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

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

(submitted by the evaluating Competent Authority)



**DIGRAIN SPRAY**

Product type 18

Etofenprox as included in the Union list of approved active substances

Case Number in R4BP: BC-CS018005-42

Evaluating Competent Authority: FR

Date: [Septembrer 2017]

Updated: April 2021

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**Note to the reader**

This PAR has been updated with the post-authorisation data provided by the applicant and is based on the PAR of the first authorisation.

In this consolidated PAR, the assessments related to the post authorisation data of the product are at the end of the concerned section and are highlighted in grey.

The SPC (in the first section of the PAR) corresponds to the currently authorised uses in France.

**History of the dossier**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Application type** | **refMS** | **Case number in the refMS** | **Decision date** | **Assessment carried out (i.e. first authorisation / amendment /renewal)** |
| NA-APP | FR | BC-CS018005-42 | 27.09.2017 | Initial assessment of the reference product |
| N.A | *FR* | *NA* | NA | Post authorisation data assessment |

# CONCLUSION

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

The product DIGRAIN SPRAY is emulsion oil in water (EW). All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable except for the pending long term storage stability study (2 years).

The appearance of the product is a white homogeneous emulsion with a slightly characteristic odour. It is not explosive and has no oxidising properties. The product is not flammable and it has no self-ignition temperature up to 599 °C. It has a pH value of 8.1 at 20.8 °C.

There is no effect of high temperature on the stability of the formulation, since after 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed.

After 7 days at 0 °C, the appearance and technical characteristic have not significantly changed. The product is stable at 0 °C.

Its technical characteristics are acceptable for an EW formulation.

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

This data should be addressed in post-authorisation within 1 year:

* the pending long term storage stability study (2 years) in all packaging types (PET et HDPE) including determination of packaging and chemical stability, pH, persistant foaming, pourability, trigger spray and stability of the emulsion.

**Post authorisation**

The long term stability studies performed in claimed packaging, including the stability of packaging, the active substance content, pH, persistant foaming, pourability and stability of the emulsion, the spray pattern and trigger spray before and after a accelerated storage have been provided and are acceptable.

The following data should still be addressed and are required at the renewal of the authorisation:

* The trigger spray, before and after long term storage stability study (2 years).

**Conclusion on efficacy of the product**

In conclusion, in accordance with the submitted tests and the requirements of the TNsG on PT18/19, French competent authorities (FR CA) consider that the product DIGRAIN SPRAY (Etofenprox 2 g/L), intended to be used indoors by non-professional users, has shown sufficient efficacy against:

* Crawling insects including cockroaches (e.g. *Blattella germanica*, *Blatta orientalis*), adults and nymphs;
* Mosquitos (*Aedes spp.*, *Culex spp.*, *Anopheles spp.*), adults;
* Garden ants (*Lasius niger*), workers;
* Ticks (*Ixodes ricinus*);
* House flies (*Musca domestica*).

French competent authorities (FR CA) consider that the elements presented in the dossier are not sufficient to demonstrate efficacy against:

* Cat flea (*Ctenocephalides felis*), adults and larvae;
* Scabies mites (*Sarcoptes scabei*), adults;
* House dust mites (*Dermatophagoïdes pteronyssinus*), adults and nymphs;
* Bed bugs (*Cimex lectularius*), adults and nymphs;
* Domestic house spider (*Tegenaria domestica*), adults.

Time delay and residual effect

Target organisms are knocked down within a few minutes by direct spraying, or within a few hours (1 to 4hours) after exposure. Total mortality is observed 24h after exposure.

The residual efficacy is 8 weeks on porous and non porous surfaces.

The following measure is necessary to ensure the residual effect : ”Do not clean the treated area until the treatment is finished (up to 8 weeks)”.

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

A baseline and monitor levels of effectiveness on target arthropods have to be established in key areas (at least one survey per year) in order to detect any significant changes in susceptibility to active substance. Information from resistance monitoring programs allows early detection of problems and gives information for correct decision making.

**Post authorisation**

According to the applicant, the product DIGRAIN SPRAY has not been marketed since its authorisation, thus no monitoring has been performed.

The requested data should be submitted at the renewal of the authorisation.

**Conclusion for human health**

The risk linked to the application is acceptable for non professional.

For secondary exposure:

- the risk is unacceptable for infant crawling on treated surface. Therefore a mitigation measure is proposed: The product should not be applied in zone accessible to children.

* the risk for persons (adult, child and infant) sleeping on a treated bed is also unacceptable.
* the risk linked to the exposure to volatile residues is considered acceptable.
* the risks for adult touching treated surface are acceptable.

**Conclusion on indirect exposure via residues in food**

No specific residue data was submitted in the context of this dossier.

For indoor spraying uses (private home for non-professional), the following precautionary statements are proposed:

* Evacuate animals prior to treatment
* Remove all food, feed and drinks prior treatment.
* Do not use on surfaces and facilities likely to be in contact with food, feed, drinks and animals.
* To avoid indirect contamination during nearby application, cover all surfaces and facilities likely to be in contact with food, feed, drinks and animals.

The product DIGRAIN SPRAY will not get into contact with food, feed and livestock and will not leave residues in commodities for human or animal consumption.

**Conclusion on environment and ecotoxicolgy**

Considering the service-life of sprayed surfaces and the possibility to wash some surfaces with water (i.e. in private buildings), in the case of the exposure of STP, soil and groundwater, all calculated RCR values were below 1 for etofenprox, as well as for poisonning, indicating no unacceptable risk to these environmental compartments and poisonning. However, for the surface water, sediment and soil compartments, the RCR values for etofenprox were above 1 and the risks are considered unacceptable.

By default, a value of 38.5 m² is used for the treated surface in a private house. This surface leads to the use of almost 3 L of product for one house and per day. The risk become acceptable for all the environmental compartments if the product is used in restricted areas on surfaces not regularly cleaned such as barrier treatment, maximum 2 times per year.

Therefore, it can be concluded that the use of the product DIGRAIN SPRAY when used in accordance with label recommendations, will not pose risk to the environment.

Risk mitigation measure linked to risk assessment for the environment:

* Do not discharge unused products into water courses, into pipes (sink, toilets…) nor down the drains.
* The product has to be applied only on restricted areas on surfaces not regularly cleaned, for example behind the fridge or under the oven.

**General conclusion:**

**Considering,**

* **the lack of efficacy demonstration according to the requirements of the TNsG on PT18/19 for the organims target : Cat flea (*Ctenocephalides felis*), Scabies mites (*Sarcoptes scabei*), House dust mites (*Dermatophagoïdes pteronyssinus*), Bed bugs (*Cimex lectularius*), Domestic house spider (*Tegenaria domestica*);**
* **unacceptable risk for infant crawling on treated surface regardless of the type of spraying application and for persons (adult, child and infant) sleeping on a treated bed;**
* **unacceptable risk for the surface water, sediment and soil compartments.**

**FR CA considers that the product shall be authorised only:**

* **against crawling insects including cockroaches (e.g. *Blattella germanica*, *Blatta orientalis*), Garden ants (*Lasius niger*), Ticks (*Ixodes ricinus*), by non professional users, by indoor spraying on restricted areas on surfaces not regularly cleaned and unattainable to children.**

# ASSESSMENT REPORT

## Summary of the product assessment

### Administrative information

#### Identifier of the product

| **Identifier[[1]](#footnote-2)** | **Country (if relevant)** |
| --- | --- |
| DIGRAIN SPRAY  C&F SPRAY  VESPER C&F SPRAY  DIGRAIN MICROBILLES  PHOBI MICROBILLES  DIGRAIN MICROBUBBLES  PHOBI MICROBUBBLES  INSECTANIOS PAE  INSECTAN BARRIERE A INSECTES | France |

#### 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-2017-0082 | |  |
| **Date of the authorisation** | 27/09/2017 | |
| **Expiry date of the authorisation** | 27/09/2022 | |

#### Manufacturer of the product

|  |  |
| --- | --- |
| **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 |

#### Manufacturerof the active substance

|  |  |
| --- | --- |
| **Active substance** | Etofenprox |
| **Name of manufacturer** | Mitsui Chemicals Agro, Inc. |
| **Address of manufacturer** | 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 |

### Product (family) composition and formulation

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

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

Yes

No

#### 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 % |
| **Structural formula** | Ethofenprox |

#### 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.

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

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| --- | --- | --- | --- | --- | --- |
| Etofenprox technical | 2-(4-ethoxyphenyl)-2-methylpropyl 3-phenoxybenzyl ether | Substance active | 80844-07-1 | 407-980-2 | 0.204 |
| Etofenprox pure | 2-(4-ethoxyphenyl)-2-methylpropyl 3-phenoxybenzyl ether | Substance pure | 80844-07-1 | 407-980-2 | 0.198 |

#### Information on technical equivalence

*Not relevant.*

#### Information on the substance(s) of concern

*No.*

#### Type of formulation

|  |
| --- |
| Emulsion oil in water |

### Hazard and precautionary statements

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

Based on the available data (experimental data, classification in CLP or MSDS of active substance and co-formulants), the product is classified:

| **Classification** | |
| --- | --- |
| Hazard category | Aquatic acute 1  Aquatic chronic 1 |
| Hazard statement | H400: Very toxic to aquatic life  H410: Very toxic to aquatic life with long lasting effects |
|  | |
| **Labelling** | |
| Signal words | Résultat de recherche d'images pour "GHS09 pictogram"  Warning |
| Hazard statements | H410: Very toxic to aquatic life with long lasting effects |
| Precautionary statements | P273: Avoid release to the environment.  P391: Collect spillage.  P501: Dispose of contents/container in accordance with local requirements. |
|  | |
| Note | EUH 208: Contains 2-méthyl-2H-isothiazole-3-one and 1,2-benzisothiazol-2(2H)-one. May produce an allergic reaction. |

### Authorised use(s)

#### Use description

**Table 1. Use # 1 – 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  Blattellidae (*Blattella germanica, Blatta orientalis) -* Adults & nymphs  *Lasius niger –* Adults  *Ixodes ricinus -* Adults |
| **Field of use** | Indoor use |
| **Application method(s)** | Surface spraying |
| **Application rate(s) and frequency** | The product is supplied ready to use.  Product applications are made at a rate of 77 mL/m² (equivalent to 0.15 g a.s./m²).    2 applications per year maximum.  Residual activity: until 8 weeks. |
| **Category(ies) of users** | Non-professional |
| **Pack sizes and packaging material** | Trigger bottles in PET and HDPE of suitable sizes. |

#### Use-specific instructions for use

|  |
| --- |
| - |

#### Use-specific risk mitigation measures

|  |
| --- |
|  |

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

|  |
| --- |
| - |

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

|  |
| --- |
| - |

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

|  |
| --- |
| - |

### 

### General directions for use

#### Instructions for use

|  |
| --- |
| * Always read the label or leaflet before use and follow all the instructions provided. * Respect the recommended application doses. * Apply a maximum of 20 pump strokes along a band of 1 m x 20 cm. * Before treatment, rinse surfaces to avoid potential incompatibility between products (detergents, disinfectants, insecticides…). * Inform the authorization holder if the treatment is ineffective. * Do not clean the treated area until the treatment is finished (up to 8 weeks). * The product has to be applied only on restricted areas on surfaces not regularly cleaned for example behind the fridge or under the oven. |

#### Risk mitigation measures

|  |
| --- |
| * The product should not be applied in zone accessible to children. * The product should not be applied in zone accessible to pets. * Do not spray directly on people, animals or bedding. * Evacuate animals prior to treatment. * Remove all food, feed and drinks prior treatment. * Do not use on surfaces and facilities likely to be in contact with food, feed, drinks and animals. * To avoid indirect contamination during nearby application, cover all surfaces and facilities likely to be in contact with food, feed, drinks and animals. |

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

|  |
| --- |
| * Skin contact: Remove contaminated clothing and shoes. Wash contaminated skin with soap and water. Contact poison treatment specialist if symptoms occur. * Eye contact: Immediately flush with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse with tepid water for at least 10 minutes. Get medical attention if irritation or vision impairment occurs. * Inhalation of spray mist: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Seek medical advice immediately if symptoms occur and/or large quantities have been inhaled. * Ingestion: Wash out mouth with water. Contact poison treatment specialist. Seek medical advice immediately if symptoms occur and/or large quantities have been ingested. * In case of impaired consciousness place in recovery position and seek medical advice immediately. * Keep the container or label available. |

#### 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. * The packaging must not be re-used or recycled. The disposal of this packaging in the environment will be banned. |

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

|  |
| --- |
| * Shelf-life : 2 years * Keep out of reach of children. |

### Other information

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

### 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)** |
| trigger bottle | 250 mL to 2 L | PET | The trigger spray of bottles is in PP (polypropylene). And the dip tube is in LDPE (low density polyethylene). | Non-professional | Yes |
| trigger bottle | 250 mL to 2 L | HDPE | The trigger spray of bottles is in PP (polypropylene). And the dip tube is in LDPE (low density polyethylene). | Non-professional | Yes |

### Documentation

#### Data submitted in relation to product application

**Identity, physico-chemical and analytical method data**

Studies on physico-chemical properties of the biocidal product have been provided.

**Efficacy data**

Following studies have been taken into account for the assessment of the efficacy of the product DIGRAIN SPRAY (Etofenprox 2 g/L):

* 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);
* Laboratory trial of the efficacy of the product "DIGRAIN SPRAY" against various flying and crawling target organisms;
* Simulated use trial of the efficacy of an insecticidal product intended to control various pests.

The applicant has also submitted studies performed with the product FENOX (etofenprox 300 g/L). The read across has not been accepted since formulations have been considered as too different, DIGRAIN SPRAY cannot be considered as a simple dilution of FENOX. Please see annex 1 for the complete list of the submitted studies.

**Toxicology data**

Specific data on product were provided for:

* Acute toxicity (oral-inhalation-dermal)
* Irritation (skin-eye)
* Sensitisation
* Dermal absorption

**Residues data**

No specific residue data was submitted in the context of this dossier.

**Ecotoxicology data**

Please refer to section 2.2.6.1.1.2.2 and 2.2.6.2.3.

#### 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.

## Assessment of the biocidal product

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

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

|  |  |
| --- | --- |
| **Product Type(s)** | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| **Where relevant, an exact description of the authorised use** | Digrain Spray is intended for indoor use for amateur users, in private homes via general surface spraying for the protection of health and materials against a variety of crawling and flying insects. Product applications are made at a maximum rate of 1 L / 13 m² (equivalent to 0.15g a.s./m²). The product is supplied ready to use. |
| **Target organism (including development stage)** | Blattellidae: German cockroach - Adults & nymphs  Blattidae: Oriental cockroach - Adults & nymphs  Cimicidae: Bed bug - Adults & nymphs  Formicinae: Garden ant - Adults  Pulicidae: Cat flea - Adults & larvae  Culicidae: Aedes mosquitoes - Adults  Culicidae: Anopheles mosquitoes - Adults  Culicidae: Culex mosquitoes - Adults  Pyroglyphidae: House mites - Adults & nymphs  Agelenidae Domestic house spider - Adults  Ixodidae: Ticks - Adults  Acaridae: Scabies mites - Adults |
| **Field of use** | Indoor |
| **Application method(s)** | Spraying  The product is supplied ready for use in handheld trigger bottles up to 2 L in size, made of PET or HDPE. |
| **Application rate(s) and frequency** | 1 L for 13 m². The product is supplied ready for use in handheld trigger bottles up to 2 L in size, made of PET or HDPE.  2 times/year |
| **Category(ies) of user(s)** | Non-professional |
| **Pack sizes and packaging material** | Bottle Plastic: HDPE 250 mL to 2 L  Bottle Plastic: PET 250 mL to 2 L |

### Physical, chemical and technical properties

#### Active ingredient

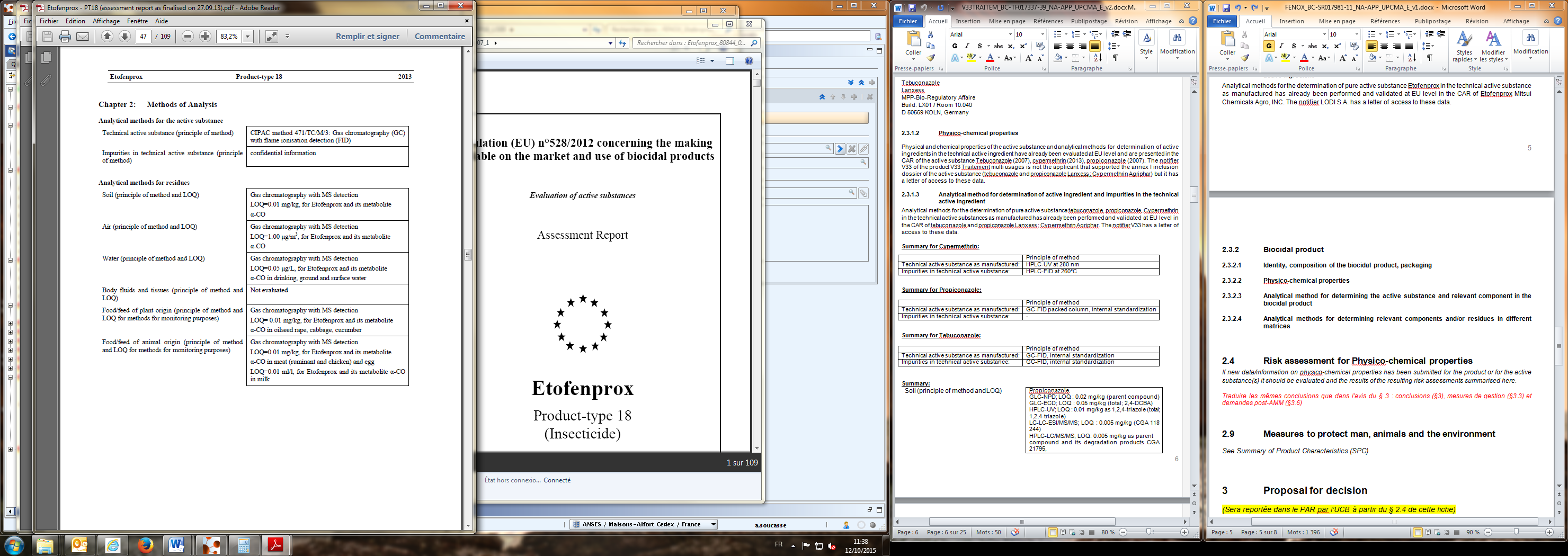
##### Physico-chemical properties

Physical and chemical properties of the active substance and analytical methods for the determination of active ingredients in the technical active ingredient have already been evaluated at EU level and are presented in the CAR of the active substance Etofenprox (2013). The notifier LODI S.A. of the product DIGRAIN SPRAY is not the applicant that supported the Annex I inclusion dossier of the active substance (Etofenprox Mitsui Chemicals Agro, INC) but it has a letter of access to these data.

##### Analytical method for determination of active ingredient and impurities in the technical active ingredient

Analytical methods for the determination of pure active substance Etofenprox in the technical active substance as manufactured has already been performed and validated at EU level in the CAR of Etofenprox Mitsui Chemicals Agro, INC. The notifier LODI S.A. has a letter of access to these data.

Methods for body fluids and tissues are not required since Etofenprox is not classified as toxic or highly toxic.



#### Biocidal ingredient

##### Identity, composition of the biocidal product, packaging

The biocidal product is not the same as the one assessed for the inclusion of the active substances in Annex I of the Directive 98/8/EC. The composition of the product is confidential and is presented in a confidential annex. The product contains 0,204 % w/w of Etofenprox as technical active substance.

For non-professional:

-Trigger bottle in PET of 250 mL to 2 L

-Trigger bottle in HDPE of 250 mL to 2 L

The trigger spray of bottles is in PP (polypropylene). And the dip tube is in LDPE (low density polyethylene).

##### Physico-chemical properties

|  |  |  |
| --- | --- | --- |
| Trade Name | DIGRAIN SPRAY | |
| Manufacturer’s development code number | - | |
| Ingredient of preparation | Function | Content (% w/w) |
| Etofenprox (CAS n°80844-07-1) | Technical Active substance | 0.204 |
| Etofenprox (CAS n°80844-07-1) | Pure Active substance | 0.198 |
| Formulants | Details on confidential PAR | |
| Physical state of preparation | Liquid | |
| Nature of the preparation | EW (emulsion oil in water) | |

Concentrations of use: the product is ready-to-use.

There are preservatives (2-methyl-3(2H)-isothiazolone: MIT and 1,2-benzisothiazol-3(2H)-one: BIT) in the biocidal product which are in the review program for TP6.

