (M-1, M-2, M-12 (or EN 1-93/3)) and soil (M-1, M-2, M-8, M-12 (or EN 1-93/3), EN 1-101/4 (or Metabolite F)) metabolites have been taken into account in the environmental risk assessment of ACTIBIOL FOGGING PROFESIONAL.

The following table summarizes the % of each metabolite from its parent compound in each environmental compartment.

	Etofenprox		***PBO***				
	4'-OH	**α-CO**	**M1**	**M2**	**M8**	**M12**	**Metabolite F**
Soil	-*	-*	5.9%	14.4%	9%	19.4%	6.6%
Surfacewater	-	63.6%	7.6%	40.7%	-	6.6%	-
Sediment	21.4%	-			-		-

For the assessment, the molar weight of each metabolite has been considered in the estimation of PECs values:

Molar mass (g/mol)	393	299	252.29	296.32	356.38	208.22	340.38

PEC metabolite = PEC parent x formation fraction x (molar weight metabolite / molar weight parent).

An overview for the PNECs for the active substances and its relevant metabolites are given in the tables below:

Summary of PNECs values: Etofenprox

Etofenprox			
	Value	**Unit**	**Note and reference**
$PNEC_{STP}$	2.25E-02	mg/L	CAR active substance.
$PNEC_{aquatic\ Freshwater}$	5.40E-06	mg/L	CAR active substance.
$PNEC_{sediment\ of\ freshwater}$	6.30E-03	mg/kg wwt	CAR active substance.
$PNEC_{soil}$	6.33E-03	mg/kg wwt	ENV WGIV2016*
$PNEC_{oral,birds}$	33.3	mg/kg feed	CAR active substance.
$PNEC_{oral,mammals}$	24.7	mg/kg feed	CAR active substance.
α–CO			
$PNEC_{STP}$	n.r.	-	-

$PNEC_{aquatic\ Freshwater}$	4.40E-05	mg/L	CAR active substance.
$PNEC_{sediment\ of\ freshwater}$	n.r.	-	-
$PNEC_{soil}$	n.r.	-	-
$PNEC_{oral,birds}$	n.r.	-	-
$PNEC_{oral,mammals}$	n.r.	-	-
4'-OH			
$PNEC_{STP}$	n.r.	-	-
$PNEC_{aquatic\ Freshwater}$	n.r.	-	-
$PNEC_{sediment\ of\ freshwater}$	1.20E-02	mg/kg wwt	CAR active substance.
$PNEC_{soil}$	n.r.	-	-
$PNEC_{oral,birds}$	n.r.	-	-
$PNEC_{oral,mammals}$	n.r.	-	-

* According to the available data in the CAR, a $PNEC_{soil}$ of 1.79 x 10^{-2} mg a.i./kg $_{wet\ soil}$ (eq. to 2.024 x 10^{-2} mg a.i./kg $_{dry\ soil}$) with an assessment factor of 100 was validated for the etofenprox approbation. However, at the ENV WGIV2016 was discussed the new data about etofenprox toxicity for soil organisms and a $NOEC_{TWA}$ of 0.357 mg $_{a.i.}$/kg $_{dry\ soil}$ and AF of 50 were used to calculate the PNEC soil $PNEC_{soil}$ = 7.15 x 10^{-3} mg $_{a.i.}$/kg $_{dry\ soil}$ ($PNEC_{soil}$ = 6.33 x 10^{-3} mg $_{a.i.}$/kg $_{wet\ soil}$).

Summary of PNECs values: PBO

PBO			
	Value	**Unit**	**Note and reference**
$PNEC_{STP}$	2.89	mg/L	CAR active substance.
$PNEC_{aquatic\ Freshwater}$	0.00148	mg/L	CAR active substance.
$PNEC_{sediment\ of\ freshwater}$	0.00933	mg/kg wwt	ENV WGV2019*
$PNEC_{soil}$	0.098	mg/kg wwt	CAR active substance.
$PNEC_{oral,birds}$	10	mg/kg feed	CAR active substance.
$PNEC_{oral,mammals}$	20	mg/kg feed	CAR active substance.
BCF_{fish}	290	L/kg	CAR active substance.
$BCF_{earthworm}$	757	L/kg	CAR active substance.
BMF	1		CAR active substance.
Metabolite of PBO: M1			
	Value	**Unit**	**Note and reference**
$PNEC_{STP}$	n.r.	-	PNEC value not available.
$PNEC_{aquatic\ Freshwater}$	0.0028	mg/L	CAR active substance.
$PNEC_{sediment\ of\ freshwater}$	n.r.	-	-
$PNEC_{soil}$	0.098	mg/kg wwt	PNEC of parent compound, as reported in CAR of PBO.
Metabolite of PBO: M2			
	Value	**Unit**	**Note and reference**
$PNEC_{STP}$	n.r.	-	-
$PNEC_{aquatic\ Freshwater}$	0.0033	mg/L	CAR active substance.
$PNEC_{sediment\ of\ freshwater}$	n.r.	-	-
$PNEC_{soil}$	0.098	mg/kg wwt	PNEC of parent compound, as reported in CAR of PBO.
Metabolite of PBO: M8			
	Value	**Unit**	**Note and reference**
$PNEC_{STP}$	n.r.	-	-
$PNEC_{aquatic\ Freshwater}$	n.r.	-	-
$PNEC_{sediment\ of\ freshwater}$	n.r.	-	-

$PNEC_{soil}$	0.098	mg/kg wwt	PNEC of parent compound, as reported in CAR of PBO.
Metabolite of PBO: M12			
	Value	**Unit**	**Note and reference**
$PNEC_{STP}$	n.r.	-	-
$PNEC_{aquatic\ Freshwater}$	0.0023	mg/L	CAR active substance.
$PNEC_{sediment\ of\ freshwater}$	n.r.	-	-
$PNEC_{soil}$	0.098	mg/kg wwt	PNEC of parent compound, as reported in CAR of PBO.
$PNEC_{oral,birds}$	10	mg/kg feed	PNEC of parent compound, as reported in CAR of PBO.
$PNEC_{oral,mammals}$	20	mg/kg feed	PNEC of parent compound, as reported in CAR of PBO.
BCF_{fish}	89.5	L/kg	CAR active substance.
$BCF_{earthworm}$	15.8	L/kg	CAR active substance.
BMF	1		CAR active substance.
Metabolite of PBO: EN 1-101/4			
	Value	**Unit**	**Note and reference**
$PNEC_{STP}$	n.r.	-	-
$PNEC_{aquatic\ Freshwater}$	n.r.	-	-
$PNEC_{sediment\ of\ freshwater}$	n.r.	-	-
$PNEC_{soil}$	0.098	mg/kg wwt	PNEC of parent compound, as reported in CAR of PBO.

***** At the ENV WGV2019, the PNECsed was re-calculated based on the lowest endpoint from the C. riparius study and an assessment factor of 10 which provides a PNEC of 0.04292 mg a.s. /Kg dwt (0.00933 mg a.s. /Kg wwt), since with the addition of the new Lumbriculus study the long-term tests with species representing different living and feeding conditions are three.

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

No studies have been performed with the formulated product and the classification presented in this report relies on the ecotoxicity data available for both active substances.

Since Etofenprox and PBO are very toxic compared to other substances in the formulation, no other constituent apart from the active substances has an influence on the environmental classification and labelling of the product.

Substance	Classification	%	Acute Tox (M_{factor})	Chronic Tox (M_{factor})
Etofenprox	Aquatic Acute 1, H400; Aquatic Chronic 1, H410	0.475	100	1000
Piperonyl Butoxide (PBO)	Aquatic Acute 1, H400; Aquatic Chronic 1, H410	1.425	1	1

According to CLP Regulation, applying the additivity formula, the toxicity of the mixture is calculated using each substance toxicity values:

a) Acute tox classification

Acute tox category 1 = 0.475*100 + 1.425*1 = 48.25 ≥ 25

The mixture is classified as Aquatic acute 1, H400.

b) Chronic tox classification

Chronic tox category 1 = 0.475*1000 + 1.425*1 = 476.425 ≥ 25%

The mixture is classified as Aquatic chronic 1, H410.

Classification and labelling of the Product ACTIBIOL FOGGING PROFESIONAL	
Value/conclusion	**Aquatic Acute 1 ; H400** **Aquatic Chronic 1 ; H410**

Further Ecotoxicological studies

No data is available on the product. Please refer to active substances' data on correspondent AR.

