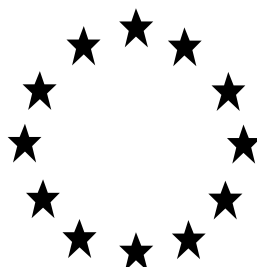


Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

**PRODUCT ASSESSMENT REPORT OF A
BIOCIDAL PRODUCT FOR RENEWAL OF
NATIONAL AUTHORISATION APPLICATIONS**

(submitted by the evaluating Competent Authority)



FENOX

Product type 18

Etofenprox as included in the Union list of approved active substances

Case Number in R4BP: BC-AD065446-53

Evaluating Competent Authority: FR

Revised date: 17/01/2024

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1 HISTORY OF THE DOSSIER

| Application type | refMS | Case number in the refMS | Decision date | Assessment carried out (i.e. first authorisation / amendment /) |
|------------------|-------|--------------------------|---------------|--|
| NA-APP | FR | BC-SR017981-11 | 27/09/2017 | First authorisation |
| NA-MAC | FR | BC-MV038380-18 | 22/05/2019 | Major Changes : <ul style="list-style-type: none"> - Addition of a category of user : professional user - Addition of uses by general surface spraying against new target organisms: <i>Cimex lectularius</i>, <i>Tribolium confusum</i>, <i>Sitophilus oryzae</i>, <i>Rhyzopertha dominica</i>, <i>Oryzaephilus surinamensis</i>, <i>Lasioderma serricornis</i> (larvae only). |
| N.A | FR | - | - | Post authorisation data assessment |
| NA-RNL | FR | BC-AD065446-53 | 30/11/2022 | Renewal |
| NA-AAT | FR | BC-HH087199-27 | 26/06/2023 | Amendments, in the PAR only, following discussions with concerned member state (EL) in the frame of mutual recognition in sequence. No change in the SPC. |
| NA-AAT | FR | na | 25/02/2024 | Discussions with concerned members states in the frame of mutual recognition in sequence. Referral to CG: revised assessment and SPC. |

2 CONCLUSION

INTRODUCTION OF THE APPLICATION

France, as e-CA, received an application from LODI S.A.S. for renewal of authorisation for the biocidal product FENOX.

The biocidal product FENOX containing 29.34 % of etofenprox¹ is a product type 18 against crawling insects including cockroaches and bed bugs by non-professional users, by indoor spraying, and against crawling insects including cockroaches, pests of stored products and bed bugs by professional users, by indoor spraying.

SUMMARY AND OVERALL CONCLUSION OF THE ASSESSMENT

Physico-chemical properties and analytical methods

The product FENOX is an emulsifiable concentrate (EC). All studies have been performed in accordance with the current requirements and the results are deemed acceptable.

The appearance of the product is a translucent liquid with a slight odour. In aqueous solution (1% dilution), it has a pH value of 6.40 at 19.9°C.

There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C or after 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. Long term stability studies demonstrate that the product is stable for at least 3 years when stored at ambient temperature in its commercial packaging.

Its technical characteristics are acceptable for an EC formulation.

The formulation is not classified for the physico-chemical aspect.

The analytical methods are acceptable.

Efficacy

Efficacy of the product FENOX has been demonstrated against crawling insects (including cockroaches), bed bugs, and stored-goods attacking insects (confused flour beetle, rice weevil, lesser grain borer, sawtoothed grain beetle and tobacco beetle) in the conditions of use detailed in the SPC.

Resistance

Resistance to etofenprox is documented for several groups of insects including notably cockroaches and bedbugs.

A monitoring of scientific literature related to the resistance of the target organisms to the active substance etofenprox is requested at the next renewal.

The authorization holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management.

Substances of concern (SoCs)

¹ COMMISSION IMPLEMENTING REGULATION (EU) No 1036/2013 of 24 October 2013 approving etofenprox as an existing active substance for use in biocidal products for product- type 18.

None of the co-formulant included in the product was identified as substance of concern for human health and/or the environment.

Risk for Human Health

The product FENOX is classified for lactation H362.

Primary exposure (professional users)

The risk is considered acceptable for professional users during spraying with the following PPE:

- Gloves during mixing and loading;
- Gloves, impermeable coverall and mask APF 4 during spraying;
- Gloves and coated coverall during the cleaning of spray equipment.

Primary exposure (non-professional users)

The risk is considered acceptable for non-professional users during spraying.

Secondary exposure (general public)

Estimated secondary exposures of infant crawling in treated surface are superior to AEL. Therefore mitigation measures are proposed:

- **The product should not be applied in zone accessible to children and to pets.** If it is applied on rooms accessible to children, the following mitigation measure is proposed: **children should not access treated areas until all necessary treatments and cleaning have been finalised”.**

Estimated secondary exposures of persons (adult, child and infant) sleeping in a treated bed are superior to AELs. Therefore, the risk is considered unacceptable and a mitigation measure is proposed for bed bugs use:

- **For bedding, the application should be restricted to the bed frame and box spring. Do not treat the mattress, bed linen and pillows. The mattress, bed linen and pillows must be treated by other methods.**

Risk for consumer under indirect exposure via food

No specific residue data was submitted in the framework of this dossier. The intended indoor uses in industrial, commercial, public premises and private homes via surface spraying are not expected to lead to contamination of food, feed or livestock considering the following precautionary statements:

- Remove all food, feed and drinks prior to treatment.
- 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.
- To avoid indirect contamination during nearby application, cover all surfaces and facilities likely to be in contact with food, feed, drinks and animals.

Risk for the environment

The environmental risk assessment of the product FENOX is based on the active substance and two environmentally relevant metabolites, aCO and 4'OH. No substance of concern has been identified for the environment.

According to the CG-59 discussions (28/11/2023), the simultaneity factor of 0.00204 corresponding to a maximal use frequency of 2 times/year can be applied for professional use only. The simultaneity factor of 0.00815 corresponding to a use frequency of 3-11 times/year will be applied for non-professional use, as it can be expected that non-professional users would use the product at a higher use frequency in realistic conditions due to the wide variety of target organisms.

It was also concluded during the CG-59 discussions that an instruction for use will include that a handheld trigger spray needs to be used by non-professional users, as this complies with the efficacy data and is covered by the environmental risk assessment based on surface treatment.

The product FENOX will not pose risk to the environmental compartments for an application of the product in restricted areas (covered by the barrier treatment scenario) for 2 applications per year for professional users. Therefore, the specific instruction of use must be respected:

“The product has to be applied only on restricted areas on surfaces not regularly cleaned, for example:

- behind or under the fridge, under the kitchen sink, under the oven or the water heater, in all cracks and crevices that can be an harbourage for cockroaches.
- on the bedspring, on the feet of the bed, under furnitures, along plinths, behind headboard, on the wall behind the bed, furnitures and all crack and crevices that can be harbourage for bed bugs.”

For non-professional users, a maximal use frequency of 2 times/year is not considered realistic as:

- more uses are expected by non-professional users considering the wide range of target organisms (bed bugs, cockroaches and stored goods attacking insects) that are present all year round and can occur throughout the house (stored goods attacking insects more likely in kitchen and bed bugs more likely in bedrooms etc);
- the target organisms are difficult to eradicate from the house, so in case of non-professional use reinfestation is likely.

Therefore, a simultaneity factor of 0.00815 (corresponding to 3-11 applications/year) should be applied leading to non-acceptable risks for the aquatic and terrestrial compartments. The product will not be authorized for non-professionals.

Comparative assessment

The active substance etofenprox contained in the product FENOX meets the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and is considered as a candidate for substitution. Therefore, a comparative assessment of the product FENOX is required.

The outcomes of this comparative assessment does not lead to refuse the authorisation of the product FENOX or to limit some uses.

Overall conclusion

The conformity to the uniform principles, as defined in the Regulation (EU) n°528/2012, for the product FENOX is reported in the table below, for each use.

| Uses | Application rates | Conditions of use | Conclusions |
|---|--|---|---|
| <p>Crawling insects including cockroaches (e.g. <i>Blattella germanica</i>, <i>Blatta orientalis</i>), adults and nymphs.</p> <p>Bed bugs (<i>Cimex lectularius</i>), adults and nymphs.</p> | <p>Product applications are made at a maximum rate of 0.5 mL/m².</p> <p>The product is used diluted in water at a rate of 0.5 mL of product diluted in 50 mL water for 1 m².</p> | <p>Non professionals users</p> <p>Indoor</p> <p>Surface spraying</p> <p>11 applications per year maximum.</p> | <p>Non acceptable for the aquatic and terrestrial compartments</p> |
| <p>Crawling insects including cockroaches (e.g. <i>Blattella germanica</i>, <i>Blatta orientalis</i>), adults and nymphs.</p> <p>Stored-goods attacking insects:</p> <ul style="list-style-type: none"> - Confused flour beetle (<i>Tribolium confusum</i>), adults; - Rice weevil (<i>Sitophilus oryzae</i>), adults; - Lesser grain borer (<i>Rhyzopertha dominica</i>), adults; - Sawtoothed grain beetle (<i>Oryzaephilus surinamensis</i>), adults; - Tobacco beetle (<i>Lasioderma serricornis</i>), larvae. | <p>Product applications are made at a maximum rate of 0.5 mL/m².</p> <p>The product is used diluted in water at a rate of 0.5 mL of product diluted in 50 mL water for 1 m².</p> | <p>Professionals users</p> <p>Indoor</p> <p>Surface spraying</p> <p>2 applications per year maximum.</p> | <p>Acceptable</p> |
| <p>Bed bugs (<i>Cimex lectularius</i>), adults and nymphs.</p> | <p>Product applications are made at a maximum rate of 0.5 mL/m².</p> <p>The product is used diluted in water at a rate of 0.5 mL of product diluted in 50 mL water for 1 m².</p> | <p>Professionals</p> <p>Indoor</p> <p>Surface spraying</p> <p>2 applications per year maximum.</p> <p>A second application is needed after 15 days.</p> | <p>Acceptable</p> |

3 ASSESSMENT REPORT

3.1 Summary of the product assessment

3.1.1 Administrative information

3.1.1.1 Identifier of the product

| Identifier | Country (if relevant) |
|---|-----------------------|
| FENOX FIVEX LE 30 TENEXINE EMULSTIQUE 300 PHOBI FENOX PHOBI-E ETO CONCENTRATE ULV ETOF 300 CONCENTRE ETOFENPROX 300 ETHOS 30 EC | France |

3.1.1.2 Authorisation holder

| | | |
|---|----------------|---|
| Name and address of the authorisation holder | Name | LODI SAS |
| | Address | Parc d'Activités des Quatre Routes 35 390 Grand Fougeray France |
| Authorisation number | FR-2017-0081 | |
| Date of the authorisation | | |
| Expiry date of the authorisation | | |

3.1.1.3 Manufacturer(s) of the products

| | |
|--|---|
| Name of manufacturer | LODI SAS |
| Address of manufacturer | Parc d'Activités des Quatre Routes 35 390 Grand Fougeray France |
| Location of manufacturing sites | Parc d'Activités des Quatre Routes 35 390 Grand Fougeray France |

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

| | |
|--|---|
| Active substance | Etofenprox |
| Name of manufacturer | Mitsui chemicals crop & life solutions, inc |
| Address of manufacturer³ | Nihonbashi Dia Building, 1-19-1, Nihonbashi 103-0027 Chuo-ku, Tokyo Japan |
| Location of manufacturing sites | Omuta Works, 30 Asamuta-cho, Omita 836-8610 Fukuoka Japan |

3.1.2 Product composition and formulation

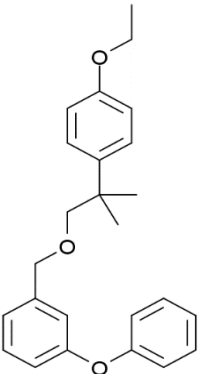
NB: the full composition of the product according to Annex III Title 1 is provided in the confidential annex.

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

Yes

No

3.1.2.1 Identity of the active substance

| Main constituent(s) | |
|--|--|
| ISO name | Etofenprox |
| IUPAC or EC name | 2-(4-ethoxyphenyl)-2-methylpropyl 3-phenoxybenzyl ether |
| EC number | 407-980-2 |
| CAS number | 80844-07-1 |
| Index number in Annex VI of CLP | |
| Minimum purity / content | ≥ 97.2 % |
| Structural formula |  |

3.1.2.2 Candidate(s) for substitution

According to the AR of etofenprox, this active substance does not fulfil the PBT nor the vPvB criteria. Nonetheless, the substance is candidate for substitution, as it fulfils the B and T criteria.

3.1.2.3 Qualitative and quantitative information on the composition of the biocidal product²

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
|----------------------|---|------------------|------------|-----------|-------------|
| Etofenprox technical | 2-(4-ethoxyphenyl)-2-methylpropyl 3-phenoxybenzyl ether | Active substance | 80844-07-1 | 407-980-2 | 29.34 |

3.1.2.4 Information on technical equivalence

Not relevant.

The source use is the same than in the CAR of the active substance.

3.1.2.5 Information on the substance(s) of concern

Please see the confidential annex for further details.

3.1.2.6 Assessment of endocrine disruption (ED) properties of the biocidal product

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) 2017/2100.

No indications of endocrine-disrupting properties according to Regulation (EU) 2017/2100 were identified for the non-active substances contained in the biocidal product.

See Confidential annex for further details.

3.1.2.7 Type of formulation

| |
|-------------------------------|
| EC - Emulsifiable concentrate |
|-------------------------------|

3.1.3 Hazard and precautionary statements³

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

| Classification | |
|-------------------|--|
| Hazard category | Additional category for effects on or via lactation Aquatic acute 1 Aquatic chronic 1 |
| Hazard statement | H362: May cause harm to breast-fed children. H400: Very toxic to aquatic life H410: Very toxic to aquatic life with long lasting effects |
| Labelling | |
| Signal words | GHS09 Warning |
| Hazard statements | H362: May cause harm to breast-fed children. H410: Very toxic to aquatic life with long lasting effects |

| Classification | |
|--------------------------|---|
| Precautionary statements | P201: Obtain special instructions before use. P260: Do not breathe spray. P263: Avoid contact during pregnancy/while nursing. P264: Wash hands thoroughly after handling. P270: Do not eat, drink or smoke when using this product. P308 + P313: If exposed or concerned: Get medical advice. P273: Avoid release to the environment. P391: Collect spillage. P501: Dispose of container in accordance with local requirements. |
| Note | |

3.1.4 Authorised use(s)

3.1.4.1 Use description

Table 2. Use #2 – Professional users - Crawling insects including cockroaches and stored goods attacking insects

| | |
|---|--|
| Product Type | 18 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Crawling insects including cockroaches (e.g. <i>Blattella germanica</i> , <i>Blatta orientalis</i>), adults and nymphs. Stored goods attacking insects: - Confused flour beetle (<i>Tribolium confusum</i>), adults; - Rice weevil (<i>Sitophilus oryzae</i>), adults; - Lesser grain borer (<i>Rhyzopertha dominica</i>), adults; - Sawtoothed grain beetle (<i>Oryzaephilus surinamensis</i>), adults; - Tobacco beetle (<i>Lasioderma serricorne</i>), larvae. |
| Field of use | Indoor (institutions, food industries, in domestic areas) |
| Application method(s) | Surface spraying |
| Application rate(s) and frequency | 0.5 mL/m ² The product is used diluted in water at a rate of 0.5 mL of product diluted in 50 mL water for 1 m ² . The dilution rate of 1% corresponds to dissolving of 1 sachet (5 ml) in 500 ml of water (this volume covers the area of 10 m ²) and that 50 ml of the thus diluted product is to be applied to 1m ² . The biocidal effect appears in few minutes. |

| | |
|--|---|
| | The residual efficacy is up to 2 weeks when applied against stored goods attacking insects and up to 12 weeks when applied against cockroaches. 2 applications per year maximum. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | Bottle : HDPE, PET or HDPE/EVOH* : to 1 L 5 mL, 10 mL or 25 mL in water soluble sachets (PVA: polyvinyl Alcohol) packed in Box Polystyrene which contains 250 mL (50 sachets of 5 mL, 25 sachets of 10 mL or 10 sachets of 25 mL). <i>*EVOH = PVA : Polyvinyl alcohol</i> |

3.1.4.2 Use-specific instructions for use

- Take into account the life cycle and characteristics of target insects to adapt treatments. In particular, target the most susceptible stage of the pest, timing of applications and areas to be treated.
- Adopt integrated pest management methods such as the combination of chemical, physical control methods and other public health measures, taking into account local specificities (climatic conditions, target species, conditions of use, etc.).
- Avoid exclusive repeated use of insecticides from the same chemical subgroup which for etofenprox is IRAC subgroup 3A,
- Alternate products containing active substances with different mode of action (i.e. from other IRAC Mode of Action groups).
- The product has to be applied only on restricted areas on surfaces not regularly cleaned, that can be an harbourage for target organisms for example: behind or under the fridge, under the kitchen sink, under the oven or the water heater, in all cracks and crevices.

3.1.4.3 Use-specific risk mitigation measures

- Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) during mixing and loading phase.
- Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), impermeable coverall and a respiratory mask (APF 4) during product spraying phase.
- Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) and coated coverall during the cleaning of spray equipment.

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

-

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

-

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

-

3.1.4.7 Use description

Table 3. Use #3 –Professional users – Bed bugs

| | |
|---|---|
| Product Type | 18 |
| Where relevant, an exact description of the authorised use | |
| Target organism (including development stage) | Bed bugs (<i>Cimex lectularius</i>), adults and nymphs. |
| Field of use | Indoor (institutions, food industries, in domestic areas) |
| Application method(s) | Surface spraying |
| Application rate(s) and frequency | 0.5 mL/m ² . The product is used diluted in water at a rate of 0.5 mL of product diluted in 50 mL water for 1 m ² . The dilution rate of 1% corresponds to dissolving of 1 sachet (5 ml) in 500 ml of water (this volume covers the area of 10 m ²) and that 50 ml of the thus diluted product is to be applied to 1m ² . A second application is needed after 15 days. Eradication is obtained one week after the second application. The biocidal effect appears in few minutes. The residual efficacy is up to 12 weeks when applied against bed bugs. 2 applications per year maximum. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | Bottle : HDPE, PET or HDPE/EVOH* : to 1 L 5 mL, 10 mL or 25 mL in water soluble sachets (PVA : polyvinyl Alcohol) packed in Box Polystyrene which contains 250 mL (50 sachets of 5 mL, 25 sachets of 10 mL or 10 sachets of 25 mL). *EVOH = PVA : Polyvinyl alcohol |

3.1.4.8 Use-specific instructions for use

- Take into account the life cycle and characteristics of target insects to adapt treatments. In particular, target the most susceptible stage of the pest, timing of applications and areas to be treated.
- Adopt integrated pest management methods such as the combination of chemical, physical control methods and other public health measures, taking into account local specificities (climatic conditions, target species, conditions of use, etc.).
- Avoid exclusive repeated use of insecticides from the same chemical subgroup which for etofenprox is IRAC subgroup 3A,

- Alternate products containing active substances with different mode of action (i.e. from other IRAC Mode of Action groups).
- The product has to be applied only on restricted areas on surfaces not regularly cleaned, that can be harbourage for bed bugs, for example: on the bedspring, on the feet of the bed, under furniture, along plinths, behind headboard, on the wall behind the bed, furniture and all crack and crevices.

3.1.4.9 Use-specific risk mitigation measures

- Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) during mixing and loading phase.
- Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), impermeable coverall and a respiratory mask (APF 4) during product spraying phase.
- Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) and coated coverall during the cleaning of spray equipment.
- For bedding, the application should be restricted to the bed frame and box spring.
- Do not treat the mattress, bed linen and pillows.
- The mattress, bed linen and pillows must be treated by other methods.

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

-

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

-

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

-

3.1.5 General directions for use

3.1.5.1 Instructions for use

- Inform the authorization holder if the treatment is ineffective.
- Do not clean the treated area until the treatment is finished (up to 12 weeks with regard to the target organisms).
- Always dissolve the whole sachets for the application.

3.1.5.2 Risk mitigation measures

- The product should not be applied in zone accessible to children and to pets.

- If it is applied on rooms accessible to children, children should not access treated areas until all necessary treatments and cleaning have been finalized.
- Remove all food, feed and drinks prior to treatment.
- 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.
- To avoid indirect contamination during nearby application, cover all surfaces and facilities likely to be in contact with food, feed, drinks and animals.

3.1.5.3 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: If symptoms occur call a POISON CENTRE or a doctor.
- IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.
- IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.
- Keep the container or label available.

3.1.5.4 Instructions for safe disposal of the product and its packaging

- Do not discharge unused products into water courses, into pipes (sink, toilets...) nor down the drains.
- Dispose of unused product, its packaging and all other waste in accordance with local regulations.

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

- Shelf-life of 3 years in the commercial packaging.

3.1.6 Other information

-

3.1.7 Packaging of the biocidal product

| Type of packaging | Size/volume of the packaging | Material of the packaging | Type and material of closure(s) | Intended user (e.g. professional, non-professional) | Compatibility of the product with the proposed packaging materials (Yes/No) |
|-------------------|------------------------------|---------------------------|---------------------------------|---|---|
| Bottle | 1L | HDPE, PET or HDPE/EVOH* | | Professionnal | Yes |

| | | | | | |
|-----|--|-------------|---|---------------|-----|
| Box | 50 x 5 mL, 25 x 10mL or 10 x 25mL in water soluble sachets (PVA) | Polystyrene | - | Professionnal | Yes |
|-----|--|-------------|---|---------------|-----|

*EVOH = PVA : Polyvinyl alcohol

3.1.8 Documentation

3.1.8.1 Data submitted in relation to product application

Please see annex 1 for the complete list of the submitted studies.