| **(Sub)Section (Annex point)** | | **Method** | **Purity/specifications** | **Results** | **Reference** | **FR evaluation** | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **B3.1** | **Appearance (IIB, III 3.1)** | | | | |  | |
|  | Physical state and nature |  |  |  |  |  | |
|  | Colour | visual method | Test item: Etofenprox 2g/L  Batch n°: RTU20141126Etof | A white, homogeneous emulsion The odour was found to be slightly more intense without altering the smell of the product. | Tallon, A. 2014, study LODI.05/2014 | Acceptable | |
| **B3.2** | **Explosive properties (IIB, III 3.2)** | Statement  EU method A.14 | - | Etofenprox 2 g/L EW (RTU) has a qualitative composition of etofenprox (active substance), XXXX, XXXX, XXX, XXX, XXX, XXX, XXX and XXX. An evaluation of the structural groups in the structural formula of each substance, including the oxygen balance, establishes beyond reasonable doubt that the substance is incapable of rapid decomposition with evolution of gasses release of heat. Therefore, testing according to EU Method A.14 for explosive properties is not required. Etofenprox 2 g/L EW (RTU) has no potential for explosivity. | Richerioux S. 2015, study LODI.05/2015 | Acceptable,  The product has no explosive properties. |
| **B3.3** | **Oxidising properties (IIB, III 3.3)** | Statement | - | The principle of this study is to have information on chemical formula and hydrodynamics of each ingredient in Etofenprox 2 g/L RTU in order to assess if the formulation is capable of reactive exothermically with comustable materials and if it has oxidising properties. Each component of Etofenprox 2 g/L RTU is studied independently. For each componend, oxygen balance (OB) is calculated and information on chemical groupd are provided. No component of Etofenprox 2 g/L RTU is associated with oxidising properties, therefore the formulation does not contain oxidising properties. | Richerioux S. 2015, study LODI.06/2015 | Acceptable,  The product has no oxidizing properties. | |
| B3.4 | **Flash-point and other indications of flammability or spontaneous ignition (IIB, III 3.4)** | | | | |  | |
|  | Flash point | Statement | - | The formulated product Etofenprox 2g/L RTU contains XX% of XXX? 0.20% of the active ingredient, etofenprox, and XX% of the solvent XXX. Etofenprox was found to possess a flash point > 110 ºC, while for XXX the flash point is > 180 ºC according to their Safety Data Sheets. These two components are not classified as flammable liquids under Regulation (EC) No 1272/2008 as the flash points are greater than 60 ºC. | - | Acceptable  The preparation is not flammable. |
|  | Auto-flammability | EC A15 | Test item: Etofenprox 2g/L  Batch n°: RTU20141126Etof | No auto-ignition temperature was observed up to 599 °C (corrected temperature). | Demangel B. 2015, report 14-912011-007 | Acceptable  The preparation is not flammable at ambient temperature. | |
|  | Other indications of flammability: | - | - | - | - | - | |
| **B3.5** | **Acidity / alkalinity (IIB, III 3.5)** | | | | |  | |
|  | pH value | CIPAC MT 75.3 | Test item: Etofenprox 2g/L  Batch n°: RTU20141126Etof | The average pH of Etofenprox 2g/L RTU was 8.1 at 20.8ºC. | Tallon, A. 2015, LODI.18/2014 | Acceptable | |
|  | Acidity / Alkalinity | - | - | Not necessary | - | - | |
| **B3.6** | **Relative density (IIB, III 3.6)** | | | | |  | |
|  | Relative density | oscillating densitometer | Test item: Etofenprox 2 g/L RTU  Batch n°: RTU20150122Etof | The relative density D20/20 was found to be 1.0023. | Tallon, A. 2015, LODI.20/2015 | Acceptable | |
|  | Bulk density | - | - |  | - | - | |
| **B3.7** | **Storage stability-stability and shelf life (IIB, III 3.7)** | | | | |  | |
|  | Stability after accelerated storage for 14 days at 54°C | CIPAC MT 36.3 | Test item: Etofenprox 2 g/L RTU  Batch n°: RTU20150122Etof | Appearance of commercial packaging:   |  |  |  |  | | --- | --- | --- | --- | |  | **Initial** | **After 14 days at 54°C** | **After 21 days at 54°C** | | HDPE bottle | White round bottle. No leak of the bottle or the cap. White liquid, no deposit | No change, no deformation | No change, no deformation | | Weight in HDPE bottle | 1057.93 | 1056.86 | 1056.27 | | % variation | - | -0.1% | -0.15% | | PET bottle | White round bottle. Clean bottle | No change, no deformation | No change, no deformation | | Weight in PET bottle | 278.34 | 276.98 | 276.37 | | % variation | - | -0.5% | -0.7% | | HDPE bottle with trigger\* | Bottle opaque, ergonomic and black. Clean bottle. White liquid | No change, no deformation, dry box | No change, no deformation, dry box | | Weight in HDPE bottle with trigger | 573.98 | 573.33 | 573.00 | | % variation | - | -0.2% | -0.2% |   \*polypropylene | Richerioux S. 2015, report LODI.04/2013  Richerioux S. 2015, report LODI.03/2015 | Acceptable  The preparation is stable after storage for 14 and 21 days at 54°C in commercial packaging.  The SA content has been found to be stable in glass flask. This result cannot be extrapolated to plastic packages.  Chemical stability of the product stored in PET and HDPE has been requested in shelf life study in post-authorisation. | |
|  |  | Method for AS content validated in study LODI 04/2014  CIPAC MT 46.3  CIPAC MT 75.3  CIPAC MT 36.3 | ETOFENPROX 2 g/L RTU Batch No RTU 20150122Etof  ETOFENPROX 2 g/L RTU Batch No RTU 20150122Etof  Etofenprox 2 g/L  Batch IN0190216 | Storage in glass flask with PE cap   |  |  |  | | --- | --- | --- | |  | **Initial** | **After 21 days at 54°C in bottle** | | SA content (g/L) | 2.11 | 2.02 | | % variation content | / | -4.27 |   Storage in white opaque PET flask   |  |  |  |  | | --- | --- | --- | --- | |  | **Initial** | **After 14 days at 54°C** | **After 21 days at 54°C** | | Appearance | Homogeneous white opaque liquid | No change | No change | | pH pure | 7.90 at 21.3°C | 7.36 at 21.0°C | 7.15 at 20.8°C |   Storage in glass flask with PE cap   |  |  |  |  | | --- | --- | --- | --- | |  | **Initial** | **After 14 days at 54°C** | **After 21 days at 54°C** | | Initial emulsification | Homogeneous white liquid | Homogeneous white liquid | Homogeneous white liquid | | Emulsion stability after 30 min, 2h, 24h | Homogeneous white liquid | Homogeneous white liquid | Homogeneous white opaque liquid | | Re-emulsification after 30 sec | Homogeneous white liquid | Homogeneous white liquid | Homogeneous white liquid | | Final emulsion stability after 30 min | Homogeneous white liquid | Homogeneous white liquid | Homogeneous white liquid |   Emulsion characteristics of **undiluted** test item are stable.  Spray pattern for Etofenprox 2g/L RTU stored in PEHD bottle with trigger   |  |  |  |  | | --- | --- | --- | --- | |  | **Initial** | **After 7 days at 54°C** | **After 14 days at 54°C** | | Mean spray delivered amount for 10 sprays | 6.36 g | 6.39 g | 6.42 g | | Mean spray delivered amount | 0.636 g | 0.639 g | 0.642 g | | Varaition | / | 0.47% | 0.94% | | Nozzle observations | Presence of droplets around the nozlle | Presence of droplets around the nozlle | Presence of droplets around the nozlle | | Mean Spray pattern | Outer diameter  18.7 cm | Outer diameter  20.2 cm | Outer diameter  20.1 cm | | Internal diameter  10.7 cm | Internal diameter  10.2 cm | Internal diameter  10.2 cm | | Richerioux, S. 2015, study No LODI.04/2015  Doyen A. 2015, DEFITRACES report No. 15-912011-002  Tallon, A. 2016, study No LAB2016-04 (non GLP)  Richerioux S. 2020, Study N° LAB2020-01 | Emulsion characteristics of the product have been assessed in glass flask. According to the Guidance on information requirements for biocidal products (version 1.1), extrapolation is possible between all packaging types for water based formulations.  Determination of the pH of the product stored in HDPE has been requested in shelf life study in post-authorisation.  Spray pattern is stable after storage at 54°C during 14 days. | |
|  | Stability after storage at low temperatures | CIPAC MT 75.3  CIPAC MT 36.3 | ETOFENPROX 2 G/L RTU  Batch RTU20141126Etof | |  |  |  | | --- | --- | --- | |  | Initial | After 7days at 0°C | | Appearance | Homogeneous white opaque liquid | No change | | pH 1% w/v  in standard water D | 7.90 at 21.3°C | 6.84 at 19.8°C after 1‘  6.92 at 20.0°C after 2’ |   Storage in closed glass bottle. | Doyen A. 2015, report n° 14-912011-005 | Acceptable  The preparation is stable at low temperature. | |
|  | Shelf life following storage at ambient temperature | GIFAP Monograph n°17 | Etofenprox 2 g/L  Batch RTU 20141126Etof | Packaging stability  Storage in PET bottle   |  |  |  |  | | --- | --- | --- | --- | |  | **Initial** | **After 6 months at 20°C** | **After 12 months at 20°C** | | Aspect | White liquid without deposit | White liquid without visible deposit | White liquid without visible deposit | | Chemical stability |  |  |  | | %variation | / | -0.44% | -0.84% | | Packaging | Bottle round, white, opaque with a white cap. Bottle clean. | No leak or deformation | No leak or deformation |   Storage in PEHD bottle   |  |  |  |  | | --- | --- | --- | --- | |  | **Initial** | **After 6 months at 20°C** | **After 12 months at 20°C** | | Aspect | White liquid without deposit | White liquid without visible deposit | White liquid without visible deposit | | Chemical stability |  |  |  | | Packaging %variation | / | -0.02% | -0.05% | | Packaging | Bottle round, white, opaque with a white cap. Bottle clean. | No leak or deformation | No leak or deformation | | Richerioux, S. 2016, study No LODI.15/2014 (for packaging stability)  Richerioux, S. 2016, study No LODI.08/2014 (for chemical stability) | The final report of long term storage stability in commercial packaging will have to be provided with the following data:  - The test of persistent foam even if the product is not diluted.  - The test of emulsion-re-emulsion.  - The pourability.  Note that all packaging types must be assessed.  Consequently determination of chemical stability, pH, emulsion characteristics, pourability, trigger spray and persistent foaming should be conducted in PET and HDPE. | |
|  |  |  |  | Storage in PEHD bottle with trigger   |  |  |  |  | | --- | --- | --- | --- | |  | **Initial** | **After 6 months at 20°C** | **After 12 months at 20°C** | | Aspect | White liquid without deposit | / | / | | Chemical stability |  |  |  | | %variation | / | -0.01% | -0.05% | | Packaging | Bottle clean, ergonomic, oval, opaque and black with a black trigger. | No leak or deformation | No leak or deformation |   Chemical stability   |  |  |  |  | | --- | --- | --- | --- | |  | **Initial** | **After 6 months at 20°C** | **After 12 months at 20°C** | | Chemical stability | 2.03 g/L | 1.97 g/L | 1.98 g/L | | %variation | / | -2.96% | -2.46% |   Internal specific method (LAB\_I\_047)  The analytical method was validated in study LODI.04/2014  Packaging for storage unknown |  |  | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Etofenprox 2 g/L  *Batches* IN0190216 (pourability, persistent foaming, emulsion characteristics)  RTU20141126Etof (compatibility between product and packaging, content of active substance)  RTU20150505Etof (pH determination). | Chemical stability Packaging: PET   |  |  |  |  | | --- | --- | --- | --- | |  | **Initial** | **After 18 months at 20°C** | **After 24 months at 20°C** | | Chemical stability | 2.03 g/L | 1.83 g/L | 1.91 g/L | | %variation | / | -9.85% | -5.91% |   Internal specific method (LAB\_I\_047\_e)  The analytical method was validated in study LODI.04/2014  Packaging: PET   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | |  | **Initial** | **After 6 months at 20°C** | **After 12 months at 20°C** | **After 18 months at 20°C** | **After 24 months at 20°C** | **After 36 months at 20°C** | | pH (CIPAC MT 75.3) | 8.16 | 7.78 | 7.47 | 7.43 | 7.23 | 7.37 |   Packaging :PET  CIPAC MT 36.3   |  |  |  |  | | --- | --- | --- | --- | |  | **Initial** | **After 6 months at 20°C** | **After 12 months at 20°C** | | Initial emulsification | Homogeneous white liquid | Homogeneous white liquid | Homogeneous white liquid | | Emulsion stability  -30’  -2h | - Homogeneous white liquid  - Homogeneous white liquid | - Homogeneous white liquid  - Homogeneous white liquid | - Homogeneous white liquid  - Homogeneous white liquid | | After 24h | Homogeneous white liquid | Homogeneous white liquid | Homogeneous white liquid | | Final emulsion stability | Homogeneous white liquid | Homogeneous white liquid | Homogeneous white liquid |  |  |  |  | | --- | --- | --- | |  | **After 24 months at 20°C** | **After 36 months at 20°C** | | Initial emulsification | Homogeneous white liquid | Homogeneous white liquid | | Emulsion stability  -30’  -2h | - Homogeneous white liquid  - Homogeneous white liquid | - Homogeneous white liquid  - Homogeneous white liquid | | After 24h | Homogeneous white liquid | Homogeneous white liquid | | Final emulsion stability | Homogeneous white liquid | Homogeneous white liquid |   Packaging for storage unknown   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | **Initial** | **After 12 months** | **After 24 months** | **After 36 months** | | Aspect | Homogeneous white liquid | Homogeneous white liquid | Homogeneous white liquid | Homogeneous white liquid | | Persistent foaming (CIPAC MT 47.2)  After 1’ | No foam | 10 mL | 5 mL | No foam | | Pourability  CIPAC MT 148 | Mean residue: R=0.16%  Mean rinsed residue: R’=0.15% | Mean residue: R=0.15%  Mean rinsed residue: R’=0.19% | Mean residue: R=0.14%  Mean rinsed residue: R’=0.18% | Mean residue: R=0.12%  Mean rinsed residue: R’=0.19% |   White opaque PET flask.  Storage in HDPE bottle with trigger   |  |  |  |  | | --- | --- | --- | --- | |  | **Initial** | **After 18 months at 20°C** | **After 24 months at 20°C** | | Aspect | White liquid without deposit | / | / | | Packaging | Bottle is ergonomic, black and opaque with a trigger. The bottle is clean. | No leak or deformation | No leak or deformation |   Storage in HDPE bottle 1L   |  |  |  |  | | --- | --- | --- | --- | |  | **Initial** | **After 18 months at 20°C** | **After 24 months at 20°C** | | Aspect | White liquid without deposit | White liquid | White liquid | | Packaging | Bottle round, white, opaque with a white cap. Bottle clean. | No leak or deformation | No leak or deformation |     Storage in PET bottle 250mL   |  |  |  |  | | --- | --- | --- | --- | |  | **Initial** | **After 18 months at 20°C** | **After 24 months at 20°C** | | Aspect | White liquid without deposit | / | / | | Packaging | Bottle round, white, opaque with a white cap. Bottle clean. | No leak or deformation | No leak or deformation | | Tallon A. 2017, study No LODI.09/2014 (for chemical stability of AS)  Tallon A. 2018, study No LODI.23/2015 (for chemical stability of AS)  Tallon A. 2019, study No LAB2016-05 (for chemical stability of AS)  Richerioux S. 2019, study No 16-912011-002 (for chemical stability of AS)  Tallon A. 2017, study No LODI.09/2014 (for packaging stability) | The trigger spray before and after long term storage are still missing. The reference of the trigger spray should be mentioned.  The product is stable 2 years at ambient temperature in PET and HDPE packagings.  Packaging in one study, is not provided, but eCA considers that that the emulsion stability is acceptable. |
| **B3.8** | **Technical characteristics (IIB, III 3.8)** | | | | |  |
|  | Wettability | - | - | - | - | - |
|  | Persistent foaming | CIPAC MT 47.2 | Etofenprox 2 g/L  Batch IN0190216 | Concentration: pure  Test temperature: 20 °C ± 2 °C  10”: 0 mL (2 assays) | Doyen, A. 2016, study No 16-912011-002 | Test is not compliant with the method CIPAC MT 47.2 (foam should be measured after 10 sec, 1 min, 3 min and 12 min of standing). However, as no foam was detected after 10 seconds, no further data is required. |
|  | Suspensibility | - | - | - | - | - |
|  | Spontaneity of dispersion | - | - | - | - | - |
|  | Dilution stability | - | - | - | - | - |
|  | Dry sieve test | - | - | - | - | - |
|  | Wet sieve test | - | - | - | - | - |
|  | Dust content / Particle size of dust |  |  |  |  | - |
|  | Friability and attrition characteristics of granules |  |  |  |  | - |
|  | Bulk or tap density |  |  |  |  | - |
|  | Emulsifiability / Emulsion stability / Re-emulsifiability | CIPAC MT 36.3 | Etofenprox 2 g/L  Batch IN0190216 | Undiluted product   |  |  | | --- | --- | | 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 stability after 30 min | Homogeneous white liquid | | Tallon, A. 2016, study No LAB2016-05 (non GLP) | Acceptable |
|  | Stability of dilute emulsions | - | - | - | - | - |
|  | Flowability | - | - | - | - | - |
|  | Pourability (including rinsed residue) | CIPAC MT 148 | Etofenprox 2 g/L  Batch IN0190216 | |  |  | | --- | --- | | Assay 1:  Residue 0.16%  Rinsed residue 0.13% | Assay 2:  Residue 0.16%  Rinsed residue 0.16% | | Doyen, A. 2016, study No 16-912011-002 | Acceptable |
|  | Dustability following accelerated storage | - | - | - | - | - |
| **B3.9** | **Compatibility with other products (IIB, III 3.9)** | - | - | - | - | - |
| **B3.10** | **Surface tension and viscosity (-)** | | | | |  |
|  | Surface tension | EC A5 Method  OECD Guideline 115 | Test item: ETOFENPROX 2G/L RTU  Batch: RTU20141126Etof | The surface tension was found to be 30.8 ± 0.4 mN/m at 20.1ºC ± 0.1ºC. | Benjamin, D., 2015 report 13-912011-006 | Acceptable  The preparation is surface active. |
|  | Dynamic viscosity | OECD Test Guideline 114 (Viscosity of Liquids) | Test item: ETOFENPROX 2G/L RTU  Batch: EC20130114Etof | The viscosity was found to vary with the shear rate and ranged from 1.22 mPa.s to 2.24 mPa.s at 20ºC and from 1.04 mPa.s to 1.78 mPa.s at 40°C. | Demangel, B. 2015, report14-912011-006 | The preparation is a non-Newtonian liquid.  Acceptable |
| **B 3.11** | **Particle size distribution (-)** | - | - | - | - | - |

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Explosives | Statement | - | The product Etofenprox 2g/L RTU is not explosive. Etofenprox 2g/L RTU has a qualitative composition of etofenprox (active substance), isopropyl adipate and Tween 80. An evaluation of the structural groups in the structural formula of each substance, including the oxygen balance, establishes beyond reasonable doubt that the substance is incapable of rapid decomposition with evolution of gasses 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.  FR: The product has no explosive properties. | Richerioux S. 2015, study LODI.09/2015 |
| 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 | Statement | - | The product Etofenprox 2g/L RTU is not flammable. Test is not required as Etofenprox 2g/L RTU contains more than 95% w/w water and as no ingredient is classified as flammable.  FR: The preparation is not highly flammable. |  |
| Flammable solids | - | - | Not required as the product is a liquid product. | - |
| Self-reactive substances and mixtures | - | - | Not required as the product is a liquid product. | - |
| Pyrophoric liquids | EU method A.13 | Test item: Etofenprox 2g/L  Batch n°: RTU20150122Etof | The ability of Etofenprox 2g/L RTU to ignite spontaneously when exposed to air or to char or ignite a filter paper on contact with air was assessed using two procedures. Etofenprox 2g/L RTU is not considered to have pyrophoric properties since the liquid does neither ignite spontaneously nor char a filter paper under the conditions of these tests. | Richerioux S. 2015, study LODI.07/2015+ am n°1 LODI.07/2015 |
| Pyrophoric solids | - | - | Not required as the product is a liquid product. | - |
| Self-heating substances and mixtures | - | - | Not required as the product is a liquid product. | - |
| Substances and mixtures which in contact with water emit flammable gases | - | - | Not required as the product is a liquid product. | - |
| Oxidising liquids | Statement | - | The principle of this study was to have information on chemical formula and hydrodynamics of each ingredient in Etofenprox 2g/L RTU in order to assess if the formulation is capable of reactive expothermically with comustable materials and if it has oxidising properties. No component of Etofenprox 300 g/L EC is associated with oxidising properties therefore the formulation does not contain oxidising properties.  FR: The product has no oxidizing properties. | Richerioux S. 2013, study LODI.05/2013+am1 study LODI.05/2013 |
| 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 | - | One co-formulant is corrosive to metals, but it is in very low quantity so the product is not corrosive to metals.  It has been shown that XXXX (present in Etofenprox XXg/L RTU in 0.1%), and classified as corrosive to Aluminium in the pH of 10-12, has no corrosive properties in the more neutral pH of the formulation. Consequently Etofenprox 2g/L RTU is not to be classified as corrosive to metals (Carbon Steel and Aluminium) under Regulation (EC) No 1272/2008 and no experimental determination according to UN Test C.1 needs to be performed.  FR: the product is not corrosive to metal. | Zurita Blasco, D.,2015, report 15 LKC 06 |
| Auto-ignition temperatures of products (liquids and gases) | Statement | - | Etofenprox 300 g/L EC does not ignite spontaneously under the conditions of the first test. Etofenprox 300 g/L EC does neither ignite spontaneously nor char the filter paper under the conditions of the second test  FR: The preparation is not flammable at ambient temperature. | Richerioux S. 2013, study LODI.08/2013 |
| Relative self-ignition temperature for solids | - | - | Not required as the product is a liquid product. | - |

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

The product DIGRAIN SPRAY is emulsion oil in water (EW). All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable except for the pending long term storage stability studies which are still missing.

The appearance of the product is a white homogeneous emulsion with a slightly characteristic odour. It is not explosive and has no oxidising properties. The product is not flammable and it has no self-ignition temperature up to 599 °C. It has a pH value of 8.1 at 20.8 °C.

There is no effect of high temperature on the stability of the formulation, since after 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed.

After 7 days at 0°C, the appearance and technical characteristic have not significantly changed. The product is stable at 0°C.

Its technical characteristics are acceptable for an EW formulation.

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

This data should be addressed in post-authorisation within 1 year:

* the pending long term storage stability study (2 years) in all packaging types (PET and HDPE) including determination of packaging and chemical stability, pH, persistant foaming, pourability and stability of the emulsion.

**Post authorisation**

The long term stability studies performed in claimed packaging, including the stability of packaging, the active substance content, pH, persistant foaming, pourability and stability of the emulsion, the spray pattern and trigger spray before and after a accelerated storage have been provided and are acceptable.

The following data should still be addressed and are required at the renewal of the authorisation:

* the trigger spray, before and after long term storage stability study (2 years).

##### Analytical method for determining the active substance and relevant component in the biocidal product

**Validation of the analytical method for quantification of Etofenprox in Etofenprox 2g/L RTU, Richerioux S., 2014, final report n° LODI.04/2014, LODIGROUP PA des Quatre Routes 35390 GRAND FOUGERAY, FRANCE**

Principle of the method:

Test item is quantified by a GC method using a FID detector after SPE extraction. An internal standard method is used for this quantification.

Test item: Etofenprox 2g/L RTU

Batch RTU20141126Etof, RTU20141126Etof-A, RTU20141126Etof-B, RTU20141126Etof-C, RTU20141126Etof-D, RTU20141126Etof-E.

GLP: Yes

Results

**Etofenprox:**

Specificity: chromatograms (standard, matrix without internal standard, stressed sample with 0.5mL of acetic acid) have been provided. The specificity is acceptable.

Linearity:

A calibration curve was realised at 5 concentration levels with n=3 in the range 0.96 to 1.44 g/L, r=0.99960.

Recovery:

The accuracy was tested and it is acceptable.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Recovery | | | | | | Mean recovery | RSD |
| Etofenprox content | 98.548 | 98.534 | 97.555 | 98.548 | 98.534 | 97.555 | 98.2 | 0.52 |
| 97.560 | 98.043 | 96.839 | 97.560 | 98.043 | 96.839 | 97.5 | 0.56 |
| 97.334 | 96.957 | 96.973 | 96.352 | 96.999 | 97.212 | 97.0 | 0.35 |

Extraction Yield:



|  |  |  |  |
| --- | --- | --- | --- |
|  | Theoretical content (g/L) | Experimental content(g/L)-Mean of two preparations | Y (%) |
| Sample A | 2.070 | 1.982 | 95.75 |
| Sample B | 2.071 | 1.926 | 93.00 |
| Sample C | 2.056 | 1.887 | 91.78 |
| Sample D | 2.058 | 1.950 | 94.75 |
| Sample E | 2.072 | 1.879 | 90.69 |
|  | | **Mean extraction yield** | **93.19%** |

Repeatability:

The repeatability was tested with n=3 repeat 3 times at one concentration level and on two days.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Etofenprox content | | | | | | Mean | RSD (%) |
| 1.19243 | 1.19226 | 1.18041 | 1.19243 | 1.19226 | 1.18041 | 1.188 | 0.55 |
| 1.18047 | 1.18632 | 1.17175 | 1.18047 | 1.18632 | 1.17175 | 1.180 | 0.56 |
| 1.17774 | 1.17318 | 1.17337 | 1.16586 | 1.17369 | 1.17627 | 1.173 | 0.35 |

Conclusion:

The method is validated.

##### Analytical methods for determining relevant components and/or residues in different matrices

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.

### Risk assessment for Physico-chemical properties

No physico-chemical hazards could be identified neither for the active substance nor for the biocidal product. Therefore there is no risk arising from physico-chemical properties according to the Assessment Report Etofenprox.

### Effectiveness against target organisms

#### Function

MG 03: Pest Control

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

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

DIGRAIN SPRAY is a ready-to-use emulsion in water product (2 g etofenprox/L).

DIGRAIN SPRAY (Etofenprox 2 g/L EW) is intended for indoor use by non-professionals in private homes via general surface spraying. For this use, following target organisms are claimed:

* Cockroaches (*Blattella germanica* and *Blatta orientalis*), adults and nymphs;
* Bed bugs (*Cimex lectularius*), adults and nymphs;
* Garden Ants (*Lasius niger*), adults;
* Cat fleas (*Ctenocephalides felis*), adults and larvae;
* House mites (*Dermatophagoïdes pteronyssinus*), adults and nymphs;
* Scabies mites (*Sarcoptes scabei*), adults;
* Mosquitos (*Aedes albopictus*, *Aedes aegypti*, *Culex pipiens*, *Anopheles gambiae*), adults;
* House flies (*Musca domestica*), adults ;
* Ticks (*Ixodes ricinus*), adults;
* Domestic house spiders (*Tegenaria domestica*), adults.

The product is also claimed to be effective on “crawling and flying insects”.

Details on application:

*Description of application system used*

The product is supplied ready for use in handheld trigger bottles up to 1 L in size.

*Application rate*

Spray application to be applied at a rate of 1 L product / 13 m² i.e. 77 mL product / m².

#### Effect on target organisms and efficacy

a) Effects on target organisms

As described in the Assessment Report, Etofenprox acts on harmful organisms by direct contact and ingestion with a broad spectrum of action.