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

No data is available on the product. Please refer to active substances' data on correspondent AR.

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

No data is available on the product. Please refer to active substances' data on correspondent AR.

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

No data is available on the product. Please refer to active substances' data on correspondent AR.

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

Not applicable.

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

According to the applicant, the product ACTIBIOL FOGGING PROFESIONAL is a ready to use product for use indoors at domestic and industrial premises (e.g. attics, false ceilings, garages, storage rooms, and rooms with low frequency of use).

If the product is intended to be used indoors in difficult-to-access areas at household and industrial premises, areas that are not cleaned at all and not connected to STP (such as false ceilings) the exposure of the different environmental compartments is negligible. However, if the product is used in areas that can be subjected to cleaning although rarely as garages, storage rooms and attics, the environmental compartments could be indirectly exposed by STP. Therefore, this scenario was taken into account for the risk assessment as the worst case.

Scenarios	Areas	Waste water (STP)	Surface water	Sediment	Soil	Groundwater	Air
Non-cleaned premises	False ceilings or any other difficult-to-access storage premises	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant
Premises that can be potentially cleaned **Scenario [1]**	Attics used for storage, garages and storage rooms	Yes (direct)	Yes (indirect)	Yes (indirect)	Yes (indirect)	Yes (indirect)	Not relevant

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

At first view, no further studies are regarded necessary. Information on the active substances is considered enough for the environmental risk assessment of the product. Moreover, the product does not contain any other substance deemed of concern to the environment other than the active substances.

Leaching behaviour (ADS)

No new data is deemed necessary.

Testing for distribution and dissipation in soil (ADS)

No further data is deemed necessary.

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

No further data is deemed necessary.

Testing for distribution and dissipation in air (ADS)

Not required as active substances are regarded as not volatile and the intended indoor use does not let the distribution of the residues in the atmosphere.

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

The product is not intended to be applied near surface waters or water sources. It must be applied only indoors.

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)

As the product is used exclusively indoors, the exposure and risk of bees and other arthropods is considered negligible.

Synergistic effects between the components of the product

The mode of action of Piperonyl Butoxide is complex. According to the literature, 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 (detoxification) 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 may be 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.

As stated in the ECHA Guidance, Volume IV Environment, Parts B+ C, v.2. (October 2017) about synergism effects, Tier 4 should be used if product tests are not already available. These tests should only be employed in situations, where well-founded suspicions for synergistic interactions require clarification, or as last option where results of predictive modelling (tiers 1-3) indicate unacceptable risks for environment. In these cases the most sensitive species from the single substance data should be tested.

Piperonyl butoxide increases the toxicity of other biocides e.g. pyrethrins, pyretroids or carbamates by inhibiting their cytochrome P450-driven metabolization. However, no evidence of increased toxicity is available for the combination of this substance with Etofenprox.

Furthermore, it should be taken into account whether there are direct emissions to water and soil which is not the case for this product.

Therefore, based on the lack of evidence of any increase of toxicity of Etofenprox in the presence of Piperonyl butoxide and considering that no direct emissions to water or soil occur after product application, the applicant considered that animal testing with the product is not sufficiently justified, specially considering the restricted uses that can be authorised.

So, from this argument, it can be concluded that synergistic effects are not relevant for the authorisation of this product.

Endocrine-disrupting properties for environment: screening for co-formulants

The biocidal product contains the active substance etofenprox, which has not yet been evaluated according to the scientific criteria set out in the Regulation (EU) No 2017/2100.

According to BPC opinion, Piperonyl Butoxide is not considered to have endocrine disrupting properties and there is no indication for endocrine disrupting properties of the co-formulants of the product.

Further information can be found in the confidential annex to the PAR.

2.2.8.2 Exposure assessment

General information

Assessed PT	PT 18
Assessed scenarios	**Scenario [1]** *Air space treatment with wet cleaning methods after product's application in garages or any storage room subjected to be cleaned, at industrial and domestic premises where the potential risk is assessed.*
ESD(s) used	- ESD for insecticides, acaricides and products to control other arthropods (PT18) for household and professional uses' ENV/JM/MONO(2008)14 (ESD 2008)

	- Technical Agreements for Biocides Environment (TAB ENV), October 2022.
Approach	• Scenario 1: Average consumption
Distribution in the environment	All emission scenarios have been developed from EUSES 2.2.0 program. Calculated based the Volume IV Part B+C (2017)
Groundwater simulation	No
Confidential Annexes	Yes
Life cycle steps assessed	- Production: No - Formulation No - Use: Yes - Service life: No

The following table summarizes the scenarios considered in the environmental risk assessment and their correspondence with the intended uses established in section 2.1.4 of the current dossier:

Scenarios	Uses #[1]	Indoor / Outdoor	User	Type of application	EUSES scenario	Target pest	Application rate	
							Etofenprox	PBO
[1]	#1 & #2	Indoor	P	Fogging (air space application)	18.2.1	Crawling insects[2]	9.55E-07 kg/m^3	2.85E-06 kg/m^3

P: Professional.
[1] As indicated in the section 2.1.4 Authorized uses.
[2] Flies deemed as worst case in EUSES program.

2.2.8.2.1 Emission estimation

Under the above assumptions, the following emission estimation has been calculated for the disinfestation by fogging on domestic and industrial premises considering wet cleaning methods after application in garages and accesible storage rooms.

Scenario [1]: disinfestation by fogging treatment of domestic and industrial premises considering wet cleaning methods after application.

For each compartment, the following parameters have been considered in the environmental risk assessment for each active substance **when "wet" cleaning methods are done**:

Resulting local emission to relevant environmental compartments		
Compartment	Percentage [%] fate and distribution in the STP	
	Etofenprox*	PBO
Air	0.00	0.00002
Water	1.51	75.82
Sludge	92.8	24.18
Degraded in STP	5.9	0

***** Agreed at WGIV 2016 (post approval)

Scenario [1]: disinfestation by air space treatment of domestic and industrial premises considering wet cleaning methods after application.

The following table summarize the input parameters for this scenario:

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 1: Indoor disinfestation by fogging treatment			
Fraction of substance in commercial product			Concentration in the product:
PBO	0.01425	[-]	PBO: 1.425 % w/w
Etofenprox	0.00475	[-]	Etofenprox: 0.475 % w/w

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 1: Indoor disinfestation by fogging treatment			
Representative pest considered	Flies	[-]	As representative **worse case** of fleas, carpet beetle, cloth moths and cockroaches
Selected treatment	Air space	[-]	"Whole house / air space treatment" selected as a **worse case**
Total volume treated… in a standard house in a large building	 325 2436	 m^3 m^3	ESD PT18 defauls
Wet cleaning zone… in a standard house in a large building	 38.5 180	 m^2 m^2	ESD PT18 defauls
Number of standard houses connected to the same STP	4000	[-]	ESD PT18 defauls
Number of large buildings connected to the same STP	300	[-]	ESD PT18 defauls
Container type/volume considered	Nebulizer/20	L	20L is the maximum size of containers
Quantity of commercial product applied per m^3	0.2	g/m^3	262ml $_{product}$ /1000m^3 and a density of 0.7671g/ml
Number of applications per day In a standard house In a large building	 1 1	 [-] [-]	ESD PT18 defauls
Frequency of application in standard houses and large buildings	1-2 times a year	[-]	This means a simultaneity factor of 0.002042 ESD PT18
Cleaning efficiency	1	[-]	Wet method ENV 149 (TAB,2022)
Applicator coveralls	Washable	[-]	It can be also disposable, if indicated in the label as a restriction for the use of this product. Washable has been indicated as a worse case.