3.1.8.2 Access to documentation

LODI S.A. has access to analytical methods on the active substance Etofenprox with a Letter of Access of Mitsui Chemicals Agro, INC.

3.2 Assessment of the biocidal product

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

Table 1. Intended use # 1 – Spraying by non professional users

| | |
|---|---|
| Product Type | 18 |
| Where relevant, an exact description of the authorised use | Insecticides, acaricides and products to control other arthropods (Pest control) |
| Target organism (including development stage) | Crawling insects including cockroaches (e.g. <i>B. germanica</i> , <i>B. orientalis</i>), adults and nymphs; Bed bugs (<i>Cimex lectularius</i>), adults and nymphs. |
| Field of use | Indoor |
| Application method(s) | Surface spraying |
| Application rate(s) and frequency | Product applications are made at a maximum rate of 0.5 mL/m ² (equivalent to 0.15 g a.s./m ²). The product is used diluted in water at a rate of 0.5 mL of product diluted in 50 mL water for 1 m ² . Residual efficacy: up to 12 weeks. 2 applications per year maximum. |
| Category(ies) of users | Non-professionals |
| Pack sizes and packaging material | Box Polystyrene wich contains 12 x 5 mL water soluble sachets (PVA*) |

*EVOH = PVA : Polyvinyl alcohol

Table 2. Intended use # 2 – Spraying by professional users

| | |
|---------------------|----|
| Product Type | 18 |
|---------------------|----|

| | |
|---|--|
| Where relevant, an exact description of the authorised use | Insecticides, acaricides and products to control other arthropods (Pest control) |
| Target organism (including development stage) | Crawling insects including German cockroach (<i>B. germanica</i>), adults and nymphs. Oriental cockroach (<i>B. orientalis</i>), adults and nymphs Bed bugs (<i>Cimex lectularius</i>), adults and nymphs <i>Tribolium confusum</i> , adults <i>Sitophilus oryzae</i> , adults <i>Rhyzopertha dominica</i> , adults <i>Oryzaephilus surinamensis</i> , adults <i>Lasioderma serricorne</i> , larvae |
| Field of use | Indoor |
| Application method(s) | Surface spraying in public or private building and in food industries (food production line only) |
| Application rate(s) and frequency | 50 mL in 5 L of water to treat 100m ² Product applications are made at a maximum rate of 0.5 mL/m ² (equivalent to 0.15 g a.s./m ²). The product is used diluted in water at a rate of 0.5 mL of product diluted in 50 mL water for 1m ² . The residual efficacy is up to 2 weeks when applied on porous and non-porous against food-stored pests. The residual efficacy is up to 12 weeks when applied against bed bugs and <i>B. orientalis</i> on non-porous surfaces and porous surfaces (except for cockroaches). |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | HDPE, PET or HDPE/EVOH bottles : up to 1L PVA Water soluble sachets of 5 mL, 10 mL or 25 mL conditioned in PS box : Up to 250 mL (i.e. 50 sachets of 5 mL; 25 sachets of 10 mL or 10 sachets of 25 mL). *EVOH = PVA : Polyvinyl alcohol |

3.2.2 Physical, chemical and technical properties

Concentration of uses: 1% v/v

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | Comment | | | | |
|--|---|---|--|---|----------------|------------------------------|------------------------------|----------------------------|---|
| Physical state at 20 °C and 101.3 kPa Colour at 20 °C and 101.3 kPa Odour at 20 °C and 101.3 kPa | visual method | Test item: Etofenprox PESTANAL Batch n°: SZBB101XV | Translucent liquid with a slight odour. | Richerieux S. 2013, study LODI.09/2013 | Acceptable | | | | |
| pH value | CIPAC MT 75.3 | Test item: Etofenprox 300 g/L EC Batch n°: EC20130114 Etof | Etofenprox 300 g/L EC diluted at 1% m/V in distilled water has a pH value of 6.40 at 19.9°C. | Mériadec, E. 2013, report LODI.01/2013 | Acceptable | | | | |
| Acidity / alkalinity | CIPAC MT 191 | Test item: Etofenprox 300 g/L EC Batch n°: EC20130114 Etof | The acidity of Etofenprox 300 g/L EC calculated as H ₂ SO ₄ was determined to be 0.00736 % m/m at 19.9°C, but it is not necessary. | Mériadec, E. 2013, report LODI.01/2013 | Acceptable | | | | |
| Relative density / bulk density | Pycnometer measurement | Test item: Etofenprox 300 g/L EC Batch n°: EC20130114 Etof | D = 1.031 ± 0.001 (Density is dimensionless, density of test item at 21 °C relative to the density of water at 4°C). | Demangel, B. 2013, report 13-912011-004 | Acceptable | | | | |
| Storage stability test – accelerated storage | Method for quantitation of AS is validated in | Test item: Etofenprox PESTANAL | Appearance of commercial packaging: <table border="1" style="margin-left: auto; margin-right: auto;"> <tr> <td style="width: 50px; height: 20px;"></td> <td style="width: 50px; text-align: center;">Initial</td> <td style="width: 50px; text-align: center;">After 14 days at 54°C</td> <td style="width: 50px; text-align: center;">After 21 days at 54°C</td> </tr> </table> | | Initial | After 14 days at 54°C | After 21 days at 54°C | Richerieux S. 2013, report | Tests for pH and emulsion characteristics (at the |
| | Initial | After 14 days at 54°C | After 21 days at 54°C | | | | | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | | | | Reference | Comment |
|----------|---|--|--|------------------------------------|------------------------------------|---------------------------|--|---|
| | the study LODI.04/2012 CIPAC MT 46.3 CIPAC MT 75.3 | Batch n°: SZBB101XV Test item: Etofenprox 300 G/L EC Batch n°: IN0191114 | PET bottle | White round bottle. No leak | No change, no deformation | No change, no deformation | LODI.07/2013 Richerieux S. 2013, report LODI.08/2013 Doyen A. 2015, DEFITRACE S report No. 15-912011-003 | lowest and highest use concentration) should be determined in all packaging types. Consequently, the following data are still missing: -pH determination of the product stored in HDPE and water soluble bags -emulsion characteristics of the product stored in HDPE and PET, and diluted at 1% v/v As these tests should |
| | | HDPE bottle | White round bottle. No leak | No change, no deformation | No change, no deformation | | | |
| | | PS Box | White square box made in PS* with lid | No change, no deformation, dry box | No change, no deformation, dry box | | | |
| | | Water soluble sachets | Tranparent water soluble sachet. No leak | No change, no deformation. | No change, no deformation | | | |
| | | Plastic bag | Dry rectangular transparent plastic bag | No change, no deformation. | No change, no deformation | | | |
| | | AS content in PET bottle | 30.91 | 30.85 | 31.07 | | | |
| | | % variation | - | -0.19% | +0.52 | | | |
| | | AS content in HDPE bottle | 30.91 | 31.02 | 30.81 | | | |
| | | % variation | - | +0.36 | -0.32 | | | |
| | | AS content in water soluble sachets | 30.73 | 30.70 | 30.39 | | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | | | | Reference | Comment | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|--|-------------|---|------|---|---|-----------------------|------------|----------------------------------|---|-----------|-------------------------------|--|--------------------|---|-------|---|---|---|---|---|-----------|--|----------|--|-----------|--|--|---------|--|--|-----------|--|--|--|--|
| | | | <table border="1"> <tr> <td>% variation</td> <td>-</td> <td>-0.1</td> <td>-1.11</td> </tr> </table> | % variation | - | -0.1 | -1.11 | | | | | be covered by the long term storage study (3 years), no other data is required. | | | | | | | | | | | | | | | | | | | | | | | | | | |
| % variation | - | -0.1 | -1.11 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | *Polystyrene pH determination of the product stored in PET | | | | Doyen A. 2015, DEFITRACE S report No. 15-912011-001 | Regarding other packages, emulsion characteristics of the product diluted at 1% should be provided in all packaging. Considering that emulsion properties are not supposed to be disturbed by the packaging, we consider results of the | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | After 14 days at 54°C in water soluble bags | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | <table border="1"> <thead> <tr> <th></th> <th>Initial</th> <th>After 14 days at 54°C</th> </tr> </thead> <tbody> <tr> <td>Appearance</td> <td>Homogeneous yellow limpid liquid</td> <td>No change, no deformation</td> </tr> <tr> <td>Packaging</td> <td>Water soluble transparent bag</td> <td>Water soluble transparent hardened bag</td> </tr> <tr> <td>% weight variation</td> <td>/</td> <td>-0.7%</td> </tr> <tr> <td rowspan="4">Emulsion characteristics: After 30": Emulsification</td> <td>1% v/v in std water A at 30°C: Homogeneous white opaque liquid.</td> <td>1% v/v in std water A at 30°C: Homogeneous white opaque liquid.</td> </tr> <tr> <td>1% v/v in std water D at 30°C: Homogeneous white opaque liquid.</td> <td>1% v/v in std water D at 30°C: Homogeneous white opaque liquid.</td> </tr> <tr> <td>After 30'</td> <td></td> </tr> <tr> <td>After 2h</td> <td></td> </tr> <tr> <td>After 24h</td> <td></td> <td></td> </tr> <tr> <td>Re-emul</td> <td></td> <td></td> </tr> <tr> <td>After 30'</td> <td></td> <td></td> </tr> </tbody> </table> | | | | | Initial | After 14 days at 54°C | Appearance | Homogeneous yellow limpid liquid | No change, no deformation | Packaging | Water soluble transparent bag | Water soluble transparent hardened bag | % weight variation | / | -0.7% | Emulsion characteristics: After 30": Emulsification | 1% v/v in std water A at 30°C: Homogeneous white opaque liquid. | 1% v/v in std water A at 30°C: Homogeneous white opaque liquid. | 1% v/v in std water D at 30°C: Homogeneous white opaque liquid. | 1% v/v in std water D at 30°C: Homogeneous white opaque liquid. | After 30' | | After 2h | | After 24h | | | Re-emul | | | After 30' | | | | |
| | Initial | After 14 days at 54°C | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Appearance | Homogeneous yellow limpid liquid | No change, no deformation | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Packaging | Water soluble transparent bag | Water soluble transparent hardened bag | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| % weight variation | / | -0.7% | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Emulsion characteristics: After 30": Emulsification | 1% v/v in std water A at 30°C: Homogeneous white opaque liquid. | 1% v/v in std water A at 30°C: Homogeneous white opaque liquid. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1% v/v in std water D at 30°C: Homogeneous white opaque liquid. | 1% v/v in std water D at 30°C: Homogeneous white opaque liquid. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | After 30' | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | After 2h | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| After 24h | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Re-emul | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| After 30' | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | | | Reference | Comment | |
|--|--|--|---|---|--|---|---|--|
| | CIPAC MT 36.3 | Test item: ETOFENPROX 300 g/L Batch n° IN0260316 | Persistent foaming | 1% v/v in std water D 10" : 17 mL 1': 13 mL 3': 10 mL 12': 6 mL | 1% v/v in std water D 10" : 22 mL 1': 17 mL 3': 12 mL 12': 10 mL | Tallon A. 2016, study n° LAB2016-01 (non GLP) | test could be applicable to other packages. | |
| Dissolution rate of water soluble bags | 1st assay: 11" 2nd assay: 7" | 1st assay: 14" 2nd assay: 15" | Emulsion stability after storage for 14 days at 54°C in glass flask | | | | | |
| Emulsion characteristics | 25% v/v in water D Initial: Homogeneous white opaque liquid | 25% v/v in water D Initial: Homogeneous white opaque liquid | After 30 min | Homogeneous white opaque liquid | Homogeneous white opaque liquid | Richerieux S. 2013, report LODI.01/2015 | | |
| After 2h | Homogeneous white opaque liquid | Homogeneous white opaque liquid | After 24h | 1 mL of sedimentation | 1 mL of sedimentation | | | |
| Re-emul. after 30 sec | Homogeneous white opaque liquid | Homogeneous white opaque liquid | Final emulsion after 30 min | Homogeneous white opaque liquid | Homogeneous white opaque liquid | | | |
| | | | After 21 days at 54°C in PET bottle | | | | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | | | Reference | Comment |
|----------|----------------------|--|---|--|--|---|---------|
| | | | | Initial | After 21 days at 54°C | Tallon A. 2016, study n° LAB2016-01 (non GLP) | |
| | | | Product aspect | Translucent pale yellow liquid | No change | | |
| | | | PET bottle | White round bottle and opaque with a white cap. Clean bottle. | No change, no deformation | | |
| | | | PET bottle % variation content | / | -0.068% | | |
| | | | Product aspect | Translucent pale yellow liquid | No change | | |
| | | | HDPE measuring bottle | Oval bottle and slightly opaque with two caps. Clean bottle. | No change, no deformation | | |
| | | | % variation content HDPE measuring bottle | / | -0.065% | | |
| | | | Emulsion stability after storage for 21 days at 54°C in glass flask | | | | |
| | | | Emulsion characteristics | 25% v/v in water D Initial: Homogeneous white opaque liquid | 25% v/v in water D Initial: Homogeneous white opaque liquid | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | | | Reference | Comment |
|--|--|---|---|---------------------------------|---------------------------------|--|---|
| | | | After 30 min | Homogeneous white opaque liquid | Homogeneous white opaque liquid | | |
| | | | After 2h | Homogeneous white opaque liquid | Homogeneous white opaque liquid | | |
| | | | After 24h | 1 mL of sedimentation | Homogeneous white opaque liquid | | |
| | | | Re-emul. after 30 sec | Homogeneous white opaque liquid | Homogeneous white opaque liquid | | |
| | | | Final emulsion after 30 min | Homogeneous white opaque liquid | Homogeneous white opaque liquid | | |
| Storage stability test – long term storage at ambient temperature | Method for quantitation of AS is validated in the study LODI.04/2012 | Test item: V33 traitement multi usages Batch n°: 04020920PT | <u>Storage in commercial packaging material</u> | | | Richerieux S. 2013, report LODI.10/2013 Richerieux S. 2013, report LODI.13/2013 | Acceptable The product is stable after 3 years storage at ambient temperature. Chemical stability and |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | | | | Reference | Comment |
|----------|----------------------|--|---------------------------|---|------------------------------------|------------------------------------|--|---------|
| | | | | Initial | After 18 months at 20°C | After 24 months at 20°C | | |
| | | | PET bottle | White round bottle. No leak. | No change, no deformation | No change, no deformation | packaging stability (e.g. studies LODI.11/2013 and LODI.14/2013) and stability of the physical and technical properties (e.g. LAB 2016-03 and LODI.22/2015) are considered demonstrated. Persistence of foam test was carried out separately (see below). | |
| | | | HDPE/EVOH bottle | White round bottle. No leak. | No change, no deformation | No change, no deformation | | |
| | | | PS* Box | White square box made in PS* with lid | No change, no deformation, dry box | No change, no deformation, dry box | | |
| | | | Water soluble sachets** | Transparent water soluble sachet. No leak | No change, no deformation. | No change, no deformation | | |
| | | | Plastic bag | Dry rectangular transparent plastic bag | No change, no deformation. | No change, no deformation | | |
| | | | AS content in PET bottle | 30.91 | 31.21 | 31.04 | | |
| | | | % variation | - | +1.40 | +0.55 | | |
| | | | AS content in HDPE bottle | 30.91 | 30.56 | 30.92 | | |
| | | | % variation | - | +0.10 | -0.03 | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | | | | Reference | Comment |
|----------|----------------------|--|---|--|------------------------------------|-------|-----------|---------|
| | | | AS content in water soluble sachets** | 30.73 | 30.32 | 30.11 | | |
| | | | % variation | - | -1.33 | -2.02 | | |
| | | | *polystyrene; **polyvinyl alcohol | | | | | |
| | | | Intermediate report in commercial packaging | | | | | |
| | | | | Initial | After 18 months at 30°C | | | |
| | | | PET bottle | White round bottle. No leak | No change, no deformation | | | |
| | | | HDPE/EVOH bottle | White round bottle. No leak | No change, no deformation | | | |
| | | | PS* Box | White square box made in PS* with lid | No change, no deformation, dry box | | | |
| | | | Water soluble sachets | Tranparent water soluble sachet. No leak | No change, no deformation. | | | |
| | | | Plastic bag | Dry rectangular transparent plastic bag | No change, no deformation. | | | |
| | | | Content of AS in PET bottle | 30.91 | 30.77 | | | |
| | | | % variation | - | -0.45 | | | |
| | | | Content of AS in HDPE bottle | 30.91 | 30.32 | | | |
| | | | % variation | - | -1.91 | | | |
| | | | Content of AS in water soluble sachets | 30.73 | 29.65 | | | |
| | | | % variation | - | -3.51 | | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | | | | Reference | Comment |
|----------|----------------------|---|----------------------|--|---------------------------------|---|--|---------|
| | | | *polystyrene | | | | | |
| | GIFAP Monograph n°17 | ETO FENPROX 300 G/L Batch EC 20130114Eto f Batch EC 20130114Eto f-d | Packaging stability | | | | Richerieux S. 2016, Study No LODI.11/2013 Richerieux S. 2016, Study No LODI.14/2013 | |
| | | | | Initial | After 3 years at 20°C | After 3 years at 30°C | | |
| | | | PET bottle | White round bottle. No leak of the bottle or the cap | No leak or deformation | No leak or deformation | | |
| | | | PEHD/EVOH bottle | White round bottle. No leak of the bottle or the cap | No leak or deformation | No leak or deformation | | |
| | | | PS box | White square box made in polystyrene with lid | Dry box. No hole or deformation | No trace of sample. Dry box. No hole or deformation | | |
| | | | Water soluble sachet | Transparent water soluble sachet. No leak | No leak or seepage | No leak or seepage | | |
| | | | Plastic bag | Dry rectangular transparent plastic bag | Dry bag. No trace of sample | Dry bag. No trace of sample | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | | | | Reference | Comment | | | | | | | | | | | | | | | | | | | | | | | | |
|--------------------|-------------------------------------|--|---|--|--|--|-----------|---------|-----------------------|-----------------------|--------|-------------------------------------|-----------|-----------|--------------------|--------|------------------------------------|------------------------------------|------------|---|------------------------------------|------------------------------------|--|---------|-----------------------|-----------------------|--------|-------------------------------------|-----------|-----------|--|--|
| | | | <p><u>Chemical stability</u> Results for batch EC20130114Etof packaged in PEHD/EVOH and PET bottles:</p> <table border="1" data-bbox="965 491 1765 1066"> <thead> <tr> <th></th> <th>Initial</th> <th>After 3 years at 20°C</th> <th>After 3 years at 30°C</th> </tr> </thead> <tbody> <tr> <td>Aspect</td> <td>Translucent liquid with slight odor</td> <td>Unchanged</td> <td>Unchanged</td> </tr> <tr> <td>Chemical stability</td> <td>30.91%</td> <td>30.31% (PEHD/EVOH) 30.23% (PET)</td> <td>30.32% (PEHD/EVOH) 29.73% (PET)</td> </tr> <tr> <td>%variation</td> <td>/</td> <td>-1.94% (PEHD/EVOH) -2.20% (PET)</td> <td>-1.91% (PEHD/EVOH) -3.82% (PET)</td> </tr> </tbody> </table> <p>Results for batch EC20130114Etof-d packaged in water soluble sachet:</p> <table border="1" data-bbox="965 1173 1765 1383"> <thead> <tr> <th></th> <th>Initial</th> <th>After 3 years at 20°C</th> <th>After 3 years at 30°C</th> </tr> </thead> <tbody> <tr> <td>Aspect</td> <td>Translucent liquid with slight odor</td> <td>Unchanged</td> <td>Unchanged</td> </tr> </tbody> </table> | | | | | Initial | After 3 years at 20°C | After 3 years at 30°C | Aspect | Translucent liquid with slight odor | Unchanged | Unchanged | Chemical stability | 30.91% | 30.31% (PEHD/EVOH) 30.23% (PET) | 30.32% (PEHD/EVOH) 29.73% (PET) | %variation | / | -1.94% (PEHD/EVOH) -2.20% (PET) | -1.91% (PEHD/EVOH) -3.82% (PET) | | Initial | After 3 years at 20°C | After 3 years at 30°C | Aspect | Translucent liquid with slight odor | Unchanged | Unchanged | | |
| | Initial | After 3 years at 20°C | After 3 years at 30°C | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Aspect | Translucent liquid with slight odor | Unchanged | Unchanged | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Chemical stability | 30.91% | 30.31% (PEHD/EVOH) 30.23% (PET) | 30.32% (PEHD/EVOH) 29.73% (PET) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| %variation | / | -1.94% (PEHD/EVOH) -2.20% (PET) | -1.91% (PEHD/EVOH) -3.82% (PET) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | Initial | After 3 years at 20°C | After 3 years at 30°C | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Aspect | Translucent liquid with slight odor | Unchanged | Unchanged | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | | | | | | Reference | Comment |
|----------|----------------------|---|--------------------|--|--|--|--|--|-----------|---------|
| | | | Chemical stability | 30.73% | 30.29% | 29.72% | | | | |
| | | | %variation | / | -1.43% | -3.29% | | | | |
| | | Test item: Etofenprox 300g/L EC Batch n°: EC20150122 Etof | | Initial | After 12 months at 30°C | After 18 months at 30°C | After 24 months at 30°C | After 36 months at 30°C | | |
| | | | 1L HDPE bottle | Round, opaque and white bottle with a white cap. | White round bottle. No leak. The bottle is slightly digged | White round bottle. No leak. The bottle is slightly digged | White round bottle. No leak. The bottle is slightly digged | White round bottle. No leak. The bottle is slightly digged | | |
| | | | Sample aspect | Translucent light yellow liquid | No change, | No change, | No change, | No change, | | |
| | | | | | | | | | | |