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

b) Efficacy data

The applicant submitted following studies:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
| **Method of application** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Surface treatment | Indoor  Crawling insects | DIGRAIN SPRAY  etofenprox 2 g/L | *Blattella germanica* (adult males)  *Lasius niger* (adult) | Laboratory test  CEB n°135 | Time to knockdown all insects (KT100) and the mortality after 24 hours was assessed.  Typical surfaces treated measured 15 cm X 15 cm (concrete and ceramic tiles)  Temperature: 20 to 21°C  Relative humidity : 63 to 72%  1 hour of exposure time after complete drying (4 hours)  4 replications  Application rates:  75 mL on 1 m² => 150 mg a.s./m² | For the two target organisms :  100% KD within 1 hour.  100% mortality within 24h.  **Application rate validated:**  **75 mL DIGRAIN SPRAY on 1 m² => 150 mg a.s./m²** | Serrano (2015)  RI=1 |
| Direct spray  Surface treatment  Residual efficacy | Indoor  Crawling insects  Flying insects | DIGRAIN SPRAY  etofenprox 2 g/L | *Blattella germanica* (adults, nymphs) *Blatta orientalis* (adults, nymphs) *Lasius niger* (adults) *Ctenocephalides felis* (adults, Larvae) *Cimex lectularius* (adults, nymphs) *Dermatophagoïdes pteronyssinus* (adults, nymphs) *Sarcoptes scabei* (adults)  *Ixodes ricinus* (adults) *Tegenaria domestica* (adults)  *Culex quinquefasciatus* (adults) *Aedes albopictus* (adults) *Anopheles gambiae* (adults) | Laboratory test  CEB n°135 / 159 | DIRECT SPRAY TEST:  Product was directly sprayed onto the target organisms at the dose of 75 mL/m².  Time to knockdown all insects (KT100) and the mortality after 24 hours was assessed.  SURFACE TREATMENT:  Room of 60 m3  Typical surfaces treated measured 15 cm X 15 cm (wooden, steel, concrete and ceramic tiles)  Temperature: 20 - 25 °C  Relative humidity : 69 to 74 %  Smooth ventilation: 1m3/h  1 hour of exposure time after complete drying (2 hours)  Tested residual efficacy: 8 weeks.  Storage of the panels at 22°C±2°C and relative humidity of 70 ± 5%, under a photoperiod of 16 hours light (1200 lux) and 8 hours darkness.  4 replications  Application rate: 75 mL / m² | DIRECT SPRAY TEST: 100% KD within 30 seconds for all test organisms except adult *B. orientalis* (1 min), adult bed bug (1 min) and spider (1min); 100% mortality within 24h.  SURFACE TREATMENT / RESIDUAL SPRAY TRIAL: KT100 (D0)= 1h for all modalities. KT100 (Bed bugs) (D0 + 2 weeks) = 1h except for adults on concrete and wood (2h) KT100 (D0 + 8 weeks) = 1 to 4h, except for adult cockroaches on porous surfaces and spiders on all surfaces.=>no KD  100 % mortality was achieved within 24 hours until 8 weeks for all test organisms, on both porous and non-porous surfaces.  **Application rate validated:**  **75 mL DIGRAIN SPRAY on 1 m² => 150 mg a.s./m²** | Serrano (2016)  RI=1 |
| Surface treatment  Residual efficacy | Indoor  Crawling insects  Flying insects | DIGRAIN SPRAY  etofenprox 2 g/L | *Blattella germanica* (adults, nymphs) *Blatta orientalis* (adults, nymphs) *Lasius niger* (adults) *Ctenocephalides felis* (adults, Larvae)  *Dermatophagoïdes pteronyssinus* (adults, nymphs) *Sarcoptes scabei* (adults)  *Ixodes ricinus* (adults) *Tegenaria domestica* (adults)  *Musca domestica* (adults) *Culex quinquefasciatus* (adults) *Aedes albopictus* (adults) *Anopheles gambiae* (adults) | Laboratory test / Simulated used test  Test chamber in conditions simulating the conditions of use, by setting treated panels of two types of materials, porous and non-porous (50% of the floor area), releasing arthropods and counting their mortality after 24 hours of exposure.  The target organisms had the choice not to be in contact with the product and were not forced to be in contact with the treatment to reach water and food sources. | Test chamber: 12 m3 (6 m²) kept at a temperature 22°C +/- 1°C, a relative humidity of 60% +/- 5% and 8 hours light per day (800 lux).  4 replicates for each test condition: test product or untreated control \* target organism \* storage duration.  A few cardboards (to give harbourages to the insects) and a water + food source were set on the floor of the test chamber.  The residual efficacy of the product was assessed right after treatment and 8 weeks later.  Application rate:  75 mL / m² | 100 % mortality was achieved within 24 hours until 8 weeks for all test organisms, on both porous and non-porous surfaces.  **Application rate validated:**  **75 mL DIGRAIN SPRAY on 1 m² => 150 mg a.s./m²** | Serrano (2016)  RI=2 |

Submitted efficacy data are compliant with the requirements and criteria of the TNsG PT18/19 for the following claimed uses:

- Use against cockroaches (including *Blattella germanica, Blatta orientalis*);

- Use against garden ants (*Lasius niger*);

- Use against ticks (*Ixodes ricinus*);

- Use against mosquitoes (*Aedes sp., Culex sp., Anopheles sp.*);

- Use against house flies (*Musca domestica*).

The general claim “crawling insects” can be validated as effectiveness against cockroaches has been demonstrated.

For the following uses, submitted efficacy data are compliant with the requirements of the TNsG PT18/19 (2012), but some test results do not satisfy the criteria of the TNsG PT18/19 (2012) or test conditions are not representative enough of the field conditions:

- Use against fleas (*Ctenocephalides felis*): Laboratory and semi-field tests have been submitted but experimental conditions are not representative of the field conditions and therefore not sufficiently reliable. Indeed, adult cat fleas are most of the time living on the pet delivering their eggs to the resting place of the pet (e.g. carpets, rugs, baskets, sofas etc.). A field test or a simulated-use test with representative surfaces as pieces of carpets with different fiber lenghts and densities and demonstrating residual efficacy should have been provided in support of the authorisation.

- Use against house dust mites (*D. pteronyssinus*), by spraying, for non-professional users. Laboratory and semi-field tests have been submitted but experimental conditions are not representative of the field conditions and therefore not sufficiently reliable. Indeed, house dust mites are mostly living on beddings and other textile surfaces (e.g. carpets, rugs, baskets, sofas etc.). Tests have been conducted on ceramic, wooden, concrete and metal surfaces.

- Use against bed bugs (*Cimex lectularius*), by spraying, for non-professional users. A laboratory showing good efficacy on 4 types of surfaces (concrete, metal, wood and ceramic), has been submitted, but typical surfaces like for example textile fabrics would have been more relevant to test considering the infestation areas of this kind of insects. So, it is concluded that efficacy of this product against bed bugs has not been sufficiently demonstrated.

- Use against scabies mites (*Sarcoptes scabei*): Laboratory and semi-field tests have been submitted but considering the mode of contamination of this pest (mostly spread by direct, prolonged, skin-to-skin contact and sometimes indirectly by sharing articles such as clothing, towels, or bedding used by an infested person), tested surfaces (wooden, ceramic, steel, concrete) doesn't seem to be relevant. Furthermore, the number of scabies mites in the tests is low (10 per replicate).

- Use against Domestic house spider (*Tegenaria domestica*): Laboratory and semi-field tests have been submitted whereas section 2.2.2 of the TNsG states that for other arthropods a field trial should be provided or a good justification why this is not appropriate. No justification of non submission has been provided by the applicant. Moreover, the number of spiders in the tests is considered as too low (5 per replicate).

The general claim “flying insects” cannot be validated as effectiveness against wasps hasn’t been demonstrated.

#### Mode of action including time delay

Etofenprox shares its mode of action with other pyrethroid derivatives. It acts on the nerve system by disturbing the normal neurotransmittance (as a sodium channel modulator).

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.

Residual activity has been demonstrated until 8 weeks. After 8 weeks there is no knock down anymore on adult cockroaches and spiders but there is still 100 % mortality after 24 hours.

#### Occurrence of resistance  - resistance management / Unacceptable Effect

As described in the Assessment Report, etofenprox is an IRAC[[2]](#footnote-3) 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 in *B. germanica*, a resistance mechanism against etofenprox (and other pyrethroids) has been described in the literature. 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 in susceptible insect populations, the following recommendations have to be implemented:

* Always read the label or leaflet before use and follow all the instructions provided.
* Respect the recommended application doses.
* The users should inform the registration holder if the treatment is ineffective.
* Establish a baseline and monitor levels of effectiveness on populations in key areas (at least one survey per year) in order to detect any significant changes in susceptibility to active substance. Information from resistance monitoring programs allows early detection of problems and gives information for correct decision making.
* The authorization holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management.

**Post authorisation**

According to the applicant, the product DIGRAIN SPRAY has not been marketed since its authorisation, thus no monitoring has been performed.

**The requested data should be submitted at the renewal of the authorisation.**

#### Evaluation of the label claim

French competent authorities (FR CA) assessed that the product DIGRAIN SPRAY (Etofenprox 2 g/L) has shown a sufficient efficacy for the following uses:

* Crawling insects including cockroaches (e.g. *B. germanica*, *B. orientalis*), adults and nymphs;
* Mosquitos (*Aedes spp.*, *Culex spp.*, *Anopheles spp.*), adults;
* Garden ants (*L. niger*), workers;
* Use against ticks (*I. ricinus*);
* Use against house flies (*M. domestica*).

The application rate validated is the following:

Spraying (direct and surface treatment)

The recommended application rate (porous and non-porous surfaces) is 1 L product for 13 m² of treated area i.e. 77 mL / m².

The product is efficient during 8 weeks.

Concerning the claim “acute effect in a few minutes until 8 weeks”, submitted tests permit either to validate “acute efficacy in a few minutes by direct spraying” or “within a few hours (1-4 h) by surface treatment, until 8 weeks”.

The following measure is necessary to ensure the residual effect : ”Do not clean the treated area until the treatment is finished (up to 8 weeks)”.

Submitted data are not sufficient to validate use againt cat fleas, house dust mites, bed bugs, scabies mites and domestic house spiders, nor the general claim “Flying insects”.

### Risk assessment for human health

#### Hazard potential

##### Toxicology of the active substance

The toxicology of the active substance was examined extensively according to standard requirements. The results of this toxicological assessment can be found in the CAR.

The threshold limits and labelling regarding human health risks listed in Annex 3 “Toxicology and metabolism” must be taken into consideration.

The toxicological reference values used in the risk assessment are summarised in the following table:

|  | Value  (mg/kg/d) | Study | SF |
| --- | --- | --- | --- |
| AEL long-term | 0.011 | Rat 2-year feeding study | 100 |
| AEL medium-term | 0.06 | Rat subchronic feeding study | 100 |
| AEL acute | 0.085 | Rat developmental neurotoxicity feeding study | 100 |
| ADI | Not determined |  |  |
| ARfD | Not determined |  |  |

##### Toxicology of the substance(s) of concern

The biocidal product does not contain substances of concern.

The basis for health assessment of the substance of concern is laid out in Annex 4 “Toxicology – biocidal product”

##### Toxicology of the biocidal product

The toxicology of the biocidal product was examined appropriately according to standard requirements. The basis for the health assessment of the biocidal product is laid out in Annex 4 ”Toxicology – biocidal product”.

###### **Percutaneous absorption**

The formulation is an aqueous emulsion (2 g/L) corresponding to DIGRAIN SPRAY product.

An in vitro dermal absorption of formulated radiolabeled etofenprox has been investigated using  
human skin. The rate and extent of absorption was assessed following topical application of the  
aqueous solution to human skin.

The integrity of the human skin used for each test vessel was confirmed by assessing the  
permeability of tritiated water prior to the experiment.

The etofenprox formulation was applied to the skin surface of appropriate cells. Aliquots of  
receptor fluid were taken for analysis at 0, 0.5, 1, 2, 4, 6, 8, 10, 12 and 24 hours after application.  
After the 8 hour sampling point the dose formulation was removed from the test skin by washing the  
area using a 3 % soap solution. Following the 24 hour sampling time-point the test system was  
dismantled and the skin retained for solubilisation and analysis of radioactivity. Skin fractionation  
was performed by tape stripping and strips retained for solubilisation and analysis of radioactivity.  
The remaining Franz cells donor and receptor chambers were washed with acetonitrile and the  
washings retained for analysis of radioactivity.

The results were analysed according to the EFSA guidance on dermal absorption 2012[[3]](#footnote-4).

* Low recovery was observed for several replicats. Applicant considered that etofenprox is known to bind to various materials including glass and the solubility in the receptor fluid was assessed at higher concentrations than detected in the main permeability experiment and therefore the remaining material is not considered to be associated with the receptor fluid samples. He considered this material as not absorbed and may be associated with the donor chamber. This justification was judged by eCA as not enough robust. In this context, a normalisation correction was realised.
* Less than 75 % of the total absorption in receptor fluid occurred within the first 12 hours of the experiment. In this context, the amount of active substance in stratum corneum (excluded the first two tape strips) was considered as absorbed.
* Therefore the absorbed dose was determined considering: the amount of active substance in stratum corneum + skin+ receptor fluid + receptor chamber wash.
* A significant variation between replicates exists (the relative standard deviation is superior to 25 %) (5.01%). In this context, the standard deviation was added to the mean corrected value (7.16%) to determine the potentially absorbed dose.

**To conclude, a dermal absorption value of 12 % is proposed.**

###### **Acute toxicity**

Oral

The product Etofenprox 2 g/L RTU (DIGRAIN SPRAY) was administered to a group of 6 female Sprague Dawley rats at the single dose of 2000 mg/kg. The experimental protocol was established on the basis of the OECD guideline 423. No mortality occurred during the study. No clinical signs related to the administration of the test item were observed. The body weight evolution of the animals remained normal throughout the study. The macroscopical examination of the animals at the end of the study did not reveal treatment related changes.

In conclusion the DL50 of the product is higher than 2000 mg/kg body weight by oral route in the rat.

According to the criteria for classification of CLP regulation, the product DIGRAIN SPRAY must not be classified.

Inhalation

A group of six RccHan : WIST strain rats (three males and three females) was exposed to an aerosol atmosphere. The animals were exposed for four hours using a nose only exposure system, followed by a fourteen day observation period. The mean achieved atmosphere concentration was 5.59 mg/L with a mean Mass Median Aerodynamic diameter of 1.99 µm and an inhalable fraction (< 4µm) of 82.4%.

No mortality was observed in animals.

Common abnormalities noted during the study included increased respiratory rate, hunched posture, pilo-erection and wet fur. Animals recovered to appear normal on day 3 post-exposure.

One male showed no body weight gain on the first day post-exposure. From Days 1 to 3 post-exposure, a further male showed no body weight gain and two female animals exhibited body weight losses. One other female animal showed no body weight gain from Days 3 to 7 post-exposure. Body weight gains were then noted in all animals during the final week of the recovery period.

Three animals exhibited either dark patches on the lungs or gaseous distension of the stomach at necropsy. No macroscopic abnormalities were detected amongst the other three animals at necropsy.

No deaths occurred in a group of six rat exposed to a mean maximum attainable atmosphere concentration of 5.59 mg/L for four hours. It was therefore considered that the acute inhalation median lethal concentration of DIGRAIN SPRAY was greater than 5.59 mg/L.

According to the criteria for classification of CLP regulation, the product DIGRAIN SPRAY is not classified.

Dermal

The product DIGRAIN SPRAY was applied onto the intact skin of 10 Sprague Dawley rats (5males and 5 females) at the single dose of 2000 mg/kg body weight. The experimental protocol was established on the basis of the OECD guideline 402.

No mortality occurred during the study.

Neither cutaneous reactions nor systemic clinical signs related to the administration of the test item were observed.

The body weight evolution of the animals remained normal throughout the study.

The macroscopic examination of the animals at the end of the study did not reveal treatment-related changes.

In conclusion, the LD50 of DIGRAIN SPRAY is higher than 2000 mg/kg body weight.

According to the criteria for classification of CLP regulation, the product DIGRAIN SPRAY is not classified.

###### **Irritation and corrosivity**

Skin irritation

The product DIGRAIN SPRAY was applied at the dose of 0.5 mL, under semi-occlusive dressing during 4 hours on an undamaged skin area of 3 New Zealand rabbits. The experimental protocol was established according to the OECD guideline 404. The skin reactions were appreciated 1 hour, 24, 48 and 72 hours after removal of the patch. If no reaction is observed 72 hours after treatment the study is terminated. In case of persistent reactions, additional observations can be carried out from D7 to D14 in order to determine the reversible character of the lesions observed.

Very slight to well defined erythema was noted on the treated area of all animals, 1 hour after the patch removal. Very slight oedema was noted on the treated area of one animal, 1 hour after the patch removal. The erythematous reaction was totally reversible between days 1 and 3 and the oedematous reaction was totally reversible on day 2.

Dryness of the skin was noted in one animal on day 3 and in a second animal on days 3 and 7.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Skin reaction | Observation time | Animal 1 | Animal 2 | Animal 3 |
| Erythema and eschar | 24h | 0 | 1 | 2 |
| 48h | 0 | 1 | 1 |
| 72h | 0 | 0 | 0 |
| **mean** | **0** | **0.67** | **1** |
| Oedema formation | 24h | 0 | 0 | 1 |
| 48h | 0 | 0 | 0 |
| 72h | 0 | 0 | 0 |
| **mean** | **0** | **0** | **0.33** |

According to the criteria for classification of CLP regulation, the product DIGRAIN SPRAY is not classified.

Eye irritation

The product DIGRAIN SPRAY was instilled into the eye of 3 New Zealand rabbits at the dose of 0.1 mL. The other eye remained untreated serving as control. The experimental protocol was established on the basis of the OECD guideline 405.

Ocular examinations were performed on both right and left eyes 1 hour, 24, 48 and 72 hours following  
treatment.

If no reaction is observed 72 hours after instillation, the study is terminated. In case of persistent reactions,  
additional observations can be carried out from D7 to D21 in order to determine the reversible character of the  
lesions observed.

The conjunctivae reactions observed during the study have been slight and totally  
reversible: a slight redness was noted 1 hour after the test item instillation in 2 animals and totally reversible on day 1, associated to a slight chemosis noted 1 hour after the test item instillation in one animal and  
totally reversible on day 1.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Animal | Observation time | CONJUNCTIVAE | | IRIS | CORNEA |
| CHEMOSIS | REDNESS | LESION | OPACITY |
| 1 | 24h | 0 | 0 | 0 | 0 |
| 48h | 0 | 0 | 0 | 0 |
| 72h | 0 | 0 | 0 | 0 |
| Mean | 0 | 0 | 0 | 0 |
| 2 | 24h | 0 | 0 | 0 | 0 |
| 48h | 0 | 0 | 0 | 0 |
| 72h | 0 | 0 | 0 | 0 |
| Mean | 0 | 0 | 0 | 0 |
| 3 | 24h | 0 | 0 | 0 | 0 |
| 48h | 0 | 0 | 0 | 0 |
| 72h | 0 | 0 | 0 | 0 |
| Mean | 0 | 0 | 0 | 0 |

According to the criteria for classification of CLP regulation, the product DIGRAIN SPRAY is not classified.

###### **Sensitisation**

The aim of the study was to evaluate the possible allergenic activity of the test item after intradermal  
and topical administration in guinea pigs.

Before the main assay, a preliminary assay was realized in order to determine:

* Intradermal injection of the Maximal Non Necrotizing Concentration
* Determination by topical application of the Pre-Maximal Non Irritant Concentration
* Determination by topical application of the Maximal Non Irritant Concentration.

In the main assay, after induction (intradermic injection at 5% and topical application at 100%) of 20 Guinea Pigs of treated group with DIGRAIN SPRAY and a 10-day rest phase, the challenge phase, under occlusive dressing for 24 hours, consisted to a single topical application of the test item at 100% and diluted at 50 % in distilled water. The experimental protocol was established according to OECD guideline 406.

No cutaneous reaction attributable to allergy was recorded in animals from the treated groups after the  
challenge phase.

No cutaneous intolerance reaction was recorded in animals from the negative control groups after the  
challenge phase.

According to the criteria for classification of CLP regulation, the product DIGRAIN SPRAY is not classified.

**However, the product contains sensitizing substances in concentration triggering the sentence EUH 208: Contains 2-méthyl-2H-isothiazole-3-one and 1,2-benzisothiazol-2(2H)-one. May produce an allergic reaction.**

###### **Other studies**

Not relevant.

#### Human exposure assessment

##### Identification of main paths of human exposure towards active substance from its use in biocidal product

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Exposure path** | **Industrial use** | **Professional use** | **Non professional use** | **General public** |
| Inhalation | Not relevant | Not relevant | YES | YES |
| Dermal | Not relevant | Not relevant | YES | YES |
| Oral | Not relevant | Not relevant | NO | YES |

##### Direct exposure as a result of use of the active substance in biocidal product

###### **Exposure of professional users**

Not relevant.

###### **Exposure of non-professional users**

*In Annex 5 “Safety for non-professional operators and the general public”, the results of the exposure calculations for the active substance.*

The product can be applied by spraying. It is available on ready to use packaging (trigger bottles up to 2 L).

In this context, no mixing and loading is needed.

Non-professional use of 2 g/L etofenprox based on label indications:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Application site | Application type | Dilution (product:water) | Application rate diluted product | Application rate of active | Concentration of a.i. as applied |
| General hygiene (residential)  INDOOR | Surface spray | No dilution | 1 L/13 m2 | 0.15 g/m2 | 0.2 % |

Exposure during spraying is calculated using the Consumer Spraying and Dusting Model 2  
from the TNsG 2002 (p 199) and reviewed in User guidance.

The dermal absorption value of 12 % is used.

The following values are used to estimate exposure:

|  |  |  |
| --- | --- | --- |
| **Parameter** | **Value** | **Source** |
| Hands/forearms exposure | 36.1 mg product/minute | TNsG 2002 and reviewed in the user guidance |
| Legs feet face exposure | 9.7 mg product/minute | TNsG 2002 and reviewed in the user guidance |
| Inhalation | 10.5 mg product/m3 | TNsG 2002 and reviewed in the user guidance |
| Duration of exposure | 10 minutes | TNsG 2002 |
| Dermal absorption | 12 % | See section 2.7.1.3.1 |
| Inhalation absorption | 100 % |  |
| Concentration of active substance | 0.2 % |  |
| Body weight | 60 kg | HEEG opinion 17 |

The exposure is summarized in the following table:

| **Tier** | **Dermal exposure** | **Inhalation exposure** | **Total exposure** |
| --- | --- | --- | --- |
| PPE | Systemic dose | Systemic dose | Systemic dose |
|  | mg a.i. / kg bw /day | mg a.i. / kg bw /day | mg a.i. / kg bw /day |
| **Task – time frame:** | **Spraying (non-professional)** | | |
| Tier 1:  Without PPE | 1.83E-03 | 7.29E-05 | 1.9E-03 |

##### Indirect exposure as a result of use of the active substance in biocidal product

Four scenarios of exposure will be 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 touchs 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.

###### **Exposure to volatile residue**

The assessment was realised according to the HEEG opinion 13 “Assessment of inhalation exposure of volatilised biocides active substance”.

The following values are used to estimate exposure:

|  |  |  |
| --- | --- | --- |
| **Parameter** | **Value** | **Source** |
| Vapor pressure | 8.13E-07 Pa | CAR |
| Molecular weight | 376.47 g/mol | CAR |
| Adult body weight | 60 kg | HEEG opinion 17 |
| Child body weight | 23.9 kg | HEEG opinion 17 |
| Infant body weight | 10 kg | HEEG opinion 17 |

The exposure is summarized in the following table:

|  |  |
| --- | --- |
| Population | Systemic exposure (mg/kg/d) |
| Adult | 3.35E-05 |
| Child | 6.31E-05 |
| Infant | 6.79E-05 |

###### **Exposure of a toddler[[4]](#footnote-5) who crawls on treated surface with a hand to mouth transfer**

In the post-application phase, toddler can be highly exposed, due to their specific time-activity pattern (crawling on treated surface, hand to mouth contact and low body weight). This exposure was estimated based on the approach proposed in Consexpo fact sheet “Cleaning products”. ConsExpo software wasn’t 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 ConsExpo the transfer coefficient of 0.6 m2/h will be used.

From this surface a fraction of active substance is dislodgeable:

* For wet surface, a default value of 100% will be used ;
* For dried surface, the value of 30 % proposed in TNsG and ConsExpo for dried surface will be used in first tier. Studies about transfer of etofenprox from vinyl flooring and carpet flooring were provided in the biocide active substance CAR. The values obtained in this studies will be used as refinement. For example from carpet, dislodgeable fraction of 11 % after 4 hours (acute exposure) and 4 % after 7 days (chronic exposure) were observed.

If dermal exposure of children occurs, they can also be exposed orally via hand–mouth contact. 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.

For the exposure to wet and dry surface, the dermal absorption values of 12 % will be used. This value is closed the value proposed in the CAR (13.8 %).