Calculations for Scenario [1]

The following table summarizes the ways of emission to the environment obtained from ECHA ESD PT18 for each active substance (Indoor Spraying_Flies_Air Space_Whole house):

Etofenprox

Local emission [kg.d^{-1}]	Professional use	
	Standard houses	Large buildings
Emissions during Mixing/loading		
Local emission to air	0.00E+00	0.00E+00
Local emission to applicator	0.00E+00	0.00E+00
Local emission to floor	0.00E+00	0.00E+00
Emissions during application step		
Local emission to air	2.95E-08	2.21E-07
Local emission to applicator	2.95E-08	2.21E-07
Local emission to floor	1.42E-06	1.06E-05
Local emission to treated surfaces	0.00E+00	0.00E+00
Emissions during cleaning residues of mixing/loading		
Local emission to wastewater from washing applicators' coveralls	0.00E+00	0.00E+00
Local emission to wastewater from wet cleaning the floor	0.00E+00	0.00E+00
Emissions during cleaning residues from application		
Local emission to wastewater from washing applicators' coveralls	2.95E-08	2.21E-07
Local emission to wastewater from wet cleaning the floor	4.25E-07	3.18E-06
Local emission to wastewater from wet cleaning the treated surfaces	0.00E+00	0.00E+00

TOTAL emission	Professional use
Local emission to air	3.76E-07
Local emission to wastewater	5.79E-06

PBO

Local emission [kg.d^{-1}]	Professional use	
	Standard houses	Large buildings
Emissions during Mixing/loading		
Local emission to air	0.00E+00	0.00E+00
Local emission to applicator	0.00E+00	0.00E+00
Local emission to floor	0.00E+00	0.00E+00
Emissions during application step		
Local emission to air	2.64E-07	1.98E-06
Local emission to applicator	2.64E-07	1.98E-06
Local emission to floor	1.27E-05	9.50E-05

Local emission [kg.d^{-1}]	**Professional use**	
	Standard houses	**Large buildings**
Local emission to treated surfaces	0.00E+00	0.00E+00
Emissions during cleaning residues of mixing/loading		
Local emission to wastewater from washing applicators' coveralls	0.00E+00	0.00E+00
Local emission to wastewater from wet cleaning the floor	0.00E+00	0.00E+00
Emissions during cleaning residues from application		
Local emission to wastewater from washing applicators' coveralls	2.64E-07	1.98E-06
Local emission to wastewater from wet cleaning the floor	3.80E-06	2.85E-05
Local emission to wastewater from wet cleaning the treated surfaces	0.00E+00	0.00E+00

TOTAL emission	**Professional use**
Local emission to air	3.37E-06
Local emission to wastewater	5.19E-05

2.2.8.2.2 Fate and distribution in exposed environmental compartments

Releases into the environment can take place from processes at any stage of the life-cycle of substances. However, as a worse case, the local scale environmental emissions associated **with wet-cleaning methods** after the indoor use for ACTIBIOL FOGGING PROFESIONAL, are considered for PECs calculations. The direct routes of potential environmental exposure are summarized in the following table according with the intended use of the biocidal product:

Identification of relevant receiving compartments based on the exposure pathway								
Scenarios	**Areas**	**Wastewater (STP)**	**Surface water**	**Sediment**	**Soil**	**Groundwater**	**Air**	**Non-targeted biota**
Non-cleaned premises	False ceilings, non-used garages or any other difficult-to-access storage	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant

	premises							
Premises that can be potentially cleaned **Scenario [1]**	Attics, garages and storage rooms	Yes (direct)	Yes (indirect)	Yes (indirect)	Yes (indirect)	Yes (indirect)	Not relevant	Not relevant

n.r. not relevant.

The following table shows some of the input parameters considered in the environmental assessment for each active substance:

Input parameters (only set values) for calculating the fate and distribution of Etofenprox in the environment			
Input	**Value**	**Unit**	**Remarks**
Molecular weight	376.47	g/mol	
Melting point	37.4 ± 0.1°C	°C	
Boiling point	>200	°C	
Vapour pressure (at 25ºC)	8.13×10^{-7}	Pa	
Water solubility (at 20°C)	22.5×10^{-3}	mg/l	pH 7
Log Octanol/water partition coefficient	6.9	Log 10	pH 7
Organic carbon/water partition coefficient (Koc)	28 524	l/kg	(Freundlich coefficient)
Henry's Law Constant (at 25º C)	0.0136	$Pa/m^3/mol$	
Biodegradability	No readily biodegradable		
DT_{50} for photolysis in surface water	13.3	d	
DT_{50} for biodegradation in surface water	19.7	d (at 12ºC)	
DT_{50} for biodegradation in sediment	61.1	d (at 12ºC)	
DT_{50} for biodegradation in soil	22.8	d (at 12ºC)	
Specific degradation rate constant with OH radicals	6.216e-11	$cm^3/molec \cdot s$	
BCF fish	2565	$L.kg^{-1}$	
BCF earthworm	95281	$L.kg^{-1}$	EUSES 2.2
BMF	2	-	
Input parameters (only set values) for calculating the fate and distribution of PBO in the environment			
Input	**Value**	**Unit**	**Remarks**
Molecular weight	338.43	g/mol	
Melting point	-10	°C	PBO is a liquid both at ambient temperature and even at – 10 °C
Boiling point	203	°C	at 2.78 mbar
Vapour pressure (at 25ºC)	1.33×10^{-5}	Pa	

Input parameters (only set values) for calculating the fate and distribution of Etofenprox in the environment			
Input	**Value**	**Unit**	**Remarks**
Water solubility (at 20°C)	28.9	mg/L	pH=7
Log Octanol/water partition coefficient	4.8	Log 10	
Organic carbon/water partition coefficient (Koc)	2506.5	L/kg	WGV2019 The WG agreed with the proposed value of Koc=2506.5 mL/g excluding two soil types and using arithmetic mean.
Henry's Law Constant (at 20º C)	1.648×10^{-4}	atm/m^3/mol	
Biodegradability	No readily biodegradable		
DT_{50} for biodegradation in surface water	1×10^6	d (at 12ºC)	
DT_{50} for hydrolysis in surface water	1×10^6	d (at 12ºC /pH)	
DT_{50} for photolysis in surface water	1×10^6	d	
DT_{50} for degradation in soil(1)	58.3	d (at 12ºC)	
DT_{50} for degradation in air	3.597	h	

(1) In general, a normalised geometric mean value of 58.3 days should be considered for risk assessment purposes (CAR PBO)

2.2.8.2.3 Calculated PEC values

Calculations for Scenario [1] have been developed by EUSES 2.2.0 either for domestic and industrial uses except secondary poisoning calculated in the following section:

***Etofenprox* Summary table on calculated PEC values**								
Scenarios	**PEC_{STP}**	**PEC_{sw}**	**PEC_{sed}**	**$PEC_{soil\ 30d\_agric}$**	**PEC_{GW}**	**PEC_{air}**	**PEC_{Fish}**	**$PEC_{Earthworm}$**
	[mg/L]	[mg/L]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[mg.L_{-1}]	[mg/m^3]	[mg.kg^{-1}]	[mg.kg^{-1}]
Industrial and domestic scenarios								
[1]- Professional	7.33E-07	7.03E-08	4.36E-05	5.12E-06	2.82E-09	8.60E-11	3.61E-04	2.42E-04

***PBO* Summary table on calculated PEC values**								
Scenarios	**PEC_{STP}**	**PEC_{sw}**	**PEC_{sed}**	**$PEC_{soil\ 30d\_agric}$**	**PEC_{GW}**	**PEC_{air}**	**PEC_{Fish}**	**$PEC_{Earthworm}$**
	[mg/L]	[mg/L]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[mg.L_{-1}]	[mg/m^3]	[mg.kg^{-1}]	[mg.kg^{-1}]

Industrial and domestic scenarios								
[1]- Professional	1.97 E-05	1.96 E-06	1.08E-04	1.93E-05	2.13 E-07	7.70E-10	5.68E-04	1.47E-04

- ***Etofenprox metabolites***

The main metabolite in surface water is α–CO. The highest percentage of α–CO, relatively to the amount of Etofenprox initially applied, was determined to be 63.6%. The PECs of Etofenprox were multiplied by 63.6% to estimate the PECs of the metabolite α–CO according to the Assessment Report of Etofenprox, taking into account a molar mass of 299 g/mol.

In the same way, the amount of the main metabolite in sediment, 4'-OH was set considering the highest percentage of 4'-OH relatively to the amount of Etofenprox initially applied (21.4%).The PECs of Etofenprox were multiplied by 21.4% to estimate the PECs of the metabolite 4'-OH according to the Assessment Report of Etofenprox, taking into account a molar mass of 393 g/mol.

PEC metabolites for Etofenprox:

Summary table on calculated PEC values for Etofenprox metabolites		
Scenarios	**PECsw_α–CO**	**PECsed_4'-OH**
	[mg/L]	[mg/kg_{wwt}]
Industrial and domestic scenarios		
[1]- Professional	3.55E-08	9.75E-06

- ***PBO metabolites***

Soil compartment is assessed taken into account the five main metabolites of PBO. Moreover, PEC values for aquatic compartment are estimated for metabolites, M1, M2 and M12. Exposure for secondary poisoning is only considered of concern for Metabolite M12.