Richerieux S. 2018, report LODI.02/2015

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | | | | | | Reference | Comment |
|----------|----------------------|--|--|---|----------------------------------|----------------------------------|--|----------------------------------|-----------|---------|
| | | | Weight (g) | 1077.46 | 1077.34 | 1077.20 | 1077.05 | 1076.69 | | |
| | | | % variation | / | -0.01% | -0.02% | -0.04% | -0.07% | | |
| | | | <u>Storage in commercial packaging: material 1L PEHD and biocidal product were introduced in a 250 mL PEHD measuring bottle:</u> | | | | | | | |
| | | | | Initial | After 12 months at 30°C | After 18 months at 30°C | After 24 months at 30°C | After 36 months at 30°C | | |
| | | | 250mL HDPE bottle | Round, opaque and white bottle with two white caps. | White round bottle. No leak. The | White round bottle. No leak. The | White round bottle. No leak. The bottle is | White round bottle. No leak. The | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | | | | | | Reference | Comment |
|---------------|---------------------------------|--|------------|------------|---------------------------|---------------------------|-----------------|---------------------------|---|---------|
| | | | | | bottle is slightly digged | bottle is slightly digged | slightly digged | bottle is slightly digged | Richerieux S. 2018, report LODI.14/2014 | |
| Sample aspect | Translucent light yellow liquid | No change, | No change, | No change, | No change, | | | | | |
| Weight (g) | 312.22 | 312.26 | 312.27 | 312.28 | 312.29 | | | | | |
| % variation | / | 0.01% | 0.02% | 0.02% | 0.02% | | | | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | | | | | | Reference | Comment |
|----------|----------------------|--|----------------|--|------------------------------|---------------------------|---------------------------|---------------------------|-----------|---------|
| | | | | Initial | After 12 months at 20°C | After 18 months at 20°C | After 24 months at 20°C | After 36 months at 20°C | | |
| | | | 1L HDPE bottle | Round, opaque and white bottle with a white cap. | White round bottle. No leak. | No change, no deformation | No change, no deformation | No change, no deformation | | |
| | | | Sample aspect | Translucent light yellow liquid | No change, | No change, | No change, | No change, | | |
| | | | Weight (g) | 1068.64 | 1068.81 | 1068.84 | 1068.87 | 1069.02 | | |
| | | | % variation | / | 0.02% | 0.02% | 0.02% | 0.04% | | |
| | | | | | After 12 months at 20°C | After 18 months at 20°C | After 24 months at 20°C | After 36 months at 20°C | | |
| | | | 250 mL | Round, opaque and white | White round bottle. | No change, no | No change, no | No change, no | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | | | | | | Reference | Comment | |
|---|----------------------|--|--|---------------------------------|------------|---|-------------|-------------|---------------------------------|---|-----------|
| | | | HDPE bottle | bottle with two white caps. | No leak. | deformation | deformation | deformation | | | |
| | | | Sample aspect | Translucent light yellow liquid | No change, | No change, | No change, | No change, | | | |
| | | | Weight (g) | 313.84 | 313.94 | 313.98 | 314.01 | 314.1 | | | |
| | | | % variation | / | 0.03% | 0.04% | 0.05% | 0.08% | | | |
| | CIPAC MT36.3 | Etofenprox 300 g/L EC (diluted at 1%) | Test item was stored in polyethylene bottle, sealed with a polyethylene cap. Test was performed before and after storage for 36 months at 20°C±2°C. | | | | | | Tallon 2019 Study N° LAB2016-03 | Acceptable. Emulsion is stable for 36 months at 1% v/v in polyethylene. However stability of emulsion and re-emulsification after long term storage at ambient temperature in PET and water soluble bags are missing. | |
| At initial time (1% v/v in CIPAC water D) : | | | | | | <table border="1"> <tr> <td data-bbox="958 970 1400 1010">Assay No.</td> <td data-bbox="1400 970 1774 1010">T initial</td> </tr> </table> | | Assay No. | | | T initial |
| Assay No. | T initial | | | | | | | | | | |
| Volume of test item (mL) | | | | | | 1.0 | | | | | |
| Initial emulsification Observation after 30s | | | | | | Homogeneous white liquid | | | | | |
| Emulsion stability on standing | | | After 30 min | | | Homogeneous white liquid | | | | | |
| | | | After 2h | | | Homogeneous white liquid | | | | | |
| Re-emulsification: after 24h Observation after 30s | | | | | | Homogeneous white liquid | | | | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | | Reference | Comment | | | | | | | |
|---|---|--|--|--------------------------|---|--------------------------|--------------------------|--|--------------------------|--|--|--|--|
| | | | <table border="1"> <tr> <td data-bbox="965 336 1402 411">Final emulsion stability Observation after 30 min</td> <td data-bbox="1402 336 1765 411">Homogeneous white liquid</td> </tr> </table> | | Final emulsion stability Observation after 30 min | Homogeneous white liquid | | <p>Considering that emulsion properties are not supposed to be disturbed by the packaging between HDPE and PET, we consider results of the test could be applicable to PET packaging.</p> <p>As emulsion stability data in water soluble bag after accelerated storage and data on long term stability in HPDE were found acceptable. We consider results of the test could be</p> | | | | | |
| Final emulsion stability Observation after 30 min | Homogeneous white liquid | | | | | | | | | | | | |
| | | | <p>At 6 months (1% v/v in CIPAC water D), 12 months, 24 months and 36 months :</p> | | | | | | | | | | |
| | | | <table border="1"> <tr> <td data-bbox="965 528 1182 592">Assay No.</td> <td data-bbox="1182 528 1765 592">T 6 months, 12 months, 24 months, 36 months</td> </tr> </table> | Assay No. | T 6 months, 12 months, 24 months, 36 months | | | | | | | | |
| Assay No. | T 6 months, 12 months, 24 months, 36 months | | | | | | | | | | | | |
| | | | <table border="1"> <tr> <td data-bbox="965 603 1402 639">Volume of test item (mL)</td> <td data-bbox="1402 603 1765 639">1.0</td> </tr> </table> | Volume of test item (mL) | 1.0 | | | | | | | | |
| Volume of test item (mL) | 1.0 | | | | | | | | | | | | |
| | | | <table border="1"> <tr> <td colspan="2" data-bbox="965 644 1402 719">Initial emulsification Observation after 30s</td> <td data-bbox="1402 644 1765 719">Homogeneous white liquid</td> </tr> </table> | | Initial emulsification Observation after 30s | | Homogeneous white liquid | | | | | | |
| Initial emulsification Observation after 30s | | Homogeneous white liquid | | | | | | | | | | | |
| | | | <table border="1"> <tr> <td data-bbox="965 729 1182 869" rowspan="2">Emulsion stability on standing</td> <td data-bbox="1182 729 1402 799">After 30 min</td> <td data-bbox="1402 729 1765 799">Homogeneous white liquid</td> </tr> <tr> <td data-bbox="1182 799 1402 869">After 2h</td> <td data-bbox="1402 799 1765 869">Homogeneous white liquid</td> </tr> </table> | | Emulsion stability on standing | After 30 min | Homogeneous white liquid | After 2h | Homogeneous white liquid | | | | |
| Emulsion stability on standing | After 30 min | Homogeneous white liquid | | | | | | | | | | | |
| | After 2h | Homogeneous white liquid | | | | | | | | | | | |
| | | | <table border="1"> <tr> <td data-bbox="965 879 1402 954">Re-emulsification: after 24h Observation after 30s</td> <td data-bbox="1402 879 1765 954">Homogeneous white liquid</td> </tr> </table> | | Re-emulsification: after 24h Observation after 30s | Homogeneous white liquid | | | | | | | |
| Re-emulsification: after 24h Observation after 30s | Homogeneous white liquid | | | | | | | | | | | | |
| | | | <table border="1"> <tr> <td data-bbox="965 959 1402 1034">Final emulsion stability Observation after 30 min</td> <td data-bbox="1402 959 1765 1034">Homogeneous white liquid</td> </tr> </table> | | Final emulsion stability Observation after 30 min | Homogeneous white liquid | | | | | | | |
| Final emulsion stability Observation after 30 min | Homogeneous white liquid | | | | | | | | | | | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | Comment | | | | | | | | | | | | | | | | | | | | | |
|---|----------------------|--|---|--------------------------|--|----------------|----|------|------|------------|------|------|-------------|------|------|-------------|------|------|-------------|------|------|-------------|------|------|-----------------------------------|---|
| | | | | | applicable to water soluble packaging. | | | | | | | | | | | | | | | | | | | | | |
| | CIPAC MT 75.3 | Etofenprox 300 g/L EC | <p>pH determination after 3 years of storage at 30°C±2°C The test item was stored in polyethylene bottle, sealed with a polyethylene cap during all the study.</p> <table border="1"> <thead> <tr> <th>T</th> <th>pH (1%)</th> <th>Temperature °C</th> </tr> </thead> <tbody> <tr> <td>T0</td> <td>5.67</td> <td>19.6</td> </tr> <tr> <td>T 6 months</td> <td>5.18</td> <td>18.9</td> </tr> <tr> <td>T 12 months</td> <td>4.93</td> <td>19.5</td> </tr> <tr> <td>T 18 months</td> <td>5.16</td> <td>18.9</td> </tr> <tr> <td>T 24 months</td> <td>5.17</td> <td>19.9</td> </tr> <tr> <td>T 36 months</td> <td>5.28</td> <td>20.2</td> </tr> </tbody> </table> | T | pH (1%) | Temperature °C | T0 | 5.67 | 19.6 | T 6 months | 5.18 | 18.9 | T 12 months | 4.93 | 19.5 | T 18 months | 5.16 | 18.9 | T 24 months | 5.17 | 19.9 | T 36 months | 5.28 | 20.2 | Tallon 2018 Study N° LODI.22/2015 | <p>Acceptable. pH is stable after 3 years of storage at 30 °C in polyethylene bottle.</p> <p>Considering that pH is not supposed to be disturbed by the packaging and results from accelerated storage study in PET, we consider results of the test could be applicable to PET and water soluble bags packaging.</p> |
| T | pH (1%) | Temperature °C | | | | | | | | | | | | | | | | | | | | | | | | |
| T0 | 5.67 | 19.6 | | | | | | | | | | | | | | | | | | | | | | | | |
| T 6 months | 5.18 | 18.9 | | | | | | | | | | | | | | | | | | | | | | | | |
| T 12 months | 4.93 | 19.5 | | | | | | | | | | | | | | | | | | | | | | | | |
| T 18 months | 5.16 | 18.9 | | | | | | | | | | | | | | | | | | | | | | | | |
| T 24 months | 5.17 | 19.9 | | | | | | | | | | | | | | | | | | | | | | | | |
| T 36 months | 5.28 | 20.2 | | | | | | | | | | | | | | | | | | | | | | | | |
| Storage stability test - low temperature | CIPAC MT 75.3 | Test item: ETOFENPROX 300 g/L EC | <u>Storage in closed glass bottle</u> | Doyen A. 2015, report n° | Acceptable | | | | | | | | | | | | | | | | | | | | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | | | Reference | Comment |
|---|---|---|---|-----------------------------------|---------------------------|---------------|---|
| stability test for liquids | CIPAC MT 36.3 | Batch n°: EC20141127 Etof | | Initial | After 7days at 0°C | 14-912011-004 | The preparation is stable at low temperature. |
| | | | Appearance | Homogeneous yellow limpid liquid. | No change | | |
| | | | Emulsion stability of 1% w/v in std water A at 30°C initially | Homogeneous | Homogeneous | | |
| | | | after 30 minutes | Homogeneous | Homogeneous | | |
| after 2 hours | Homogeneous | Homogeneous | | | | | |
| after 24 hours | Homogeneous with white deposit of <1 mL | Homogeneous with white deposit of <1 mL | | | | | |
| after re-emulsification after 24 h | Homogeneous | Homogeneous | | | | | |
| 30 minutes after the re-emulsification | Homogeneous | Homogeneous | | | | | |
| Emulsion stability of 1% w/v in std water D at 30°C | Homogeneous | | | | | | |
| | Homogeneous | | | | | | |
| | Homogeneous with white deposit of <1 mL | | | | | | |
| | Homogeneous with white | | | | | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | | | Reference | Comment |
|----------|------------------------------------|--|--|--|--|---|---------|
| | | | initially after 30 minutes after 2 hours after 24 hours after re-emulsification after 24 h 30 minutes after the re-emulsification | deposit of <1 mL Homogeneous Homogeneous | Homogeneous Homogeneous Homogeneous Homogeneous with white deposit of <1 mL Homogeneous Homogeneous | | |
| | CIPAC MT 39.3 CIPAC MT 36.3 | Test item: ETOFENPROX 300 g/L Batch n° IN0240116 | Storage in white opaque PET flasks | | | DOYEN, A. 2016, report No 16-912011-003 (GLP) | |
| | | | Appearance | Homogeneous yellow limpid liquid | Homogeneous yellow limpid liquid | | |
| | | | Emulsion characteristics | 25% v/v in water D and A at 30°C | 25% v/v in water D and A at 30°C | | |
| | | | Initial After 30 min After 2h After 24h | Homogeneous white opaque liquid | Homogeneous white opaque liquid | | |
| | | | Re-emul. after 30 sec | Homogeneous white opaque liquid | Homogeneous white opaque liquid | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | | | Reference | Comment |
|--|----------------------|--|--|---------------------------------|---------------------------------|-----------|---|
| | | | Final emulsion after 30 min | Homogeneous white opaque liquid | Homogeneous white opaque liquid | | |
| Effects on content of the active substance and technical characteristics of the biocidal product - light | | | Active substance is not light sensitive. | | | | The packaging is opaque than can reduce the impact of light on the product. Moreover, the active substance is not sensitive to light. Therefore, no degradation of the product by the light is expected. Acceptable |
| Effects on content of the active substance and technical characteristics of the biocidal product - temperature and humidity | | | See accelerated storage The product is stable at temperature and is a liquid. | | | | Acceptable |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | Comment | | | | | | | | | | | | | | |
|---|---|---|---|---|------------|-----------|-------------|------------------|-------------|---------------|-------------|----------------|---|------------------------------------|-------------|--|-------------|--|------------|
| Effects on content of the active substance and technical characteristics of the biocidal product - reactivity towards container material | | | See results of storages above. Packagings are stable and compatible with the product. | | Acceptable | | | | | | | | | | | | | | |
| Wettability | - | - | - | - | - | | | | | | | | | | | | | | |
| Suspensibility, spontaneity and dispersion stability | - | - | - | - | - | | | | | | | | | | | | | | |
| Wet sieve analysis and dry sieve test | - | - | - | - | - | | | | | | | | | | | | | | |
| Emulsifiability, re-emulsifiability and emulsion stability | CIPAC MT 36.3 (visual method) | Test item: ETO FENPROX 300 G/L EC Batch: EC20130114 Etof ETO FENPROX 300 g/L Batch IN0260316 | Emulsion stability of 1% w/v dilution <table border="1"> <tr> <td>Emulsion stability of 1% w/v in std water A at 30°C</td> <td></td> </tr> <tr> <td>initially</td> <td>Homogeneous</td> </tr> <tr> <td>after 30 minutes</td> <td>Homogeneous</td> </tr> <tr> <td>after 2 hours</td> <td>Homogeneous</td> </tr> <tr> <td>after 24 hours</td> <td>Homogeneous with white deposit of <1 mL</td> </tr> <tr> <td>after re-emulsification after 24 h</td> <td>Homogeneous</td> </tr> <tr> <td>30 minutes after the re-emulsification</td> <td>Homogeneous</td> </tr> </table> | Emulsion stability of 1% w/v in std water A at 30°C | | initially | Homogeneous | after 30 minutes | Homogeneous | after 2 hours | Homogeneous | after 24 hours | Homogeneous with white deposit of <1 mL | after re-emulsification after 24 h | Homogeneous | 30 minutes after the re-emulsification | Homogeneous | Doyen A. 2015, report n° 14-912011-004 Tallon A. 2016, study n° LAB2016-03 (no GLP) Tallon A. 2016, study n° LAB2016-02 (no GLP) | Acceptable |
| Emulsion stability of 1% w/v in std water A at 30°C | | | | | | | | | | | | | | | | | | | |
| initially | Homogeneous | | | | | | | | | | | | | | | | | | |
| after 30 minutes | Homogeneous | | | | | | | | | | | | | | | | | | |
| after 2 hours | Homogeneous | | | | | | | | | | | | | | | | | | |
| after 24 hours | Homogeneous with white deposit of <1 mL | | | | | | | | | | | | | | | | | | |
| after re-emulsification after 24 h | Homogeneous | | | | | | | | | | | | | | | | | | |
| 30 minutes after the re-emulsification | Homogeneous | | | | | | | | | | | | | | | | | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | Comment | | | | | | | | | | | | |
|---|--|--|---|---|--|-------------------------------------|--------------------------|--|--------------------------|--------------------------------|--------------------------|-----------------------------|--------------------------|-------------------------------------|---------------------------------|--|--|
| | | | <table border="1"> <tr> <td data-bbox="965 341 1406 762"> Emulsion stability of 1% w/v in std water D at 30°C initially after 30 minutes after 2 hours after 24 hours after re-emulsification after 24 h 30 minutes after the re-emulsification </td> <td data-bbox="1406 341 1765 762"> Homogeneous Homogeneous Homogeneous with white deposit of <1 mL Homogeneous with white deposit of <1 mL Homogeneous Homogeneous </td> </tr> </table> <p data-bbox="965 810 1765 837">Emulsion stability of 1% v/v dilution in standard water D:</p> <table border="1"> <tr> <td data-bbox="994 842 1397 922">Initial emulsification after 30 sec</td> <td data-bbox="1397 842 1736 922">Homogeneous white liquid</td> </tr> <tr> <td data-bbox="994 927 1397 1070">Emulsion stability after 30 min after 2h after 24h</td> <td data-bbox="1397 927 1736 1070">Homogeneous white liquid</td> </tr> <tr> <td data-bbox="994 1075 1397 1155">Re-emulsification after 30 sec</td> <td data-bbox="1397 1075 1736 1155">Homogeneous white liquid</td> </tr> <tr> <td data-bbox="994 1160 1397 1240">Final emulsion after 30 min</td> <td data-bbox="1397 1160 1736 1240">Homogeneous white liquid</td> </tr> </table> <p data-bbox="965 1287 1765 1315">Emulsion stability of 25% v/v dilution in standard water D:</p> <table border="1"> <tr> <td data-bbox="994 1319 1397 1399">Initial emulsification after 30 sec</td> <td data-bbox="1397 1319 1736 1399">Homogeneous white opaque liquid</td> </tr> </table> | Emulsion stability of 1% w/v in std water D at 30°C initially after 30 minutes after 2 hours after 24 hours after re-emulsification after 24 h 30 minutes after the re-emulsification | Homogeneous Homogeneous Homogeneous with white deposit of <1 mL Homogeneous with white deposit of <1 mL Homogeneous Homogeneous | Initial emulsification after 30 sec | Homogeneous white liquid | Emulsion stability after 30 min after 2h after 24h | Homogeneous white liquid | Re-emulsification after 30 sec | Homogeneous white liquid | Final emulsion after 30 min | Homogeneous white liquid | Initial emulsification after 30 sec | Homogeneous white opaque liquid | | |
| Emulsion stability of 1% w/v in std water D at 30°C initially after 30 minutes after 2 hours after 24 hours after re-emulsification after 24 h 30 minutes after the re-emulsification | Homogeneous Homogeneous Homogeneous with white deposit of <1 mL Homogeneous with white deposit of <1 mL Homogeneous Homogeneous | | | | | | | | | | | | | | | | |
| Initial emulsification after 30 sec | Homogeneous white liquid | | | | | | | | | | | | | | | | |
| Emulsion stability after 30 min after 2h after 24h | Homogeneous white liquid | | | | | | | | | | | | | | | | |
| Re-emulsification after 30 sec | Homogeneous white liquid | | | | | | | | | | | | | | | | |
| Final emulsion after 30 min | Homogeneous white liquid | | | | | | | | | | | | | | | | |
| Initial emulsification after 30 sec | Homogeneous white opaque liquid | | | | | | | | | | | | | | | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | | Reference | Comment |
|--|----------------------|---|--|---|---|------------|
| | | | Emulsion stability after 30 min after 2h after 24h | Homogeneous white opaque liquid | | |
| | | | Re-emulsification after 30 sec | Homogeneous white opaque liquid | | |
| | | | Final emulsion after 30 min | Homogeneous white opaque liquid | | |
| Disintegration time | - | - | - | - | - | - |
| Particle size distribution, content of dust/fines, attrition, friability | - | - | - | - | - | - |
| Persistent foaming | CIPAC MT 47.1 | Test item: ETO FENPROX 300 G/L EC Batch EC 20130114Eto f | Persistent foaming CIPAC MT 47.1 1% v/v in standard water D Test temperature: 20 ± 2°C | 10": 2 mL 1': 1 mL 3': 1 mL 12': 0 mL | Doyen A, 2013, report n°13- 912011- 005 | Acceptable |
| | | ETO FENPROX 300 G/L EC Batch IN0191114 | Persistent foaming CIPAC MT 47.2 1% v/v in standard water D Test temperature: 20 ± 2°C | 10": 17 mL 1': 13 mL 3': 10 mL 12': 6 mL | Doyen A. 2015, DEFITRACE S report No. 15- 912011- 001 | |
| | | | | | Doyen, A. 2016, study No 16- | |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | Comment |
|--|--|---|---|---|---|
| | | | | 912011-003 | |
| Pourability | - | - | - | - | - |
| Burning rate — smoke generators | - | - | - | - | - |
| Burning completeness — smoke generators | - | - | - | - | - |
| Composition of smoke — smoke generators | - | - | - | - | - |
| Spraying pattern — aerosols | | | | | |
| Physical compatibility | - | - | - | - | - |
| Chemical compatibility | - | - | - | - | - |
| Degree of dissolution and dilution stability | - | - | - | - | - |
| Surface tension | EC A5 Method OECD Guideline 115 | Test item: ETO FENPROX 300 G/L EC Batch: EC20130114 Etof | The surface tension was found to be 34.8 ± 0.4 mN/m at $20.1^\circ\text{C} \pm 0.1^\circ\text{C}$ (1% v/v dilution). | Benjamin, D., 2013 report 13-912011-003 | Acceptable The preparation is surface active. |
| Viscosity | OECD Test Guideline 114 (Viscosity of Liquids) | Test item: ETO FENPROX 300 G/L EC Batch: EC20130114 Etof | The dynamic viscosity of Etofenprox 300 g/L EC is 39cP ($=37.83$ mm ² /s) at $20.0^\circ\text{C} \pm 0.2^\circ\text{C}$. | Meriadec, E.2013, report LODI.04/2013 | Acceptable. Viscosity at 40 °C was not determined. |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | Comment |
|----------|----------------------|--|---------|-----------|--|
| | | | | | However, the composition is sufficient to conclude that the product is not classified for aspiration hazard, therefore the determination of the viscosity at 40 °C is not necessary. |

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

The product FENOX is an emulsifiable concentrate (EC). All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.