The exposure is summarized in the following table:

| **Tier** | **Dermal exposure** | **Oral exposure** | **Total exposure** |
| --- | --- | --- | --- |
| PPE | Systemic dose | Systemic dose | Systemic dose |
|  | mg a.i. / kg bw /day | mg a.i. / kg bw /day | mg a.i. / kg bw /day |
| **Task** | **Infant crawling on treated surface with hand to mouth transfer – Wet surface default dislodgeable fraction (100%)** | | |
| Wet surface  Spraying | 9.72E-01 | 2.70E-01 | 1.24 |
| **Task** | **Infant crawling on treated surface with hand to mouth transfer**  **- dry surface default dislodgeable fraction (30%)** | | |
| Dry surface  Spraying | 2.92E-01 | 8.10E-02 | 3.73E-01 |
| **Task** | **Infant crawling on treated surface with hand to mouth transfer**  **– dry surface dislodgeable fraction from carpet after 4 hours (11%)** | | |
| Dry surface  Spraying  From carpet  Acute exposure | 1.07E-01 | 2.97E-02 | 1.37E-01 |
| **Task** | **Infant crawling on treated surface with hand to mouth transfer**  **– dry surface dislodgeable fraction from carpet after 7 days (4%)** | | |
| Dry surface  Spraying  From carpet  Chronic exposure | 3.89E-02 | 1.08E-02 | 4.97E-02 |

###### Exposure to an adult touching a treated surface with its hands (wet and dry surface)

In the post-application phase, an adult can be exposed if he touchs a treated surface (wet or dried) with its hands (palms of both hands).

From this surface a fraction of active substance is dislodgeable:

* For wet surface, a default value of 100 % will be used.
* For dried surface, the value of 30 % proposed in TNsG for dried surface will be used.

###### For the exposure to wet and dry surface, the dermal absorption values of 12 % will be used.

The exposure is summarized in the following table:

| **Tier** | **Dermal exposure** | **Total exposure** |
| --- | --- | --- |
| PPE | Systemic dose | Systemic dose |
|  | mg a.i. / kg bw /day | mg a.i. / kg bw /day |
| **Task** | **Adult touching a treated surface with hands – Wet surface default dislodgeable fraction (100%)** | |
| Spraying | 1,26E-02 | 1,26E-02 |
| **Task** | **Adult touching a treated surface with hands – dry surface default dislodgeable fraction (30%)** | |
| Spraying | 3.78E-03 | 3.78E-03 |

###### **Exposure of adult, child and infant who sleep in a bed treated against bed bugs**

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 HEEG opinion 17. The body will not be in direct contact with bed, as there is sheet. In this context, a protection factor of 50 % is considered.

From this surface a fraction of active substance is dislodgeable:

* For dried surface, the value of 30 % proposed in TNsG for dried surface will be used.

The dermal absorption values used for the previous scenario (12 % for dried surface) will be used.

The exposure is summarized in the following table:

| **Tier** | **Dermal exposure** | **Oral exposure** | **Total exposure** |
| --- | --- | --- | --- |
| PPE | Systemic dose | Systemic dose | Systemic dose |
|  | mg a.i. / kg bw /day | mg a.i. / kg bw /day | mg a.i. / kg bw /day |
| **Task – time frame:** | **Secondary exposure:**  **adult, child and infant who sleep in a bed treated against bed bugs** | | |
| Dried surface  Adult | 7.67E-02 | NR | 7.67E-02 |
| Dried surface  Child | 1.07E-01 | NR | 1.07E-01 |
| Dried surface  Infant | 1.42E-01 | NR | 1.42E-01 |

NR: not relevant

##### Indirect exposure via residues in food

No specific residue data was submitted in the context of this dossier. The product DIGRAIN SPRAY is intended to be applied for indoor spraying uses (private home) by non-professional.

For indoor spraying uses (private home for non-professional), the following precautionary statements are proposed:

- Evacuate animals prior to treatment

- Remove all food, feed and drinks prior treatment.

- Do not use on surfaces and facilities likely to be in contact with food, feed, drinks and animals.

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

The product DIGRAIN SPRAY will not get into contact with food, feed and livestock and will not leave residues in commodities for human or animal consumption.

In Annex 6 “Residue behaviour”, residue data are laid out.

##### Combined exposure

A non-professional who treats his house can be exposed during treatment, to volatile residue and during sleeping in a treated bed for example.

A non professional could also be exposed to volatile residue and to residue after touching a treated surface. As a worst case, only assessment of a non proefessionnal who touchs a wet surface is presented.

The combined exposure is summarised in the following table:

|  |  |
| --- | --- |
| Scenario | Total systemic exposure (mg/kg/d) |
| Non-professional Spraying | 1.9E-03 |
| Exposure to volatile residue | 3.35E-05 |
| Exposure during sleeping in a treated bed (dry) | 7.67E-02 |
| Exposure during touching a treated surface (wet) | 1,26E-02 |
| **Non-professional: exposure during Spraying + exposure to volatile residue + exposure during sleeping in a treated bed** | 7.86E-02 |
| **Non-professional: exposure during Spraying + exposure to volatile residue + exposure during touching wet treated surface** | 1.45E-02 |

A combined exposure for infant could be realised considering that the infant is exposed to the volatile residue, after crawling on treated area and sleeping in a treated bed. However, as individual risk is ever unacceptable for crawling and sleeping no combined exposure for secondary exposure is determined.

#### Risk assessment for human health

##### Risk for direct exposure

###### **Professional users**

Not relevant.

###### **Non-professional users**

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

Comparison of estimated professional exposure to AEL is summarised in the following table:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Scenario  PPE | Estimated Exposure (mg/kg/d) | AEL  (mg/kg/d) | %AEL | Acceptable/not acceptable |
| **Spraying** | | | | |
| Spraying Without PPE | 1.90E-03 | 8.5E-02 | 2% | Acceptable |

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

##### Risk for indirect exposure

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

A delayed effect until 8 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 6.0E-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.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Scenario | Estimated Exposure (mg/kg/d) | AEL  (mg/kg/d) | %AEL | Acceptable/not acceptable |
| **Exposure to volatile residue** | | | | |
| Adult | 3,35E-05 | 6E-02 | 0.06% | Acceptable |
| Child | 6,31E-05 | 6E-02 | 0.11% | Acceptable |
| Infant | 6,79E-05 | 6E-02 | 0.11% | Acceptable |
| **Infant crawling on treated surface with hand to mouth transfer – Wet surface default dislodgeable fraction (100%)** | | | | |
| Wet surface  Spraying | 1.24 | 8.5E-02 | 1461% | **Not acceptable** |
| **Infant crawling on treated surface with hand to mouth transfer**  **- dry surface default dislodgeable fraction (30%)** | | | | |
| Dry surface  Spraying | 3.73E-01 | 6E-02 | 621% | **Not acceptable** |
| **Infant crawling on treated surface with hand to mouth transfer**  **– dry surface dislodgeable fraction from carpet after 4 hours (11%)** | | | | |
| Dry surface  Spraying  Acute exposure | 1.37E-01 | 8.5E-02 | 161% | **Not acceptable** |
| **Infant crawling on treated surface with hand to mouth transfer**  **– dry surface dislodgeable fraction from carpet after 7 days (4%)** | | | | |
| Dry surface  Spraying  Subchronic exposure | 4.97E-02 | 6E-02 | 83% | Acceptable |
| **Adult touching a treated surface with hands – Wet surface default dislodgeable fraction (100%)** | | | | |
| Spraying | 1.26E-02 | 8.5E-02 | 15% | Acceptable |
| **Adult touching a treated surface with hands – dry surface default dislodgeable fraction (30%)** | | | | |
| Spraying | 3.78E-03 | 6E-02 | 6% | Acceptable |
| **Exposure during sleeping in a treated bed (dry)** | | | | |
| Dried surface  Adult | 7.67E-02 | 6E-02 | 128% | **Not acceptable** |
| Dried surface  Child | 1.07E-01 | 6E-02 | 178% | **Not acceptable** |
| Dried surface  Infant | 1.42E-01 | 6E-02 | 237% | **Not acceptable** |

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 chronic exposure of an infant crawling on a carpet. However, acute exposure of this scenario is unacceptable. As no information on comportment in function of the time is available (no information between 4h and 7 days), the risk is considered unacceptable for all scenarios. Furthermore, the carpet is not representative of all type of surfaces in which the product can be applied. In this context, a mitigation measure is proposed: **The product should not be applied in zone accessible to children.**

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.

##### Risk for consumers via residues in food

Based on the intended indoor uses (private home – non-professional) and the proposed restriction measures, the acute and chronic exposure to residues resulting from the intended use is unlikely to cause a dietary risk to consumers. The product DIGRAIN SPRAY 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:

**For indoor spraying uses** (private home for non-professional):

- Evacuate animals prior to treatment

- Remove all food, feed and drinks prior treatment.

- Do not use on surfaces and facilities likely to be in contact with food, feed, drinks and animals.

- 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 combined exposure

A delayed effect until 8 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 sleeping in a treated bed AND 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.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Scenario | Estimated Exposure (mg/kg/d) | AEL  (mg/kg/d) | %AEL | Acceptable/ Unacceptable |
|  | | | | |
| Non-professional: exposure during Spraying + exposure to volatile residue + exposure during sleeping in a treated bed | **7.86E-02** | 8.5E-02 | 92.51% | Acceptable |
| Non-professional: exposure during Spraying + exposure to volatile residue + exposure during touching wet treated surface | 1.45E-02 | 8.5E-02 | 17% | Acceptable |

Estimated exposure is inferior to AEL.

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.

##### Summary of risks characterisation of the product for human health

The risk linked to the application is acceptable for non professional.

For secondary exposure:

- the risk is unacceptable for infant crawling on treated surface. Therefore a mitigation measure is proposed: The product should not be applied in zone accessible to children.

- the risk for persons (adult, child and infant) sleeping on a treated bed is also unacceptable. Therefore, the uses for which this type of exposure is expected cannot be accepted.

- the risk linked to the exposure to volatile residues is considered acceptable.

- the risks for adult touching treated surface are acceptable.

### Risk assessment for the environment

#### Fate and distribution in the environment of the active substance etofenprox

|  |
| --- |
| The section 2.2.6.1 is written by FRCA, based on the available data provided by the applicant. |

##### Degradation

###### Abiotic degradation

Hydrolysis in function of pH

Etofenprox is hydrolytically stable in sterile buffer solutions at pH 4, 7 and 9 even if metabolite [14C]-α-CO was found to be stable in aqueous buffer acetonitrile solution at pH 4 and 7, but was hydrolysed at pH 9 (DT50= 42.8 days, 25°C) to form PENA and m-PBAcid that are expected to be of minor importance under environmental conditions.

Photolysis in water

Etofenprox is photo-degraded under simulated sunlight, with DT50 values of 13.3 and 22.4 days (12°C) in sterile buffer solution and natural pond water, respectively. The metabolite α-CO was the major photo-degradate that does not undergo photolysis: 63.6% is the maximum of α-CO found in the photolysis study.

Photolysis in soil

Etofenprox dissipates with a calculated disappearance time DT50 of 19.3 days at 20-22°C. No major degradation products were found.

Photodegradation in air

The photochemical oxidative degradation of etofenprox was calculated using the computer simulation software AopWin v1.92. An overall OH rate constant of 62.16 x 10-12 cm3/molecule-sec was determined, resulting in an estimated half-life in air of 6.2 hours (24 hour day) at 25°C (5x105 OH/cm3).

###### Biotic degradation

Aquatic compartment

* Ready biodegradation / inherent biodegradation

Etofenprox is classified as ”not readily biodegradable” (17 % mineralisation after 28 days).

* Degradation in water/sediment system

The DT50 value for degradation in the entire system of etofenprox was 38.1 days (12 °C). For dissipation in the water phase, the DT50 was 19.7 days and the DT50 for dissipation in the sediment phase was 61.1 days.

The metabolite 4’-OH was the major product of etofenprox degradation: 21.4% is the maximum of 4’-OH found in the water sediment study. For the product degradation 4’-OH, mainly found in sediment, the DT50 value for degradation in the entire system was 55.3 days and the DT50 for dissipation in the sediment phase was 105.8 days at 12°C. Thus, in the environmental risk assessment, a PECsediment for 4’-OH is calculated, as a major product of etofenprox degradation.

Degradation in STP

* Data provided for the substance approval (CAR)[[5]](#footnote-6).

An OECD 314B test confirms a significant initial partitioning of Etofenprox between the aqueous and solid phases of the activated sludge.Etofenprox degrades in biotic sludge with a DT50 value of 2.5 days at 12 °C. 11 metabolites were found in addition to 14CO2 but only one metabolite (M3) once exceeded 10 % of AR with 24.8 % after 2 days of incubation. However it was degraded rapidly to 1.0 % after 7 days and to 0.1 % after 14 and 30 days of incubation. From the available data a degradation half-life of 0.9 days was calculated for M3, at 20.1 °C.

**Table 2: Degradation test of etofenprox in STP (OECD314B)**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Guideline** | **Test para-meter** | **Inoculum** | | | **Test substance concentration** | **Incubation period** | **Degradation** | | | **Reference** |
| **Type** | **Concentration** | **Adaptation** |  | **Rate constant k** | **r2** | **DT50** |
| OECD 314B (2008) Biodegradation in activated sludge | Parent compound dis-appearance  CO2 evolution  formation of meta-bolites | Activa-ted sludgefrom a plant treating predominantly domestic waste water | 4.3 g/L | No | 1.5 µg/L | 30 days, 20.1°C | 0.527 | 0.8928 | 1.3 days (20.1°C) converted to  **2.5 days** at 12°C. | Study A7.1.2.1.1  Doc. III-A7.1.2.1.1 |

* Data provided for the product authorisation (PAR)

At the product authorisation stage, the applicant provided a study OECD 314A with etofenprox. The characterisitics of the study are summarized in the following table:

**Table 3: Degradation tests of Etofenprox in sewer (OECD 314A) and in STP (OECD 314B)**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Guideline** | **Media** | **Endpoint / Type of test** | **Exposure** | | **Result** | **Remarks** | **Reference** |
| **Design** | **Duration** |  |
| OECD 314A | Freshly sampled sewer wastewater, from domestic plant | Primary test: degradation of etofenprox (radiolabelled) in biotic and abiotic conditions  Secondary test: sorption of etofenprox (radiolabelled) in water phase and solid phase | Anaerobic conditions in the dark | 4 days | 14C-Etofenprox degraded slowly in biologically active wastewater samples and was stable in abiotic wastewater samples.  94.3% etofenprox in raw sewage after 1 hour  14.7% etofenprox into water phase after 1 day | RI=1 | Völkel, 2014. Unpublished report  IUCLID 10.4/01 |
| OECD 314B | Freshly sampled digester sludge, from a domestic plant | Parent compound dis-appearance,  CO2 evolution,  formation of meta-bolites:  14C-etofenprox (P-label) test  14C-etofenprox (B-label) test | Aerobic conditions in the dark | 8 days  30 days | Metabolite M10.1 was characterised as a major metabolite and identified as OH-Palc.  Confirms the results from the OECD 314B already validated in the CAR of etofenprox | Not used in the environmental risk assessment | Völkel, 2014. Unpublished report  IUCLID 10.4/02 |

The metabolite M10.1, also called OH-Palc, was identified as a ‘major metabolite’ **in the aqueous phase** according to the study of Völkel (2014, OECD 314B). The amount of OH-Palc is about the threshold value of 10 % (red line in figure 1) after 1 day and does not decrease below this value during 8 days.

**Figure 1**

The available data about this degradation product, provided by the applicant and also after FR CA QSAR study, are presented below.

The metabolite OH-Palc is a phenol with an additional hydroxyl group in a short alkyl chain in para position. It is therefore structurally different from the parent molecule etofenprox and obviously different phys‑chem properties and toxicity are anticipated.

|  |  |
| --- | --- |
| **Parameters of metabolite OH-Palc** | |
| Chemical name: | 3-(4-hydroxyphenyl)-2-methylpropyl alcohol |
| Structure: |  |
| Molecular weight: | 166.2 g/mol |

With a QSAR approach (chemicalize.org and Epiweb 4.1) it is possible to get information about this degradation product:

|  |  |
| --- | --- |
| **Parameters of metabolite OH-Palc** | |
| Chemical name: | 3-(4-hydroxyphenyl)-2-methylpropyl alcohol |
| Log Kow | 2.00 |
| Vapor pressure | 6.14E-03 Pa (25°C) |
| Water solubility | 1.559E04 mg/L (25°C) |
| pKa | 10.29 and 15.47 |

Associated with a molecule such as OH-Palc the physical chemical properties such as high water solubility and low Kow can be considered and it can be concluded that the environmental compartments potentially exposed to the transiently formed metabolite OH‑Palc formed in the activated sludge tank of an STP are i) the STP itself and ii) surface water after dilution of the STP effluent. OH-Palc does not partition into the sludge which may be deposited on soil and it is unlikely that the sediment compartment will be exposed from partitioning of solubilised OH‑Palc in surface water. OH-Palc is under neutral form at relevant environmental pH, according to pKa values above.

|  |  |  |
| --- | --- | --- |
| **Parameters of metabolite OH-Palc according to ECOSAR (Epiweb 4.1)** | | **Active substance** |
| Chemical name: | 3-(4-hydroxyphenyl)-2-methylpropyl alcohol | Etofenprox |
| ***Acute toxicity*** |  |  |
| Toxicity for fish (mg/L) | LC50 (96h) = 29.121 | LC50 (96h) = 2.7E-03 |
| Toxicity for Daphnia (mg/L) | LC50(48h) = 8.749 | LC50(48h) = 1.2E-03 |
| Toxicity for algae (mg/L) | EC50(96h)= 40.260 | EC50(96h)= >5.6E-02 |
| ***Chronic toxicity*** |  |  |
| Toxicity for fish (mg/L) | NOEC = 2.938 | NOEC = 6.2E-05 |
| Toxicity for Daphnia (mg/L) | NOEC = 1.664 | NOEC = 5.4E-05 |

Metabolite OH-Palc is formed by biodegradation of etofenprox in the activated sludge tank, hence the available effect data on etofenprox to activated sludge microorganism are also considered to cover the effect of OH‑Palc.

About persistence, considering a screening approach with PBT profiler and thereafter a WoE approach:

For OH-Palc,

SMILES: CC(CO)CC1=CC=C(O)C=C1

|  |  |  |
| --- | --- | --- |
|  | Half-Life  (days) | % in Each medium |
| Water | 15 | 18 |
| Soil | 30 | 81 |
| Sediment | 140 | 0 |
| Air | 0.32 | 0 |

For Etofenprox,

SMILES: C1CC(OCC)CCC1C(C)(C)COCC2CC(OC3CCCC3)CCC2

|  |  |  |
| --- | --- | --- |
|  | Half-Life  (days) | % in Each medium |
| Water | 60 | 4 |
| Soil | 120 | 49 |
| Sediment | 540 | 47 |
| Air | 0.26 | 0 |

OH-Palc seems to be less persistent that the Parent.

Consequently it can be considered that the environmental risk assessment for OH-Palc is covered by the substance parent. Etofenprox is highly toxic to aquatic invertebrates and fish and the PNEC was established from the NOEC of daphnia elucidated as the most sensitive species. According to the available data in ECOSAR, the toxicity of OH-Palc is covered by the one of etofenprox.

Thus, the major metabolite OH-Palc should not be considered for the aquatic risk assessment.

Terrestrial compartment

* Aerobic degradation

In aerobic condition, the DT50 (12 °C) value for Etofenprox is 22.8 days, and 12 days at 20°C. None of the soil metabolites (except CO2 and bound residues) exceeded 10 % AR (study A 7.2.2.1, Doc. III-A 7.2.2.1).

* Anaerobic degradation

No data are available.

##### Distribution

Etofenprox was adsorbed to the 5 soils with a mean arithmetic KFOC value of 28 524 L/kg. This value is used as a Koc value in the environmental risk assessment.

##### Accumulation

Etofenprox has a potential for bioaccumulation as indicated by its high octanol/water partition coefficient: logPow of 6.9.

The BCFfish calculated according to the TGD (eq75) gives a value of 46131 L/kg. This value is comparable to the BCF found experimentally in the fat of the fish. The experimental BCFfish, corrected for a whole body lipid content of 5 %, is 2565 L/kg .

BCFearthworm is calculated according to Guidance on BPR[[6]](#footnote-7) (eq. 82d): 95281 L/kg.

##### Behaviour in air

The vapour pressure of etofenprox was determined to be 8.13 x 10-7 Pa at 25 °C and the Henry’s Law Constant 0.0136 Pa x m3/mol at 25 °C (Doc. III-A 3.2). Additionally, the photochemical oxidative degradation of Etofenprox results in an estimated half-life in air of 6.2 hours (24 hour day) at 25 °C.

According to these results, no significant amounts of gaseous etofenprox are expected to be in air.

#### Effects on environmental organisms for active substance etofenprox

|  |
| --- |
| The section 2.2.6.2 is written by FRCA, based on the available data provided by the applicant. |

##### Aquatic compartment (including water, sediment and STP)

###### Aquatic organisms

**Table 4: Existing endpoints for aquatic organisms**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Test item** | **Species** | **Endpoints** | **Toxicity (mg as/L)** | **Reference** |
| **Fish- Acute data** | | | | |
| **Etofenprox** | *Onchorhynchus mykiss* | LC50 – 96h  NOEC | **2.7E-03**  0.66E-03 | 7.4.1.1-01 |
| **Etofenprox** | *Lepomis macrochirus* | LC50 – 96h  NOEC | 13.0E-03  6.9E-03 | 7.4.1.1-02 |
| **α-CO** | *Onchorhynchus mykiss* | LC50 – 96h  NOEC | **>48E-03**  **≥48E-03** | 7.4.1.1-03 |
| **Fish- Chronic data** | | | | |
| **Etofenprox** | *Onchorhynchus mykiss* | NOEC – 21d | 3.2E-03 | 7.4.3.1 |
| **Etofenprox** | *Danio rerio* | NOEC – 40 d | 25E-03 | 7.4.3.2-01 |
| **Etofenprox** | *Danio rerio* | NOEC – 140 d | 6.2E-05 | 7.4.3.2-02 |
| **Aquatic invertebrate- Acute data** | | | | |
| **Etofenprox** | *Daphnia magna* | EC50 – 48h  NOEC | **1.2E-03**  **8.9E-05** | 7.4.1.2-01 |
| **α-CO** | *Daphnia magna* | EC50 – 48h  NOEC | **>44E-03**  **≥44E-03** | 7.4.1.2-02 |
| **Aquatic invertebrate- Chronic data** | | | | |
| **Etofenprox** | *Daphnia magna* | NOEC – 21d | 5.4E-05 | 7.4.3.4 |
| **Algae** | | | | |
| **Etofenprox** | *Pseudokirchneriella subcapitata* | EbC50 – 72h  ErC50 – 72h | >5.6E-02  >5.6E-02 | 7.4.1.3-01 |
| **α-CO** | *Pseudokirchneriella subcapitata* | EbC50 – 72h  ErC50 – 72h | >5.3E-02  >5.3E-02 | 7.4.1.3-02 |

Additional endpoints: none

Justification of PNECwater:

Daphnia is the most sensitive species tested with a NOEC – 21d = 5.4E-05 mg a.i./L. Since long-term NOECs from at least three types of organisms (fish, Daphnia and algae) are available, the NOEC is divided by the assessment factor of 10, according to the Guidance on the BPR6.

**🡪 PNECwater = 5.4 x 10-6 mg a.i./L.**

*Degradation product:* α-CO

Among the acute studies available on fish, invertebrates and algae with the metabolite α-CO, the test with Daphnia magna gives the lowest 48-hour EC50-value of > 44 µg/L.44 µg/L is used in the risk assessment. According to the TGD on risk assessment, a factor of 1000 is used to calculate the PNEC.

**🡪 PNECwater for metabolite α-CO = 4.4 x 10-5 mg/L**

###### Sediment dwelling organisms

**Table 5: Existing endpoints for sediment dwelling organisms**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Test item** | **Species** | **Endpoints** | **Toxicity (mg as/kg)** | **Reference** |
| **Sediment dwelling organisms- Acute toxicity** | | | | |
| **Etofenprox** | *Chironomus riparius* | NOEC –10d  EC50 | 3.8E-03  >2.1E-02 | 7.4.3.5.1-01 |
| **4’-OH** | *Chironomus riparius* | NOEC – 48h  EC50 | 1.8E-02  5.0E-02 | 7.4.3.5.1-02 |
| **Sediment dwelling organisms- Chronic toxicity** | | | | |
| **Etofenprox** | *Chironomus riparius* | NOEC – 25d | 3.8E-03 (nominal) | 7.4.3.5.1-03 |
| **Etofenprox** | *Chironomus riparius* | NOEC – 28d | 2.9 mg/kgdwt (mean measured)  eq. to 0.63mg/kgwwt | 7.4.3.5.1-04 |

Additional endpoints: none

Justification of PNECsediment

Calculating the the PNEC sediment from NOEC derived in the Chironomus OECD 218 (2.9 mg/kg dwt = 0.63 mg/kg wwt) and using an assessment factor of 100 for one chronic test:

**🡪 PNECsediment = 6.3 x 10-3 mg a.i./kg wwt**

*Degradation product: 4’-OH*

Acute toxicity test with and the metabolite is available in sediment dwelling organisms. The PNECwater is calculated by applying an assessment factor of 1000 to this EC50.