	PBO				
	M1	**M2**	**M8**	**M12**	**Metabolite F**
Soil	5.9%	14.4%	9.9%	19.4%	6.6%
Surfacewater	7.6%	40.7%	-	6.6%	-
Sediment			-		-
Molar mass (g/mol)	252.29	296.32	356.38	208.22	340.38

PEC metabolites for PBO:

M1:

Summary table on calculated PEC values			
Scenarios	**$PECs_w$**	**$PEC_{soil\ 30d\_agric}$**	**PEC_{GW}**
	[mg/L]	[mg/kg_{wwt}]	[$mg.L^{-1}$]
[1]- Professional	1.11E-07	8.49E-07	9.37E-09

M2:

Summary table on calculated PEC values			
Scenarios	**$PECs_w$**	**$PEC_{soil\ 30d\_agric}$**	**PEC_{GW}**
	[mg/L]	[mg/kg_{wwt}]	[$mg.L^{-1}$]
[1]- Professional	6.98E-07	2.43E-06	2.69E-08

M8:

Summary table on calculated PEC values		
Scenarios	**$PEC_{soil\ 30d\_agric}$**	**PEC_{GW}**
	[mg/kg_{wwt}]	[$mg.L^{-1}$]
[1]- Professional	1.83E-06	2.02E-08

M12:

Summary table on calculated PEC values					
Scenarios	**$PECs_{w}$**	**$PEC_{soil\ 30d\_agric}$**	**PEC_{GW}**	**PEC_{fish}**	**$PEC_{earthworm}$**
	[mg/L]	[mg/kg_{wwt}]	[$mg.L^{-1}$]	[mg/kg]	[mg/kg]
[1]_Tier [1]_Professional	7.96E-08	2.30E-06	2.54E-08	7.12E-06	5.95E-06

EN 1-101/4:

Summary table on calculated PEC values		
Scenarios	**$PEC_{soil\ 30d\_agric}$**	**PEC_{GW}**
	[mg/kg_{wwt}]	[$mg.L^{-1}$]
[1]_Tier [1]_Professional	1.28E-06	1.41E-08

2.2.8.2.4 Primary and secondary poisoning

No primary or secondary poisoning is considered relevant after product application as the treatment is only developed indoors in rarely used facilities without ventilation so the likely to reach the environment is negligible.

The log Kow of the active substances Etofenprox (log Pow =6.9) and PBO (log Pow = 4.8) shows that both substances have a potential of bioaccumulation and is expected to enter the food chain. Therefore, a risk of secondary poisoning of birds and/or mammals via ingestion of contaminated food (e.g. earthworms or fish) could be expected in case treated surfaces are cleaned as it can occurs in some of the premises intended to be treated such as garage and some store facilities, and were assessed in the present dossier. Therefore, considering a worse case scenario where a miuse of the product occurs (not recommended in the label) and treated surfaces are cleaned using wet methods, mammals and birds may consume contaminated worms from the contaminated soil (indirect exposure from STP). The concentration of the active substance in earthworms is calculated according to the Guidance for BPR IV-B.

Calculated PECs for fish eating organisms

All calculations below were performed according to Eq. 95 of the Guidance:

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

Etofenprox

Variable/parameter (unit)		Symbol	Unit	Value	Source
Predicted Environmental Concentration in fish-eating predators	*Professional*	$PEC_{oral,\ fish\text{-}eating\ predator}$	[$mg.kg_{wet\ fish}^{-1}$]	3.61E-04	Output
Predicted Environmental Concentration in water	*Professional*	PEC_{water}	[$mg.L^{-1}$]	7.03E-08	Input
Bioconcentration Factor for fish on wet weight basis		BCF_{fish}	[$L.kg_{wet\ fish}^{-1}$]	2565 ([1])	Input
Biomagnification factor in fish		*BMF*	[-]	2 ([2])	Default

[1] According to CAR of Etofenprox.
[2] According to CAR of Etofenprox

PBO

Variable/parameter (unit)		Symbol	Unit	Value	Source
Predicted Environmental Concentration in fish-eating predators	*Professional*	$PEC_{oral,\ fish\text{-}eating\ predator}$	[$mg.kg_{wet\ fish}^{-1}$]	5.68E-04	Output
Predicted Environmental Concentration in water	*Professional*	PEC_{water}	[$mg.L^{-1}$]	1.96E-06	Input
Bioconcentration Factor for fish on wet weight basis		BCF_{fish}	[$L.kg_{wet\ fish}^{-1}$]	290 ([1])	Input

Biomagnification factor in fish	*BMF*	[-]	1 ([2])	Default

[1] According to CAR of PBO.
[2] According to CAR of PBO.

Metabolite M-12

Variable/parameter (unit)		**Symbol**	**Unit**	**Value**	**Source**
Predicted Environmental Concentration in fish-eating predators	*Professional*	$PEC_{oral,\ fish\text{-}eating\ predator}$	[$mg.kg_{wet\ fish}^{-1}$]	7.12E-06	Output
Predicted Environmental Concentration in water	*Professional*	PEC_{water}	[$mg.L^{-1}$]	7.96E-08	Input
Bioconcentration Factor for fish on wet weight basis		BCF_{fish}	[$L.kg_{wet\ fish}^{-1}$]	89.5 ([1])	Input
Biomagnification factor in fish		*BMF*	[-]	1 ([2])	Default

[1] According to CAR of PBO.
[2] According to CAR of PBO.

Calculated PECs to worm eating predators

All calculations below were performed according to eq. 100 of the Guidance:

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

Etofenprox

Variable/parameter (unit)		**Symbol**	**Unit**	**Value**	**Source**
Predicted Environmental Concentration in earthworm-eating predators	*Professionals*	$PEC_{oral,\ earthworm\text{-}eating\ predator}$	[$mg.kg_{wet\ earthworm}^{-1}$]	2.42E-04	Output
Concentration in earthworm on wet weight basis	*Professionals*	$C_{earthworm}$	[$mg.kg_{wet\ earthworm}^{-1}$]	2.42E-04	Output
Bioconcentration Factor for earthworms on wet weight basis		$BCF_{earthworm}$	[$L.kg_{wet\ earthworm}^{-1}$]	95281 ([1])	Input
Concentration in porewater	*Professionals*	$C_{porewater}$	[$mg.L^{-1}$]	2.82E-09	Input
Concentration in soil	*Professionals*	C_{soil}	[$mg.kg_{wwt}^{-1}$]	5.12E-06	Input
Fraction of gut loading in worm		F_{gut}	[$kg_{dwt}.kg_{wwt}^{-1}$]	0.1 ([2])	Default
Conversion factor for soil concentration wet-dry weight soil		$CONV_{soil}$	[$kg_{wwt}.kg_{dwt}^{-1}$]	1.13 ([2])	Default

[1] According to Etofenprox CAR.
[2] Default values were obtained from ECHA Guidance on the BPR (October 2017)

PBO

Variable/parameter (unit)		Symbol	Unit	Value	Source
Predicted Environmental Concentration in earthworm-eating predators	*Professionals*	$PEC_{oral,\ earthworm\text{-}eating\ predator}$	[$mg.kg_{wet\ earthworm}^{-1}$]	1.47E-04	Output
Concentration in earthworm on wet weight basis	*Professionals*	$C_{earthworm}$	[$mg.kg_{wet\ earthworm}^{-1}$]	1.47E-04	Output
Bioconcentration Factor for earthworms on wet weight basis		$BCF_{earthworm}$	[$L.kg_{wet\ earthworm}^{-1}$]	757 ([1])	Input
Concentration in porewater	*Professionals*	$C_{porewater}$	[$mg.L^{-1}$]	2.13E-07	Input
Concentration in soil	*Professionals*	C_{soil}	[$mg.kg_{\ wwt}^{-1}$]	1.93E-05	Input
Fraction of gut loading in worm		F_{gut}	[$kg_{dwt}.kg_{wwt}^{-1}$]	0.1 ([2])	Default
Conversion factor for soil concentration wet-dry weight soil		$CONV_{soil}$	[$kg_{wwt}.kg_{dwt}^{-1}$]	1.13 ([2])	Default