The appearance of the product is a translucent liquid with a slight odour. In aqueous solution (1% dilution), it has a pH value of 6.40 at 19.9°C.

There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C or after 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. The product is considered stable after 3 years at ambient temperature.

Its technical characteristics are acceptable for an EC formulation.

3.2.3 Physical hazards and respective characteristics

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | Comments |
|----------------------|---------------------------------|---|--|---|---|
| Explosives | Statement | - | An evaluation of the structural groups in the structural formula of each substance, including the oxygen balance, establishes beyond reasonable doubt that the product is incapable of rapid decomposition with evolution of gas release of heat. Therefore, testing according to EU Method A.14 for explosive properties is not required. Etofenprox 300 g/L EC has no potential for explosivity. | Richerieux S. 2013, study LODI.05/20 13+am1 study LODI.05/20 13 | The energy decomposition is higher than 300J/g, but less than 500J/g. |
| | <i>DSC screening test</i> | Test item: Etofenprox 300 g/L EC Batch: LAB0308202 101 | At 394°C, an exothermic peak was recorded with an energy around 460J/g. | Lecomte L., 2021 <i>Report 21-912011-002</i> | The product is not considering explosive based on the composition statement of the product. |
| Flammable gases | - | - | Not required as the product is a liquid product. | - | - |
| Flammable aerosols | - | - | Not required as the product is a liquid product. | - | - |
| Oxidising gases | - | - | Not required as the product is a liquid product. | - | - |
| Gases under pressure | - | - | Not required as the product is a liquid product. | - | - |
| Flammable liquids | EU Method A9 ISO Standard 3679. | Test item: Etofenprox 300 g/L EC Batch n°: EC2013011 4Etof | The product Etofenprox 300 g/L EC is not flammable. The flash point of Etofenprox 300 g/L EC was determined according to EU Method A9 and ISO Standard 3679. The flash point of Etofenprox 300 g/L EC was 137.0 ± 0.5 °C (corrected value). | Demangel B. 2013, report 13-912011-001 | The product is not classified as flammable according to CLP regulation. |
| Flammable solids | - | - | Not required as the product is a liquid product. | - | |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | Comments |
|---------------------------------------|----------------------|--|--|--|--|
| Self-reactive substances and mixtures | DSC screening test | Test item: Etofenprox 300 g/L EC Batch: LAB0308202 101 | At 394°C, an exothermic peak was recorded with an energy around 460J/g. | Lecomte L., 2021 Report 21-912011-002 | Acceptable The product is not classified as self-reactive. |
| | SADT Test H4 | Test item: Etofenprox 300 g/L EC Batch Number 97233 (400028513) | The maximum heat accumulation temperature of the SADT H.4 test is over 75°C. The substance is therefore exempt from classification as a self-reactive substance of UN Class 4, Division 4.1. | K. Arif, 2022 GLP301601 1702R1/2022 | |
| Pyrophoric liquids | - | | Experience in use shows that the product is not pyrophoric | | Acceptable |
| Pyrophoric solids | - | - | Not required as the product is a liquid product. | - | Acceptable |
| Self-heating substances and mixtures | - | - | Not required as the product is a liquid product. | - | Not totally correct. On the other hand, it is recognized that liquids have a low contact surface with air and are generally not classified for this hazard. |
| Substances and mixtures which in | - | - | The product is intended to be used after dilution in water and experience in use shows no emission of gases. | - | Acceptable |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | Comments |
|---|----------------------|--|--|---|---|
| contact with water emit flammable gases | | | | | |
| Oxidising liquids | Statement | - | The principle of this study was to have information on chemical formula and hydrodynamics of each ingredient in Etofenprox 300 g/L EC in order to assess if the formulation is capable of reactive exothermically with combustible materials and if it has oxidising properties. No component of Etofenprox 300 g/L EC is associated with oxidising properties therefore the formulation is not classified for oxidising properties. | Richerieux S. 2013, study LODI.08/20 13 | The product does not contain components classified Ox.1, Ox.2 or Ox.3 and oxygen are linked to carbons or hydrogens only, therefore, the product is not classified as oxidising liquid according to CLP regulation. |
| Oxidising solids | - | - | Not required as the product is a liquid product. | - | |
| Organic peroxides | - | - | Not required as the product is a liquid product. | - | |
| Corrosive to metals | Statement | - | According to CLP regulation, a product is not classify corrosive to metal if: <ul style="list-style-type: none"> - substances and mixtures have no acidic or basic functional groups (i.e. neutral pH) - substances or mixtures does not containing halogen; - substances not able to form complexes with metals and mixtures containing such substances. | | According to CLP regulation, the product is not expected to have corrosive to metal properties. |

| Property | Guideline and Method | Purity of the test substance (% (w/w)) | Results | Reference | Comments |
|--|----------------------|--|--|-----------------------------------|---|
| | | | The product has a neutral pH (no acidic/basic agent) and does not contain halogen nor complexing agents. | | |
| Auto-ignition temperatures of products (liquids and gases) | EEEC A15 | Test item: Etofenprox 300 g/L EC Batch n°: EC2013011 4Etof | The mean self-ignition temperature of the test item was 430 ± 8 °C | A. DOYEN,, 201 No. 13-912011-0023 | Acceptable The product is not classify having auto-ignition properties. |
| Relative self-ignition temperature for solids | - | - | Not required as the product is a liquid product. | - | |
| Dust explosion hazard | - | - | Not required as the product is a liquid product. | - | |

Conclusion on the physical hazards and respective characteristics of the product

The formulation is not classified for the physico-chemical aspect.

3.2.4 Methods for detection and identification

Principle of the analytical method:

Into a 50mL volumetric flask, weight about 0.2g of Etofenprox 300g/L EC and make to volume with acetonitrile for GC, active substance is quantified by a GC method using a FID detector. An internal standard method is used for this quantification.

| 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 |
| | | | | | Mean | RSD | | |
| Etofenprox | GC/FID | 50% of ai content in product - | N=5 (in triplicates) | No interferences | 103.3% at | At 1.22g/L (n=18), mean | - | Richerieux S., 2012, final report |

| | | | | | | | | |
|--|--|---|--|------------------------------------|---|---------------|--|------------------------|
| | | 15.54% w/w (n=3) 100% of ai content in product - 30.49% w/w (n=3) 150% of ai content in product - 45.48% w/w (n=3) | From 0.96 to 1.44 g/L Y=2.26456 x+0.00449 R ² =0.9996 | chromatogra ms were provided | 15.54% w/w 103.5% at 30.49% w/w 101.6% at 45.48% w/w | RSD=0.60 % | | n° LODI.04/201 2 |
|--|--|---|--|------------------------------------|---|---------------|--|------------------------|

Analytical methods for monitoring, soil, water, air, foodstuff or plant and animal origins and human tissues and body fluids

| Analyte (type of analyte e.g. active substance) | Analytical method | Fortification range / Number of measurements | Linearity | Specificity | Recovery rate (%) | | | Limit of quantification (LOQ) or other limits | Reference |
|---|-------------------|--|-----------|-------------|-------------------|------|-----|---|-----------|
| | | | | | Range | Mean | RSD | | |
| Analytical methods for Etofenprox residues in soil, air and water are available in Assessment Report Etofenprox Product-type 18 (September 2013). A letter of access from Mitsui Chemicals Agra. INC has been provided. Validation data are available in Annex 2. | | | | | | | | | |

Conclusion on the methods for detection and identification of the product

An analytical for the determination of active substance in the biocidal product was provided and validated. Analytical methods for monitoring in soil, water, air, foodstuff or plant and animal origins and human tissues and body fluids are provided at EU level (CAR of active substance).

3.2.5 Efficacy against target organisms

3.2.5.1 Function and field of use

MG 03: Pest Control

Product Type 18: Insecticides, acaricides and products to control other arthropods.

FENOX is an emulsifiable concentrate used diluted in water or undiluted and is intended to be used against crawling insects including cockroaches, bed bugs and some stored goods attacking insects, indoor in private homes (professionals and non-professional users), public buildings and in food industries (professional users).

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

The product is intended to be used against the following target organisms:

- Indoor use by non-professional users against:
 - Crawling insects including cockroaches (*B. germanica*, *B. orientalis*), adults and nymphs;
 - Bed bugs (*C. lectularius*), adults and nymphs;
- Indoor use, by professional users, against:
 - Crawling insects including cockroaches (*B. germanica*, *B. orientalis*), adults and nymphs;
 - Bed bugs (*C. lectularius*), adults and nymphs;
 - Confused flour beetle (*T. confusum*), adults;
 - Rice weevil (*S. oryzae*), adults;
 - Lesser grain borer (*R. dominica*), adults;
 - Sawtoothed grain beetle (*O. surinamensis*), adults;
 - Tobacco beetle (*L. serricorne*), larvae.

Application rate: at a maximum rate of 0.5 mL/m². The product is used diluted in water at a rate of 0.5 mL of product diluted in 50 mL water for 1 m².

3.2.5.3 Effects on target organisms, including unacceptable suffering

Target insects are knocked down and killed upon contact with the active ingredient.

3.2.5.4 Mode of action, including time delay

According to the Assessment report of the active substance (Sept. 2013), etofenprox shares its mode of action with other pyrethroid derivatives. It is an insecticide acting by direct contact and ingestion. It acts on sodium channels of the insect nervous system by disturbing the normal neurotransmittance.

The effect begins around a few minutes after direct spraying and around a few hours after contact with treated surfaces, in the laboratory trials submitted by the applicant.

3.2.5.5 Efficacy data

The following table summarises the efficacy studies submitted with the product FENOX 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 |
| PT18 | Indoor Crawling insects Surface treatment | FENOX (etofenprox 300 g/L) | <i>B. germanica</i> (adults) | Laboratory test Dose range testing CEB n°135 | Time to knockdown all insects (KT100) and the mortality after 24h was assessed. Typical surfaces treated measured 15cmx15cm (concrete and ceramic tiles) Temperature: 25+/-2°C Relative humidity : 65+/-5% 1h of exposure time after complete drying (2h) 4 replications (25 insects per replicate) Application rates: 5 mL Fenox into 1L water per 20m ² 10 mL Fenox into 1L water per 20m ² 20 mL Fenox into 1L water per 20m ² | <i>B. germanica</i>: 5 mL/L water per 20m ² : 16% and 27% mortality in 24h respectively on porous and non-porous surfaces. 10 mL/L water per 20m ² : 100% KD within 1h on concrete and within 45min on ceramic. 100% mortality in 24h. 20 mL/L water per 20m ² : 100% KD within 45min on both surfaces. 100% mortality in 24h. Application rate validated: 10 mL/L water per 20 m² => 0.5 ml /m² | Serrano (Feb. 2016) Report 2055e-DRT-SIM/0316 R RI=1 |
| PT18 | Indoor Crawling insects Surface treatment | FENOX (etofenprox 300 g/L) | <i>B. germanica</i> (adult males) | Laboratory test CEB n°135 | Time to knockdown all insects (KT100) and the mortality after 24h was assessed. Typical surfaces treated measured 15cmx15cm (concrete and ceramic tiles) Temp.: 20 to 21°C R.H.: 63 to 72% 1h of exposure time after complete drying (4h) 4 replications (25 insects per replicate) Application rate: 0.5 mL Fenox into 19.5 mL water on 1 m ² => 150 mg a.s./m ² | 100% KD within 1h. 100% mortality within 24h. Application rate validated: 0.5 mL Fenox into 19.5 mL water on 1 m² | Serrano (March 2015) Report 1889/021 5R RI=1 |

| | | | | | | | |
|------|--|----------------------------------|--|---|--|---|--|
| PT18 | Indoor Crawling insects Direct spray Surface treatment Residual efficacy | FENOX (etofenprox 300 g/L) | <i>Blatta orientalis</i> (adults, 3rd instar nymphs) <i>Cimex lectularius</i> (adults, last instar nymphs) | Laboratory test CEB n°135 / 159 | DIRECT SPRAY TEST: Product was directly sprayed onto the test organisms at the dose of 50mL/m ² . KT100 and mortality after 24h were assessed. SURFACE TREATMENT: Room of 60 m ³ 15cmx15cm wooden, steel, concrete and ceramic tiles Temp.: 20-25°C R.H.: 65 to 78% Smooth ventilation: 1m ³ /h 1h of exposure time after complete drying (2h) Tested residual efficacy: 4, 8 and 12 weeks depending on the test organisms. Storage of the panels at 22±2°C and 70±5% R.H., under a photoperiod of 16h light (1200 lux) and 8h darkness. 4 replicates of 25 adults mixed sex + 4 replicates of 25 nymphs Application rate: 50mL Fenox into 5L water per 100m ² | Direct spray test: 100% KD within 30 seconds for all test organisms except <i>B. orientalis</i> (1 min). 100% mortality within 24h. <u>Surface treatment / residual spray trial:</u> 100% mortality was achieved within 24h until 12 weeks for all test organisms on both porous and non-porous surfaces. Application rate validated: 50mL Fenox into 5L water per 100m² => 0,5 ml/m ² Ageing up to 12 weeks shows increasing KD times up to 24h on Oriental cockroaches in porous surfaces (absorbent materials). | Serrano (May 2016) Report 2055c-F-LAB/0316 R RI=1 |
| PT18 | Indoor Stored-product pests Crawling insects Surface treatment Residual efficacy | FENOX (etofenprox 300 g/L) | <i>C. lectularius</i> (adults) <u>Stored-product pests :</u> <i>T. confusum</i> <i>S. oryzae</i> <i>S. granarius</i> <i>R. dominica</i> <i>O. surinamensis</i> <i>L. serricornis</i> 2 to 4 weeks adults (except for tobacco) | Laboratory test CEB n°135bis / 106 Field study for stored-products pests. | The test was conducted in a real empty storage premise (138m ² and 691m ³). Pests were not exposed directly to the product but inside boxes (35x25x15cm). The treatment room was kept in controlled climatic conditions: 21±2°C, 65±10% R.H., light 1200 lux. For surface treatment, the product was applied using a pressurized sprayer at the dose of 50mL in 5L on 100m ² . The residual efficacy of the product was assessed right after treatment | 100% KD after 1h exposure for all test organisms. 2 weeks after treatment: 100% KD, 4h after exposure for all stored products pests. 12 weeks after treatment: 100% KD, 4h after exposure for <i>C. lectularius</i> . 100% mortality was achieved within 24h after treatment for all test organisms, until 2 weeks for stored goods attacking insects and until 12 weeks for bed bugs. | Serrano (May 2016) Report 2055f-F-FI/0316R RI=2 |

| | | | | | | | |
|------|--|----------------------------|------------------------------|-------------------------------------|--|---|--|
| | | | beetle - last instar larvae) | | <p>and, depending on the target organisms, 2 weeks later. Assessment of KD and mortality after 1h exposure to the treatment.</p> <p>Application: surface treatment in 5 replicates each. For each replicate, the boxes containing the 25 insects were placed in 4 locations inside the test room (2 batches at 1.80m height and 2 on the floor, but not closer than 50cm from the walls). For Stored product pests, 100g of grain containing 25 adults (or larvae) were placed in boxes. The other target organisms were placed in a plastic box containing one shelter, food and water sources, a gauze net allowing air exchanges and a cardboard on the top of the box in order to represent cracks and crevices.</p> | Application rate validated: 50mL FENOX into 5L per 100m ² => 0,5 ml/m ² | |
| PT18 | <p>Indoor</p> <p>Crawling insects</p> <p>Cockroaches</p> <p>Surface treatment</p> <p>Residual efficacy</p> | FENOX (etofenprox 300 g/L) | <i>B. germanica</i> | <p>Field study</p> <p>CEB n°249</p> | <p>Control of natural infestations in multi-family public housing. 10 apartments (60m²): 5 treated + 5 controls.</p> <p>For each treatment, only the kitchen was treated (12m² for all apartments), and the weight used was recorded.</p> <p>The product was applied in the preferred insect's locations (and unreachable to humans and pets) as: under the fridge, under the kitchen sink, under the oven and the water-heater, on all cracks and crevices that can be an harbourage for cockroaches</p> <p>Assessments (sticky traps) were done 1, 7, 14, 30, 60 and 90 days after treatment.</p> | <p>Population reduction</p> <p>D1 = 57%</p> <p>D7 = 86.4%</p> <p>D14 = 92.5%</p> <p>D30 to D90 > 95%</p> <p>Application rate validated: 50mL Fenox into 5L water per 100m² => 0,5 ml/m²</p> <p>The natural population evolution recorded in the untreated buildings proved an increasing along the trial (12.5% at the end of the trial).</p> | <p>Serrano (June 2015)</p> <p>Report 1894-1a/0215R</p> <p>RI=1</p> |