🡪 PNECwater for metabolite 4’-OH = 5.02 x 10-5 mg/L

This value is metabolite-specific and higher than the PNECwater ofetofenprox which is 5.4 x 10-6 mg a.i./L.

From this value, the PNECsediment is calculated according to the equilibrium partitioning theory (TGD on Risk assessment, Formula 70. RHOsusp=1150, Ksusp-water = 278).

🡪 **PNECsediment for metabolite 4’-OH = 1.2 x 10-2 mg/kg wwt**

###### STP micro-organisms

**Table 6: Existing endpoints for STP micro-organisms**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Guideline/Test method** | **Species/inoculums** | **Endpoint / type of test** | **Exposure design duration** | **Result [mg a.s./L]** | | **Remarks** | **Reference** |
| EC10 | EC50 |
| **OECD 209** | Activated sludge from predominantly domestic wastewater treating plant | Oxygen consumption /Bacterial respiration inhibition | Aerobic activated sludge incubated under defined conditions- 3 hours | ≥ 100 (nominal)  ≥ 0.0225 mg/L (=WS1) | > 100 (nominal)  > 0.0225 mg/L (=WS1) | 5 concentrations tested, no inhibitory effect on the respiration rate of activated sludge | 7.4.1.4 |

1 WS: water solubility

Additional endpoints: none

Justification of PNECSTP

Since the tested concentration exceeds by far the water solubility (0.0225 mg/L) of etofenprox, the NOEC value is set equal to the water solubility. PNEC for STP micro-organisms is derived according to TM decisions without applying an assessment factor.

**🡪 PNECSTP micro-organisms = 2.25 x 10-2 mg a.i./L**

##### Atmosphere

###### There are no data on biotic effects of etofenprox in atmosphere. Etofenprox is not expected to contribute to global warming, ozone depletion in the stratosphere, or acidification on the basis of its physical and chemical properties. It has a very low vapour pressure (8.13.10-7 Pa) and a rapid photo-oxidative degradation in air (DT50 = 2.07 hours).

##### Terrestrial compartment

In the CAR of Etofenprox, short term toxicity data are available for primary producers (i.e. plants), consumers (i.e. earthworms) and decomposers (i.e. micro-organisms):

**Table 7: Existing endpoints for soil organisms**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Species** | **Type of test** | **Endpoint**  **(mg/kgdry soil)** | **Standardised endpoint**  **(mg/kgdry soil)** | **Reference** |
| **Soil microorganisms** | Long-term effects on soil nitrogen turnover and short-term respiration**-** 28d | NOEC ≥ 0.893  EC50 > 0.893 | NOEC ≥ 2.024 | A 7.5.1.1 |
| **Earthworms** | Mortality  Weight  Behaviour- 14d | LC50 = 47.2 | LC50 = 16.1 | 7.5.1.2 |
| **Plants** | Seedling  emergence and seedling growth  Vegetative vigour- 21d | EC50 > 200  converted to 10 cm deep soil: > 0.117 | EC50 > 0.234 | 7.5.1.3 |

Data about toxicity of etofenprox for bees:

According to an acute **oral** toxicity test, the mortality of bees exposed to etofenprox was studied during 96h (IIIA - 7.5.3.2-01). The LD50 (mg/bee) for this test are 3.1E-05 (48 hr), 2.7E-05 (72 hr) and 2.4E-05 (96 hr). The standardised endpoint is LD50=2.4E-05 mg/bee.

According to an acute **contact** toxicity test, the mortality of bees exposed to etofenprox was studied during 72h (IIIA - 7.5.3.2-02). The LD50 (mg/bee) for this test are 1.4E-05 (48 hr) and 1.4E-05 (72 hr). The standardised endpoint is LD50=1.4E-05 mg/bee.

News data have been provided at the product authorisation stage by the applicant. These studies are summarized in the table below:

**Table 8: Additional endpoints on soil organisms**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Species** | **Type of test** | **Endpoint**  **(mg/kgdry soil)** | **Standardised endpoint**  **(mg/kgdry soil)** | **Reference (PAR Digrain)** |
| **Earthworms** | OECD 222:  Mortality  Weight  Behaviour -28d | *Effects on mortality:*  NOEC=250 mg a.i./kg dry soil (nominal)  LOEC >250 mg a.i./kf dry soil (nominal)  *Effects on reproduction:*  NOEC=62.5 mg a.i./kg dry soil (nominal)  LOEC=125 mg a.i./kf dry soil (nominal) | *Effects on reproduction:*  NOEC=21.3 mg a.i./kg dry soil (standard soil)  RI= 3 | Etofenprox: Earthworm Reproduction Test (*Eisenia fetida*)- Hutcheson. K.  IUCLID 9.2.2/01 |
| **Non target arthropods :*Collembola Isotomidae*** | OECD 232:  Mortality  Reproduction- 28d | *Effects on reproduction:*  EC50=8.46 mg a.i./kg dry soil (Initial measured)  NOEC=1.06 mg a.i./kg dry soil (measured)  LOEC=1.91 mg a.i./kg dry soil (initial measured) | **NOEC= 0.721 mg a.i./kg dry soil (standard soil)**  RI= 2 | Toxicity of Etofenprox on Reproduction of Folsomia candida (*Collembola Isotomidae*) in Artificial Soil- Sandrock.C.-IUCLID 3.2.2/02 |
| **Non target arthropods: *Hypoaspis aculeifer*** | OECD 226:  Mortality  Reproduction- 14d | *Overall effect:*  NOEC= 83 mg a.i/ kg dry soil (nominal)  LOEC=182 mg a.i/ kg dry soil (nominal)  *Reproduction:*  EC50= 188.5 mg a.i./kg dry soil | *Overall effect:*  NOEC= 56.4 mg a.i/ kg dry soil (standard soil)  RI= 2 | Toxicity of etofenprox on reproduction of predatory mite Hypoaspis aculeifer- Witte. B. (2013)-IUCLID 9.2.2/03 |
| ***Soil Microflora*** | OECD 217 : Soil Microorganisms: Carbon Transformation Test  OECD 216: Soil Microorganisms: Nitrogen Transformation Test | *Carbon transformation:*  NOEC=2.5 mg a.i./kg dry soil (nominal)  LOEC= 12.5 mg a.i./kg dry soil (nominal)  *Nitrogen transformation:* NOEC=0.5 mg a.i./kg dry soil (nominal)  LOEC= 2.5 mg a.i./kg dry soil (nominal) | *Nitrogen transformation:*  NOEC= 1.19mg a.i./kg dry soil(standard soil)  RI=1 | Etofenprox: Effects on the Activity of the Soil Microflora under Laboratory Conditions (Nitrogen and Carbon Transformation Test)- Stojanowitsch. M. (2014) |

Justification of PNECsoil

Considering the valid NOEC values (soil micro-organisms and soil dwelling organism) for two trophic levels, a safety factor of 50 should be used according to Table 23 of the Guidance for BPR: Volume IV, part B (Version 1.0 April 2015). According to the WGIV2016-ENV discussion, the lack of data on chronic toxicity on plant does not allow determining the most sensitive species in the terrestrial compartment. Consequently, an assessment factor of **50** was adopted at WGIV2016-ENV to derive the PNEC soil.

Then, the most sensitive species is *Folsomia candida, with a* NOEC = 0.721 mg a.i./kg dry soil (standard soil). The substance has a DT50 in soil of 12 days (20°C)– so in the chronic tests we would expect a decrease in the concentration during the study period. According to the WGIV2016-ENV discussion, a TWA approach is used to calculate a NOECTWA:

**With,**

Test duration (*Folsomia candida*) = 28 days

K = 5.77E-02 d-1

F TWA= 4.96E-01 (eq. 95 Guidance on the BPR)

NOEC = 7.21E-01 mg a.i./kg dry soil (standard soil)

A NOEC TWA of **0.357 mg a.i./kg dry soil** is thus used to calculate the PNEC soil.

🡪 PNECsoil = 7.15 x 10-3 mg a.i./kg dry soil

🡪 **PNECsoil = 6.33 x 10-3 mg a.i./kg wet soil**

##### Non compartment specific effect relevant to the food chain

Given its high octanol/water partition coefficient (Log Kow of 6.9), etofenprox has a potential for bioaccumulation. Therefore, a risk of secondary poisoning could be expected via ingestion of contaminated food (e.g. earthworms or fish) by birds and mammals.

**Table 9: PNEC for birds and mammals**

|  |  |  |  |
| --- | --- | --- | --- |
| **Species** | **Type of test** | **Endpoint** | **Reference** |
| **Birds (mallard duck)** | Dietary exposure | LD50 >2000 mg/kg b.w | A 7.5.3.1.1 |
| Dietary exposure- 5d | LC50 > 5000 mg/kg diet | A 7.5.3.1.2-01 |
| **Birds (bobwhite quail)** | Dietary exposure-5d | LC50 > 5000 mg/kg diet | A 7.5.3.1.2 -02 |
| Dietary exposure-22 weeks | NOELreproduction= 1000 mg/kg diet | A 7.5.3.1.3 |
| **Rat (Sprague-Dawley strain)** | Multigeneration reproduction / chronic- 66 weeks | NOAEL= **37** mg/kg diet eq. to 740 kg a.i./kg food | A 6.8.2 |

**PNECoral, bird**

According to the Guidance on BPR, results from long-term (reproduction) studies are strongly preferred, in combination with a safety factor of 30.

**🡪 PNEC oral, bird = 33.3 mg a.i./kg diet**

**PNECoral, mammal**

For the assessment of secondary poisoning, the results always have to be presented as the concentration in food. The NOAEL can be converted to NOEC with the following formula:

*NOECmammal, food\_chr* = *NOAELmammal, food\_chr* \* *CONVmammal*

Where: *CONVmammal* = 20 (bw/dfi)

Therefore, the NOECmammal is calculated to be 740 kg a.i./kg food. This value is divided by a safety factor of 30 to calculate the PNECoral, mammal.

**🡪 PNEC oral, mammal = 24.7 mg a.i./kg food.**

##### Summary of PNECs of the active substance etofenprox and its degradation products

**Table 10: Summary of PNEC**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Compartment** | **Species** | **Endpoint** | **Safety factor** | **PNEC** |
| Etofenprox | | | | |
| (Fresh) Water | *Daphnia magna* | NOEC= 5.4E-05 mg/L | 10 | 5.4E-06 mg/L |
| Sediment | *Chironomus riparius* | NOEC= 0.63 mg/kg wwt | 100 | 6.3E-03 mg/kgwwt |
| Microorganisms (STP) | NR | Water solubility= 2.25E-02 mg/L | NR | 2.25E-02 mg/L |
| Soil | *Folsomia candida* | NOEC= 0.721mg/kg dry soil  **NOECTWA= 0.357mg/kg dry soil** | 50 | 7.15 x 10-3 mg/kg dry soil  **6.33 x 10-3 mg/kg wet soil** |
| Oral birds | Bobwhite quail | NOEL=1000 mg/kg diet | 30 | 33.3 mg a.i./kg diet |
| Oral mammals | Rat | NOECmammal is calculated to be 740 kg a.i./kg food | 30 | 24.7 mg a.i./kg food |
| α-CO | | | | |
| (Fresh) Water | *Daphnia magna* | EC50> 4.4 E-02 mg/L | 1000 | 4.4E-05 mg/L |
| 4’-OH | | | | |
| Sediment | *Chironomus riparius* | EPM |  | 1.2E-02 mg/kgwwt |

##### PBT and ED Assessment

###### PBT assessment

*P criterion:*

-Water/sediment

Etofenprox is not readily biodegradable. In a water/sediment degradation study DT50 values (first order, degradation) for the entire system were 6.5 and 20.1 days at 20°C for pond and lake, respectively. Etofenprox dissipates very fast from the water phase with a DT50 value dissipation of 2.1d (pond) and 10.4d (lake). Therefore dissipation from the sediment phase with a DT50 of 17.9 days (pond) and 32.2 days (lake) was considered more relevant for the assessment of the P criterion than degradation in the water phase. The DT50 dissipation from the sediment phase used in the assessment of persisitence is thus 61.1 days at 12 °C.

Thus, etofenprox does not meet the P criterion.

-Soil

In an aerobic degradation study in soil Etofenprox degraded with a mean DT50 value of 22.8 days at 12 °C.

Thus, etofenprox does not meet the P criterion.

*B criterion:*

The BCFfish value is 2565 L/kg (corrected for a whole body lipid content of 5 %).

Thus, etofenprox meets the B-criterion.

*T criterion:*

The chronic toxicity determined in the fish life cycle study with zebrafish is 0.000062 mg etofenprox/L (NOEC). For Daphnia, the NOEC was determined to be 0.000054 mg a.s./L .

Thus, etofenprox meets the T-criterion.

In conclusion, etofenprox is neither a vPvB, nor a PBT substance.

###### ED assessment

There is no indication of endocrine potential of Etofenprox.

###### 

#### Effects on environmental organisms for biocidal product

No test with the biocidal product has been provided by the applicant at the authorization product stage.

#### Environmental exposure assessment

|  |
| --- |
| Please notice that the environmental exposure assessment (section 2.2.6.4) is reported as provided by the applicant. The FR CA position is presented in **green evaluation boxes at the end each part of the environmental exposure section.** |

##### Assessment of exposure to the environment

###### Input scenario parameters

All calculations within the exposure scenarios apply to etofenprox only, as other constituents of the Etofenprox 2 g/L EW (RTU) product formulation (DIGRAIN SPRAY) are not considered to be compounds of concern.

DIGRAIN SPRAY is intended for indoor use by non-professionals in private homes *via* general surface spraying for the protection of health and materials against a variety of crawling and flying insect pests. Product applications are made at a maximum rate of 1 L/13 m2 (equivalent to 0.15 g a.s./m2). The product is in a ready-to-use (RTU) form.

The exposure assessment was conducted as described in Emission Scenario Document OECD ‘ESD for insecticides, acaricides and products to control other arthropods (PT18) for household and professional uses’ ENV/JM/MONO(2008)14 (ESD 2008), using EUSES modelling. A summary of the scenario input parameters can be found in Table 11. A full list of the input parameters, in the form of the EUSES output file, can be found in annex 7.

The scenario with the local emission to waste water and subsequently the standard sewage treatment plant (STP) was assessed for private use (houses treated by non-professionals) considering application and cleaning events using the defaults for general surface treatment. According to ESD 2008 it is not relevant to consider the mixing / loading stage for ready-to-use (RTU) products.

For the emission to air, applicator, floor and treated surfaces during application, default emission fractions were used. The default number 1 of application per day was used, though this parameter is not considered relevant since it is used both in the numerator and denominator in the formula for emissions described in ESD 2008 and embedded in EUSES. The treated area in a standard household was considered to be 38.5 m2 as concluded in the Biocide Technical Meeting, 15-19 February 2010 (TM-I-2010).

For the cleaning events, it was assumed that the applicator is washable and the surfaces are wet cleaned with the default efficiency of 50 %. Potential environmental releases of etofenprox resulting from indoor use should only be associated with hard surface treatments that are wet cleaned. The default cleaning efficiency, i.e. the maximum % area exposed to cleaning is considered conservative as the potential degradation and/or sorption onto the different materials exposed is not taken into account. The known adsorptive behavior of the active substance etofenprox is therefore neglected. In addition, the product is intended to remain on the treated surfaces with efficacious residual activity for many weeks and as a consequence the active substance will have undergone partial degradation once cleaned from the treated surfaces. Where regular cleaning is essential or customary, it is extremely unlikely that this type of formulation would provide effective control due to potential losses after application.

For the local emission from indoor spray use to waste water it was assumed that 4000 houses are connected to the standard STP with a simultaneity factor of 0.204 % corresponding to maximum two annual treatments.

**Table 11: Summary of input parameters for scenario**

|  |  |
| --- | --- |
| **Input parameter** | **Value** |
| Usage/production title | Non-professional use |
| Scenario choice for biocides | (18) Insecticides |
| Additional scenario information | (18.2.1) Indoor, spray application |
| Emission scenario | Local emissions (STP) |
| Fraction of active ingredient | 0.2% |
| Surface or air space treatment | Surface treatment (area) |
| Application scope | General surface treatment |
| Treatment rate, amount of product per area | 0.15 g/m2 |
| Area of treated surface, house | 38.5 m2 \* |
| Washable or disposable applicators | Washable |
| Cleaning method for treated surfaces | Other methods (wet cleaning) |
| Cleaning efficiency | 50% |
| Number of houses per STP | 4000 |
| Simultaneity factor | 0.204%\*\* |
| \* Concluded on in the Biocide Technical Meeting, 15-19 February 2010 (TM-I-2010)  \*\* The efficacy data support that treatment is not needed on a daily or monthly basis and a few treatments per year may be sufficient. For this assessment the number of treatments is restricted to two applications annually. The simultaneity factor (Fsimultaneity) is calculated according to the following formula as given in ESD 2008 and agreed on in the Assessment Report Etofenprox PT18: Fsimultaneity = (0.54 × 37.82)/100 = 0.204% | | |

###### Physico-chemical, environmental degradation and partitioning data on etofenprox

The physico-chemical, environmental degradation and partitioning data on etofenprox presented in Table 12 have been used in the risk assessments.

**Table 12: Modelling input physical-chemical and fate data of etofenprox**

|  |  |  |
| --- | --- | --- |
| Modelling Parameter | Value | Source |
| Physical-Chemical Data | | |
| Molecular weight (g/mol) | 376.47 | Assessment Report Etofenprox PT18 |
| Melting point (°C) | 37.4 | Assessment Report Etofenprox PT18 |
| Vapour pressure at 25°C (Pa) | 8.13 x 10-7 | Assessment Report Etofenprox PT18 |
| Octanol-water partition coefficient (log Pow ) | 6.9 | Assessment Report Etofenprox PT18 |
| Water solubility at 20°C (mg/L) | 0.0225 | Assessment Report Etofenprox PT18 |
| Henry’s law constant at 25ºC (Pa x m3/mol) | 0.0136 | Assessment Report Etofenprox PT18 |
| Organic carbon-water partition coefficient, KFOC (L/kg) | 28524 | Assessment Report Etofenprox PT18 |
| BCF earthworm (L/kg) | 95281 | Assessment Report Etofenprox PT18 |
| BCF fish (whole fish) (L/kg) | 2565 | Assessment Report Etofenprox PT18 |
| Readily biodegradability | Not readily biodegradable | Assessment Report Etofenprox PT18 |
| Degradation in STP at 20°C DT50 (d) | 1.3 | Assessment Report Etofenprox PT18 |
| Partitioning in sewer, fraction of emission directed to STP by sewer (%) | 90 | Völkel, 2014 [4] |
| Partitioning in primary settler Fraction in water (%)  Fraction bound to sludge (%) | 14.7  85.3 | Völkel, 2014 [4] |
| Partitioning in activated sludge tank Fraction in water (%)  Fraction bound to sludge (%) | 1.6  98.2 | Assessment Report Etofenprox PT18 |
| Photolysis in surface water at 25°C DT50 (d) | 4.7 | Assessment Report Etofenprox PT18 |
| Biodegradation in surface water at 12°C DT50 (d) | 38.1 | Assessment Report Etofenprox PT18 |
| Biodegradation in aerated sediment (pond) at 12°C DT50 (d) | 61.1 | Assessment Report Etofenprox PT18 |
| Degradation in air at 25°C DT50 (h) | 6.2 | Assessment Report Etofenprox PT18 |
| Degradation in soil at 12°C DT50 (d) | 22.8 | Assessment Report Etofenprox PT18 |

Data have been generated since the approval of etofenprox PT18 which are available for refinement of default values for partitioning to and in the STP. A schematic is provided in annex 7 to illustrate the refinement use of STP data.

In an OECD 314A study (Völkel, 2014), degradation and partitioning in the sewer were investigated. Following degradation, there was a decline of etofenprox of 20.7 % and 10.1 % after 1 hour and 4 days after treatment, respectively. Conservatively, a fraction of 90 %, based on a 10 % reduction from degradation, has been used for entry into the STP from the sewer. The study also investigated partitioning between solid and aqueous phases after 1 and 4 days. In the aqueous phase of biologically active waste water, 14C-etofenprox was present at 14.7 % of the amount applied after 1 day and at 7.7 % after 4 days. The value of 14.7 % of the 90 % of the etofenprox entering the STP from the sewer was considered as partitioning to water in the primary settler resulting in a value of 13.23 % in water.

From the OECD 314B study (Völkel, 2012) submitted and evaluated for active substance approval, the Assessment Report confirms a significant initial partitioning of etofenprox between the aqueous and solid phases of the activated sludge. The emission fractions for partitioning agreed in the assessment report.

**Table 13: EUSES input parameters**

|  |  |
| --- | --- |
| **EUSES input parameters** | **Value** |
| Fraction of emission directed to water by STP (%) | 0.21 |
| Fraction of emission directed to sludge by STP (%) | 89.76 |
| Fraction of the emission degrade in STP (%) | 0 |

A full list of input parameters used in the determination of PEC values resulting from uses of DIGRAIN SPRAY are presented as EUSES output files inannex 8.

The total emission to waste water from one house of the 4000 houses connected to the standard STP was found to be 0.00289 kg/day. The local emission to waste water during episode with a simultaneity factor of 0.204 % for 4000 houses resulted in 0.0236 kg/day. The local PEC values derived by EUSES STP modelling in the relevant compartments: STP, surface water (fresh water), sediment, soil and groundwater (worst case based on soil pore water), can be found in Table 13. The PEC values for the assessment of secondary poisoning by fish- and worm- eating birds and mammals are also presented in Table 14.

**Table 14: PEC following spray application in private houses**

|  |  |
| --- | --- |
|  | **Value** |
| PECSTP (mg/L) | 2.47 x 10-5 |
| PECwater (mg/L) | 2.37 x 10-6 |
| PECsediment (mg/kg wwt) | 1.47 x 10-3 |
| PECsoil (mg/kg wwt) | 0.0258 |
| PECgroundwater (mg/L) | 1.42 x 10-5 |
| PECoral,fish (mg/kg) | 1.67 x 10-5 |
| PECoral,worm (mg/kg) | 0.609 |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **FR CA position:**  *Input parameters for scenario*  According to the available data provided by the applicant, the parameters in the table below are used in the risk assessment by FR CA:  **Table 15: Summary of input parameters for scenario**   |  |  | | --- | --- | | **Input parameter** | **Value** | | Usage/production title | Non-professional use | | Scenario choice for biocides | (18) Insecticides | | Additional scenario information | (18.2.1) Indoor, spray application | | Emission scenario | Local emissions (STP) | | Fraction of active ingredient | 0.204 % | | Surface or air space treatment | Surface treatment (area) | | Application scope | General surface treatment | | Treatment rate, amount of product per area | 0.157 g/m2 | | Area of treated surface, house | 38.5 m2 | | Washable or disposable applicators | Washable | | Cleaning method for treated surfaces | Other methods (wet cleaning) | | Cleaning efficiency | 50 % | | Number of houses per STP | 4000 | | Simultaneity factor | 0.204 % |   *Modelling input physical-chemical and fate data of etofenprox*  **Table 16: Modelling input physical-chemical and fate data of etofenprox**   |  |  |  | | --- | --- | --- | | **Modelling Parameter** | **Value** | **Source** | | Molecular weight (g/mol) | 376.47 | Assessment Report Etofenprox PT18 | | Melting point (°C) | 37.4 | Assessment Report Etofenprox PT18 | | Fraction of emission directed to water by STP  Fraction of emission directed to sludge by STP | 1.5  92.6[[7]](#footnote-8) | Völkel, 2014[[8]](#footnote-9) | | Degradation in soil at 12°C DT50 (d) | 22.8 | Assessment Report Etofenprox PT18 | |

###### Aquatic compartment (surface water, sediment, STP)

The EUSES simulation is available inannex 8.