[1] According to PBO CAR.
[2] Default values were obtained from ECHA Guidance on the BPR (October 2017)

Metabolite M-12

Variable/parameter (unit)		Symbol	Unit	Value	Source
Predicted Environmental Concentration in earthworm-eating predators	*Professionals*	$PEC_{oral,\ earthworm\text{-}eating\ predator}$	[$mg.kg_{wet\ earthworm}^{-1}$]	5.95E-07	Output
Concentration in earthworm on wet weight basis	*Professionals*	$C_{earthworm}$	[$mg.kg_{wet\ earthworm}^{-1}$]	5.95E-07	Output
Bioconcentration Factor for earthworms on wet weight basis		$BCF_{earthworm}$	[$L.kg_{wet\ earthworm}^{-1}$]	15.8 ([1])	Input
Concentration in porewater	*Professionals*	$C_{porewater}$	[$mg.L^{-1}$]	2.54E-08	Input
Concentration in soil	*Professionals*	C_{soil}	[$mg.kg_{\ wwt}^{-1}$]	2.30E-06	Input
Fraction of gut loading in worm		F_{gut}	[$kg_{dwt}.kg_{wwt}^{-1}$]	0.1 ([2])	Default
Conversion factor for soil concentration wet-dry weight soil		$CONV_{soil}$	[$kg_{wwt}.kg_{dwt}^{-1}$]	1.13 ([2])	Default

[1] According to PBO CAR.
[2] Default values were obtained from ECHA Guidance on the BPR (October 2017)

2.2.8.3 Risk characterisation

PBO is a common substance used in biocides as a synergist and hence, following the Transitional Guidance on mixture toxicity assessment for the environment (2014) a careful evaluation with the available data is indispensable for the risk assessment process under the assumption that the risk assessment should be based on the mixture assessment data as a whole, and then comparable to the ERA for single substances.

Therefore, in order to fulfil with the BPR a mixture toxicity assessment has been developed for ACTIBIOL FOGGING PROFESIONAL deeming the two active substances Etofenprox (0.475% w/w) and PBO (1.425% w/w). Outputs showed that due to the CLP classification of substances of concern, no further risk should be derived from the use of ACTIBIOL FOGGING PROFESIONAL from those already estimated, and hence, the risk assessment estimated by the inclusion of the two active substances as main toxic ingredients must be regarded enough and acceptable for the environmental toxicity of the product.

Risk Quotient of the product (RQproduct) is estimated in a Tier 1 as the sum of the PEC/PNEC quotients for each active substance. Hence, for each compartment, the following RQproduct was calculated as:

$$\mathbf{RQ_{product}} = \sum_{i=1}^{n} \left(\frac{PEC}{PNEC}\right)_i$$

2.2.8.3.1 Atmosphere

Conclusion: According to the ECHA Guidance on the BPR: Volume IV, Environment (Version 2.0, October 2017), there is currently no appropriate guidance to calculate a PNECair. The physical-chemical properties of the active substances in the environment, such as vapour pressure (<0.1 mPa), and molecular weights, indicate that the active substance will not readily volatilise into the atmosphere at ambient temperature and pressure. In view of that, although the product is intended to be applied by fogging treatment, no long time is expected to be in atmosphere hence, no risk is foreseen for air compartment.

2.2.8.3.2 Sewage treatment plant (STP)

Summary table on calculated PECstp/PNECmicroorganism values			
Scenario	**PEC/PNEC$_{STP}$ for Etofenprox**	**PEC/PNEC$_{STP}$ for PBO**	**RQ$_{product}$ $=\sum_{i=1}^{n}\left(\frac{PEC}{PNEC}\right)_i$**
[1]- Professional	3.26E-05	6.81E-06	3.94E-05

Conclusion: There is no risk to micro-organisms in a sewage treatment plant (STP/WWTP) resulting from product residue's losses after wet cleaning treatment.

2.2.8.3.3 Aquatic compartment

The following table shows the potential risk derived from the product's formulation for each compartment for each active substance and their relevant metabolite.

- *For surface water*

Summary table on calculated PECsurfacewater/PNECsurfacewater values							
Scenario	**PEC$_{sw}$/PNEC$_{sw}$ for Etofenprox**	**PEC$_{sw}$/PNEC$_{sw}$ for α-CO metabolite**	**PEC$_{sw}$/PNEC$_{sw}$ for PBO**	**PEC$_{sw}$/PNEC$_{sw}$ for M1 metabolite**	**PEC$_{sw}$/PNEC$_{sw}$ for M2 metabolite**	**PEC$_{sw}$/PNEC$_{sw}$ for M12 metabolite**	**RQ$_{product}$ $\sum_{i=1}^{n}\left(\frac{PEC}{PNEC}\right)_i$**
Industrial and domestic scenarios							
[1]- Professional	1.30E-02	8.06E-04	1.32E-03	3.97E-05	2.12E-04	3.46E-05	1.54E-02

- *For sediment*

Summary table on calculated PECsediment/PNECsediment values				
Scenario	**$PEC_{sed}/PNEC_{sed}$ for Etofenprox**	**$PEC_{sed}/PNEC_{sed}$ for 4'-OH metabolite**	**$PEC_{sed}/PNEC_{sed}$ for PBO**	**$RQ_{product} = \sum_{i=1}^{n} \left(\frac{PEC}{PNEC}\right)_i$**
Industrial and domestic scenarios				
[1]- Professional	6.93E-03	8.13E-04	1.16E-02	1.94E-02

Conclusion: There is no risk for aquatic compartments (surface-water and sediment) resulting from product application and after a posterior wet cleaning of the treated premises in both domestic and industrial premises.

2.2.8.3.4 Terrestrial compartment

According to the intended use, direct emissions to the soil compartment are considered not relevant for indoor application. However, indirect exposure of agricultural soils through fertilization with sludge from a STP is considered relevant when wet cleaning methods are used in the treated premises and these are connected to STP.

Summary table on calculated PECsoil/PNECsoil values								
Scenario	**$PEC_{soil}/PNEC_{soil}$ for Etofenprox**	**$PEC_{soil}/PNEC_{soil}$ for PBO**	**$PEC_{soil}/PNEC_{soil}$ for M1 metabolite**	**$PEC_{soil}/PNEC_{soil}$ for M2 metabolite**	**$PEC_{soil}/PNEC_{soil}$ for M8 metabolite**	**$PEC_{soil}/PNEC_{soil}$ for M12 metabolite**	**$PEC_{soil}/PNEC_{soil}$ for metabolite F**	**$RQ_{product} = \sum_{i=1}^{n} \left(\frac{PEC}{PNEC}\right)_i$**
Industrial and domestic scenarios								
[1]- Professional	8.09E-04	1.97E-04	8.66E-06	2.48E-05	1.87E-05	2.35E-05	1.31E-05	1.09E-03

Conclusion: There is no risk for soil compartment resulting from product application and a later wet cleaning for any of the treated premises at industrial and domestic sites.

2.2.8.3.5 Groundwater

Summary table on calculated PECgw (µg/L)								
Scenario	**PECgw for Etofenprox**	**PECgw for PBO**	**PECgw for M1 metabolite**	**PECgw for M2 metabolite**	**PECgw for M8 metabolite**	**PECgw for M12 metabolite**	**PECgw for metabolite F**	**$RQ_{product} = \sum_{i=1}^{n} \left(\frac{PEC}{PNEC}\right)_i$**
Industrial and domestic scenarios								
[1]- Professional	2.82E-06	2.13E-04	9.37E-06	2.69E-05	2.02E-05	2.54E-05	1.41E-05	3.12E-04

Conclusion: There is no risk for groundwater resulting from product application and a later wet cleaning for any of the treated premises at industrial and domestic sites.