| | | | | | Application rate: 50 mL Fenox into 5L of water per 100m ² => 6ml of product in 600 ml water on the 12m ² kitchen area. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------|---|----------------------------|-----------------------|--------------------------------|---|---|---|------|--------------|----|--|-----|--|-------|-------|-------|-------|-------|---|---|---|-----|---|-----|---|----|---|------|---|-----|---|---|---|-----|---|-----|---|----|---|------|---|------|---|----|---|------|---|-----|--|------|------|-----|-------------|-----|-------------|---------|---|---|----|-----|---|-------|---|----|----|-----|----|------|---|----|---|----|----|-----|--|------|----|-----|------------|----|-------------|--|
| PT18 | Indoor Crawling insects Cockroaches Surface treatment Residual efficacy | FENOX (etofenprox 300 g/L) | <i>B. orientalis</i> | Field study CEB n°249 | Control of natural infestations in premises (restaurants, bakeries, butcheries). 10 premises (12 to 62m ²): 5 treated + 5 controls. Assessments (sticky traps) were done 1, 7, 14, 30, 60 and 90 days after treatment. The product was applied in the preferred insect's locations (and unreachable to humans and pets) as: under the fridge, under the kitchen sink, under the oven and the water-heater, on all cracks and crevices that can be an harbourage for cockroaches Application rate: 50 mL Fenox into 5L water per 100 m ² | Population reduction D1 = 67.7% D7 = 82% D14= 89.3% D30 to D90 >95% Application rate validated: 50mL Fenox into 5L water per 100m ² => 0,5 ml/m ² | Serrano (June 2015) Report 1894-1b/0215R RI=1 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| PT18 | Indoor Crawling insects Bed bugs Surface treatment Residual efficacy | FENOX (etofenprox 300 g/L) | <i>C. lectularius</i> | Field study Internal method | Control of natural infestations in apartments and hotel rooms. 8 sites: 5 treated + 3 controls. For each treatment, only the bedroom (from 12 to 28 m ²) have been treated, and the weight used was recorded. The product was applied in the preferred insect's locations (and unreachable to humans and pets) as: under the bed on the floor and foot of the bed (head side) / in the crevices and cracks of the plinth at the junction of the floor and the wall / on the mattress / on the bed structure at the head of the bed / on all cracks | <table border="1"> <thead> <tr> <th rowspan="2"></th> <th rowspan="2">Flat</th> <th rowspan="2">Pre-trapping</th> <th colspan="2">D1</th> <th colspan="2">D90</th> </tr> <tr> <th>Total</th> <th>% red</th> <th>Total</th> <th>% red</th> </tr> </thead> <tbody> <tr> <td rowspan="5">Fenox</td> <td>1</td> <td>7</td> <td>0</td> <td>100</td> <td>0</td> <td>100</td> </tr> <tr> <td>2</td> <td>15</td> <td>1</td> <td>93.3</td> <td>0</td> <td>100</td> </tr> <tr> <td>3</td> <td>9</td> <td>0</td> <td>100</td> <td>0</td> <td>100</td> </tr> <tr> <td>4</td> <td>17</td> <td>1</td> <td>94.1</td> <td>1</td> <td>94.1</td> </tr> <tr> <td>5</td> <td>13</td> <td>2</td> <td>84.6</td> <td>0</td> <td>100</td> </tr> <tr> <td></td> <td>Mean</td> <td>12.2</td> <td>0.8</td> <td>94.4</td> <td>0.2</td> <td>98.8</td> </tr> <tr> <td rowspan="3">Control</td> <td>6</td> <td>8</td> <td>10</td> <td>-25</td> <td>9</td> <td>-12.5</td> </tr> <tr> <td>7</td> <td>12</td> <td>11</td> <td>8.3</td> <td>10</td> <td>16.7</td> </tr> <tr> <td>8</td> <td>10</td> <td>7</td> <td>30</td> <td>11</td> <td>-10</td> </tr> <tr> <td></td> <td>Mean</td> <td>10</td> <td>9.3</td> <td>4.4</td> <td>10</td> <td>-1.9</td> </tr> </tbody> </table> <p>After 90 days, the population reduction exceeds 90% relative to untreated sites. Nevertheless,</p> | | Flat | Pre-trapping | D1 | | D90 | | Total | % red | Total | % red | Fenox | 1 | 7 | 0 | 100 | 0 | 100 | 2 | 15 | 1 | 93.3 | 0 | 100 | 3 | 9 | 0 | 100 | 0 | 100 | 4 | 17 | 1 | 94.1 | 1 | 94.1 | 5 | 13 | 2 | 84.6 | 0 | 100 | | Mean | 12.2 | 0.8 | 94.4 | 0.2 | 98.8 | Control | 6 | 8 | 10 | -25 | 9 | -12.5 | 7 | 12 | 11 | 8.3 | 10 | 16.7 | 8 | 10 | 7 | 30 | 11 | -10 | | Mean | 10 | 9.3 | 4.4 | 10 | -1.9 | Serrano (June 2015) Report 1894-6/0215R RI=2 |
| | Flat | Pre-trapping | D1 | | D90 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | Total | % red | Total | % red | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Fenox | 1 | 7 | 0 | 100 | 0 | 100 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 2 | 15 | 1 | 93.3 | 0 | 100 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 3 | 9 | 0 | 100 | 0 | 100 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 4 | 17 | 1 | 94.1 | 1 | 94.1 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 5 | 13 | 2 | 84.6 | 0 | 100 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | Mean | 12.2 | 0.8 | 94.4 | 0.2 | 98.8 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Control | 6 | 8 | 10 | -25 | 9 | -12.5 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 7 | 12 | 11 | 8.3 | 10 | 16.7 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 8 | 10 | 7 | 30 | 11 | -10 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | Mean | 10 | 9.3 | 4.4 | 10 | -1.9 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

| | | | | | and crevices that can be an harbourage for bed bugs. Assessments (sticky traps) were done 1 and 90 days after treatment. Application rate: 50mL Fenox into 5L water per 100m ² | treatment has not been repeated and then 100% efficacy has not been achieved. This result doesn't fulfil the criteria of the efficacy guidance Vol II part B/C, version 2018 (section 5.6.4.6.3.1) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|--|----------------------------|---|--|---|---|--|---------------|---------------|----------|---------------------------------------|----|----|---|----|----|---|-------|--|---|---|-------|-----|---|---|------|-----|---|---|------|------|---|---|------|---|
| PT18 | Indoor Crawling insects Bed bugs Surface treatment Residual efficacy | FENOX (etofenprox 300 g/L) | <i>C. lectularius</i> Mixed population | Field study Internal method Control of natural infestations in a retirement home. 5 sites: four 30 m ² apartments and one collective living room. The product was sprayed by trained staff or experienced assessor. | PRE-TEST PERIOD : Observations of presence of living insects (adults and/or larvae) in mattress or linings or furniture folds for faecal spotting and blood-trails on sheets, specific counting of insects in the bed environment (bedspring, sheets) and the floor. TEST PERIOD : 2 applications were performed per test site (D0 and D14). Treatment was applied, for the floor, under each furniture (as bed, sofa, night table and couch) and for walls treatment, treatment was applied behind the bedhead and each furniture present in the room. Porous surfaces were concerning the plinths and the bedsprings and hard surfaces for walls and the floors. The product was not sprayed on mattress, bed linen and pillows. Observation were made on D-1, D7, D14, D21, D28 and D104. Application rate: 50mL Fenox into 5L water per 100m ² | <table border="1"> <thead> <tr> <th></th> <th>Living adults</th> <th>Living nymphs</th> <th>Efficacy</th> </tr> </thead> <tbody> <tr> <td>D0 (before 1st treatment)</td> <td>96</td> <td>44</td> <td>-</td> </tr> <tr> <td>D7</td> <td>39</td> <td>7</td> <td>67.1%</td> </tr> <tr> <td>D14 (before 2nd treatment)</td> <td>7</td> <td>1</td> <td>94.3%</td> </tr> <tr> <td>D21</td> <td>0</td> <td>0</td> <td>100%</td> </tr> <tr> <td>D28</td> <td>0</td> <td>0</td> <td>100%</td> </tr> <tr> <td>D104</td> <td>0</td> <td>0</td> <td>100%</td> </tr> </tbody> </table> <p>Diminution of living population was observed 1 week after the first treatment and was >90% at D14. The eradication of the population was observed 1 week (D21) after the second treatment. Furthermore eradication of the population is confirmed 3 months after treatment with 0 living adults and larvae.</p> | | Living adults | Living nymphs | Efficacy | D0 (before 1 st treatment) | 96 | 44 | - | D7 | 39 | 7 | 67.1% | D14 (before 2 nd treatment) | 7 | 1 | 94.3% | D21 | 0 | 0 | 100% | D28 | 0 | 0 | 100% | D104 | 0 | 0 | 100% | Guicherd A. (Nov. 2017) Report 17LODCIO 01 RI=2 |
| | Living adults | Living nymphs | Efficacy | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| D0 (before 1 st treatment) | 96 | 44 | - | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| D7 | 39 | 7 | 67.1% | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| D14 (before 2 nd treatment) | 7 | 1 | 94.3% | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| D21 | 0 | 0 | 100% | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| D28 | 0 | 0 | 100% | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| D104 | 0 | 0 | 100% | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

Efficacy assessment is based on the data submitted for the first authorisation. No further studies have been submitted for the renewal of the product FENOX, as efficacy guidance Vol II part B/C are not been amended

Submitted efficacy data are compliant with the requirements and criteria of the BPR guidance part B/C (2018) for the following claims:

- Use against crawling insects including cockroaches (e.g. *B. germanica*, *B. orientalis*);
- Use against stored-goods attacking insects i.e. adult stage of *T. confusum*, *S. oryzae*, *R. dominica*, *O. surinamensis* and larvae of *L. serricorne*;
- Use against bed bugs (*C. lectularius*).

Conclusion on the efficacy of the product

The product FENOX has shown a sufficient efficacy against crawling insects including cockroaches, bed bugs and stored-goods attacking insects (i.e. adult stage of *T. confusum*, *S. oryzae*, *R. dominica*, *O. surinamensis* and larvae of *L. serricorne*), when applied by spraying at the application rate of 0.5 mL Fenox diluted in 50 mL water per 1 m² of treated area (porous and non-porous surfaces).

3.2.5.6 Occurrence of resistance and resistance management

As described in the Assessment Report (Sept. 2013), etofenprox is an IRAC⁴ Mode of Action group 3A insecticide. Resistance to etofenprox and other pyrethroids is documented for several groups of insects.

B. germanica belongs to those insect species with the highest numbers of observed resistance cases against pyrethroids worldwide. Resistance cases occurred on all continents under highly diverse climatic conditions. Specifically for *B. germanica*, a resistance mechanism against etofenprox (and other pyrethroids) has been described in the literature⁵. No resistance to etofenprox is reported in the scientific literature for ants.

Regarding ticks, populations of *Rhipicephalus sanguineus* s.l. have been reported to exhibit sodium channel target site insensitivity to permethrin and etofenprox, which is likely due to the prolonged use of pyrethroids against many pests in and around the home⁶.

⁴ IRAC: Insecticide Resistance Action Committee. <http://www.irc-online.org/>

⁵ Gliniewicz A, *et al.* [Susceptibility of cockroaches *Blattella germanica* L. collected from hospitals to selected pyrethroid and carbamate insecticides]. *Rocz Panstw Zakl Hig.* 1996;47(3):333-41. Polish. PMID: 9026900.

⁶ Tucker NSG *et al.* Prevalence and distribution of pathogen infection and permethrin resistance in tropical and temperate populations of *Rhipicephalus sanguineus* s.l. collected worldwide. *Med Vet Entomol.* 2021 Jun;35(2):147-157. doi: 10.1111/mve.12479.

Resistance is also reported for bed bugs⁷⁸ and mosquitoes belonging to *Aedes* spp. *Anopheles* spp. and *Culex* spp.⁹¹⁰¹¹¹²¹³¹⁴¹⁵¹⁶¹⁷.

Resistance against one chemical belonging to a specific group of chemicals is known to confer cross-resistance against other compounds belonging to the same group. The use of etofenprox will therefore have an impact on the resistance development against other pyrethroid insecticides and *vice versa*. 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.

To ensure a satisfactory level of efficacy and avoid the development of resistance the recommendations proposed in the SPC have to be implemented.

A monitoring of scientific literature related to the resistance of the target organisms to the active substance etofenprox is requested at the renewal.

The authorization holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management.

3.2.5.7 Known limitations

None

3.2.5.8 Evaluation of the label claims

See Efficacy conclusion above.

-
- ⁷ Tawatsin A, *et al.* Insecticide resistance in bedbugs in Thailand and laboratory evaluation of insecticides for the control of *Cimex hemipterus* and *Cimex lectularius* (Hemiptera: Cimicidae). *J Med Entomol.* 2011 Sep;48(5):1023-30. doi: 10.1603/me11003.
- ⁸ Dang K. *et al.* Insecticide resistance and resistance mechanisms in bed bugs, *Cimex* spp. (Hemiptera: Cimicidae). *Parasit Vectors.* 2017 Jun 29;10(1):318. doi: 10.1186/s13071-017-2232-3.
- ⁹ Fonseca-González I. *et al.* Insecticide resistance status of *Aedes aegypti* (L.) from Colombia. *Pest Manag Sci.* 2011 Apr;67(4):430-7. doi: 10.1002/ps.2081.
- ¹⁰ Koou SY. *et al.* Pyrethroid resistance in *Aedes aegypti* larvae (Diptera: Culicidae) from Singapore. *J Med Entomol.* 2014 Jan;51(1):170-81. doi: 10.1603/me13113.
- ¹¹ Francis S. *et al.* Screening of insecticide resistance in *Aedes aegypti* populations collected from parishes in Eastern Jamaica. *PLoS Negl Trop Dis.* 2020 Jul 27;14(7):e0008490. doi: 10.1371/journal.pntd.0008490.
- ¹² Koffi AA. *et al.* Insecticide resistance status of *Anopheles gambiae* s.s population from M'Bé: a WHOPES-labelled experimental hut station, 10 years after the political crisis in Côte d'Ivoire. *Malar J.* 2013 May 4;12:151. doi: 10.1186/1475-2875-12-151.
- ¹³ Menze B.D. *et al.* Multiple Insecticide Resistance in the Malaria Vector *Anopheles funestus* from Northern Cameroon Is Mediated by Metabolic Resistance alongside Potential Target Site Insensitivity Mutations. *PLoS One.* 2016 Oct 10;11(10):e0163261. doi: 10.1371/journal.pone.0163261.
- ¹⁴ Richards S.L. *et al.* Insecticide Susceptibility Screening against *Culex* and *Aedes* (Diptera: Culicidae) Mosquitoes From the United States. *J Med Entomol.* 2018 Feb 28;55(2):398-407. doi: 10.1093/jme/tjx198.
- ¹⁵ Ghorbani F. *et al.* High Resistance of Vector of West Nile Virus, *Culex pipiens* Linnaeus (Diptera: Culicidae) to Different Insecticides Recommended by WHO in Northern Iran. *J Arthropod Borne Dis.* 2018 Mar 18;12(1):24-30. PMID: 30018991.
- ¹⁶ Richards S.L. *et al.* Baseline Insecticide Susceptibility Screening against Six Active Ingredients for *Culex* and *Aedes* (Diptera: Culicidae) Mosquitoes in the United States. *J Med Entomol.* 2017 May 1;54(3):682-695. doi: 10.1093/jme/tjw231.
- ¹⁷ Rahimi S. *et al.* Resistant status of *Culex pipiens* complex species to different imagicides in Tehran, Iran. *J Vector Borne Dis.* 2020 Jan-Mar;57(1):47-51. doi: 10.4103/0972-9062.308800.

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

FENOX is not intended to be used with other biocidal products.

3.2.6 Risk assessment for human health

3.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

| Summary table of animal studies on skin corrosion /irritation | | | | | |
|--|---------------------------------------|---|---|--|------------------|
| Method, Guideline, GLP status, Reliability | Species, Strain, Sex, No/group | Test substance, Vehicle, Dose levels, Duration of exposure | Results <i>Average score (24, 48, 72h)/ observations and time point of onset, reversibility; other adverse local / systemic effects, histopathological findings</i> | Remarks <i>(e.g. major deviations)</i> | Reference |
| OECD 404 Reliability 1 GLP | New Zealand rabbits 3 | Fenox 0.5 ml Semi occlusive dressing during 4 hours on an undamaged skin area | Skin reaction appreciated 1 hour, 24, 48 and 72 hours after removal of the patch. Mean score 24-48 and 72h: Erythema and eschar: Animal 1: 1 Animal 2: 1 Animal 3: 1 reaction was reversible on day 7 Oedema formation: Animal 1: 0.33 Animal 2: 0 Animal 3: 0.33 | Dryness of the skin was noted in all animal on day 7 and totally reversible on day 14 in 2 animals. Still noted on day 14 in the last one. | Richeux, 2013 |

| | | | | | |
|--|--|--|---|--|--|
| | | | reaction was totally reversible on day 3. | | |
|--|--|--|---|--|--|

Conclusion used in Risk Assessment – Skin corrosion and irritation

| | |
|--|--|
| Value/conclusion | Not classified |
| Justification for the value/conclusion | Mean score of reaction and observed effects are compared to CLP regulation criteria. |
| Classification of the product according to CLP | Not classified |

Eye irritation

| Summary table of animal studies on serious eye damage and eye irritation | | | | | |
|--|--------------------------------|---|---|--|---------------|
| Method, Guideline, GLP status, Reliability | Species, Strain, Sex, No/group | Test substance, Dose levels, Duration of exposure | Results | Remarks (e.g. major deviations) | Reference |
| OECD guideline 405 GLP Reliability 1 | New Zealand rabbits 3 | Fenox 0.1 mL in one eye. | <p>Average score (24, 48, 72h)/ observations and time point of onset, reversibility</p> <p>Ocular examinations were performed on both right and left eyes 1 hour, 24, 48 and 72 hours following treatment.</p> <p>Mean score (24, 48 and 72h) Conjunctivae chemosis Animal 1: 0.33 Animal 2: 0.33 Animal 3: 0.33</p> <p>Conjunctivae redness Animal 1: 0.7 Animal 2: 1 Animal 3: 1</p> <p>Iris and cornea opacity: 0 for all animals</p> <p>At day 3, all effects are reversible.</p> | The other eye remains untreated and serves as control. | Richeux, 2013 |

| Conclusion used in Risk Assessment – Eye irritation | |
|--|--|
| Value/conclusion | Not classified |
| Justification for the value/conclusion | Mean score of reaction and observed effects are compared to CLP regulation criteria. |
| Classification of the product according to CLP | Not classified |

Respiratory tract irritation

| Conclusion used in the Risk Assessment – Respiratory tract irritation | |
|--|--|
| Justification for the conclusion | No study is provided. Classification is determined according to the rules by calculation of the CLP regulation. None component is classified for this endpoint. |
| Classification of the product according to CLP | Not classified |

Skin sensitization

| Summary table of animal studies on skin sensitisation | | | | | |
|--|---------------------------------------|--|--|--|------------------|
| Method, Guideline, GLP status, . Reliability | Species, Strain, Sex, No/group | Test substance, Vehicle, Dose levels, duration of exposure Route of exposure (topical/intradermal, if relevant) | Results (EC3-value or amount of sensitised animals at induction dose); evidence for local or systemic toxicity (time course of onset) | Remarks (e.g. major deviations) | Reference |
| OECD guideline 406 Reliability 1 GLP | Guinea pigs 10/group 5/control | Fenox Induction: Intradermic injection = 2% Topical application = 100% 10-day rest Challenge: topical application under occlusive dressing for 24h with test item | No cutaneous reaction attributable to allergy in treated group and no cutaneous intolerance reaction in negative control group | Before the main assay, a preliminary assay was realized in order to determine the tested | Richeux, 2013 |

Summary table of animal studies on skin sensitisation

| | | | | | |
|--|--|---|--|----------------|--|
| | | diluted at 20% and 10% in liquid paraffin | | concentration. | |
|--|--|---|--|----------------|--|

Conclusion used in Risk Assessment – Skin sensitisation

| | |
|--|--|
| Value/conclusion | Not classified |
| Justification for the value/conclusion | Reaction and observed effects are compared to CLP regulation criteria. |
| Classification of the product according to CLP | Not classified. |

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation

| | |
|--|--|
| Value/conclusion | Not classified |
| Justification for the value/conclusion | No study is provided. Classification is determined according to the rules by calculation of the CLP regulation. None component is classified for this endpoint. |
| Classification of the product according to CLP | Not classified |

Acute toxicity

Acute toxicity by oral route

Summary table of animal studies on acute oral toxicity

| Method Guideline GLP status, Reliability | Species, Strain, Sex, No/group | Test substance Dose levels Type of administra tion (gavage, in diet, other) | Signs of toxicity (nature, onset, duration, severity, reversibility) | Value LD50 | Remarks (e.g. major deviations) | Refere nce |
|---|---|---|--|-----------------------|---|-----------------------|
| OECD guideline 423 GLP Reliability 1 | 6 females Sprague Dawley rats | Fenox 2000 mg/kg bw | No mortality No clinical sign Body weight evolution is normal Not change in macroscopical examination | >2000 mg/kg bw | | Colas, S., 2009 |

| Value used in the Risk Assessment – Acute oral toxicity | |
|---|---|
| Value | Not classified |
| Justification for the selected value | LD 50 value is compared to the value of CLP regulation. |
| Classification of the product according to CLP and DSD | Not classified |

Acute toxicity by inhalation

| Summary table of animal studies on acute inhalation toxicity | | | | | | |
|--|--|---|--|------------|---------------------------------|------------------------|
| Method, Guideline, GLP status, Reliability | Species, Strain, Sex, No/group | Test substance, form (gas, vapour, dust, mist) and particle size (MMAD) Actual and nominal concentration, Type of administration (nose only / whole body/ head only) | Signs of toxicity (nature, onset, duration, severity, reversibility) | LC50 | Remarks (e.g. major deviations) | Reference |
| OECD guideline 436 GLP Reliability 1 | Three males and three females RccHan : WIST strain rats | Exposure to aerosol atmosphere of fenox by nose only during 4 hours 14 days of observation Mean achieved atmosphere concentration: 5.22 mg/L with with mean MMAD of 2.02 µm and an inhalable fraction (< 4µm) of 79.2%. | No mortality Increase respiratory rate, hunched posture, piloerection and wet fur. Animals recovered to appear normal on day 5 or 6 post-exposure. One animal exhibited dark patches | >5.22 mg/L | | Griffiths, D. R., 2013 |

| | | | | | | |
|--|--|---------------------------------|--|--|--|--|
| | | (target concentration = 5 mg/L) | on the lungs. No macroscopic abnormalities were detected amongst the other animals at necropsy | | | |
|--|--|---------------------------------|--|--|--|--|

| Value used in the Risk Assessment – Acute inhalation toxicity | |
|---|---|
| Value | Not classified |
| Justification for the selected value | Compared to the criteria for classification of CLP regulation |
| Classification of the product according to CLP and DSD | Not classified |