**Table 17: extract from Table 13**

|  |  |
| --- | --- |
|  | **Value** |
| PECSTP (mg/L) | 2.47 x 10-5 |
| PECwater (mg/L) | 2.37 x 10-6 |
| PECsediment (mg/kg wwt) | 1.47 x 10-3 |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| **FR CA position:**  According to the intended uses no direct exposure to surface water, only indirect exposure *via* STP are possible. The concentration during an emission episode is calculated for exposure of aquatic organisms. The Emission Scenario Document OECD ‘ESD for insecticides, acaricides and products to control other arthropods (PT18) for household and professional uses’ ENV/JM/MONO(2008)14 (ESD 2008) is used for the environmental risk assessment.  **Table 18: Release of etofenprox to waste water for one application of Digrain- Surface spray- Use claimed by the applicant**   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Parameter** | **Symbol** | **Value** | **Unit** | **Source** | | ***Product Information*** | | | | | | Product Name | (-) | Digrain spray | (-) | (-) | | Active Ingredient | (-) | Etofenprox | (-) | (-) | | Treatment Rate of etofenprox | Qai | 1,57E-01 | gai.m-2 | Output | | Product formulation and container type | (-) | Liquid 1 liter | (-) | Pick-list | | Treatment Sub-category | (-) | Surface spray / Total Surface | (-) | Pick-list | | User Type | (-) | Non professional | (-) | Pick-list | | ***Indoor application by spraying - Application*** | | | | | | Number of applications per day, house | Nappl | 1 | (-) | Default | | Fraction emitted to air | Fappli,air | 0,020 | (-) | Default | | Fraction emitted to applicator | Fappli,applicator | 0,020 | (-) | Default | | Fraction emitted to floor | Fappli,floor+treated | 0,960 | (-) | Output | | Emission to air | Eapplication,air | 1,21E-04 | Kg.d-1 | Output | | Emission to applicator | Eapplication,applicator | 1,21E-04 | Kg.d-1 | Output | | Emission to floor | Eapplication,floor+treated | 5,80E-03 | Kg.d-1 | Output | | ***Indoor application by spraying – Cleaning before the next application*** | | | | | | Fraction emitted to wastewater from applicator (washable coveralls) | Fapplicator,ww | 1 | (-) | Default | | Fraction emitted to wastewater from floor / treated surface during the cleaning step | Ftreated surface,ww | 1 | (-) | Default | | Cleaning efficiency (Spray-Surface) | FCE | 0,500 | (-) | Default | | Emission from applicator to waste water during the cleaning step | Eapplicator,ww | 1,21E-04 | Kg.d-1 | Output | | Emission to waste water from floor/treated during the cleaning step | Etreated,ww | 2,90E-03 | Kg.d-1 | Output | | Number of houses per STP | Nbuildings/STP | 4,00E+03 | (-) | Default | | Simultaneity factor | Fs | 0.204 | % | Default | | ***Release to waste water for one application*** | | | | | | Local Emission to STP | *Elocalwater* | 2,47E-02 | Kg.d-1 | Output |   The main metabolite in surface water is α–CO. The highest percentage of α–CO, relatively to the amount of Etofenprox initially applied, was determined to be 63.6 %, in the aqueous photolysis study (Doc. III-A 7.1.1.1.2/01; Study A 7.1.1.1.2/01). The PECs of Etofenprox were multiplied by 63.6% to estimate the PECs of the metabolite α–CO according to the CAR of etofenprox.  The main metabolite in sediment is 4’-OH. The highest percentage of 4’-OH, relatively to the amount of etofenprox initially applied, was determined to be 21.4 %, in the water sediment study (Doc.III-A 7.1.2.2.2/01 and A 7.1.2.2.2/02; Study and amendment A 7.1.2.2.2/01, Study A 7.1.2.2.2/02 and /03). The PECs of etofenprox were multiplied by 21.4 % to estimate the PECs of the metabolite 4’-OH according to the CAR of etofenprox.  The aquatic PEC calculations are presented in the table below.  **Table 19: PEC calculations for etofenprox and its degradation products (α-CO and 4’-OH) in the aquatic compartment**   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Symbol** | **Parameter** | **Value** | **Unit** | **Reference** | | Elocal STP (Etofenprox) | Local Emission to STP | 2.47E-02 | [kg.d-1] | Output | | PECSTP | PEC in the treated wastewater | 1.85E-04 | [mg.L-1] | Guidance for BPR IV B-Eq. 33 | | PEClocalwater | PEC in water during emission episode | 1.77E-05 | [mg.L-1] | Guidance for BPR IV B-Eq. 45 | | PEClocalwater-αCO | PEC in water during emission episode | 1.13E-05 | [mg.L-1] | 63,5% of PECwater etofenprox | | PEClocalsed | PEC in sediment during emission episode | 1.10E-02 | [mg.kg-1wwt] | Guidance for BPR IV B-Eq. 50 | | PEClocalsed-4'OH | PEC in sediment during emission episode | 2.36E-03 | [mg.kg-1wwt] | 21,4% of PECsed etofenprox | |

###### Atmospheric compartment

|  |
| --- |
| **FR CA position:**  The atmospheric compartment is not relevant. |

###### Terrestrial compartment (soil and groundwater)

The EUSES simulation is available in annex 8.

**Table 20: extract from Table 13**

|  |  |
| --- | --- |
| PECsoil (mg/kg wwt) | 0.0258 |
| PECgroundwater (mg/L) | 1.42 x 10-5 |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **FR CA position:**  The terrestrial compartment is exposed through the contaminated sludge spread on soil. By leaching, the groundwater can also be exposed to etofenprox. The PEC in soil and groundwater are presented below.  **Table 21: PEC calculations for etofenprox in the terrestrial compartment**   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Symbol** | **Parameter** | **Value** | **Unit** | **Reference** | | PEClocal soil | PEC soil 30d (concentration in agric. soil after 10 years over 30 days) | 2.79E-02 | [mg.kg-1wwt] | Guidance for BPR IV B-Eq. 55 | | PEC local soil porewater | PEC in porewater | 1.54E-05 | [mg.L-1] | Guidance for BPR IV B-Eq. 67 | |

###### Non-compartmental-specific exposure relevant to the food chain (secondary poisoning)

The EUSES simulation is available inannex 8.

**Table 22: extract from table 13**

|  |  |
| --- | --- |
| PECoral,fish (mg/kg) | 1.67 x 10-5 |
| PECoral,worm (mg/kg) | 0.609 |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **FR CA position:**  The high octanol/water partition coefficient (log Pow =6.9) of etofenprox indicates a potential for bioaccumulation in the terrestrial and in the aquatic food chain. Therefore, the concentration of contaminated food (e.g. earthworms or fish) via ingestion by birds and/or mammals is calculated.  According to the guidance for BPR IV B, it is considered that 50 % of the diet comes from PEClocal, thus the PEC calculation for fish predator and Predicted Environmental Concentration in earthworms (PECoral, fish-predator and Cearthworm) take into account this refinement.  **Table 23: PECoral fish predator for etofenprox**   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Symbol** | **Parameter** | **Value** | **Unit** | **Reference** | | PECwater | PEC in water during emission episode | 1.77E-05 | Kg.d-1 | Output | | BMF | Biomagnification factor in fish | 2 | [-] | Output | | PECoral, fish-predator | Predicted Environmental Concentration in food (fish) | 4.55E-02 | [mg.kg-1] | Guidance for BPR IV B-Eq. 76 |   Cearthworm is calculated according to equation 82c of Guidance for BPR IV B.  **Table 24: PEC oral earthworm-predator according to ESD PT18[[9]](#footnote-10)**   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Parameter** | **Definition** | **Unit** | **Value** | | | **Mammals** | **Birds** | | Bioconcentration factor for earthworm on wet weight basis | BCF | L:kg-1wet earthworm | 95281 | | | Fraction of gut loasing in worm | Fgut | kgdwt.kg-1wwt | 0.1 | | | Conversion factor for soil concentration wet-dry weight soil | CONVsoil | kgwwt.kg-1dwt | 1.13 | | | Predicted environmental concentration in porewater | PEClocalsoil,porewater | mg.L-1 | 1.54E-05 | | | Predicted environmental concentration in soil | PEClocalsoil | mg.kg-1wwt | 2.79E-02 | | | Predicted Environmental Concentration in earthworms | Cearthworm | mg.kg-1wwt | 1.32 | | | Predicted Environmental Concentration in food | PECfood | mg.kg-1food | 6.60E-01 | | |

#### Risk characterisation for the environment

|  |
| --- |
| Please notice that the risk characterisation for the environment (section 2.2.6.5) is reported as provided by the applicant. The FR CA position is presented in **green evaluation boxes at the end each part of the risk characterisation section.** |

Risk characterisation ratios are calculated by dividing the PEC from Table 14by the respective compartment PNEC from Table 10.

The following risk characterisation ratios (Table 25) were calculated with EUSES for spray use in private houses:

**Table 25: Risk characterisation ratios (PEC/PNEC) following spray use in private houses**

|  |  |
| --- | --- |
| **Environmental compartment** | **PEC/PNEC** |
| STP | 1.1 x 10-3 |
| Water (freshwater) | 0.439 |
| Sediment (freshwater) | 0.234 |
| Soil | 0.406 |
| Fish-eating birds and mammals (freshwater) | 6.76 x 10-7 |
| Worm-eating birds and mammals | 0.0247 |

##### Indoor surface spray

###### Aquatic compartment (including water, sediment and STP)

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **FR CA position:**  The PEC/PNEC ratios calculated by FR CA for the aquatic compartment are presented below.  **Table 26: PEC/PNEC ratios for the aquatic compartment**   |  |  |  |  | | --- | --- | --- | --- | | **Substance/degradation product** | **PEC** | **Risks** | **Risks** | | Etofenprox | PNECwater = 5.4E-06 mg/L | | **Unacceptable** | | 1,77E-05 | **3.29** | | α-CO | PNECwater = 4.40E-05 mg/L | | Acceptable | | 1,13E-05 | 2.57E-01 | | Etofenprox | PNEC sed =6.30E-03 mg/Kgwwt | | **Unacceptable** | | 1,10E-02 | **1.75** | | 4’-OH | PNEC sed =1.20E-02 mg/Kgwwt | | Acceptable | | 2,36E-03 | 1.97E-01 | | Etofenprox | PNEC STP =2.25E-02 mg/L | | Acceptable | | 1,85E-04 | 8.23E-03 |   The risk is unaceptable for etofenprox in water and sediment. |

###### Atmospheric compartment

|  |
| --- |
| **FR CA position:**  The atmospheric compartment is not relevant. |

###### Terrestrial compartment (including soil and groundwater)

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **FR CA position:**  The PEC/PNEC ratios calculated by FR CA for the terrestrial compartment are presented below.  Table 27: PEC/PNEC ratios for the terrestrial compartment   |  |  |  |  | | --- | --- | --- | --- | |  | **PEC [mg/L]** | **PEC/PNEC [-]** | **Risks** | | Soil | PNECsoil = 6.33E-03 mg/L | | **Unacceptable** | | 2.79E-02 | **4.41** | | Groundwater | Threshold value in groundwater : 1E-04 mg/L\* | | Acceptable | | 1.54E-05 | 1.54E-01 |   \* Directive 98/83/EC  The risk is unacceptable for soil. |

###### Non-compartmental specific effects relevant to the food chain (secondary poisoning)

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **FR CA position:**  The PEC/PNEC ratios calculated by FR CA for secondary poisonning are presented below.  **Table 28: PEC/PNEC ratios for the fish predators**   |  |  |  |  | | --- | --- | --- | --- | |  | **PEC (mg/kg)** | **PEC/PNEC** | **Risks** | | Fish predators : birds | PNECbirds=33.3 mg/kg diet | | Acceptable | | 4.55E-02 | 1.37E-03 | | Fish predators : mammals | PNECmammals=24.7 mg/kg bw/d | | Acceptable | | 4.55E-02 | 1.84E-03 |   **Table 29: PEC/PNEC ratios of etofenprox for earthworm predators**   |  |  |  |  | | --- | --- | --- | --- | |  | **PEC** | **PEC/PNEC** | **Risks** | | Earthworm predators : birds | PNECbirds=33.3 mg/kg diet | | Acceptable | | *6.60E-01* | 1.98E-02 | | Earthworm predators : mammals | PNECmammals=24.7 mg/kg bw/d | | Acceptable | | *6.60E-01* | 2.67E-02 |   For secondary poisonning, the risk is acceptable for non-target organisms. |

###### Conclusion

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **FR CA position:**  Considering the service-life of sprayed surfaces, according to the use claimed by the applicant, and the possibility to wash some surfaces with water (i.e. in private buildings), in the case of the exposure of STP, soil and groundwater, all calculated RCR values were below 1 for etofenprox, as well as for poisonning, indicating no unacceptable risk to these environmental compartments and poisonning. However, for the surface water, sediment and soil compartments, the RCR values for etofenprox were above 1 and the risks are considered unacceptable.  By default, a value of 38.5 m² is used for the treated surface in a private house. The risk becomes acceptable for all the environmental compartments if a more restricted use leading to lower releases towards the environmental compartments is assessed: the barrier treatment as described in point “ENV 88” p31 of the “Technical agreements for biocides-December 2016”.  **Table 30: Release of etofenprox to waste water for one application of DIGRAIN SPRAY- Barrier treatment scenario- Restricted use proposed by FR CA**   |  |  |  |  |  | | --- | --- | --- | --- | --- | | *Parameter* | *Symbol* | Value for non-professional uses | *Unit* | *Source* | | **Private house** |  | | ***Product Information*** | | | | | | Product Name | (-) | Digrain | (-) | (-) | | Active Ingredient | (-) | Etofenprox | (-) | (-) | | Fraction of etofenprox in product | Fai | 2.04E-03 | (-) | Input | | Treatment Rate of etofenprox | Qai | 1.57E-01 | gas.m-2 | Output | | Quantity of commercial product used for the preparation | Qprod, prep | 1.54E+03 | g | Output | | Treatment Sub-category | (-) | Barrier treatment | (-) | Pick-list | | User Type | (-) | Non professional | (-) | Pick-list | | Area treated per house | AREAtreated | 20 | m2 | Default value for barrier treatment – Technical Agreements for Biocides (2016) | | Area wet cleaned per house | AREAwet cleaned | 5.9 | m3 | WG I 2017, reflect the area wet cleaned in a domestic home (barrier) | | ***Indoor application by spraying - Application*** | | | | | | Emission to applicator | Eapplication,applicator | 6.29E-05 | Kg.d-1 | Output | | Emission to floor | Eapplication,floor+treated | 8.88E-04 | Kg.d-1 | Output | | ***Indoor application by spraying – Cleaning before the next application*** | | | | | | Emission from applicator to waste water during the cleaning step | Eapplicator,ww | 6.29E-05 | Kg.d-1 | Output | | Emission to waste water from floor/treated during the cleaning step | Etreated,ww | 4.44E-04 | Kg.d-1 | Output | | Local Emission to STP by house/building (no release to municipal waste) | Elocal*water* | 5.07E-04 | Kg.d-1 | Output | | ***Release to waste water for one application*** | | | | | | Local Emission by STP during emission episode (no release to municipal waste) - TOTAL Houses (+ buildings if professionnals) | Elocal STP | 4.14E-03 | Kg.d-1 | Output |   The risk characterisation for the cumulated emissions due to the use of DIGRAIN SPRAY considering a barrier treatment scenario in houses is presented below:  **Table 31: risk characterisation for the cumulated emissions due to the use of DIGRAIN SPRAY - barrier treatment scenario**   |  |  |  | | --- | --- | --- | | **Substance/degradation product** | **PEC** | **PEC/PNEC** | | Etofenprox | *PNECwater = 5.4E-06 mg/L* | | | 2.97E-06 | **0.55** | | αCO | *PNECwater = 4.40E-05 mg/L* | | | 1.50E-06 | 3.41E-02 | | *Etofenprox* | *PNEC sed =6.30E-03 mg/Kgwwt* | | | 1.85E-03 | **0.29** | | *4’-OH* | *PNEC sed =1.20E-02 mg/Kgwwt* | | | 4.13E-04 | 3.44E-02 | | *Etofenprox* | *PNEC STP =2.25E-02 mg/L* | | | 3.10E-05 | 1.38E-03 | |  |  |  | | **Etofenprox** | **PEC** | **PEC/PNEC** | | Soil | *PNECsoil = 6.33E-03 mg/L* | | | 4.68E-03 | 7.39E-01 | | Groundwater | *Threshold value 1E-04 mg/L* | | | 2.58E-06 | 2.58E-02 | |  |  |  | | **PEC/PNEC ratios for the fish predators- Non -Professional** | | | | **Etofenprox** | **PEC** | **PEC/PNEC** | | Fish predators : birds | *PNECbirds=*33.3 mg/kg diet | | | 7.63E-03 | 2.29E-04 | | Fish predators : mammals | *PNECmammals=*24.7 mg/kg diet | | | 7.63E-03 | 3.09E-04 | | **PEC/PNEC ratios for the fish predators- Non- Professional** | | | | **Etofenprox** | **PEC** | **PEC/PNEC** | | Earthworm predators : birds | *PNECbirds=*33.3 mg/kg diet | | | 1.11E-01 | 3.32E-03 | | Earthworm predators : mammals | *PNECmammals=*24.7 mg/kg diet | | | 1.11E-01 | 4.47E-03 |   Therefore, it can be concluded that the use of the product DIGRAIN SPRAY in restricted areas (covered by the barrier treatment scenario), will not pose risk to the environment.  Risk mitigation measure linked to risk assessment for the environment:   * Do not discharge unused products into water courses, into pipes (sink, toilets…) nor down the drains. * The product has to be applied only on restricted areas on surfaces not regularly cleaned, for example behind the fridge or under the oven. |

### Measures to protect man, animals and the environment

*See Summary of Product Characteristics (SPC)*

### Comparative assessment

Taking into account that no product is authorized for the same uses, Anses concludes that there is no adequate chemical diversity in line with Article 23(3)(b) and the technical guidance note on comparative assessment.

Since etofenprox does not meet the exclusion criteria as outlined in Article 5(1), no further assessment is needed at this point. The comparative assessment for DIGRAIN SPRAY can be finalised at the screening stage and the product can be authorised for a period not exceeding 5 years in accordance with Article 23(6) of BPR.

Annex 1: List of studies reviewed

##### List of new data[[10]](#footnote-11) submitted in support of the evaluation of the active substance

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Section No** | **Reference No** | **Author** | **Year** | **Title** | **Owner of data** | **Letter of Access** | | **Data protection claimed** | |
|  |  |  |  | **Yes** | **No** | **Yes** | **No** |
| A7 | IUCLID 10.4/01 | Völkel, W. | 2014 | 14C-Etofenprox - Biodegradation in a Sewer System | Mitsui Chemicals Agro, Inc. |  |  |  |  |
| A7 | 10.4/02 | Völkel, W. | 2014 | 14C-Etofenprox (P and B label) - Biodegradation in activated sludge under aerobic conditions | Mitsui Chemicals Agro, Inc. |  |  |  |  |
| A7 | IUCLID 9.2.2/03 | Witte.B | 2013 | Effects of Etofenprox on Reproduction of the Predatory Mite Hypoaspis aculeifer in Artificial Soil | Mitsui Chemicals Agro, Inc. |  |  |  |  |
| A7 | IUCLID 9.2.2/01 | Hutcheson, K. | 2014 | Etofenprox: Earthworm Reproduction Test (Eisenia fetida) | Mitsui Chemicals Agro, Inc. |  |  |  |  |
| A7 | IUCLID 3.2.2/02 | Sandrock C | 2014 | Toxicity of Etofenprox on Reproduction of Folsomia candida (Collembola: Isotomidae) in Artificial Soil | Mitsui Chemicals Agro, Inc. |  |  |  |  |
| A7 | Table 8 | Stojanowitsch M. | 2014 | Etofenprox: Effects on the Activity of the Soil Microflora under Laboratory Conditions (Nitrogen and Carbon Transformation Test) | Mitsui Chemicals Agro, Inc. |  |  |  |  |