2.2.8.3.6 Primary and secondary poisoning

Summary table on secondary poisoning via the aquatic food chain					
Scenario	***PEC*$_{oral,\ fish\text{-}eating\ predator}$ *(mg/kg)***	**PNEC$_{birds}$ (mg/kg diet)**	**PNEC$_{mammals}$ (mg/kg diet)**	**PEC/PNEC$_{birds}$**	**PEC/PNEC$_{mammals}$**
Etofenprox					
Professionals	3.61E-04	33.3	24.7	1.08E-05	1.46E-05
PBO					
Professionals	5.68E-04	10	20	5.68E-05	2.84E-05
M12					
Professionals	7.12E-06	10	20	7.12E-07	3.56E-07
Summary table on secondary poisoning via the terrestrial food chain					
Scenario	***PEC*$_{oral,\ earthworm\text{-}eating\ predator}$ *(mg/kg)***	**PNEC$_{birds}$ (mg/kg diet)**	**PNEC$_{mammals}$ (mg/kg diet)**	**PEC/PNEC$_{birds}$**	**PEC/PNEC$_{mammals}$**
Etofenprox					
Professionals	2.42E-04	33.3	24.7	7.27E-06	9.80E-06
PBO					
Professionals	1.47E-04	10	20	1.47E-05	7.34E-06
M12					
Professionals	5.95E-07	10	20	5.95E-08	2.97E-08

Conclusion: In view of these outcomes, there is no potential risk for birds and mammals as secondary poisoning at aquatic compartment.

2.2.8.3.7 Mixture toxicity

Mixture toxicity is considered as **Risk Quotient of the product (RQproduct).** This total product risk is estimated as the sum of the PEC/PNEC quotients for each active substance estimated before and can be found in the section before for each environmental compartment.

Overall conclusion on the risk assessment for the environment of the product
In view of the previous outputs, when attics, false ceilings, garages and store rooms in both industrial and domestic premises are cleaned with wet cleaning methods after being treated with ACTIBIOL FOGGING PROFESIONAL by professional users, there is not potential risk for the environmental compartments.

2.2.9 Measures to protect man, animals and the environment

In order to protect man, animals and the environment the following assumptions are proposed by QUIMUNSA for the use of ACTIBIOL FOGGING PROFESIONAL product under acceptable risk conditions.

- The product must be used only indoors.
- The treated premises must be sealed and signposted in order to avoid the entry of anybody in the premise during the treatment
- Let the product act for at least 12 hours.
- Always that can be possible, treated premises must be ventilated before the re-entrance.
- Read the label carefully before using the product.
- Do not apply on food or kitchen utensils. It cannot be applied on surfaces, areas or enclosures where food is handled, prepared or has to be served or consumed.
- Do not use in the presence of people and / or pets.
- Avoid contact with the treated surfaces.
- It cannot be applied in areas of children's games, nurseries and children's schools where there is a constant and continuous presence of children.

As Risk mitigation measures at application:

- Wash hands after handling the product and before eating, drinking and / or smoking.
- Routinely wash clothing and protective equipment to remove contaminants.
- Discard contaminated clothing and shoes that cannot be cleaned.

.

As Risk mitigation measures at disposal of the product and its packaging:

- The product must be managed in accordance with current regulations through authorized managers and waste must never be disposed of through sewer networks.
- Empty containers should be managed in accordance with current regulations through authorized managers.

As right conditions of storage and shelf-life of the product under normal conditions of storage:

- Protect from sunlight and avoid exposing it to temperatures above 50ºC.
- Stay away from any source of ignition.
- Do not smoke.
- Keep out of reach of children.
- Use only in well places ventilated
- Do not breathe the vapours.

2.2.10 Assessment of a combination of biocidal products

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

2.2.11 Comparative assessment

The product contains the active substance Etofenprox, which meets the criteria for substitution under Article 10 of Regulation (EU) No 528/2012. Etofenprox fulfils both the B and T categorisation. Therefore, in line with Article 23 (1) of Regulation (EU) No 528/2012 the Spanish CA has conducted a comparative assessment for the product ACTIBIOL FOGGING PROFESSIONAL according to the "Technical Guidance Note on comparative assessment of biocidal products" as agreed upon by the member states on the 55th meeting of representatives of Member States Competent Authorities for the implementation of Regulation (EU) No 528/2012 (document: CA-May15-Doc.4.3.a - Final - TNG on comparative assessment.doc).

1. - Application administrative details:

Procedure: National authorisation

Purpose: Authorisation

Case Number in R4BP: BC-MM040875-23

Evaluating Competent Authority: Spain

Applicant: QUÍMICA DE MUNGUÍA S.A.

(Prospective) Authorisation holder: QUÍMICA DE MUNGUÍA S.A.

2. - Administrative information of the BP:

Trade name: ACTIBIOL FOGGING PROFESSIONAL

Product type: 18

Active substances: Etofenprox (CAS No 80844-07-1) and Piperonyl butoxide (PBO) (CAS No 51-03-6)

3. - Intended uses for the relevant BP in the application:

According to the applicant, ACTIBIOL FOGGING PROFESSIONAL has the following intended uses.

Table 3.1 List of intended uses of the biocidal product.

Product type	PT18 - Insecticides, acaricides and products to control other arthropods.
Where relevant, an exact description of the authorised use	The biocide is a RTU liquid insecticide intended for air space treatment by cold or hot fogging (nebulization), to control the target insects in difficult-to-access indoor areas.
Target organism (including development stage)	- *Blattella germanica* (German cockroaches) - adults and nymphs - *Blatta orientalis* (Oriental cockroaches) – adults and nymphs

	- *Sitophilus granarius* (wheat weevil) - adults - *Sitophilus oryzae* (lesser rice weevil) - adults - *Rhizopertha dominica* (lesser grain borer) - adults - *Oryzaephilus surinamensis* (sawtoothed grain beetle) - adults - *Tribolium confusum* (confused flour beetle) - adults
Field(s) of use	Indoor use at domestic and industrial premises (e.g. attics, false ceilings, garages, storage rooms, and rooms with low frequency of use).
Application method(s)	Nebulizable insecticide for application by swing-fog type equipment for hot (Use #1) or cold (Use #2) nebulization.
Category of users	Professionals

4.- Mapping of existing alternatives to the relevant BP

4.1.- Identified eligible alternative BPs

The product ACTIBIOL FOGGING PROFESSIONAL has been only compared with alternative products authorised in Spain, as the searchable SPCs and a corresponding search tool in the Register for Biocidal Products (R4BP) is currently not available, Spanish CA has used the information available to the ES CA on January 2024 of the biocidal products authorised under the Directive 98/8/EC or Regulation (EU) No 528/2012. In Spain 190 PT18 products have been authorised. These products are based on 33 active substances.

4.2.- Identified eligible non-chemical alternatives

Not relevant in the screening phase.

5.- Screening phase

5.1.- Description of the assessment of the adequate chemical diversity in authorised BPs to minimise the occurrence of resistance and conclusion.

From the 190 biocidal products authorised as PT18, some of them contains imidacloprid, clothianidin, dinotefuron, etofenprox or permethrin which fulfil the subtitution criteria. Only 90 products do not contain substitute substances and are authorised for trained professional users. Only 6 products are applicated as a fog (nebulization) but none of the products could be an acceptable alternative for these target organisms.

The Spanish CA concludes that there is not an adequate chemical diversity for products in line with Article 23(3)(b) and the Technical Guidance Note on comparative assessment.

The comparative assessment is finalised at this stage. The product ACTIBIOL FOGGING PROFESSIONAL is authorised for a period not exceeding 5 years in accordance with Article 23 (6) of BPR.

3 Annexes

3.1 List of studies for the biocidal product

This section is included in the Confidential Annex 3.6 to PAR.