Acute toxicity by dermal route

| Summary table of animal studies on acute dermal toxicity | | | | | | |
|--|--|---|--|----------------|---------------------------------|-----------------|
| Method, Guideline, GLP status, Reliability | Species, strain, Sex, No/group | Test substance, Vehicle, Dose levels, Surface area | Signs of toxicity (nature, onset, duration, severity, reversibility) | LD50 | Remarks (e.g. major deviations) | Reference |
| OECD guideline 402 GLP Reliability 1 | 10 Sprague Dawley rats (5 males and 5 females) | Fenox 2000 mg/kg bw 10% of the body surface area was clear for the application of the test item | No mortality No clinical sign Cutaneous reactions (erythema and dryness) were noted from 24 hours post dose in all females and were totally reversible on day 6. | >2000 mg/kg bw | | Colas, S., 2013 |

| | | | | | | |
|--|--|--|--|--|--|--|
| | | | Body weight evolution is normal Not change in macroscopic examination | | | |
|--|--|--|--|--|--|--|

| Value used in the Risk Assessment – Acute dermal toxicity | |
|---|---|
| Value | Not classified |
| Justification for the selected value | Compared to the criteria for classification of CLP regulation |
| Classification of the product according to CLP and DSD | Not classified |

Information on dermal absorption

| Summary table of in vitro studies on dermal absorption | | | | | |
|--|---|--|--|--|-------------------|
| Method, Guideline, GLP status, Reliability | Species, Number of skin samples tested per dose, Other relevant information about the study | Test substance, Doses | Absorption data for each compartment and final absorption value | Remarks (e.g. major deviations) | Reference |
| OECD 428 Reliability 1 | Human skin 8 skin samples Analysis of receptor fluid at 0, 0.5, 1, 2, 4, 6, 8, 10, 12 and 24 hours after application. At 8h, dose formulation is removed | Fenox and Fenox diluted at concentration in active substance of 3g/L | Fenox: Less than 75 % of the total absorption in receptor fluid occurred within the first 12 hours of the experiment. Therefore, the amount of active substance in stratum corneum is considered as absorbed. | Integrity of the human skin is confirmed by assessing the permeability of tritiated water. | Webbley, K., 2015 |

| | | | | | |
|--|--|--|--|--|--|
| | <p>from the skin by washing. Following the 24h sampling time-point, system is dismantled and skin is analysed. The remaining Franz cells donor and receptor chambers were washed and the washings retained for analysis of radioactivity</p> | | <p>Low recovery for several replicats. Therefore, a normalisation correction is performed.</p> <p>The absorbed dose was determined considering: the amount of active substance in stratum corneum + skin+ receptor fluid + receptor chamber wash</p> <p>A significant variation between replicates exists (the relative standard deviation is superior to 25 %). In this context, the standard deviation (10.03%) was added to the mean corrected value (35.51%) to determine the potentially absorbed dose.</p> <p>Absorbed dose = 46%</p> <p><u>Fenox diluted:</u> Less than 75 % of the total absorption in receptor fluid occurred within the first 12 hours of the experiment. Therefore, the amount of active substance in stratum corneum is considered as</p> | | |
|--|--|--|--|--|--|

| | | | | | |
|--|--|--|--|--|--|
| | | | <p>absorbed.</p> <p>Low recovery for several replicats. Therefore, a normalisation correction is performed.</p> <p>The absorbed dose was determined considering: the amount of active substance in stratum corneum + skin+ receptor fluid + receptor chamber wash</p> <p>A significant variation between replicates exists (the relative standard deviation is superior to 25 %). In this context, the standard deviation (6.91%) was added to the mean corrected value (7.79%) to determine the potentially absorbed dose.</p> <p>Absorbed dose = 15%</p> | | |
|--|--|--|--|--|--|

| Value(s) used in the Risk Assessment – Dermal absorption | | | |
|---|--|----------------------------------|--|
| Substance | Etofenptox- fenox (300 g/l) | Etofenprox- fenox diluted (3g/l) | |
| Value(s)* | 46% | 15% | |
| Justification for the selected value(s) | EFSA guidance on dermal absorption 2012* | | |

*The study was assessed during the first authorisation assessment. It was assessed according to the EFSA guidance on dermal absorption of 2012.

In the context of this renewal, it may be reviewed with the EFSA guidance on dermal absorption of 2017. Applying this guidance 2017, dermal absorption values of 44% and 15% are obtained. This difference of absorption will not have an impact on conclusion. Therefore, the initial dermal absorption values of 46% and 15% are maintained to determine exposure. This approach is in line with the approach proposed for product using a dermal absorption study assessed during the assessment of an active substance (see note of the coordination group for biocides: dermal absorption value for the authorisation of biocidal products).

It should be noted that the dermal absorption of etofenprox is higher for the concentrated formulation, than for the diluted one. This can be explained by the presence of solvent in the concentrate (which can enhance absorption) contrary to the dilution which is constituted mainly of water.

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

No SOC is identified.

Available toxicological data relating to a mixture

Not available

Other

Based on the classification of the active substance and the experimental studies provided for the product, the product FENOX is classified H362: May cause harm to breast-fed children.

Remark: Even if etofenprox is a pyrethroid, the paresthesia is not reported in the CAR. However, in the first aid instruction, for skin exposure it is mentioned: "If symptoms occur call a POISON CENTRE or a doctor." Proposing this instruction, no self-diagnosis of paresthesia will occur and a medical specialist could suspect a paraesthesia after the description of the symptoms by the users and the precision of the active substance if it occurs.

3.2.6.2 Exposure assessment

The product FENOX is used by professional and non-professional.

It is intended to be applied by spraying on surface.

Secondary exposure can occur for general public during contact with treated surface.

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 | Not relevant | Yes | Yes | Not relevant | No | Yes | |

| Summary table: relevant paths of human exposure | | | | | | | |
|--|--------------|-----|-----|--------------|----|-----|----|
| Dermal | Not relevant | Yes | Yes | Not relevant | No | Yes | |
| Oral | Not relevant | No | No | Not relevant | No | Yes | No |

List of scenarios

| Summary table: scenarios | | | |
|---------------------------------|---|---|--|
| Scenario number | Scenario (e.g. mixing/ loading) | Primary or secondary exposure Description of scenario | Exposed group (e.g. professionals, non- professionals, bystanders) |
| 1. | Spraying | Primary exposure Exposure occurs during different tasks: mixing and loading, application and cleaning of spray equipment. | Professional |
| 2. | Spraying | Primary exposure | Non- professional |
| 3 | Volatilisation of residue | Secondary exposure | General public |
| 4 | Infant crawling on treated surface | Secondary exposure Dermal exposure and oral exposure via a hand to mouth transfer Exposure is determined for contact with wet and dry surface | General public |
| 5 | Adult who touches a treated surface | Secondary exposure Dermal exposure Exposure is determined for contact with wet and dry surface | General public |
| 6 | Adult, child and infant who sleep in a bed treated against bed bugs | Secondary exposure | General public |

Industrial exposure

Not relevant

Professional exposureScenario [1]**Description of Scenario [1]**

Considering the restrictions of application: "The product has to be applied only on restricted areas on surfaces not regularly cleaned, for example: behind or under the fridge, under the kitchen sink, under the oven or the water heater", it is therefore assumed that professional users will spray the product essentially in a downward direction.

As stated in the recommendation no. 3 of the BPC Ad hoc working group, the use of spraying model 1 model will overestimate the exposure of this type of application.
A refined approach is therefore proposed to assess exposure of professional users.

Description of Scenario [1]

The exposure during mixing and loading phase was assessed using the M&L model 4 (task 1). The exposure during spraying phase is assessed using RISKOFDERM and ART models as recommended by the BPC Ad hoc working group (recommendation no. 3) (task 2). Finally, the exposure during cleaning phase was assessed using BEAT scenario "Cleaning of the spray equipment" (task 3).

| | Parameters ¹ | Value | Source |
|--|-------------------------|-------|--------|
|--|-------------------------|-------|--------|

Task 1: Mixing and loading

The product is diluted at the rate of 50 mL of concentrate in 5 L of water. The maximum pack size containing FENOX product is 1 L and professional users can be exposed to the concentrate product when loading it in a dosing vessel. According to HEEG Opinion 1, the recommended choice for assess mixing and loading of small quantities is the model 4. This model is described in ECHA guidance: Biocides Human Health Exposure Methodology (BHHEM) p 193.

| | | | |
|-------------------|-----------------------------------|---------|--|
| Common parameters | Concentration in active substance | 300g/l | Applicant data |
| | Density | 1.031 | Applicant data |
| | Hand exposure | 0.01 mL | Mixing and loading model 4 (BHHEM) |
| | Dermal absorption | 46% | See above |
| | Body weight | 60 kg | Recommendation 14 of the ad hoc WG on human exposure |
| Tier 1 (no PPE) | Penetration factor | 100% | Default value |
| Tier 2 (gloves) | Penetration factor | 10% | HEEG opinion 9 |

Task 2: Spraying on downward position with a low pressure sprayer

According to the recommendation no.3 of the BPC Ad hoc Working Group on Human exposure, the combination of RISKOFDERM and ART models is considered as the appropriate approach for downward spraying at low pressure.

According to this recommendation the application rate of 0.3 to 3L/min is a reasonable worst case for the assessment of exposure.

This value is used with ART model to assess inhalation exposure.

However, for dermal exposure with RISKOFDERM model, the lower value of this range i.e. 0.3L/min is used.

Considering the dose per square metre (5L of diluted product to treat 100m²), this value is more realistic than 3L/min and represents a treatment of approximately 100 m² in 15 minutes.

| | | | |
|-------------------|-----------------------------------|------------------------|--|
| Common parameters | Concentration in active substance | 0.3% | Applicant data |
| | Dermal absorption | 15% | See above |
| | Body weight | 60 kg | Recommendation 14 of the ad hoc WG on human exposure |
| | Inhalation rate | 1.25 m ³ /h | |

| Description of Scenario [1] | | | |
|--|---|------------------------------|---|
| | Potential hand exposure | 24.2 µl/min | RISKOFDERM model for 75th percentile as recommended in recommendation 3 of the ad hoc WG on human exposure |
| | Potential body exposure | 81 µl/min | |
| | Inhalation exposure | 0.076 mg a.i./m ³ | ART model using the upper bound of the interquartile of 75th percentile as recommended in recommendation 3 of the ad hoc WG on human exposure |
| | Exposure duration | 120 minutes | BHHEM |
| Tier 2 gloves and coated coverall | Penetration factor for gloves | 10% | HEEG opinion 9 |
| | Penetration factor for coated coverall | 20% | HEEG opinion 9 |
| Tier 3 gloves and impermeable coverall and mask APF 4 | Penetration factor for gloves | 10% | HEEG opinion 9 |
| | Penetration factor for impermeable coverall | 5% | HEEG opinion 9 |
| | Protection factor for mask APF 4 | 4 | BHHEM |
| Task 3: Cleaning of spray equipment | | | |
| After application, professionals can be exposed to product during the cleaning of spray equipment. Exposure during the cleaning of equipment is assessed with the BEAT scenario "Cleaning of the spray equipment". | | | |
| Common parameters | Concentration in active substance | 0.3% | Applicant data |
| | Dermal absorption | 15% | See above |
| | Body weight | 60 kg | Recommendation 14 of the ad hoc WG on human exposure |
| | Body exposure | 19.28 mg/min | BEAT model |
| | Hand exposure | 35.87 mg/min | BEAT model |
| | Duration of exposure | 10 min | BHHEM |
| Tier 2 gloves and coated coverall | Penetration factor for gloves | 10% | HEEG opinion 9 |
| | Penetration factor for coated coverall | 20% | HEEG opinion 9 |
| | Penetration factor for gloves | 10% | HEEG opinion 9 |

| Description of Scenario [1] | | | |
|--|---|----|----------------|
| Tier 3 gloves and impermeable coverall | Penetration factor for impermeable coverall | 5% | HEEG opinion 9 |

1

Calculations for Scenario [1]

| Summary table: estimated exposure from professional uses | | | | | |
|---|--|------------------------------------|--------------------------------|------------------------------|-------------------------------|
| Exposure scenario | Tier/PPE | Estimated inhalation uptake | Estimated dermal uptake | Estimated oral uptake | Estimated total uptake |
| Task 1 | No PPE | Not relevant | 2.37E-02 | Not relevant | 2.37E-02 |
| | Gloves | Not relevant | 2.37E-03 | Not relevant | 2.37E-03 |
| Task 2 | No PPE | 3.16E-03 | 9.47E-02 | Not relevant | 9.78E-02 |
| | Gloves coated coverall | 3.16E-03 | 1.68E-02 | Not relevant | 1.99E-02 |
| | Gloves impermeable coverall and mask APF 4 | 7.90E-04 | 5.82E-03 | Not relevant | 6.61E-03 |
| Task 3 | No PPE | Not relevant | 4.14E-03 | Not relevant | 4.14E-03 |
| | Gloves coated coverall | Not relevant | 5.58E-04 | Not relevant | 5.58E-04 |
| | Gloves impermeable coverall | Not relevant | 3.41E-04 | Not relevant | 3.41E-04 |

Non-professional exposureScenario [2]

Description of Scenario [2]

Considering the intended uses (not limited to crack and crevice, exposure during spraying is assessed using the Consumer Spraying and Dusting Model 3.
As the product is sold in individual sachet, exposure during loading step is negligible.

| | Parameters ¹ | Value | |
|--|-----------------------------------|-------------------------------|--|
| | Hands/forearms exposure | 176 mg product/minute | BHHEM |
| | Legs feet face exposure | 120 mg product/minute | BHHEM |
| | Inhalation | 115 mg product/m ³ | BHHEM |
| | Duration of exposure | 10 minutes | Consexpo pest control factsheet. |
| | Dermal absorption | 15% | See above |
| | Inhalation absorption | 100% | Default value |
| | Concentration of active substance | 0.3% | Applicant data |
| | Body weight | 60 kg | Recommendation 14 of the ad hoc WG on human exposure |

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Calculations for Scenario [2]

| Summary table: systemic exposure from non-professional uses | | | | | |
|--|-----------------|------------------------------------|--------------------------------|------------------------------|-------------------------------|
| Exposure scenario | Tier/PPE | Estimated inhalation uptake | Estimated dermal uptake | Estimated oral uptake | Estimated total uptake |
| Scenario [2] | No PPE | 1.21E-03 | 2.24E-02 | Not relevant | 2.36E-02 |

Exposure of the general public

Four scenarios of exposure is assessed:

- Exposure to volatile residue
- Exposure of an infant who crawls on treated surface with a hand to mouth transfer (wet and dry surface)
- Exposure to an adult who touches a treated surface with its hands (wet and dry surface)
- Exposure of adult, child and infant who sleep in a bed treated against bed bugs.

These scenarios are relevant for professional and non-professional treatment.

Scenario [3]

| Description of Scenario [3] | | | |
|---|-------------------------|--------------|--|
| Exposure to volatile residue is determined according to the HEEG opinion 13 "Assessment of inhalation exposure of volatilised biocides active substance". | | | |
| | Parameters ¹ | Value | Source |
| Tier 1 | Vapor pressure | 8.13E-07 Pa | CAR |
| | Molecular weight | 376.47 g/mol | CAR |
| | Adult body weight | 60 kg | Recommendation 14 of the ad hoc WG on human exposure |
| | Child body weight | 23.9 kg | |
| | Toddler body weight | 10 kg | |

Calculations for Scenario [3]

| Exposure scenario | Estimated total uptake Mg/kg/d |
|--------------------------|---|
| Adult | 3.35E-05 |
| Child | 6.31E-05 |
| Toddler | 6.79E-05 |

Scenario [4]

| Description of Scenario [4] | | | |
|--|-------------------------|--------------------------|--|
| Exposure is determined for infant crawling on treated surface. Exposure via hand to mouth contact is also determined. This exposure is estimated based on the approach proposed in Consexpo fact sheet "Cleaning products". ConsExpo software is not used for the calculation. Dermal exposure of infants can take place on any uncovered skin, that is the head, the arms and hands, and on the legs and feet. According to the Recommendation 12 of the ad hoc WG on human exposure, a transfer coefficient of 0.2 m ² /h and 1h of exposure are used. Oral exposure is determined considering that the hands form about 20 % of the total uncovered skin. It is assumed that 50 % of the product that ends up on the hands is taken in orally (ConsExpo: Pest control Fact Sheet). This means that via hand-mouth contact 10 % of the calculated external dermal exposure is ingested and that the internal dermal exposure is 90 % of the calculated external dermal exposure. | | | |
| | Parameters ¹ | Value | Source |
| Common parameters | Application rate | 0.15 g as/m ² | Applicant data |
| | Dermal absorption | 15% | See above |
| | Oral absorption | 30% | CAR |
| | Body weight | 8 kg | Recommendation 14 of the ad hoc WG on human exposure |

| Description of Scenario [4] | | | |
|---|---|------|---------------|
| Tier 1 wet surface | Fraction of active substance dislodgeable | 100% | Default value |
| Tier 1 dried surface | | 30% | BHHEM |
| Tier 2 dried surface after 4 hours for carpet | | 11% | Study of CAR |
| Tier 2 dried surface after 7 days for carpet | | 4% | Study of CAR |

Calculations for Scenario [4]

| Summary table: systemic exposure from non-professional uses | | | | | |
|--|----------------------|------------------------------------|--------------------------------|------------------------------|-------------------------------|
| Exposure scenario | Tier/PPE | Estimated inhalation uptake | Estimated dermal uptake | Estimated oral uptake | Estimated total uptake |
| Infant crawling | Tier 1 | Not relevant | 5.06E-01 | 1.13E-01 | 6.19E-01 |
| | Tier 2 (30%) | Not relevant | 1.52E-01 | 3.38E-02 | 1.86E-01 |
| | Tier 2 - 4h (11%) | Not relevant | 5.57E-02 | 1.24E-02 | 6.81E-02 |
| | Tier 2 - 7 days (4%) | Not relevant | 2.03E-02 | 4.50E-03 | 2.48E-02 |

Scenario [5]

| Description of Scenario [5] | | | |
|---|--|--------------------------|--|
| An adult can be exposed touching a treated surface (wet and dried) with its hands (palm of both hands). | | | |
| | Parameters ¹ | Value | Source |
| | Application rate | 0.15 g as/m ² | Applicant data |
| | Dermal absorption | 15% | See above |
| | Body weight | 60 kg | Recommendation 14 of the ad hoc WG on human exposure |
| | Fraction of active substance dislodgeable from wet surface | 100% | Default value |
| | Fraction of active substance dislodgeable from dried surface | 30% | BHHEM |

| Description of Scenario [5] | | | |
|-----------------------------|------------|---------------------|--|
| | Hands area | 410 cm ² | Recommendation 14 of the ad hoc WG on human exposure |

1

Calculations for Scenario [5]

| Summary table: systemic exposure from non-professional uses | | | | | |
|---|---------------|-----------------------------|-------------------------|-----------------------|------------------------|
| Exposure scenario | Tier/PPE | Estimated inhalation uptake | Estimated dermal uptake | Estimated oral uptake | Estimated total uptake |
| Scenario [5] | Wet surface | Not relevant | 1.54E-02 | Not relevant | 1.54E-02 |
| Scenario [5] | Dried surface | Not relevant | 3.69E-03 | Not relevant | 4.61E-03 |

Scenario [6]

| Description of Scenario [6] | | | |
|---|--|--|--|
| <p>Adult, child and infant could be exposed during sleeping in a treated bed. In order to determine the exposure, it is considered that they sleep without cloth and all the surface body can be exposed. The surface body used were determined according to the recommendation 14 of the ad hoc WG.</p> <p>The body will not be in direct contact with bed, as there is sheet. In this context, a protection factor of 50 % is considered (Ad hoc Working group on Human Exposure Recommendation 8).</p> | | | |
| | Parameters ¹ | Value | Source |
| Tier 1 | Application rate | 0.15 g as/m ² | Applicant data |
| | Dermal absorption | 15% | See above |
| | Body weight | 60 kg (adult) | Recommendation 14 of the ad hoc WG on human exposure |
| | | 23.9 g (child) | |
| | | 8 kg (infant) | |
| | Fraction of active substance dislodgeable from dried surface | 30% | BHHEM |
| Body area in contact | 16600 cm ² (adult) | Recommendation 14 of the ad hoc WG on human exposure | |
| | 9200 cm ² (child) | | |
| | 4100 cm ² (infant) | | |

Calculations for Scenario [6]

| Summary table: systemic exposure from non-professional uses | | | | | |
|---|----------|-----------------------------|---------------------------------|-----------------------|--------------------------------|
| Exposure scenario | Tier/PPE | Estimated inhalation uptake | Estimated dermal uptake mg/kg/d | Estimated oral uptake | Estimated total uptake mg/kg/d |
| Scenario [6] dried | Adult | Not relevant | 9.34E-02 | Not relevant | 9.34E-02 |
| | Child | Not relevant | 1.30E-01 | Not relevant | 1.30E-01 |
| | Infant | Not relevant | 1.73E-01 | Not relevant | 1.73E-01 |

Dietary exposure

No specific residue data was submitted in the framework of this dossier. The intended indoor uses in industrial, commercial, public premises and private homes via surface spraying are not expected to lead to contamination of food, feed or livestock considering the following precautionary statements:

- Remove all food, feed and drinks prior to treatment.
- 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.
- To avoid indirect contamination during nearby application, cover all surfaces and facilities likely to be in contact with food, feed, drinks and animals.

Information of non-biocidal use of the active substance

| Summary table of other (non-biocidal) uses | | | |
|--|--|---|--|
| | Sector of use ¹ | Intended use | Reference value(s) ² |
| 1. | Plant protection products ⁽¹⁾ | Insecticide used in agriculture on several crops against sucking and biting insects | MRL from 0.01* mg/kg to 4 mg/kg listed in Reg. (EU) 2021/590 ADI = 0.03 mg/kg bw/day ARfD = 1 mg/kg bw |

¹ Reg. (EU) No 540/2011

Estimating Livestock Exposure to Active Substances used in Biocidal Products

Not relevant.