##### List of new data submitted in support of the evaluation of the biocidal product

| **Section No** | **Reference No** | **Author** | **Year** | **Title** | **Owner of data** | **Letter of Access** | | **Data protection claimed** | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **Yes** | **No** | **Yes** | **No** |
| B2 | 3,4,1/06 20°C 1Y Compatibility packaging LODI,15/2014 | Richerioux, S. | 2016 | Compatibility between Etofenprox 2g/L RTU and packagings after 1 year of storage at 20°C | LODI S.A.S. |  |  |  |  |
| B2 | 3.1/01: Appearance/odour/colour LODI.05/2014 | Tallon, A. | 2014 | Physical properties of Etofenprox 2g/L RTU after accelerated storage | LODI S.A.S. |  |  |  |  |
| B2 | 3.2/01: pH LODI.18/2014 | Tallon, A. | 2015 | pH of Etofenprox 2g/L RTU | LODI S.A.S. |  |  |  |  |
| B2 | 3.3-01: Relative density (liquids) LODI.20/2015 | Tallon, A. | 2015 | Relative density of Etofenprox 2g/L RTU | LODI S.A.S. |  |  |  |  |
| B2 | 3.4.1/01: 54ºC 2WK appearance LODI.05/2014 | Tallon, A. | 2014 | Physical properties of Etofenprox 2g/L RTU after accelerated storage | LODI S.A.S. |  |  |  |  |
| B2 | 3.4.1/02: 54ºC 3WK chemical stability LODI.04/2015 | Richerioux, S. | 2015 | Chemical stability of Etofenprox 2g/L RTU after 3 weeks of storage at 54ºC | LODI S.A.S. |  |  |  |  |
| B2 | 3.4.1/03: 54ºC 2WK and 3WK packaging stability LODI.03/2015 | Richerioux, S. | 2015 | Compatibility between Etofenprox 2g/L RTU and packaging after accelerated storage (2 and 3 weeks at 54ºC) | LODI S.A.S. |  |  |  |  |
| B2 | 3.4.1/04: 1ºC 7D pH 14 912011-005 | Demangel, B. | 2015 | Determination of pH values test after low temperature stability of liquid formulations at 0 ± 2ºC for 7 days on ETOFENPROX 2 G/L RTU | LODI S.A.S. |  |  |  |  |
| B2 | 3.4.1/05: 54ºC 2WK 3WK/pH 15-912011-002 | 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 2 G/L RTU | LODI S.A.S. |  |  |  |  |
| B2 | 3.4.1/07: 20ºC 1Y chemical stability LODI.08/2014 | Richerioux, S. | 2016 | Chemical stability of Etofenprox 2g/L RTU after 1 year of storage at 20°C | LODI S.A.S. |  |  |  |  |
| B2 | 3.4.1/08: Pourability and persistant foaming 36M/20°C\_16-912011-002 (Interim T0) | Demangel, B. | 2016 | Pourability and persistent foaming tests before, during and after a storage procedure for 36 months at 20 °C ± 2 °C on ETOFENPROX 2 G/L RTU - Results at T=0 | LODI S.A.S. |  |  |  |  |
| B2 | 3.5.4/01: Emulsion stability before and after storage at 54°C for 21 days | 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 2 G/L RTU (undiluted) | LODI S.A.S. |  |  |  |  |
| B2 | 3.5.4/02: Emulsion stability before and after storage at 20°C for 36 months (InterimT0) | 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 2 G/L RTU (undiluted) - Interim report T initial | LODI S.A.S. |  |  |  |  |
| B2 | 3.8/01: surface tension 14-912011-006 3.9/01: viscosity 14-912011-006 | Demangel, B. | 2015 | Surface tension and viscosity tests on ETOFENPROX 2 G/L RTU | LODI S.A.S. |  |  |  |  |
| B2 | 4.1/01: Explosive propterties LODI.05/2015 | Richerioux, S. | 2015 | Explosive properties of Etofenprox 2 g/L RTU | LODI S.A.S. |  |  |  |  |
| B2 | 4.13/01: Oxidising liquids LODI.06/2015 | Richerioux, S. | 2015 | Oxidising properties of Etofenprox 2 g/L RTU | LODI S.A.S. |  |  |  |  |
| B2 | 4.16/01: Corrosive to metals/statement | Zurita Blasco, D. | 2015 | Etofenprox 2g/L RTU: Corrosive to metals | LODI S.A.S. |  |  |  |  |
| B2 | 4.17.1/01: Auto-ignition temperature (liquids) 14-912011-007 | Demangel, B. | 2015 | Auto-ignition temperature of liquids on ETOFENPROX 2 G/L RTU | LODI S.A.S. |  |  |  |  |
| B2 | 4.8/01: Self reactive substances and mixtures/statement | Zurita Blasco, D, | 2015 | Etofenprox 2g/L RTU: Self-reactive properties | LODI S.A.S. |  |  |  |  |
| B2 | 4.9/01: Pyrophoric properties LODI.07/2015 | Richerioux, S. | 2015 | Study report amendment no. 1: Pyrophoric properties of Etofenprox 2 g/L RTU | LODI S.A.S. |  |  |  |  |
| B2 | 4.9/01: Pyrophoric properties LODI.07/2015 | Richerioux, S. | 2015 | Pyrophoric properties of Etofenprox 2g/L RTU | LODI S.A.S. |  |  |  |  |
| B2 | Storage stability-stability and shelf life  (IIB, III 3.7)  LODI.09/2014 | Tallon A. | 2017 | Chemical stability of Etofenprox 2g/L RTU after 2 years of storage at 20°C+/- 2°C | LODI S.A.S. |  |  |  |  |
| *B2* | Storage stability-stability and shelf life  (IIB, III 3.7)  LODI.23/2015 | Tallon A. | 2018 | pH of Etofenprox 2g/L RTU after 3 years of storage at 20°C+/- 2°C | LODI S.A.S. |  |  |  |  |
| B2 | Storage stability-stability and shelf life  (IIB, III 3.7)  LAB2016-05 | Tallon A. | 2018 | Emulsion characteristics a,d re-emulsification properties tests before and after a storage procedure at 20°C+/- 2°C for 36 months on Etofenprox 2g/L RTU (undiluted) | LODI S.A.S. |  |  |  |  |
| B2 | Storage stability-stability and shelf life  (IIB, III 3.7)  16-912011-002 | Richerioux S. | 2019 | Pourability and persistent foaming tests before,  during and after a storage procedure for 36 months at 20 °C ± 2 °C on ETOFENPROX 2 G/L RTU | LODI S.A.S. |  |  |  |  |
| B2 | Storage stability-stability and shelf life  (IIB III 3.7)  LAB2020-01 | Richerioux S. | 2020 | Spray pattern for etofenprox 2g/L RTU stored in PEHD bottle with trigger for 2 weeks at 54°C±2°C | LODI S.A.S. |  |  |  |  |
| B3 | 5/01: Methods of detection and identification LODI.04/2014 | Richerioux, S. | 2014 | Validation of the analytical method for quantification of Etofenprox in Etofenprox 2g/L RTU | LODI S.A.S. |  |  |  |  |
| **B5** | 6.7: lab cockroach, ant, comparative assay | 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) | LODI S.A.S. |  |  |  |  |
| **B5** | 6.7/01: su litter beetle | Serrano, B. | 2014 | Simulated use trial on the efficacy of a residual insecticide intended to control litter beetles (Alphitobius diaperinus) | LODI S.A.S. |  |  |  |  |
| **B5** | 6.7/02: lab volume dose determination | Serrano, B. | 2011 | Bioassay in semi-practical conditions of the insecticide efficacy of a specialty intended to control insect pests | LODI S.A.S. |  |  |  |  |
| **B5** | 6.7/03: lab surface various pests | Serrano, B. | 2008 | Bioassay of the direct and residual efficacy of an insecticide speciality against various pests | LODI S.A.S. |  |  |  |  |
| **B5** | 6.7/04: lab FOV FOA pests | Serrano, B. | 2008 | Laboratory assessment of an insecticide speciality intended to control insect pests in premises and materials of storage, transport and harvest of vegetal and animal origin foodstuff | LODI S.A.S. |  |  |  |  |
| **B5** | 6.7/05: lab red mites, litter beetle | Serrano, B. | 2012 | Laboratory assessment of an insecticide specialty intended to control poultry red mites and the litter dark beetle | LODI S.A.S. |  |  |  |  |
| **B5** | 6.7/06: lab mosquitoes, dust mites, bed bugs | Serrano, B | 2011 | Laboratory assessment of an insecticide speciality intended to control mosquitoes, dust mites and bed bugs | LODI S.A.S. |  |  |  |  |
| **B5** | 6.7/07: lab mosquitoes, bed bugs | Serrano, B. | 2011 | Laboratory assessment of an insecticide speciality intended to control mosquitoes and bed bugs in premises | LODI S.A.S. |  |  |  |  |
| **B5** | 6.7/08: lab and field flies | Serrano, B. | 2008 | Laboratory and field assessment of the efficacy of an insecticide product intended to control flies in breeding premises | LODI S.A.S. |  |  |  |  |
| **B5** | 6.7/09: field red mite | Serrano, B. | 2014 | Field testing of the efficacy of an insecticide speciality to control chicken red mites in poultry premises | LODI S.A.S. |  |  |  |  |
| **B5** | 6.7/10: field residual efficacy German cockroach | Serrano, B. | 2015 | Field testing of the efficacy of a residual insecticide spray treatment to control German cockroaches | LODI S.A.S. |  |  |  |  |
| **B5** | 6.7/11: field residual efficacy Oriental cockroach | Serrano, B. | 2015 | Field testing of the efficacy of a residual insecticide spray treatment to control Oriental cockroaches | LODI S.A.S. |  |  |  |  |
| **B5** | 6.7/12: field bed bugs | Serrano, B. | 2015 | Field testing of the efficacy of a residual insecticide spray treatment to control Bed bugs Cimex lectularius | LODI S.A.S. |  |  |  |  |
| **B5** | 6.7/13: su surface mosquitoes | Serrano, B. | 2015 | Simulated-use trial of the residual efficacy of an insecticide applied as a surface treatment against mosquitoes | LODI S.A.S. |  |  |  |  |
| **B5** | 6.7/14: su space cockroaches, mosquitoes, biting midge | Serrano, B. | 2015 | Simulated-use trial of the efficacy of an insecticide applied as a space treatment against cockroaches, mosquitoes and the biting midge Culicoides | LODI S.A.S. |  |  |  |  |
| **B5** | 6.7/15 lab spider, tick | Serrano, B. | 2015 | Laboratory assessment of the efficacy of an insecticide product applied as a surface treatment against house spider (Tegenaria domestica) and tick (Ixodes ricinus) | LODI S.A.S. |  |  |  |  |
| **B5** | 6.7/16: lab tobacco beetle, mill moth | Serrano, B. | 2014 | Laboratory trial of the efficacy of an insecticide intended to control the Tobacco beetle (*Lasioderma serricorne*) and the mill moth (*Ephestia kuehniella*) | LODI S.A.S. |  |  |  |  |
| **B5** | 6.7\_01\_Lab\_crawling insects, mites, spider, flying insects | Serrano, B. | 2016 | Laboratory trial of the efficacy of the product DIGRAIN SPRAY against various flying and crawling target organisms (cockroaches, ants, fleas, ticks, bed bugs, mites, spiders, mosquitoes) | LODI S.A.S. |  |  |  |  |
| **B5** | 6.7\_02\_Simulated use\_crawling insects, mites, spider, flying insects | Serrano, B. | 2016 | Simulated use trial of the efficacy of aninsecticidal product intended to control various pests (cockroaches, ants, fleas, ticks, spiders, mites, flies and mosquitoes) | LODI S.A.S. |  |  |  |  |
| **B6** | 8.5.1/01: Acute oral toxicity TAO423-PH-09/0032 | XXX | 2009 | Etofenprox 30CE: Acute oral toxicity in the rat, Acute toxic class method | LODI S.A.S. |  |  |  |  |
| **B6** | 8.5.2/01: Acute inhalation toxicity 41302911 | XXX | 2013 | Etofenprox 300 g/L EC: Acute inhalation toxicity (nose only) study in the rat | LODI S.A.S. |  |  |  |  |
| **B6** | 8.5.3/01: Acute dermal toxicity TAD-PH-14/0744 | XXX | 2015 | Etofenprox 2 g/L RTU: Evaluation of acute dermal toxicity in rats | LODI S.A.S. |  |  |  |  |
| **B6** | 8.1/01: Dermal irritation IC-OCDE-PH-14/0744 | XXX | 2015 | Etofenprox 2 g/L RTU: Assessment of acute dermal irritation | LODI S.A.S. |  |  |  |  |
| **B6** | 8.2/01: Eye irritation IO-OCDE-PH-14/0744 | XXX | 2015 | Etofenprox 2 g/L RTU: Assessment of acute eye irritation | LODI S.A.S. |  |  |  |  |
| **B6** | 8.3/01: Skin sensitisation SMK-PH-14/0744 | XXX | 2015 | Etofenprox 2 g/L RTU: Assessment of sensitising properties on albino guinea pigs: Maximisation test according to Magnusson and Kligman | LODI S.A.S. |  |  |  |  |
| **B6** | 8.6/01: Dermal absorption LKS/01 | Webbley, K. | 2015 | The in vitro dermal absorption of radiolabelled etofenprox in two formulated products for biocidal use | LODI S.A.S. |  |  |  |  |
| **B6** | 8.6/01: Dermal absorption LKS/01 | Webbley, K. | 2015 | Report amendment: The in vitro dermal absorption of radiolabelled etofenprox in two formulated products for biocidal use | LODI S.A.S. |  |  |  |  |

Annex 2: Analytical methods residues – active substance

**Etofenprox**

CAR IIA Etofenprox: Analytical methods for the determination of residues of a.s. and relevant metabolites.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Sample** | **Test substance** | **Analytical method** | **Fortification range/level** | **No. of measure-ments** | **Linearity** | | **Specificity** | | **Recovery rate [%]** | | | | | | | | | **Lower limit of deter-mination** | | | **Reference** | |
| **Range** | | **Mean** | | | **Std. Dev.** | | | |
| Soil | Etofenprox | **GC-MS** | 0.01 mg/kg | 5 | 0.02 – 2.0 μg/ml | | yes | | 94.5 – 108.9 | | 100.6 | | | 5.5 | | | | 0.01 mg/kg | | | Wolf, 2003a  (Section A 4.2/01) | |
| Etofenprox | **GC-MS** | 0.1 mg/kg | 5 | 0.02 – 2.0 μg/ml | | yes | | 81.1 – 94.9 | | 88.5 | | | 5.5 | | | | 0.01 mg/kg | | |
| α-CO | **GC-MS** | 0.01 mg/kg | 5 | 0.05 – 2.0 μg/ml | | yes | | 90.5 – 108.7 | | 102.5 | | | 7.2 | | | | 0.01 mg/kg | | |
| α-CO | **GC-MS** | 0.1 mg/kg | 5 | 0.05 – 2.0 μg/ml | | yes | | 70.7 – 92.3 | | 86.2 | | | 8.8 | | | | 0.01 mg/kg | | |
| Air, 20°C | Etofenprox | GC-MS | 1.0 μg/m3 | 5 | 0.01 – 1.0 μg/ml | | yes | | 75.0 –108.3 | | 98.4 | | | 13.5 | | | | 1.0 μg/m3 | | | Wolf, 2003b  (Section A 4.2/02) | |
| Etofenprox | **GC-MS** | 10.0 μg/m3 | 5 | 0.01 – 1.0 μg/ml | | yes | | 71.4 –106.8 | | 85.1 | | | 13.6 | | | | 1.0 μg/m3 | | |
| α-CO | **GC-MS** | 1.0 μg/m3 | 5 | 0.01 – 1.0 μg/ml | | yes | | 72.1 –104.3 | | 89.9 | | | 13.0 | | | | 1.0 μg/m3 | | |
| α-CO | **GC-MS** | 10.0 μg/m3 | 5 | 0.01 – 1.0 μg/ml | | yes | | 75.7 –108.3 | | 84.8 | | | 13.5 | | | | 1.0 μg/m3 | | |
| Air, 37°C | Etofenprox | **GC-MS** | 1.0 μg/m3 | 5 | 0.01 – 1.0 μg/ml | | yes | | 99.4 –109.2 | | 103.7 | | | 4.1 | | | | 1.0 μg/m3 | | |
| Etofenprox | **GC-MS** | 10.0 μg/m3 | 5 | 0.01 – 1.0 μg/ml | | yes | | 98.1 –107.2 | | 104.5 | | | 3.7 | | | | 1.0 μg/m3 | | |
| α-CO | **GC-MS** | 1.0 μg/m3 | 5 | 0.01 – 1.0 μg/ml | | yes | | 99.4 – 108.8 | | 105.2 | | | 3.6 | | | | 1.0 μg/m3 | | |
| α-CO | **GC-MS** | 10.0 μg/m3 | 5 | 0.01 – 1.0 μg/ml | | yes | | 101.5 – 107.9 | | 105.8 | | | 2.5 | | | | 1.0 μg/m3 | | |
| Drinking water | Etofenprox | GC-MS | 0.05 μg/l | 5 | 0.001 – 0.5 μg/ml | | yes | | 79.0 – 110.4 | | 98.9 | | | 13.1 | | | | 0.01 μg/l | | | Wolf, 2003c  (Section A 4.2/03) | |
| Etofenprox | **GC-MS** | 0.5 μg/l | 5 | 0.001 – 0.5 μg/ml | | yes | | 81.2 – 100.5 | | 91.2 | | | 8.8 | | | | 0.01 μg/l | | |
| α-CO | **GC-MS** | 0.05 μg/l | 5 | 0.001 – 0.5 μg/ml | | yes | | 87.6 – 102.1 | | 93.5 | | | 6.2 | | | | 0.01 μg/l | | |
| α-CO | **GC-MS** | 0.5 μg/l | 5 | 0.001 – 0.5 μg/ml | | yes | | 95.2 – 104.7 | | 100.6 | | | 4.7 | | | | 0.01 μg/l | | |
| Ground water | Etofenprox | **GC-MS** | 0.05 μg/l | 5 | 0.001 – 0.5 μg/ml | | yes | | 71.3 – 111.2 | | 101.4 | | | 17.2 | | | | 0.01 μg/l | | |
| Etofenprox | **GC-MS** | 0.5 μg/l | 5 | 0.001 – 0.5 μg/ml | | yes | | 76.3 – 107.2 | | 97.0 | | | 12.6 | | | | 0.01 μg/l | | |
| α-CO | **GC-MS** | 0.05 μg/l | 5 | 0.001 – 0.5 μg/ml | | yes | | 83.7 – 106.4 | | 99.3 | | | 9.3 | | | | 0.01 μg/l | | |
| α-CO | **GC-MS** | 0.5 μg/l | 5 | 0.001 – 0.5 μg/ml | | yes | | 105.9 –109.0 | | 107.6 | | | 1.3 | | | | 0.01 μg/l | | |
| **Sample** | **Test substance** | **Analytical method** | **Fortification range/level** | **No. of measure-ments** | **Linearity** | | **Specificity** | | **Recovery rate [%]** | | | | | | | | | **Lower limit of deter-mination** | | | **Reference** | |
| Surface water | Etofenprox | **GC-MS** | 0.05 μg/l | 5 | 0.001 – 0.5 μg/ml | | yes | | 71.7 – 85.3 | | 77.9 | | | 5.5 | | | | 0.01 μg/l | | |  | |
| Etofenprox | **GC-MS** | 0.5 μg/l | 5 | 0.001 – 0.5 μg/ml | | yes | | 70.0 – 103.4 | | 83.6 | | | 17.4 | | | | 0.01 μg/l | | |
| α-CO | **GC-MS** | 0.05 μg/l | 5 | 0.001 – 0.5 μg/ml | | yes | | 73.0 – 109.8 | | 87.6 | | | 19.5 | | | | 0.01 μg/l | | |
| α-CO | **GC-MS** | 0.5 μg/l | 5 | 0.001 – 0.5 μg/ml | | yes | | 81.9 – 109.6 | | 93.1 | | | 13.5 | | | | 0.01 μg/l | | |
| Oilseed rape (seed) | Etofenprox | GC-MS | 0.01 mg/kg | 5 | 0.05 – 2.0 μg/ml | yes | | 81.5 – 110.5 | | 93.3 | | | 11.9 | | | | 0.01 mg/kg | | | Wolf, 2001  (Section A 4.3/01) | | |
| Etofenprox | GC-MS | 0.10 mg/kg | 5 | 0.05 – 2.0 μg/ml | yes | | 90.6 – 100.5 | | 94.9 | | | 4.5 | | | | 0.01 mg/kg | | |
| Etofenprox | **GC-MS** | 2.00 mg/kg | 5 | 0.05 – 2.0 μg/ml | yes | | 72.0 – 84.0 | | 77.5 | | | 5.3 | | | | 0.01 mg/kg | | |
| α-CO | **GC-MS** | 0.01 mg/kg | 5 | 0.05 – 2.0 μg/ml | yes | | 99.4 – 107.8 | | 103.9 | | | 3.2 | | | | 0.01 mg/kg | | |
| α-CO | **GC-MS** | 0.10 mg/kg | 5 | 0.05 – 2.0 μg/ml | yes | | 79.8 – 99.3 | | 91.6 | | | 7.2 | | | | 0.01 mg/kg | | |
| Oilseed rape (seed) | Etofenprox | GC-MS | 0.01 mg/kg | 5 | 0.01 – 2.0 μg/ml | yes | | 76 – 89 | | 81 | | | 6 | | | | 0.01 mg/kg | | | Class, 2003a  (Section A 4.3/04) | | |
| Etofenprox | GC-MS | 0.10 mg/kg | 5 | 0.01 – 2.0 μg/ml | yes | | 68 – 93 | | 81 | | | 13 | | | | 0.01 mg/kg | | |
| α-CO | GC-MS | 0.01 mg/kg | 5 | 0.01 – 2.0 μg/ml | yes | | 85 – 96 | | 89 | | | 6 | | | | 0.01 mg/kg | | |
| α-CO | GC-MS | 0.10 mg/kg | 5 | 0.01 – 2.0 μg/ml | yes | | 74 – 101 | | 88 | | | 13 | | | | 0.01 mg/kg | | |
| Cabbage | Etofenprox | GC-MS | 0.01 mg/kg | 5 | 0.05 – 2.0 μg/ml | yes | | 87.0 – 108.1 | | 98.4 | | | 7.8 | | | | 0.01 mg/kg | | | Wolf, 2002  (Section A 4.3/02) | | |
| Etofenprox | **GC-MS** | 0.10 mg/kg | 5 | 0.05 – 2.0 μg/ml | yes | | 102.7 – 108.1 | | 104.4 | | | 2.2 | | | | 0.01 mg/kg | | |
| Etofenprox | **GC-MS** | 2.00 mg/kg | 5 | 0.05 – 2.0 μg/ml | yes | | 97.1 – 106.9 | | 101.2 | | | 3.6 | | | | 0.01 mg/kg | | |
| α-CO | **GC-MS** | 0.01 mg/kg | 5 | 0.05 – 2.0 μg/ml | yes | | 97.9 – 104.8 | | 100.9 | | | 3.1 | | | | 0.01 mg/kg | | |
| α-CO | GC-MS | 0.10 mg/kg | 5 | 0.05 – 2.0 μg/ml | yes | | 82.3 – 96.5 | | 88.7 | | | 6.1 | | | | 0.01 mg/kg | | |
| Cucum-ber | Etofenprox | GC-MS | 0.01 mg/kg | 5 | 0.05 – 2.0 μg/ml | yes | | 86.3 – 112.4 | | | | 99.3 | | | 11.5 | | | | 0.01 mg/kg | | | Wolf, 2003d  (Section A 4.3/03) | |
| Etofenprox | GC-MS | 0.10 mg/kg | 5 | 0.05 – 2.0 μg/ml | yes | | 79.9 – 111.8 | | | | 89.7 | | | 14.1 | | | | 0.01 mg/kg | | |
| Etofenprox | **GC-MS** | 2.00 mg/kg | 5 | 0.05 – 2.0 μg/ml | yes | | 79.3 – 112.5 | | | | 88.7 | | | 15.1 | | | | 0.01 mg/kg | | |
| α-CO | **GC-MS** | 0.01 mg/kg | 5 | 0.05 – 2.0 μg/ml | yes | | 95.5 – 108.9 | | | | 102.8 | | | 4.8 | | | | 0.01 mg/kg | | |
| α-CO | **GC-MS** | 0.10 mg/kg | 5 | 0.05 – 2.0 μg/ml | yes | | 96.6 – 111.7 | | | | 103.3 | | | 7.2 | | | | 0.01 mg/kg | | |
| Cucum-ber | Etofenprox | GC-MS | 0.01 mg/kg | 5 | 0.01 – 2.0 μg/ml | yes | | 74 – 83 | | | | 78 | | | 5 | | | | 0.01 mg/kg | | | Class, 2003a  (Section A 4.3/04) | |
| Etofenprox | GC-MS | 0.10 mg/kg | 5 | 0.01 – 2.0 μg/ml | yes | | 70 – 83 | | | | 74 | | | 7 | | | | 0.01 mg/kg | | |
| α-CO | GC-MS | 0.01 mg/kg | 5 | 0.01 – 2.0 μg/ml | yes | | 72 – 92 | | | | 85 | | | 9 | | | | 0.01 mg/kg | | |
| α-CO | GC-MS | 0.10 mg/kg | 5 | 0.01 – 2.0 μg/ml | yes | | 83 – 100 | | | | 91 | | | 7 | | | | 0.01 mg/kg | | |
| Apple | Etofenprox | GC-MS | 0.01 mg/kg | 5 | 0.01 – 2.0 μg/ml | yes | | 90 – 98 | | | | 94 | | | 4 | | | | 0.01 mg/kg | | | Class, 2003a  (Section A 4.3/04) | |
| Etofenprox | GC-MS | 0.10 mg/kg | 5 | 0.01 – 2.0 μg/ml | yes | | 88 – 109 | | | | 98 | | | 9 | | | | 0.01 mg/kg | | |
| α-CO | GC-MS | 0.01 mg/kg | 5 | 0.01 – 2.0 μg/ml | yes | | 88 – 96 | | | | 92 | | | 4 | | | | 0.01 mg/kg | | |
| α-CO | GC-MS | 0.10 mg/kg | 5 | 0.01 – 2.0 μg/ml | yes | | 89 – 106 | | | | 97 | | | 8 | | | | 0.01 mg/kg | | |
| Meat (rumi-nant) | Etofenprox | GC-MS | 0.01mg/kg | 5 | 0.01 – 1.2 μg/ml | yes | | 98.2 – 103.8 | | | | 101.9 | | | | 2.2 | | | 0.01 mg/kg | | | Wolf, 2003e  (Section A4.3/05) | |
| Etofenprox | **GC-MS** | 0.5 mg/kg | 5 | 0.01 – 1.2 μg/ml | yes | | 93.4 – 101.2 | | | | 95.8 | | | | 3.1 | | | 0.01 mg/kg | | |
| Etofenprox | **GC-MS** | 5.0 mg/kg | 5 | 0.01 – 1.2 μg/ml | yes | | 96.8 – 97.8 | | | | 97.3 | | | | 0.4 | | | 0.01 mg/kg | | |
| α-CO | **GC-MS** | 0.01 mg/kg | 5 | 0.01 – 1.2 μg/ml | yes | | 93.7 – 109.1 | | | | 104.0 | | | | 6.5 | | | 0.01 mg/kg | | |
| α-CO | **GC-MS** | 0.1 mg/kg | 5 | 0.01 – 1.2 μg/ml | yes | | 96.4 – 109.5 | | | | 101.5 | | | | 5.0 | | | 0.01 mg/kg | | |
| α-CO | **GC-MS** | 1.0 mg/kg | 5 | 0.01 – 1.2 μg/ml | yes | | 104.6 – 107.0 | | | | 105.7 | | | | 0.9 | | | 0.01 mg/kg | | |