3.2 Output tables from exposure assessment tools

3.2.1 Human Risk Assessment

Professional exposure

Scenario [1] – Mixing and loading

ACTIBIOL FOGGING PROFESIONAL					
Task / Scenario :	**PT18 mixing loading- manual loading/pouring**				
Model used :	mixing and loading model 7 "Pouring liquid into systems"				
	units	etofenprox		PBO	
		Tier 1	Tier 2	Tier 1	Tier 2
Active substance	% w/w	0,475%	0,475%	1,425%	1,425%
Body weight	kg	60		60	
Hands dermal exposure					
indicative value from model	mg/min	101	1,01	101	1,01
duration	min/event	10	10	10	10
potential dermal deposit	mg/event	1010	10	1010	10
gloves penetration	%	100%	100%	100%	100%
actual hand deposit (product)	mg/event	1010	10,1	1010	10,1
actual dermal deposit (a.s.)	**mg/event**	**4,80**	**0,048**	**14,39**	**0,144**
number of events	events/day	1	1	1	1
actual dermal deposit (a.s.)	**mg/day**	**4,80**	**0,05**	**14,39**	**0,14**
Total dermal exposure					
product deposit	mg/event	1010	10,1	1010	10,1
active substance deposit	**mg/event**	**4,80**	**0,05**	**14,39**	**0,14**
number of events	events/day	1	1	1	1
active substance deposit	**mg/day**	**4,8**	**0,05**	**14,4**	**0,14**
Skin penetration	%	70,0%	70,0%	70,0%	70,0%
active substance via the skin	mg/day	3,36	0,03	10,07	0,10
systemic dose via skin	**mg/kg bw/day**	**5,60E-02**	**5,60E-04**	**1,68E-01**	**1,68E-03**
Exposure by inhalation					
RPE worn					
indicative value from model	mg bp /m^3	0,94	0,94	0,94	0,94
mitigation factor by RPE	value	1	1	1	1
event duration	min	10	10	10	10
inhalation rate	m^3/h	1,25	1,25	1,25	1,25
a.s. concentration (during task)	**mg/m^3**	**4,47E-03**	**4,47E-03**	**1,34E-02**	**1,34E-02**
a.s. concentration through RPE(during task)	**mg/m^3**	**4,47E-03**	**4,47E-03**	**1,34E-02**	**1,34E-02**
number of events	events/day	1	1	1	1
active substance through RPE	**mg/day**	**9,30E-04**	**9,30E-04**	**2,79E-03**	**2,79E-03**
Inhaled air volume (for 8 hours)	m^3	10	10	10	10
a.s. concentration (8-hr TWA)	**mg/m^3**	**9,30E-05**	**9,30E-05**	**2,79E-04**	**2,79E-04**
Absorption via inhalation	%	100%	100%	100%	100%
systemic inhaled dose	**mg/kg bw/day**	**1,55E-05**	**1,55E-05**	**4,65E-05**	**4,65E-05**
Dose					
systemic dose	mg/kg bw/day	**5,60E-02**	**5,75E-04**	**1,68E-01**	**1,73E-03**

Risk characterisation					
TIER	**Active substance**	**Systemic exposure**	**chronic AEL**	**%AEL**	**conclusion**
1 / no PPE	Etofenprox	5,60E-02	0,011	509	NO ACEPTABLE
2 / gloves	Etofenprox	5,75E-04	0,011	5	ACEPTABLE
1 / no PPE	PBO	1,68E-01	0,2	84	ACEPTABLE
2 / gloves	PBO	1,73E-03	0,2	1	ACEPTABLE

Scenario [2] – Application as a space spray as a mist or thermal fog

Not necessary calculations.

Scenario [3] – Post-Application of the biocidal product (re-entry period in the treated room).

Task / Scenario :	PT18 fogging				
Model used :	Recomm. no. 6 - Fogging and mistting models 2 & 3				
General exposure calculator	**Calculation**				
	Etofenprox		**PBO**		
	Tier 1	**Tier 2**	**Tier 1**	**Tier 2**	**Units**
active substance	0,475	0,475	1,425	1,425	%
density	0,7671	0,7671	0,7671	0,7671	g/mL (if w/v)
Potential dermal exposure					
indicative value	21,8	21,8	21,8	21,8	mg/min
duration	15	15	15	15	min
potential dermal deposit	327	327	327	327	mg
clothing penetration	100	20	100	20	%
actual dermal deposit (product)	327	65,4	327	65,4	mg
Hand exposure in gloves	Tier 1	Tier 2	Tier 1	Tier 2	
indicative value	33	0,33	33	0,33	mg/min
duration	15	15	15	15	min
actual hand deposit (product)	495	4,95	495	4,95	mg
Actual dermal exposure					
product	822	70,35	822	70,35	mg
active substance	3,90	0,33	11,71	1,00	mg
Skin penetration	70	70	70	70	%
active substance via the skin	2,73E+00	2,34E-01	8,20E+00	7,02E-01	mg
absorbed dermal dose	4,56E-02	3,90E-03	1,37E-01	1,17E-02	mg/kg bw/d
Exposure by inhalation	**Tier 1**	**Tier 2**	**Tier 1**	**Tier 2**	
indicative value product	70,2	70,2	70,2	70,2	mg/m^3
duration	15	15	15	15	min
inhalation rate	2,08E-02	2,08E-02	2,08E-02	2,08E-02	m^3/min
inhaled volume	0,31245	0,31245	0,31245	0,31245	m^3
RPE APF	1	1	1	1	
inhaled (product)	21,93	21,93	21,93	21,93	mg
INHALATION % ai en bp	4,75E-01	4,75E-01	1,43E+00	1,43E+00	%
active substance	1,04E-01	1,04E-01	3,13E-01	3,13E-01	mg
absorbed dose at light exercise	6,95E-03	6,95E-03	2,08E-02	2,08E-02	mg ai/min
absorbed inhalation dose	1,74E-03	1,74E-03	5,21E-03	5,21E-03	mg/kg bw/d
Dose	**Tier 1**	**Tier 2**	**Tier 1**	**Tier 2**	
total	2,84E+00	3,38E-01	8,51E+00	1,01E+00	mg
body-weight	60	60	60	60	kg
systemic dose	4,73E-02	5,64E-03	1,42E-01	1,69E-02	mg/kg bw

Risk characterisation					
Tier	**Active substance**	**Systemic exposure**	**chronic AEL**	**%AEL**	**conclusion**
1 / no PPE	Etofenprox	4,73E-02	0,011	429,90	NO ACEPTABLE
2 / Protective gloves, coated coverall	Etofenprox	5,64E-03	0,011	51,23	ACEPTABLE
1 / no PPE	PBO	1,42E-01	0,2	70,93	ACEPTABLE
2 / Protective gloves, coated coverall,	PBO	1,69E-02	0,2	8,45	ACEPTABLE

Combined scenarios

Systemic Effects	Combined Exposure (M&L + Fogging)			
TIER	Estimated inhalation uptake (mg/kg bw/d)	Estimated dermal uptake (mg/kg bw/d)	Estimated oral uptake (mg/kg bw/d)	Estimated Total uptake (mg/kg bw/d)
1 (Etofenprox)	1,75E-03	1,02E-01	n.a	1,03E-01
2 (Etofenprox)	1,75E-03	4,46E-03	n.a	6,21E-03
1 (PBO)	5,26E-03	3,05E-01	n.a	3,10E-01
2 (PBO)	5,26E-03	1,34E-02	n.a	1,86E-02

Risk characterisation					
Tier	Active substance	Systemic exposure	chronic AEL	%AEL	conclusion
1	Etofenprox	1,03E-01	0,011	939	NO ACEPTABLE
2	Etofenprox	6,21E-03	0,011	56	ACEPTABLE
1	PBO	3,10E-01	0,2	155	NO ACEPTABLE
2	PBO	1,86E-02	0,2	9	ACEPTABLE

Scenario [4] - Inhalation of volatilized residues

Screening	etofenprox	PBO
AS vapour pressure Pa	8,13E-07	2,11E-05
AS MW	376,5	338,43
Gases cte	8,31451	8,31451
Temperature (K)	293	293
$AEL_{long\ term}$ (mg as/kg/d)	0,011	0,2
Cte	0,328	0,328
Result	9,13E-03	1,17E-02
Negligible	**yes**	**yes**

Scenario 5 - Toddler playing in a treated room

	Toddler playing in a treated room				
	TIER 1				
	Active substances	Etofenprox	PBO	units	
	Maximun application rate	0,262	0,262	mL BP/m^3	Section 2.2.5
	Density	0,7671	0,7671	g BP/mL	Section 2.2.2
	Weight of fraction	0,475%	1,425%	%	Section 2.1.2
	Maximun application rate	0,955	2,864	mg AS/m^3	Calculated value
	Room Height	3,48	3,48	m	Section 2.2.5
	Application rate	3,318	9,955	mg AS/m^2	
	Area treated (deposition rate)	100%	100%		worst case
	Surface residues	3,32E-04	9,96E-04	mg/cm^2	Calculated value.
	Transfer coefficient	2000	2000	cm^2/h	Recommendation
	Surface transferable residues	30%	30%		BHHEM, 2015
	Exposure period	1	1	h	
	Body weight	10	10	Kg	
	Dermal exposure	1,99E-01	5,97E-01	mg	
	Dermal Absorption	70%	70%		EFSA guidance 2(
	Systemic dermal dose	1,39E-02	4,18E-02	mg/kg bw/d	
	Oral exposure	5,97E-02	1,79E-01		
	Transferable fraction from hand to mouth	10%	10%		BHHEM, 2015
	Oral Absorption	100%	100%		Default value
	Systemic oral dose	5,97E-04	1,79E-03	mg/kg bw/d	
	Systemic dose	1,45E-02	4,36E-02	mg/kg bw/d	