3.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation

| Reference | Study | NOAEL (LOAEL) | AF ¹ | Correction for oral absorption | Value |
|-----------|-------|---------------|-----------------|--------------------------------|-------|
|-----------|-------|---------------|-----------------|--------------------------------|-------|

| | | | | | |
|----------------|---|-----------------|-----|---------------------|-------|
| AELshort-term | Rat developmental neurotoxicity feeding study | 28.4 mg/kg bw/d | 100 | 30% oral absorption | 0.085 |
| AELmedium-term | Rat subchronic feeding study | 20 mg/kd bw/d | 100 | 30% oral absorption | 0.06 |
| AELlong-term | Rat 2-year feeding study | 3.7 mg/kg bw/d | 100 | 30% oral absorption | 0.011 |
| ARfD | Not determined | | | | |
| ADI | | | | | |

Maximum residue limits or equivalent

No specific biocide MRLs are established for this active substance. Nevertheless, MRLs related to PPP uses are established under Regulation (EC) 396/2005 (See paragraph above "Information of non-biocidal use of the active substance").

Risk for industrial users

Not relevant

Risk for professional users

Professional exposure is compared to the chronic term AEL of 1.1E-02 mg/kg/d.

Systemic effects

| Task/ Scenario | Tier | AEL mg/kg bw/d | Estimated uptake mg/kg bw/d | Estimated uptake/ AEL (%) | Acceptable (yes/no) |
|--------------------------|---------------------------------|----------------|-----------------------------|---------------------------|---------------------|
| Scenario 1-task 1 | No PPE | 1.1E-02 | 2.37E-02 | 216% | No |
| | Gloves | 1.1E-02 | 2.37E-03 | 22% | Yes |
| Scenario 1-task 2 | No PPE | 1.1E-02 | 9.78E-02 | 889% | No |
| | Gloves coated coverall | 1.1E-02 | 1.99E-02 | 181% | No |
| | Gloves impermeable coverall and | 1.1E-02 | 6.61E-03 | 60% | Yes |

| | | | | | |
|-------------------------------|-----------------------------------|---------|----------|-----|-----|
| | mask APF 4 | | | | |
| Scenario 1- task 3 | No PPE | 1.1E-02 | 4.14E-03 | 38% | yes |
| | Gloves coated coverall | 1.1E-02 | 5.58E-04 | 5% | yes |
| | Gloves impermeable coverall | 1.1E-02 | 3.41E-04 | 3% | yes |

Combined scenarios

| Scenarios combined | Tier | AEL mg/kg bw/d | Estimated uptake mg/kg bw/d | Estimated uptake/ AEL (%) | Acceptable (yes/no) |
|--------------------|--|-------------------|-----------------------------------|---------------------------------|------------------------|
| [task 1 + 2 + 3] | no PPE | 1.1E-02 | 1.26E-01 | 1143 | NO |
| [task 1 + 2 + 3] | M&L: gloves Spraying and cleaning: Gloves coated coverall | 1.1E-02 | 2.28E-02 | 208 | NO |
| [task 1 + 2 + 3] | M&L: gloves Spraying: Gloves impermeable coverall and mask APF4 Cleaning: Gloves and coated coverall | 1.1E-02 | 9.54E-03 | 87 | YES |

The risk is acceptable when :

- Gloves are worn during mixing and loading;
- Gloves, impermeable coverall and mask APF 4 are worn during spraying;
- Gloves and coated coverall are worn during the cleaning of spray equipment.

Risk for non-professional users

Non-professional exposure is compared to the acute term AEL of 8.5E-02 mg/kg/d.

Systemic effects

| Task/ Scenario | Tier | AEL mg/kg bw/d | Estimated uptake mg/kg bw/d | Estimated uptake/ AEL (%) | Acceptable (yes/no) |
|-------------------|------|----------------------|-----------------------------------|---------------------------------|------------------------|
|-------------------|------|----------------------|-----------------------------------|---------------------------------|------------------------|

| | | | | | |
|-------------------|---|---------|----------|-----|-----|
| Scenario 2 | 1 | 8.5E-02 | 2.36E-02 | 28% | Yes |
|-------------------|---|---------|----------|-----|-----|

The estimated exposure during spraying is inferior to AEL. Therefore, the risk is considered acceptable for non-professional.

Remark: The exposure during the cleaning of spray equipment was not determined. However, it is considered that it will not be superior to exposure during application. If the exposure during application is multiplied by 2, the exposure is always inferior to 100% (56%). Therefore, no specific RMM is needed for rinsing step.

Risk for the general public

The exposure to wet surface is compared to the acute AEL of 8.5E-02 mg/kg/d.

A delayed effect until 12 weeks is desired. In this context, the secondary exposures (exposure to volatile residue and contact with dried surface) are compared to the subchronic AEL of 6E-02 mg/kg/d.

For refinement with carpet data, the 4 hours dislodgeable fraction is used to refine acute exposure and the 7 days dislodgeable fraction is use to refine subchronic exposure.

Systemic effects

| Task/ Scenario | Tier | AEL mg/kg bw/d | Estimat ed uptake mg/kg bw/d | Estimated uptake/ AEL (%) | Acceptable (yes/no) |
|-----------------------------|----------------------------|-------------------------------|---|--|--------------------------------|
| Scenario 3 | Adult | 6E-02 | 3.35E-05 | 0.06% | Yes |
| | Child | 6E-02 | 6.31E-05 | 0.11% | Yes |
| | Toddler | 6E-02 | 6.79E-05 | 0.11% | Yes |
| Scenario 4 | Tier 1 | 8.5E-02 | 6.19E-01 | 728% | No |
| | Tier 2 (30%) | 6E-02 | 1.86E-01 | 309% | No |
| | Tier 2 - 4h (11%) | 8.5E-02 | 6.81E-02 | 80% | Yes |
| | Tier 2 - 7 days (4%) | 6E-02 | 2.48E-02 | 41% | Yes |
| Scenario 5 | Wet surface | 8.5E-02 | 1.54E-02 | 18% | Yes |
| | Dried surface | 6E-02 | 4.61E-03 | 8% | Yes |
| Scenario 6 dried | Adult | 6E-02 | 9.34E-02 | 156% | No |

| | | | | | |
|--|--------|-------|----------|------|----|
| | | | | | |
| | Child | 6E-02 | 1.30E-01 | 217% | No |
| | Infant | 6E-02 | 1.73E-01 | 288% | No |

Estimated exposure to volatile residues is inferior to AEL.

Estimated secondary exposures of infant crawling in treated surface are superior to AEL for all scenarios, except for exposure of an infant crawling on a carpet after spraying.

However, carpet is not representative of all treated surface, therefore mitigation measures are proposed:

- **The product should not be applied in zone accessible to children.** If it is applied on rooms accessible to children, the following mitigation measure is proposed: **children should not access treated areas until all necessary treatments and cleaning have been finalised”.**

Estimated secondary exposures of an adult touching a treated surface are inferior to AELs.

Estimated secondary exposures of persons (adult, child and infant) sleeping in a treated bed are superior to AELs. Therefore, the risk is considered unacceptable and a mitigation measure is proposed:

- **For bedding, the application should be restricted to the bed frame and box spring. Do not treat the mattress, bed linen and pillows. The mattress, bed linen and pillows must be treated by other methods.**

Combined scenarios

- **For professional:**

The combined exposures (exposure during application, exposure to volatile residue and exposure during touching a wet treated surface at home) are determined and compared to the acute AEL of 8.5E-02 mg/kg/d as it is an occasional scenario (as his home will be treated only 2 times per year). This scenario is very conservative.

| Scenarios combined | AEL mg/kg bw/d | Estimated uptake mg/kg bw/d | Estimated uptake/AEL (%) | Acceptable (yes/no) |
|--|-----------------------|------------------------------------|---------------------------------|----------------------------|
| Professional: exposure during Spraying + exposure to volatile residue + exposure by contact with wet treated surface | 8.5E-02 | 2.50E-02 | 29% | Yes |

Estimated exposure is inferior to AEL for the combined scenario: exposure during Spraying + exposure to volatile residue + exposure during touching wet treated surface. Therefore, the risk is considered acceptable.

- **For non-professional:**

A delayed effect until 12 weeks is desired; however a non-professional applies the product by spraying occasionally. In this context, the combined exposures (exposure during application, exposure to volatile residue and exposure during touching a treated surface) are compared to the acute AEL of 8.5E-02 mg/kg/d.

| Scenarios combined | AEL mg/kg bw/d | Estimated uptake mg/kg bw/d | Estimated uptake/AEL (%) | Acceptable (yes/no) |
|--|----------------|-----------------------------|--------------------------|---------------------|
| Non-professional: exposure during Spraying + exposure to volatile residue + exposure by contact with wet treated surface | 8.5E-02 | 3.9E-02 | 46% | Yes |

Remark: even with a cleaning step of the equipment is considered (please see above), the exposure will be inferior to AEL.

Estimated exposure is inferior to AEL for the combined scenario: exposure during Spraying + exposure to volatile residue + exposure during touching wet treated surface. Therefore, the risk is considered acceptable.

As individual risk is ever unacceptable for infant crawling on treated area and sleeping in treated bed, no combined exposure for secondary exposure is determined.

Risk for consumers via residues in food

Based on the proposed measures, the intended indoor uses (industrial, commercial, public premises and private home) are unlikely to cause a dietary risk to consumers. The product FENOX will not get into contact with food, feed and livestock and will not leave residues in commodities for human or animal consumption. Regarding consumer health protection, there are no objections against the intended uses. The following precautionary statement should be indicated on the labels:

- Remove all food, feed and drinks prior to treatment.
- 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.
- To avoid indirect contamination during nearby application, cover all surfaces and facilities likely to be in contact with food, feed, drinks and animals.

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

[Please, refer to Guidance for Human Health Risk Assessment, Volume III, Part B - to characterise the risk in case of exposure to several active substances or substances of concern within a product]

3.2.7 Risk assessment for animal health

No guidance is available to assess the risk for animals. In this context, it is covered by the risk assessment performed for humans. The following RMM has to be added:

The product should not be applied in zone accessible to children and pets.

3.2.8 Risk assessment for the environment

3.2.8.1 Effects assessment on the environment

An overview for the PNECs for the active substance Etofenprox and its relevant metabolites are given in the tables below. All the values were agreed at the approval of the active substance except for the PNEC soil which was refined at WGIV2016:

| Compartment | PNEC (Etofenprox) | PNEC (α -CO) | PNEC (4'-OH) |
|--------------------|--|----------------------|-------------------------------------|
| STP microorganisms | 2.25E-02 mg/L | n.r. | n.r. |
| Surface water | 5.40E-06 mg/L | 4.40E-05 mg/L (CAR) | n.r. |
| Sediment (EPM) | 6.30E-03 mg/kg _{wwt} (study) | n.r. | 1.20E-02 mg/kg _{wwt} (EPM) |
| Soil | 6.33E-03 mg/kg _{wwt} (agreed at WGIV2016) | n.r. | n.r. |
| Birds | 33.3 mg/kg _{food} | n.r. | n.r. |
| Mammals | 24.7 mg/kg _{food} | n.r. | n.r. |

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.

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

| Classification of the Active Substance Etofenprox | |
|---|--|
| Value/conclusion | Very toxic to aquatic life- H400 with M-factor= 100 Very toxic to aquatic life with long-lasting effects - H410 with M-factor =1000 |

| Classification and labelling of the Product FENOX | |
|---|--|
| Value/conclusion | Aquatic Chronic 1 ; H410 Aquatic Acute 1 ; H400 |

Further Ecotoxicological studies

No new data is available.

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

No new data is available.

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

No new data is available.

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

No new data is available.

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

No new data is available.

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

The product is intended to be used indoor. Therefore, the active substance can reach the STP after wet cleaning of the treated surfaces. The active substance is then distributed at a local scale to surface water, sediment, agricultural soil and groundwater.

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

No new data is available.

Leaching behaviour (ADS)

No new data is available.

Testing for distribution and dissipation in soil (ADS)

No new data is available.

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

No new data is available.

Testing for distribution and dissipation in air (ADS)

No new data is available.

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

The biocidal product is applied indoor and is not intended to be sprayed near to surface waters. Therefore a risk assessment for spray application is not relevant.

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

The biocidal product is used indoor. Therefore a risk assessment for spray application is not relevant.

3.2.8.2 Exposure assessment

General information

| | |
|---------------------------------|---|
| Assessed PT | PT 18 |
| Assessed scenarios | <u>Scenario 1</u> : Indoor, spray application |
| ESD(s) used | <i>Emission Scenario Document for Product Type 18: Emission Scenario Document for Insecticides, acaricides and products to control other arthropods for household and professional uses, July 2008.</i> |
| Approach | Scenario 1: Average consumption |
| Distribution in the environment | <i>Calculated based on ESD model, EUSES 2.1 and Simple Treat 4.0</i> |
| Groundwater simulation | No |
| Confidential Annexes | No |
| Life cycle steps assessed | <u>Scenario 1</u> : Production: No Formulation No Use: Yes Service life: Yes |
| Remarks | No |

Emission estimation

For the first authorisation, the product has been authorized for a use in domestic areas and large buildings at the application rate of 0.5 mL pure product/m² when the treated area was restricted to a medium scale surface (corresponding to the area of a barrier treatment) for only two applications per year. The use instructions were the following:

The product has to be applied only on restricted areas on surfaces not regularly cleaned, for example:

- *behind or under the fridge, under the kitchen sink, under the oven or the water heater, in all cracks and crevices that can be an harbourage for cockroaches.*
- *on the bedspring, on the feet of the bed, under furnitures, along plinths, behind headboard, on the wall behind the bed, furnitures and all crack and crevices that can be harbourage for bed bugs.*

These use instructions justify the use of the barrier scenario. Even if the use instructions mention that "the product has to be applied only on restricted areas on surfaces not regularly cleaned", the exposure assessment is based on wet cleaning of the treated surfaces.

For containers with unspecified design, the emission factors towards floor during the preparation step are summarized in the ESD PT18 (table 3.2-3). According to the packaging claimed by the applicant, the value of 1.0E-04 for fraction emitted to floor ($F_{\text{prep, floor}}$) during professional uses is used. According to the packaging for non-professional users, the releases towards the environment are negligible as water soluble sachet are assumed to be mixed with water directly in the sprayer preventing spillages to applicator or floor.

Scenario [1] – Indoor, spray application

According to the CG-59 discussions (28/11/2023), the simultaneity factor of 0.00204 corresponding to a maximal use frequency of 2 times/year can be applied for professional use only. The simultaneity factor of 0.00815 corresponding to a use frequency of 3-11 times/year will be applied for non-professional use, as it can be expected that non-professional users would use the product at a higher use frequency in realistic conditions due to the wide variety of target organisms.

Scenario 1 is proposed for either professionals with a simultaneity factor of 0.00204 (corresponding to 2 applications/year max.) or non-professionals with a simultaneity factor of 0.00815 (corresponding to 11 applications/year max.) and a use in houses only.

| Input parameters for calculating the local emission - Professional users | | | |
|--|-----------|----------------------------------|-----------|
| Input | Value | Unit | Remarks |
| Scenario 1 – Indoor, spray application. Barrier treatment. | | | |
| Application rate of pure biocidal product | 0.5 | mL.m ⁻² | |
| Fraction of active substance (Etofenprox) | 2.934E-01 | - | technical |
| Density of the product | 1.031 | kg.L ⁻¹ | |
| Treatment rate of etofenprox | 1.51E-01 | g _{as} .m ⁻² | |

| | | | |
|--|-----------------------|--------------------|---|
| Area treated (private house) | 20 | m ² | Barrier treatment for a domestic house – TAB ENV 204 (02/2021) |
| Area wet cleaned (private house) | 5.9 | m ² | |
| Area treated (building) | 93 | m ² | Barrier treatment for a building – TAB ENV 204 (02/2021) |
| Area wet cleaned (building) | 27 | m ² | |
| Mixing/Loading | | | |
| Volume of pure product for preparation (house) | 10 | mL | 0.5 mL x 20 |
| Volume of pure product for preparation (building) | 46.5 | mL | 0.5 mL x 93 |
| Fraction emitted to air | 0 | - | D |
| Fraction emitted to applicator | 1.20E-03 | - | D |
| Fraction emitted to floor | 1.00E-04 | - | D for 1L containers with unspecific design used by professionals. |
| Emission to air | 0 | kg.d ⁻¹ | O |
| Emission to applicator -house -building | 3.63E-06 1.69E-05 | kg.d ⁻¹ | O |
| Emission to floor -house -building | 3.20E-07 1.412E-06 | kg.d ⁻¹ | O |
| Application | | | |
| Number of applications per day | 1 | - | |
| Fraction emitted to air | 0.020 | - | |
| Fraction emitted to applicator | 0.020 | - | |
| Fraction emitted to floor: -Emission factor to the floor during the insecticide surface treatment by spraying -Emission factor to the treated surface during a surface treatment by spraying | 0.960 0.11 0.85 | - | Table 3.3-5 ESD PT18 |
| Emission to air -house -building | 6.05E-05 2.81E-04 | kg.d ⁻¹ | |
| Emission to applicator -house | 6.05E-05 | kg.d ⁻¹ | |

| | | | |
|--|----------|--------------------|-----------------------------|
| -building | 2.81E-04 | | |
| Emission to floor and treated surface during application (from the wet cleaned area before cleaning) | | kg.d ⁻¹ | |
| -house | 8.57E-04 | | |
| -building | 3.92E-03 | | |
| Cleaning | | | |
| Cleaning efficiency for surfaces | 0.5 | - | D - surface |
| Cleaning efficiency for applicator | 1 | - | D |
| Emission to applicator (preparation+application) | | kg.d ⁻¹ | O |
| -house | 6.41E-05 | | |
| -building | 2.98E-04 | | |
| Emission to floor and treated surfaces (preparation + application) | | kg.d ⁻¹ | O |
| -house | 4.28E-04 | | |
| -building | 1.96E-03 | | |
| Number of houses | 4000 | | O |
| Number of large buildings | 300 | | |
| Simultaneity factor | 0.204 | % | D - 2 applications per year |

| Input parameters for calculating the local emission – Non-professional users | | | |
|---|--------------|----------------------------------|--|
| Input | Value | Unit | Remarks |
| Scenario 1 – Indoor, spray application. Barrier treatment. | | | |
| Application rate of pure biocidal product | 0.5 | mL.m ⁻² | |
| Fraction of active substance (Etofenprox) | 2.934E-01 | - | technical |
| Density of the product | 1.031 | kg.L ⁻¹ | |
| Treatment rate of etofenprox | 1.51E-01 | g _{as} .m ⁻² | |
| Area treated (private house) | 20 | m ² | Barrier treatment for a domestic house – TAB ENV 204 (02/2021) |
| Area wet cleaned (private house) | 5.9 | m ² | |
| Mixing/Loading | | | |
| Volume of pure product for preparation (house) | 10 | mL | 0.5 mL x 20 |
| Fraction emitted to air | 0 | - | D |

| | | | |
|--|-----------------------|--------------------|---|
| Fraction emitted to applicator | 1.20E-03 | - | D |
| Fraction emitted to floor | 1.00E-04 | - | D for 1L containers with unspecific design used by professionals. |
| Emission to air | 0 | kg.d ⁻¹ | O |
| Emission to applicator -house | 3.63E-06 | kg.d ⁻¹ | O |
| Emission to floor -house | 3.20E-07 | kg.d ⁻¹ | O |
| Application | | | |
| Number of applications per day | 1 | - | |
| Fraction emitted to air | 0.020 | - | |
| Fraction emitted to applicator | 0.020 | - | |
| Fraction emitted to floor: -Emission factor to the floor during the insecticide surface treatment by spraying -Emission factor to the treated surface during a surface treatment by spraying | 0.960 0.11 0.85 | - | Table 3.3-5 ESD PT18 |
| Emission to air -house | 6.05E-05 | kg.d ⁻¹ | |
| Emission to applicator -house | 6.05E-05 | kg.d ⁻¹ | |
| Emission to floor and treated surface during application (from the wet cleaned area before cleaning) -house | 8.57E-04 | kg.d ⁻¹ | |
| Cleaning | | | |
| Cleaning efficiency for surfaces | 0.5 | - | D - surface |
| Cleaning efficiency for applicator | 1 | - | D |
| Emission to applicator (preparation+application) -house | 6.41E-05 | kg.d ⁻¹ | O |

| | | | |
|--|----------|--------------------|------------------------------|
| Emission to floor and treated surfaces (preparation + application) -house | 4.28E-04 | kg.d ⁻¹ | 0 |
| Number of houses | 4000 | | 0 |
| Simultaneity factor | 0.815 | % | D - 11 applications per year |

Calculations for Scenario [1]

| Resulting local emission to relevant environmental compartments | | |
|---|---|---------------------------|
| Compartment | Local emission (E _{local,compartment}) [kg/d] | Remarks |
| STP | | |
| - PRO (houses+buildings) | 5.40E-03 | 2 applications/year max. |
| - NON-PRO (houses) | 1.61E-02 | 11 applications/year max. |

Fate and distribution in exposed environmental compartments

| Identification of relevant receiving compartments based on the exposure pathway | | | | | | |
|---|------------|---------------------|-----|------|------|-------------|
| | Freshwater | Freshwater sediment | STP | Air | Soil | Groundwater |
| Scenario 1 | Yes | Yes | Yes | n.r. | Yes | Yes |

| Input parameters (only set values) for calculating the fate and distribution in the environment | | | |
|---|---------------------------|------------------------|---------|
| Input | Value | Unit | Remarks |
| Etofenprox | | | |
| Molecular weight | 376.47 | g.mol ⁻¹ | |
| Water solubility (at 20°C) | 0.0225 | mg.L ⁻¹ | |
| Log Octanol/water partition coefficient | 6.9 | Log 10 | |
| Organic carbon/water partition coefficient (K _{oc}) | 28 524 | L.kg ⁻¹ | |
| Henry's Law Constant (at 25°C) | 0.0136 | Pa/m ³ /mol | |
| Biodegradability | Not readily biodegradable | | |
| DT ₅₀ for degradation in soil | 22.8 | d (at 12°C) | |
| BCF fish | 2565 | L.kg ⁻¹ | |
| BCF earthworm | 95281 | L.kg ⁻¹ | |
| BMF | 2 | - | |
| αCO | | | |

| | | | |
|--|-------|---------------------|--|
| Molecular weight | 299 | g.mol ⁻¹ | |
| Maximum formation fraction in water | 0.635 | - | |
| 4'-OH | | | |
| Molecular weight | 393 | g.mol ⁻¹ | |
| Maximum formation fraction in sediment | 0.214 | - | |

For the assessment the molar weight of each metabolite was also considered and the PEC calculated as follows:

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

| Calculated fate and distribution in the STP | | |
|---|----------------|-------------------------------------|
| Compartment | Percentage [%] | Remarks |
| | Scenario 1 | |
| Air | 0% | Agreed at WGIV 2016 (post approval) |
| Water | 1.5% | |
| Sludge | 92.8% | |
| Degraded in STP | 5.9% | |

Calculated PEC values

| Summary table on calculated PEC values - PRO | | | | | |
|--|--------------------|----------------------|-------------------------|-------------------------|-------------------|
| | PEC _{STP} | PEC _{water} | PEC _{sed} | PEC _{soil} | PEC _{GW} |
| | [mg/L] | [mg/L] | [mg/kg _{wwt}] | [mg/kg _{wwt}] | [mg/l] |
| Etofenprox | 4.05E-05 | 3.88E-06 | 2.41E-03 | 6.11E-03 | 3.36E-06 |
| αCO | n.c. | 1.96E-06 | n.c. | n.c. | n.c. |
| 4'-OH | n.c. | n.c. | 5.39E-04 | n.c. | n.c. |
| n.c.: not concerned | | | | | |

| Summary table on calculated PEC values - NON-PRO | | | | | |
|--|--------------------|----------------------|-------------------------|-------------------------|-------------------|
| | PEC _{STP} | PEC _{water} | PEC _{sed} | PEC _{soil} | PEC _{GW} |
| | [mg/L] | [mg/L] | [mg/kg _{wwt}] | [mg/kg _{wwt}] | [mg/l] |
| Etofenprox | 1.20E-04 | 1.16E-05 | 7.17E-03 | 1.82E-02 | 1.00E-05 |
| αCO | n.c. | 5.83E-06 | n.c. | n.c. | n.c. |
| 4'-OH | n.c. | n.c. | 1.60E-03 | n.c. | n.c. |
| n.c.: not concerned | | | | | |

Primary and secondary poisoning

Primary poisoning

The product is intended to be used indoor. Therefore, primary poisoning, *i.e.* the direct consumption of the product by birds or mammals is not considered as relevant for the product.

Secondary poisoning

| Summary table on calculated PEC values | | |
|---|---|--|
| | PEC_{oral predator (fish)} | PEC_{oral predator (earthworm)} |
| | [mg/kg _{wet fish}] | [mg/kg _{wet earthworm}] |
| Scenario 1 | 9.96E-03 | 1.44E-01 |

3.2.8.3 Risk characterisation

Atmosphere

Volatilization of Etofenprox is considered to be negligible based on its vapour pressure (8.13×10^{-7} Pa at 25°C) and Henry's law constant ($0.0136 \text{ Pa}\cdot\text{m}^3\cdot\text{mole}^{-1}$ at 20°C) values. Etofenprox would not be transported over large distances in the atmosphere in gaseous phase.

Conclusion: Emissions and PECs in air are considered as negligible. It can be concluded that the use of the product FENOX will not pose a significant risk to the atmospheric compartment.

Sewage treatment plant (STP)

| Summary table on calculated PEC/PNEC values | | |
|--|-------------------------------|-------------------------------|
| Scenario 1 | PRO | NON-PRO |
| | PEC/PNEC_{STP} | PEC/PNEC_{STP} |
| Etofenprox | 1.80E-03 | 5.35E-03 |
| αCO | n.c. | n.c. |
| 4'-OH | n.c. | n.c. |

n.c.: not concerned

Conclusion: PEC/PNEC for the STP compartment is <1. The risk is therefore acceptable.

Aquatic compartment

| Summary table on calculated PEC/PNEC values | | |
|--|---------------------------------|-------------------------------|
| PRO | | |
| Scenario 1 | PEC/PNEC_{water} | PEC/PNEC_{sed} |
| Etofenprox | 7.19E-01 | 3.83E-01 |
| αCO | 4.46E-02 | n.c. |

| | | |
|-------|------|----------|
| 4'-OH | n.c. | 4.50E-02 |
|-------|------|----------|

n.c.: not concerned

| Summary table on calculated PEC/PNEC values | | |
|--|---------------------------------|-------------------------------|
| NON-PRO | | |
| Scenario 1 | PEC/PNEC_{water} | PEC/PNEC_{sed} |
| Etofenprox | 2.12 | 1.14 |
| αCO | 1.33E-01 | n.c. |
| 4'-OH | n.c. | 1.34E-01 |

n.c.: not concerned

Conclusion: PEC/PNEC for the freshwater and sediment compartments are <1 for etofenprox and its relevant metabolites for professional applications. The risks are therefore acceptable for professionals.

PEC/PNEC for the freshwater and sediment compartments are >1 for etofenprox for non-professional applications. The risks are therefore unacceptable for non-professionals

Terrestrial compartment

| Calculated PEC/PNEC values | |
|-----------------------------------|--------------------------------|
| PRO | |
| Scenario 1 | PEC/PNEC_{soil} |
| Etofenprox | 9.64E-01 |
| αCO | n.c. |
| 4'-OH | n.c. |

| Calculated PEC/PNEC values | |
|-----------------------------------|--------------------------------|
| NON-PRO | |
| Scenario 1 | PEC/PNEC_{soil} |
| Etofenprox | 2.87 |
| αCO | n.c. |
| 4'-OH | n.c. |

Conclusion: PEC/PNEC for the soil compartment is <1 for professional applications. The risk is therefore acceptable for professional users.

PEC/PNEC for the soil compartment is >1 for non-professional applications. The risk is therefore unacceptable for non-professional users.

Groundwater

Etofenprox concentration in groundwater does not exceed the trigger value of 0.1 µg/L. The risk is therefore acceptable.

Primary and secondary poisoning

Primary poisoning

The product is intended to be used indoor. Therefore, primary poisoning, *i.e.* the direct consumption of the product by birds or mammals is not considered as relevant for the product.

Secondary poisoning

| Summary table on secondary poisoning | | | | |
|---|--|--|---|--|
| Scenario | PEC_{fish}/PNEC_{birds} | PEC_{fish}/PNEC_{mammals} | PEC_{earthworm}/PNEC_{birds} | PEC_{earthworms}/PNEC_{mammals} |
| Scenario 1 | 2.99E-04 | 4.03E-04 | 4.33E-03 | 5.83E-03 |

Conclusion: No risk for secondary poisoning is expected to occur after Biocidal Product application.

Mixture toxicity

As no substance of concern has been identified, mixture toxicity is not relevant.

Aggregated exposure (combined for relevant emission sources)

Aggregated exposure is not relevant since the environmental emissions are covered using a single scenario.

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

The environmental risk assessment of the product FENOX is based on the active substance and two environmentally relevant metabolites, aCO and 4'OH. No substance of concern has been identified for the environment.

The product FENOX will not pose risk to the environmental compartments for an application of the product in restricted areas (covered by the barrier treatment scenario) 2 times/year by professionals. Therefore, the specific instruction of use must be respected:

“The product has to be applied only on restricted areas on surfaces not regularly cleaned, for example:

- behind or under the fridge, under the kitchen sink, under the oven or the water heater, in all cracks and crevices that can be an harbourage for cockroaches.
- on the bedspring, on the feet of the bed, under furnitures, along plinths, behind headboard, on the wall behind the bed, furnitures and all crack and crevices that can be harbourage for bed bugs.”

For non-professional users, a maximal use frequency of 2 times/year is not considered realistic as:

- more uses are expected by non-professional users considering the wide range of target organisms (bed bugs, cockroaches and stored goods attacking insects) that are present all year round and can occur throughout the house (stored goods attacking insects more likely in kitchen and bed bugs more likely in bedrooms etc);
- the target organisms are difficult to eradicate from the house, so in case of non-professional use reinfestation is likely.

Therefore, a simultaneity factor of 0.00815 (corresponding to 3-11 applications/year) should be applied leading to non-acceptable risks for the aquatic and terrestrial compartments. The product will not be authorized for non-professionals.

Overall conclusion on the risk assessment for the environment of the product is summarized in the table below:

| Summary table for the risk assessment of the product FENOX | | | | | |
|--|-------------------------|---------------------------|-------------------------|--------------------------|------------------------|
| | PEC/PNEC _{STP} | PEC/PNEC _{water} | PEC/PNEC _{sed} | PEC/PNEC _{soil} | PEC/PNEC _{GW} |
| Scenario 1 PRO | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable |
| Scenario 1 NON-PRO | Acceptable | Non-acceptable | Non-acceptable | Non-acceptable | Acceptable |

3.2.9 Measures to protect man, animals and the environment

Please refer to summary of the product assessment and to the relevant sections of the assessment report

3.2.10 Assessment of a combination of biocidal products

Not relevant

3.2.11 Comparative assessment

3.2.11.1 Overall conclusion

In the technical guidance note on comparative assessment of biocidal products, it is stated that:

- a suitable number of available active substances having different modes of action on the harmful organism would be necessary to minimise resistance development or selection ;
- as a general rule, at least three different and independent "active substance/mode of action" combinations should remain available through authorized BPs for a given use in order to consider that chemical diversity is adequate.

Considering that no only one products have been identified as potential better alternatives for FENOX, FR CA concludes that there is currently no products with significantly lower overall risks for human health, animal health or the environment.

Since etofenprox does not meet the exclusion criteria as outlined in Article 5(1), no further assessment is needed at this point. The authorization for the product FENOX can be granted in accordance with the BPR 528/2012.

4 ANNEXES¹⁸

4.1 List of studies for the biocidal product

| Author(s) | Year | Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published | Data Protection Claimed (Yes/No) | Owner (PUB / ORG) |
|-------------------|------|--|---|-------------------------|
| Richerieux, S. | 2016 | Final report: Chemical and packaging stability of Etofenprox 300 g/L EC after storage at 30°C for 3 years | Yes | LODI S.A.S. |
| Demangel, B. | 2016 | Physico-chemical tests before and after an accelerated storage procedure for 14 days at 54°C ± 2 °C and a low temperature stability storage for 7 days at 0 ± 2 °C on ETOFENPROX 300 G/L EC | Yes | LODI S.A.S. |
| Tallon, A. | 2016 | Emulsion characteristics and re-emulsification properties tests before and after an accelerated storage procedure at 54 °C ± 2 °C for 21 days on ETOFENPROX 300 G/L EC (diluted at 25%) | Yes | LODI S.A.S. |
| Tallon, A. | 2016 | Emulsion characteristics and re-emulsification properties tests before and after a storage procedure at 20°C ± 2 °C for 36 months on ETOFENPROX 300 G/L EC (diluted at 25%) - Interim report T initial | Yes | LODI S.A.S. |
| Tallon, A. | 2016 | Emulsion characteristics and re-emulsification properties tests before and after a storage procedure at 20°C ± 2 °C for 36 months on ETOFENPROX 300 G/L EC (diluted at 1%) - Interim report T initial | Yes | LODI S.A.S. |
| Mériadec, E. | 2013 | Acidity-alkalinity of Etofenprox 300 g/L | Yes | LODI S.A.S. |
| Meriadec, E. | 2013 | pH of Etofenprox 300 g/L EC | Yes | LODI S.A.S. |
| Demangel, B. | 2013 | Relative density of liquids on Etofenprox 300 g/L EC | Yes | LODI S.A.S. |
| Richerieux, S. | 2013 | Chemical and packaging stability of Etofenprox 300 g/L EC after storage at 54 °C for 2 weeks | Yes | LODI S.A.S. |
| Richerieux, S. | 2013 | Chemical and packaging stability of Etofenprox 300 g/L EC after storage at 54°C for 3 weeks | Yes | LODI S.A.S. |

¹⁸ When an annex is not relevant, please do not delete the title, but indicate the reason why the annex should not be included.

| | | | | |
|----------------|------|--|-----|-------------|
| Richerieux, S. | 2014 | Chemical and packaging stability of Etofenprox 300 g/L EC after storage at 20°C for 1 year | Yes | LODI S.A.S. |
| Richerieux, S. | 2014 | Interim report A: Chemical and packaging stability of Etofenprox 300 g/L EC after storage at 20°C for 2 years (analysis after 18 months of storage) | Yes | LODI S.A.S. |
| Richerieux, S. | 2016 | Study plan: Chemical and packaging stability of Etofenprox 300 g/L EC after storage at 20°C for 3 years | Yes | LODI S.A.S. |
| Richerieux, S. | 2016 | Final report: Chemical and packaging stability of Etofenprox 300 g/L EC after storage at 20°C for 3 years | Yes | LODI S.A.S. |
| Richerieux, S. | 2014 | Chemical and packaging stability of Etofenprox 300 g/L EC after storage at 30°C for 1 year | Yes | LODI S.A.S. |
| Richerieux, S. | 2014 | Interim report A: Chemical and packaging stability of Etofenprox 300 g/L EC after storage at 30°C for 2 years (analysis after 18 months of storage) | Yes | LODI S.A.S. |
| Richerieux, S. | 2015 | Study report amendment no. 1: Chemical and packaging stability of Etofenprox 300 g/L EC after storage at 30°C for 2 years | Yes | LODI S.A.S. |
| Richerieux, S. | 2016 | Study plan: Chemical and packaging stability of Etofenprox 300 g/L EC after storage at 30°C for 3 years | Yes | LODI S.A.S. |
| Richerieux, S. | 2015 | Packaging stability of Etofenprox 300g/L EC after 3 weeks at 54°C±2°C | Yes | LODI S.A.S. |
| Richerieux, S. | 2015 | Chemical and Packaging stability of Etofenprox 300g/L after storage at 20°C for 2 years | Yes | LODI S.A.S. |
| Demangel, B. | 2015 | Physico-chemical tests before and after an accelerated storage procedure at 54 °C ± 2 °C for 14 days on ETOFENPROX 300 G/L EC | Yes | LODI S.A.S. |
| Doyen, A. | 2015 | Persistent foaming test on ETOFENPROX 300 G/L EC | Yes | LODI S.A.S. |
| Demangel, B. | 2015 | Emulsion characteristics and re-emulsification properties and determination of pH values tests before and after low temperature stability of liquid formulations at 0 ± 2 °C for 7 days on ETOFENPROX 300 G/L EC | Yes | LODI S.A.S. |
| Demangel, B. | 2015 | Determination of pH values test before and after an accelerated storage procedure at 54 °C ± 2 °C for 14 and 21 days on ETOFENPROX 300 G/L EC | Yes | LODI S.A.S. |

| | | | | |
|-------------------|------|--|-----|-------------|
| Demangel, B. | 2015 | Emulsion characteristics and re-emulsification properties and determination of pH values tests before and after low temperature stability of liquid formulations at 0 ± 2 °C for 7 days on ETOFENPROX 300 G/L EC | Yes | LODI S.A.S. |
| Demangel, B. | 2013 | Amended report: Persistent foaming test on Etofenprox 300 g/L EC | Yes | LODI S.A.S. |
| LODI GROUP | 2012 | Certificate of stability after dilution 1% v/v of Fenox | Yes | LODI S.A.S. |
| Benjamin, D. | 2013 | Surface tension test on Etofenprox 300 g/L EC | Yes | LODI S.A.S. |
| Meriadec, E. | 2013 | Study report amendment No 1, viscosity of Etofenprox 300 g/L EC | Yes | LODI S.A.S. |
| Meriadec, E. | 2013 | Viscosity of Etofenprox 300 g/L EC | Yes | LODI S.A.S. |
| Richerieux, S. | 2013 | Explosive properties of Etofenprox 300 g/L EC | Yes | LODI S.A.S. |
| Richerieux, S. | 2015 | Study report amendment no. 1: Explosive properties of Etofenprox 300 g/L EC | Yes | LODI S.A.S. |
| Richerieux, S. | 2015 | Oxidising properties of Etofenprox 300 g/L EC | Yes | LODI S.A.S. |
| Zurita Blasco, D. | 2015 | Etofenprox 300g/L EC: Corrosive to metals | Yes | LODI S.A.S. |
| K. Arif | 2022 | UN Heat Accumulation Storage Test (SADT - H.4 Test) on a Sample of FENOX | Yes | LODI S.A.S. |
| Demangel, B. | 2013 | Self ignition temperature of liquids on Etofenprox 300 g/L EC | Yes | LODI S.A.S. |
| Demangel, B. | 2013 | Flash point test on Etofenprox 300 g/L EC | Yes | LODI S.A.S. |
| Zurita Blasco, D | 2015 | Etofenprox 300g/L EC: Self-reactive properties | Yes | LODI S.A.S. |
| Richerieux, S. | 2015 | Pyrophoric properties of Etofenprox 300 g/L EC | Yes | LODI S.A.S. |
| Richerieux, S. | 2012 | Analytical method validation for determination of Etofenprox in Etofenprox 300g/L EC | Yes | LODI S.A.S. |
| Serrano, B. | 2015 | Field testing of the efficacy of a residual insecticide spray treatment to control German cockroaches – Report 1894-1a/0215R | Yes | LODI S.A.S. |
| Serrano, B. | 2015 | Laboratory comparison of the effectiveness of two insecticide products intended for the control of crawling insects in household environment (Target organisms: German cockroaches and black ants) – Report 1889/0215R | Yes | LODI S.A.S. |
| Serrano, B. | 2015 | Field testing of the efficacy of a residual insecticide spray treatment to control Bed bugs <i>Cimex lectularius</i> – Report 1894-6/0215R | Yes | LODI S.A.S. |

| | | | | |
|-------------|------|---|-----|-------------|
| Serrano, B. | 2015 | Field testing of the efficacy of a residual insecticide spray treatment to control Oriental cockroaches – Report 1894-1b/0215R | Yes | LODI S.A.S. |
| Serrano, B. | 2016 | Laboratory trial of the efficacy of the product "FENOX" against various flying and crawling target organisms – Report 2055c-F-LAB/0316R | Yes | LODI S.A.S. |
| Serrano, B. | 2016 | Simulated use trial of the efficacy of an insecticidal product intended to control various pests – Report 2055d-F-SIM/0316R | Yes | LODI S.A.S. |
| Serrano, B. | 2016 | Field trial of the efficacy of an insecticide applied as a space or surface treatment against flies, stable flies, ants, bed bugs and eight stored products pests – Report 2055f-F-FI/0316R | Yes | LODI S.A.S. |
| Guicherd A. | 2017 | Evaluation of the efficacy of an emulsifiable concentrate containing 300g/l Etofenprox for the control of bed bug (<i>Cimex lectularius</i>) infestations Field Trial: France, 2017 – Report n°17LODCI001 | Yes | LODI S.A.S. |
| XXX | 2009 | Etofenprox 30CE: Acute oral toxicity in the rat, Acute toxic class method | Yes | LODI S.A.S. |
| XXX | 2013 | Etofenprox 300 g/L EC: Acute inhalation toxicity (nose only) study in the rat | Yes | LODI S.A.S. |
| XXX | 2013 | Etofenprox 300 g/L EC: Evaluation of acute dermal toxicity in rats | Yes | LODI S.A.S. |
| XXX | 2013 | Etofenprox 300 g/L EC: Assessment of acute dermal irritation | Yes | LODI S.A.S. |
| XXX | 2013 | Etofenprox 300 g/L EC: Assessment of acute eye irritation | Yes | LODI S.A.S. |
| XXX | 2013 | Etofenprox 300 g/L EC: Assessment of sensitising properties on albino guinea pigs: Maximisation test according to Magnusson and Kligman | Yes | LODI S.A.S. |
| Webbley, K. | 2015 | The in vitro dermal absorption of radiolabelled etofenprox in two formulated products for biocidal use | Yes | LODI S.A.S. |
| Webbley, K. | 2015 | Report amendment: The in vitro dermal absorption of radiolabelled etofenprox in two formulated products for biocidal use | Yes | LODI S.A.S. |

4.2 Output tables from exposure assessment tools



expo pro.xlsx



expo non pro.xlsx

4.3 Confidential annex

See separate document.