Risk characterisation					
Tier	**Active substance**	**Systemic exposure**	**chronic AEL**	**%AEL**	**conclusion**
1	Etofenprox	1,45E-02	0,011	132	NO ACEPTABLE
1	PBO	4,36E-02	0,2	22	ACEPTABLE

	Toddler playing in a treated room				
	TIER 2				
	Active substances	Etofenprox	PBO	units	
	Maximun application rate	0,262	0,262	mL BP/m^3	Section 2.2.5
	Density	0,7671	0,7671	g BP/mL	Section 2.2.2
	Weight of fraction	0,475%	1,425%	%	Section 2.1.2
	Maximun application rate	0,955	2,864	mg AS/m^3	Calculated value
	Room Height	3,48	3,48	m	Section 2.2.5
	Application rate	3,318	9,955	mg AS/m^2	
	Area treated (deposition rate)	10%	10%		ESD no 18
	Surface residues	3,32E-05	9,96E-05	mg/cm^2	
	Transfer coefficient	2000	2000	cm^2/h	Recommendation
	Surface transferable residues	8%	5%		USA SOP 2012
	Exposure period	1	1	h	
	Body weight	10	10	Kg	
	Dermal exposure	5,31E-03	9,96E-03	mg	
	Dermal Absorption	70%	70%		EFSA guidance 20
	Systemic dermal dose	3,72E-04	6,97E-04	mg/kg bw/d	
	Oral exposure	1,59E-03	2,99E-03	mg	
	Proportion of palms of hand in contact with the treated surface	40%	40%		Recommendation
	Transferable fraction from hand to mouth	10%	10%		BHHEM, 2015
	Proportion of pesticide extracted by saliva	57%	57%		USA SOP 2012
	Oral Absorption	100%	100%		Default value
	Systemic oral dose	3,63E-06	4,54E-04	mg/kg bw/d	
	Systemic dose	3,75E-04	1,15E-03	mg/kg bw/d	

Risk characterisation					
Tier	**Active substance**	**Systemic exposure**	**chronic AEL**	**%AEL**	**conclusion**
2	Etofenprox	3,75E-04	0,011	3,41E+00	ACEPTABLE
2	PBO	1,15E-03	0,2	5,75E-01	ACEPTABLE

Scenario 6 - Adult re-entering into a treated room

Adult re-entering into a treated room				
	Etofenprox	PBO	units	
Maximun application rate	0,262	0,262	mL BP/m^3	Section 2.2.5
Density	0,7671	0,7671	g BP/mL	Section 2.2.2
Weight of fraction	0,475%	1,425%	%	Section 2.1.2
Maximun application rate	0,95465595	2,86396785	mg AS/m^3	Calculated value
Room Height	3,48	3,48	m	Applicant's data
Application rate	3,318384082	9,955152247	mg AS/m^2	
Area treated (deposition rate)	100%	100%		
Surface residues	3,32E-04	9,96E-04	mg/cm^2	
Transfer coefficient	7800	7800	cm^2/h	Recommendation
Surface transferable residues	30%	30%		Hard surfaces (TN
Exposure period	1	1	h	
Body weight	60	60	Kg	
Dermal exposure	7,77E-01	2,33E+00	mg	
Dermal Absorption	70%	70%		
Systemic dermal dose	9,06E-03	2,72E-02	mg/kg bw/d	
Oral exposure	2,33E-01	6,99E-01	mg	
Oral Absorption	100%	100%		Default value.
Transferable fraction from hand to mouth	4%	4%		Expert judgement
Systemic oral dose	1,55E-04	4,66E-04	mg/kg bw/d	
Systemic dose	9,21E-03	2,76E-02	mg/kg bw/d	

Risk characterisation					
Tier	**Active substance**	**Systemic exposure**	**chronic AEL**	**%AEL**	**conclusion**
1	etopenfrox	9,21E-03	0,011	84	ACEPTABLE
1	PBO	2,76E-02	0,2	14	ACEPTABLE

Adult re-entering in a treated room				
TIER 2				
Active substances	Etofenprox	PBO	units	
Maximun application rate	0,262	0,262	mL BP/m^3	Section 2.2.5
Density	0,7671	0,7671	g BP/mL	Section 2.2.2
Weight of fraction	0,475%	1,425%	%	Section 2.1.2
Maximun application rate	0,95465595	2,86396785	mg AS/m^3	Calculated value
Room Height	3,48	3,48	m	Section 2.2.5
Application rate	3,318384082	9,955152247	mg AS/m^2	
Area treated (deposition rate)	100%	100%		worst case
Surface residues	3,32E-04	9,96E-04	mg/cm^2	
Transfer coefficient	7800	7800	cm^2/h	Recommendation
Surface transferable residues	8%	5%		USA SOP 2012
Exposure period	1	1	h	
Body weight	60	60	Kg	
Dermal exposure	2,07E-01	3,88E-01	mg	
Dermal Absorption	70%	70%		EFSA guidance 20
Systemic dermal dose	2,42E-03	4,53E-03	mg/kg bw/d	
Oral exposure	6,21E-02	1,16E-01	mg	
Proportion of palms of hand in contact with the treated surface	40%	40%		Recommendation
Transferable fraction from hand to mouth	4%	4%		Expert judgement
Proportion of pesticide extracted by saliva	57%	57%		USA SOP 2012
Oral Absorption	100%	100%		Default value
Systemic oral dose	9,44E-06	1,77E-05	mg/kg bw/d	
Systemic dose	2,43E-03	4,55E-03	mg/kg bw/d	

Risk characterisation					
Tier	**Active substance**	**Systemic exposure**	**chronic AEL**	**%AEL**	**conclusion**
2	Etofenprox	2,43E-03	0,011	22	ACEPTABLE
2	PBO	4,55E-03	0,2	2	ACEPTABLE

Scenario [7] – Laundering work clothes

Active substances: etofenprox and PBO **Professional Fogging** **No work clothes are mandatory.**

FOGGING PROFESSIONAL				
Professionals	Potential dermal	Actual dermal depo	Fogging clothes	dermal depo
	3,27E+02	6,54E+01	2,62E+02	AMOUNT O
Indicative value from model	mg/day	261,600000		
Regular clothes penetration	%	50%	HEEG opinion 9. This protect	
product under coverall	mg/day	130,80		
product on coverall	**mg/day**	**130,80**		

Task / Scenario :	**laundering work cloths**			
Model used :				
product dilution	0%	**TIER 1**	**TIER 1**	
	units	without EPI	without EPI	
Active substance	% w/w	0,475%	1,425%	
Body weight	kg	60	60	
Potential dermal exposure **Hands exposure**				
indicative value from model*	mg/day	130,80000	130,80000	
potential dermal deposit	mg	654,00	654,00	(x 5 days work)
surface medium-sized coverall	cm^2	22700	22700	
actual deposit (product)	**mg/cm^2**	**2,88E-02**	**2,88E-02**	
Actual dermal exposure				
active substance	**mg/cm^2**	**1,37E-04**	**4,11E-04**	
Skin penetration	%	70%	70%	
active substance via the skin	**mg/cm^2**	**9,58E-05**	**2,87E-04**	
Skin surface area in contact	**cm^2**	820	820	For an adult, the
Transfer coefficient	**%**	30%	30%	TNsG 2002, par
Dose				
systemic dose	**mg/kg bw**	**3,93E-04**	**1,18E-03**	

Risk characterisation					
Tier	**Active substance**	**Systemic exposure**	**chronic AEL**	**%AEL**	**conclusion**
1	etofenprox	3,93E-04	0,011	3,57E+00	ACEPTABLE
2	PBO	1,18E-03	0,2	5,89E-01	ACEPTABLE

3.2.2 Environmental Risk Assessment

Please refer to section 2.2.8 of this PAR (i.e. Risk assessment for the environment).

3.3 New information on the active substances

No new information is provided on the active substances.

3.4 Residue behaviour

No new information is provided about residue behaviour.

3.5 Summaries of the efficacy studies

Please refer to the table included in section 2.2.5.5. of this PAR.

3.6 Confidential annex

Please refer to Confidential Annex 3.6 to PAR.