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Meat (chicken) | Etofenprox | GC-MS | 0.01mg/kg | 5 | 0.01 – 1.2 μg/ml | yes | 98.1 – 108.9 | 103.0 | 4.2 | 0.01 mg/kg |  |
| Etofenprox | **GC-MS** | 0.5 mg/kg | 5 | 0.01 – 1.2 μg/ml | yes | 92.0 – 105.3 | 97.5 | 5.7 | 0.01 mg/kg |
| Etofenprox | **GC-MS** | 5.0 mg/kg | 5 | 0.01 – 1.2 μg/ml | yes | 95.9 – 107.0 | 100.2 | 4.4 | 0.01 mg/kg |
| α-CO | **GC-MS** | 0.01 mg/kg | 5 | 0.01 – 1.2 μg/ml | yes | 102.3-105.8 | 104.4 | 1.4 | 0.01 mg/kg |
| α-CO | **GC-MS** | 0.1 mg/kg | 5 | 0.01 – 1.2 μg/ml | yes | 82.7 – 101.8 | 89.6 | 8.0 | 0.01 mg/kg |
| α-CO | **GC-MS** | 1.0 mg/kg | 5 | 0.01 – 1.2 μg/ml | yes | 90.5 – 103.2 | 99.1 | 5.1 | 0.01 mg/kg |
| Meat  (bovine) | Etofenprox | GC-MS | 0.01mg/kg | 5 | 0.01 – 2.0 μg/ml | yes | 69.0 – 106.0 | 90.0 | 19.0 | 0.01 mg/kg | Class, 2003b  (Section A 4.3/06) |
| Etofenprox | **GC-MS** | 0.1 mg/kg | 5 | 0.01 – 2.0 μg/ml | yes | 74.0 – 97.0 | 84.0 | 10.0 | 0.01 mg/kg |
| α-CO | **GC-MS** | 0.01 mg/kg | 5 | 0.01 – 2.0 μg/ml | yes | 65.0 – 87.0 | 76.0 | 11.0 | 0.01 mg/kg |
| α-CO | **GC-MS** | 0.1 mg/kg | 5 | 0.01 – 2.0 μg/ml | yes | 85.0 – 99.0 | 88.0 | 7.0 | 0.01 mg/kg |
| Fat (rumi-nant) | Etofenprox | GC-MS | 0.01 mg/kg | 5 | 0.01 – 1.2 μg/ml | yes | 97.5 – 106.2 | 102.2 | 4.2 | 0.01 mg/kg | Wolf, 2003e  (Section A 4.3/05) |
| Etofenprox | **GC-MS** | 0.5 mg/kg | 5 | 0.01 – 1.2 μg/ml | yes | 95.2 – 97.3 | 96.6 | 1.8 | 0.01 mg/kg |
| Etofenprox | **GC-MS** | 5.0 mg/kg | 5 | 0.01 – 1.2 μg/ml | yes | 86.9 – 95.4 | 89.6 | 3.5 | 0.01 mg/kg |
| α-CO | **GC-MS** | 0.01 mg/kg | 5 | 0.01 – 1.2 μg/ml | yes | 99.4 – 100.2 | 99.8 | 0.4 | 0.01 mg/kg |
| α-CO | **GC-MS** | 0.1 mg/kg | 5 | 0.01 – 1.2 μg/ml | yes | 90.9 – 91.4 | 91.2 | 0.2 | 0.01 mg/kg |
| α-CO | **GC-MS** | 1.0 mg/kg | 5 | 0.01 – 1.2 μg/ml | yes | 87.7 – 98.8 | 90.5 | 4.7 | 0.01 mg/kg |
| Fat  (bovine) | Etofenprox | GC-MS | 0.01mg/kg | 5 | 0.01 – 2.0 μg/ml | yes | 70.0 – 76.0 | 73.0 | 3.0 | 0.01 mg/kg | Class, 2003b  (Section A 4.3/06) |
| Etofenprox | **GC-MS** | 0.1 mg/kg | 5 | 0.01 – 2.0 μg/ml | yes | 66.0 – 105.0 | 79.0 | 19.0 | 0.01 mg/kg |
| α-CO | **GC-MS** | 0.01 mg/kg | 5 | 0.01 – 2.0 μg/ml | yes | 72.0 – 98.0 | 85.0 | 11.0 | 0.01 mg/kg |
| α-CO | **GC-MS** | 0.1 mg/kg | 5 | 0.01 – 2.0 μg/ml | yes | 73.0 – 100.0 | 83.0 | 13.0 | 0.01 mg/kg |

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Sample** | **Test substance** | **Analytical method** | **Fortification range/level** | **No. of measure-ments** | **Linearity** | **Specificity** | **Recovery rate [%]** | | | **Lower limit of deter-mination** | **Reference** |
| Milk | Etofenprox | GC-MS | 0.01mg/l | 5 | 0.01 – 1.2 μg/ml | yes | 72.8 – 84.3 | 78.9 | 5.2 | 0.01 mg/l | Wolf, 2003e  (Section A 4.3/05) |
| Etofenprox | **GC-MS** | 0.5 mg/l | 5 | 0.01 – 1.2 μg/ml | yes | 91.6 – 95.1 | 94.0 | 1.4 | 0.01 mg/l |
| Etofenprox | **GC-MS** | 5.0 mg/l | 5 | 0.01 – 1.2 μg/ml | yes | 91.5 – 93.8 | 92.8 | 1.0 | 0.01 mg/l |
| α-CO | **GC-MS** | 0.01 mg/l | 5 | 0.01 – 1.2 μg/ml | yes | 70.5 – 82.0 | 75.2 | 5.4 | 0.01 mg/l |
| α-CO | **GC-MS** | 0.1 mg/l | 5 | 0.01 – 1.2 μg/ml | yes | 101.3 – 108.6 | 106.3 | 3.3 | 0.01 mg/l |
| α-CO | **GC-MS** | 1.0 mg/l | 5 | 0.01 – 1.2 μg/ml | yes | 95.9 – 98.6 | 97.6 | 1.1 | 0.01 mg/l |
| Milk | Etofenprox | GC-MS | 0.01mg/l | 5 | 0.01 – 2.0 μg/ml | yes | 91.0 – 103.0 | 94.0 | 5.0 | 0.01 mg/kg | Class, 2003b  (Section A 4.3/06) |
| Etofenprox | **GC-MS** | 0.1 mg/l | 5 | 0.01 – 2.0 μg/ml | yes | 79.0 – 100.0 | 91.0 | 11.0 | 0.01 mg/kg |
| α-CO | **GC-MS** | 0.01 mg/l | 5 | 0.01 – 2.0 μg/ml | yes | 83.0 – 103.0 | 91.0 | 10.0 | 0.01 mg/kg |
| α-CO | **GC-MS** | 0.1 mg/l | 5 | 0.01 – 2.0 μg/ml | yes | 75.0 – 99.0 | 87.0 | 12.0 | 0.01 mg/kg |
| Egg  (yolk) | Etofenprox | GC-MS | 0.01 mg/kg | 5 | 0.01 – 1.2 μg/ml | yes | 85.0 – 101.5 | 93.3 | 6.7 | 0.01 mg/kg | Wolf, 2003e  (Section A 4.3/05) |
| Etofenprox | **GC-MS** | 0.5 mg/kg | 5 | 0.01 – 1.2 μg/ml | yes | 71.2 – 99.4 | 78.5 | 11.8 | 0.01 mg/kg |
| Etofenprox | **GC-MS** | 5.0 mg/kg | 5 | 0.01 – 1.2 μg/ml | yes | 73.3 – 104.7 | 90.6 | 15.9 | 0.01 mg/kg |
| α-CO | **GC-MS** | 0.01 mg/kg | 5 | 0.01 – 1.2 μg/ml | yes | 99.9 – 106.9 | 104.4 | 2.7 | 0.01 mg/kg |
| α-CO | **GC-MS** | 0.1 mg/kg | 5 | 0.01 – 1.2 μg/ml | yes | 74.5 – 107.3 | 83.3 | 13.5 | 0.01 mg/kg |
| α-CO | **GC-MS** | 1.0 mg/kg | 5 | 0.01 – 1.2 μg/ml | yes | 71.8 – 76.8 | 74.5 | 1.9 | 0.01 mg/kg |

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Sample** | **Test substance** | **Analytical method** | **Fortification range/level** | **No. of measure-ments** | **Linearity** | **Specificity** | **Recovery rate [%]** | | | **Lower limit of deter-mination** | **Reference** |
| Egg  (white) | Etofenprox | GC-MS | 0.01 mg/kg | 5 | 0.01 – 1.2 μg/ml | yes | 100.3–104.7 | 102.9 | 1.7 | 0.01 mg/kg |  |
| Etofenprox | **GC-MS** | 0.5 mg/kg | 5 | 0.01 – 1.2 μg/ml | yes | 74.5 – 80.3 | 77.8 | 2.1 | 0.01 mg/kg |
| Etofenprox | **GC-MS** | 5.0 mg/kg | 5 | 0.01 – 1.2 μg/ml | yes | 75.9 – 81.6 | 79.1 | 2.6 | 0.01 mg/kg |
| α-CO | **GC-MS** | 0.01 mg/kg | 5 | 0.01 – 1.2 μg/ml | yes | 101.0-105.2 | 102.5 | 1.6 | 0.01 mg/kg |
| α-CO | **GC-MS** | 0.1 mg/kg | 5 | 0.01 – 1.2 μg/ml | yes | 74.2 – 80.2 | 78.4 | 2.4 | 0.01 mg/kg |
| α-CO | **GC-MS** | 1.0 mg/kg | 5 | 0.01 – 1.2 μg/ml | yes | 75.4 – 82.4 | 78.8 | 2.7 | 0.01 mg/kg |
| Egg  (whole egg) | Etofenprox | GC-MS | 0.01mg/l | 5 | 0.01 – 2.0 μg/ml | yes | 65.0 – 95.0 | 78.0 | 14.0 | 0.01 mg/kg | Class, 2003b  (Section A 4.3/06) |
| Etofenprox | **GC-MS** | 0.1 mg/l | 5 | 0.01 – 2.0 μg/ml | yes | 77.0 – 82.0 | 80.0 | 2.0 | 0.01 mg/kg |
| α-CO | **GC-MS** | 0.01 mg/l | 5 | 0.01 – 2.0 μg/ml | yes | 88.0 – 104.0 | 95.0 | 6.0 | 0.01 mg/kg |
| α-CO | **GC-MS** | 0.1 mg/l | 5 | 0.01 – 2.0 μg/ml | yes | 85.0 – 97.0 | 93.0 | 5.0 | 0.01 mg/kg |

Annex 3: Toxicology and metabolism –active substance

**Etofenprox**

Threshold Limits and other Values for Human Health Risk Assessment

| **Summary** | | | |
| --- | --- | --- | --- |
|  | Value  (mg/kg/d) | Study | SF |
| AEL long-term | 0.011 | Rat 2-year feeding study | 100 |
| AEL medium-term | 0.06 | Rat subchronic feeding study | 100 |
| AEL acute | 0.085 | Rat developmental neurotoxicity feeding study | 100 |
| ADI | Not determined |  |  |
| ARfD | Not determined |  |  |
|  | | | |

|  |  |
| --- | --- |
| Inhalative absorption | 100% |
| Oral absorption | 30% |
| Dermal absorption | 13.8% (AR) |

| **Classification** | |
| --- | --- |
| with regard to toxicological data (according to the criteria in Reg. 1272/2008) | LACT. H362 |

Annex 4: Toxicology – biocidal product

**DIGRAIN SPRAY**

|  |  |
| --- | --- |
| General information | |
| Formulation Type | EW Ready to use |
| Active substance(s) (incl. content) | Etofenprox |
| Category |  |

| Acute toxicity, irritancy and skin sensitisation of the preparation | | | | |
| --- | --- | --- | --- | --- |
| Rat LD50 oral (OECD 420) | >2000 mg/kg |  |  |  |
| Rat LD50 dermal (OECD 402) | >2000 mg/kg |  |  |  |
| Rat LC50 inhalation (OECD 403) | >5.59 mg/L |  |  |  |
| Skin irritation (OECD 404) | Non irritant |  |  |  |
| Eye irritation (OECD 405) | Non irritant |  |  |  |
| Skin sensitisation (OECD 429; LLNA) | Negative |  |  |  |

| Additional toxicological information | | | | |
| --- | --- | --- | --- | --- |
| Short-term toxicity studies |  |  |  |  |
| Toxicological data on active substance(s) (not tested with the preparation) | - |  |  |  |
|  | - |  |  |  |
| Toxicological data on non-active substance(s) (not tested with the preparation) |  |  |  |  |
|  |  |  |  |  |
| Further toxicological information | - | | | |

|  |  |
| --- | --- |
| Classification and labelling proposed for the preparation with regard to toxicological properties | |
| Regulation 1272/2008/EC | EUH 208: Contains <2-méthyl-2H-isothiazole-3-one and 1,2-benzisothiazol-2(2H)-one >. May produce an allergic reaction. |

Annex 5: Safety for non-professional operators and the general public

**DIGRAIN SPRAY**



**Primary exposure:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Scenario  PPE | Estimated Exposure (mg/kg/d) | AEL  (mg/kg/d) | %AEL | Acceptable/not acceptable |
| **Spraying** | | | | |
| Spraying Without PPE | 2.36E-02 | 8.5E-02 | 28% | Acceptable |

**Secondary exposure:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Scenario | Estimated Exposure (mg/kg/d) | AEL  (mg/kg/d) | %AEL | Acceptable/not acceptable |
| **Exposure to volatile residue** | | | | |
| Adult | 3.35E-05 | 6E-02 | 0.06% | Acceptable |
| Child | 6.31E-05 | 6E-02 | 0.11% | Acceptable |
| Infant | 6.79E-05 | 6E-02 | 0.11% | Acceptable |
| **Infant crawling on treated surface with hand to mouth transfer – Wet surface default dislodgeable fraction (100%)** | | | | |
| Wet surface  Spraying | 1.49 | 8.5E-02 | 1747% | Not acceptable |
| **Infant crawling on treated surface with hand to mouth transfer**  **- dry surface default dislodgeable fraction (30%)** | | | | |
| Dry surface  Spraying | 3.73E-01 | 6E-02 | 621% | Not acceptable |
| **Infant crawling on treated surface with hand to mouth transfer**  **– dry surface dislodgeable fraction from carpet after 4 hours (11%)** | | | | |
| Dry surface  Spraying | 1.37E-01 | 8.5E-02 | 161% | Not acceptable |
| **Infant crawling on treated surface with hand to mouth transfer**  **– dry surface dislodgeable fraction from carpet after 7 days (4%)** | | | | |
| Spraying | 4.97E-02 | 6E-02 | 83% | Acceptable |
| **Exposure during sleeping in a treated bed (dry)** | | | | |
| Dry surface  Adult | 7.67E-02 | 6E-02 | 128% | Not acceptable |
| Dry surface  Child | 1.07E-01 | 6E-02 | 178% | Not acceptable |
| Dry surface  Infant | 1.42E-01 | 6E-02 | 237% | Not acceptable |

Annex 6: Residue behaviour

**Etofenprox**

Intended Use (critical application):

* Indoor spraying use by non-professionals in private homes.

Active substances: Etofenprox

Formulation of biocidal product: Ready to use product

Place of treatment: Indoors (private home)

Target organisms: cockroaches and crawling species, flying insects.

Application rate for indoor spraying by non-professional users : 1 L of DIGRAIN SPRAY 2 g/L for a treated surface of 13 m2 up to 2 applications per year in case of infestation.

The intended use descriptions (indoor uses in private home for non-professional) of the etofenprox containing biocidal products for which authorisation is sought indicate that these uses might be relevant in terms of residues in food and feed. Therefore, mitigations measures are proposed (see section 2.2.5.2.4). Based on these, the product DIGRAIN SPRAY will not get into contact with food, feed and livestock and will not leave residues in commodities for human or animal consumption.

No further data are required concerning the residue behaviour.

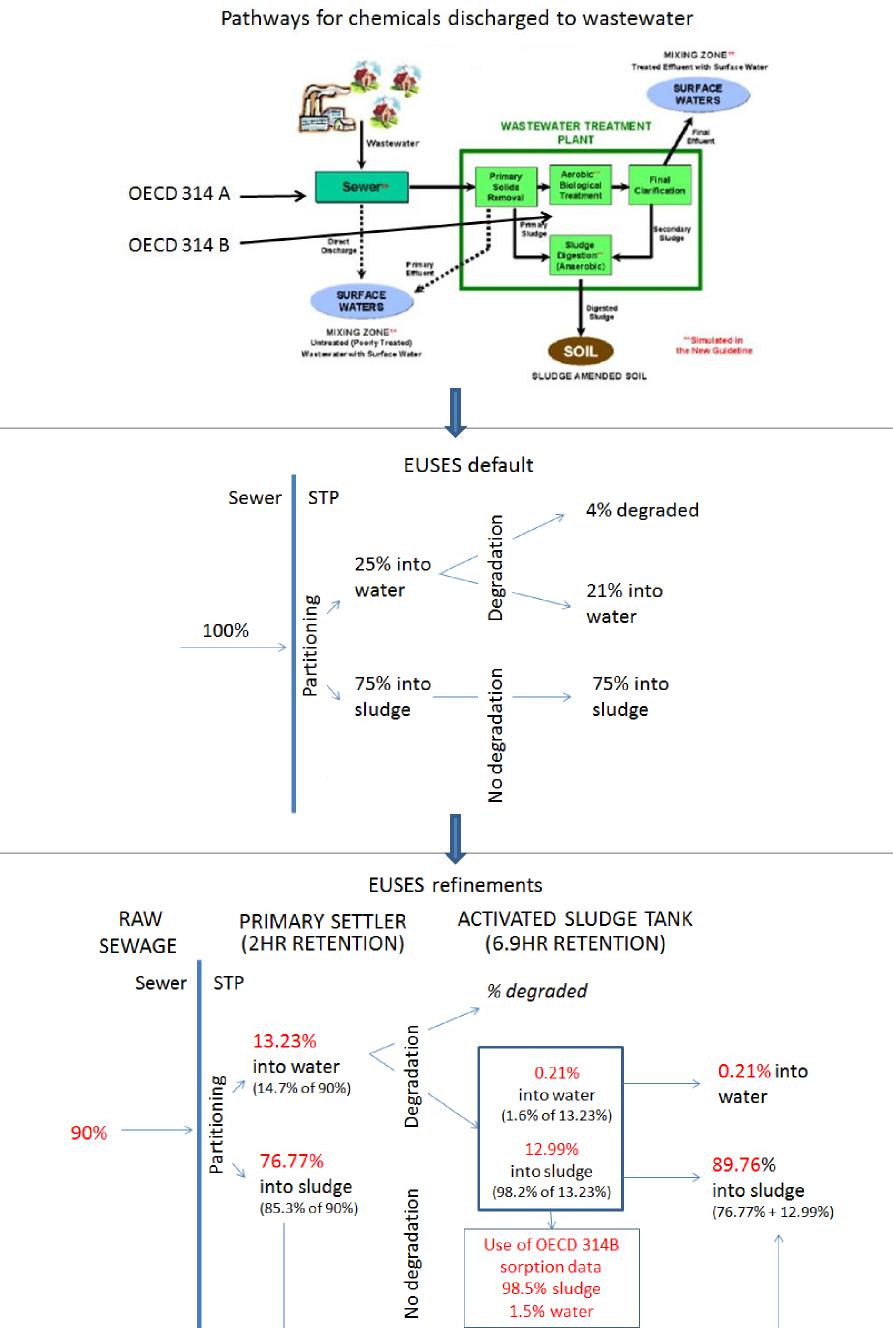
**MRLs on food and food of animal and cumulative risk assessment:**

The guideline on risk characterisation and assessment of Maximum Residue Limits (MRLs) for biocides EMA/CVMP/90250/2010 came into effect on 1 August 2015. MRLs establishment for biocidal active substance are initiated when consumer exposure represent more than 30% of ADI.

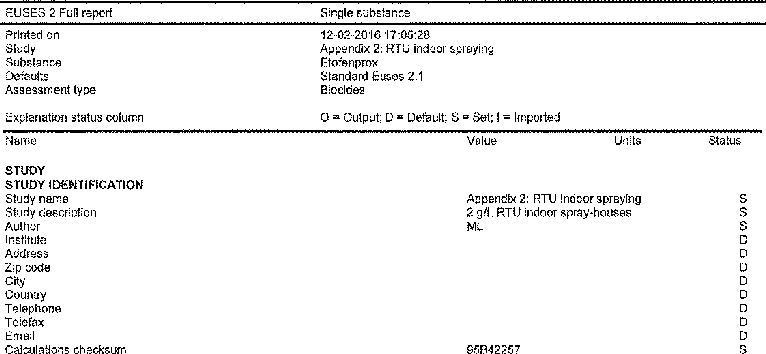
Based on risk mitigation measures the product DIGRAIN SPRAY will not get into contact with food, feed and livestock and will not leave residues in commodities for human or animal consumption. Hence consumer exposure after use of DIGRAIN SPRAY is negligible. Therefore, there is no need to establish biocides MRLs for etofenprox after use of DIGRAIN SPRAY.

Etofenprox is also authorized as a phytopharmaceutical product (PPP) but not used as a veterinary drug. As mitigation measures are proposed to reduce livestock and therefore consumer exposure, it is not necessary to perform a cumulative risk assessment.

Annex 7: Schematic to illustrate the refinement use of STP data



Annex 8: EUSES output file, indoor spray applications to private houses (private use)



|  |  |  |  |
| --- | --- | --- | --- |
| EUSES 2 Full repart | Single substance |  |  |
| Printed on Study Substance | 12-02-2016 17:05:28 Etofenprox  Appendix RTU indoor spraying | |  |
| Defaults | Standard Buses 2.1 | |  |
| Assessment type | Biocides |  |  |
| Name |  | Value Units | Status |
| DEFAULTS |  |  |  |
| DEFAULT IDENTIFICATION |  |  |  |
| General nome |  | Standard Euses 2.1 | D |
| Description |  | According to TGDs | D |
| CHARACTERISTICS OF COMPARTMENTS |  |  |  |
| GENERAL |  |  |  |
| Density of solid phase |  | 2.5 [kg,I-1] | 0 |
| Density of water phase |  | 1 [kg,I-1] | D |
| Density of air phase |  | 1,3E-03 [kg.1-1I | D |
| Environmental temperature |  | 12 [oC] | D |
| Standard temperature for Vp and Sol |  | 25 [oC] | D |
| Temperature correction method |  | Temperature correction for boat distribution | D |
| Constant ofJunge eguation |  | 0.01 [Pan] | D |
| Surface ares of aerosoi particles |  | 0.01 [m2..m-3] | D |
| Gas constant (8.314) |  | 8.314 [Pa.m3.mo1-1.1<-1] | D |
| SUSPENDED MATTER |  |  |  |
| Vokime fraction solicis h suspended motter |  | 0.1 [rn3.m-3] | D |
| Volume fraction water in suspended motter |  | 0.9 [rn3,m.-3) | D |
| Weight fraction of organic carbon in suspended motter |  | 0.1 [kg.kg-11 | D |
| Bulk density of suspended motter |  | 1.15E+03 ]kgwwlm-3] | O |
| Conversion factor wet-dry suspened malter |  | 4.6 fkgwwl.kgdwt-11 | D |
| SEDIMENT |  |  |  |
| Volume fraction sakis in sediment |  | 0.2 [m3.m-3] | D |
| Volume fraction water in sediment |  | 0.8 [m3.m-3] | D |
| Weight fraction of organic carbon 7n sediment |  | 0.05 [kg. kg-1] | D |
| SOIL |  |  |  |
| Volume fraction sakis in soli |  | 0.6 [rn3.m-3] | D |
| Volume fraction water in soli |  | 0.2 [m3.rn-3] | D |
| Volume fraction air in soi! |  | 0.2 [m3.m-3] | D |
| Weight fraction of organic carbon in soll |  | 0.02 [kg.kg-1] | D |
| Weight fraction of organic malter in soit |  | 0.034 [S0-1t0-1] | 0 |
| Bulk density of soif |  | 1.7E+03 [kgwwt.m-31 | O |
| Conversion factor wet-dry soli |  | 1.13 [kgwwl.kgdwt-1] | O |
| STP SLUDGE |  |  |  |
| Fraction of organic carbon in raw sewage siudge |  | 0.3 [kg.kg-1] | D |
| Fraction of organic carbon in settled sewage sludge |  | 0.3 [kg.kg-1[ | D |
| Fraction of argente carbon M activated sewage s1udge |  | 0.37 [kg.kg-11 | ❑ |
| Fraction of organic carbon in effluent sewage sludge |  | 0.37 [kg.kg-11 | D |
| DEGRADATION AND TRANSFORMATION RATES |  |  |  |
| Rate constant for abiotic degradation in STP |  | 0 [d-1] | D |
| Rate constant for abiotic degradation in bulk sediment |  | 0 [d-1] (12[DC]) | D |
| Rate constant for anaerobic biodegradation in sediment |  | 0 [d-1] (12[oC]) | D |
| Fraction of sediment compartment that is aerated |  | 0.1 [ro3.in-3] | D |
| Concentration of OH-radicals in atmosphere |  | 5E+05 [molecorn-3] | D |
| Rate constant for abiotic degradation in bulk soit |  | C [d-1] (12[oC]) | D |
| RELEASE ESTIMATION |  |  |  |
| Fraction of EU production volume for region |  | 100 [%] | D |
| Fraction of EU tonnage for reglon (private use) |  | 10 rh1 | ❑ |
| Fraction connected te sewor systems |  | 80 [%] | D |

EUSES 2.1.2 12-02-2016 17:05:28 Page: 2

|  |  |  |  |
| --- | --- | --- | --- |
| EUSES *2 FA* report Single substance | |  |  |
| Printed on 12-02-2016 17:05:25  Study Etofenprox  Substance Appendix 2: RTU indoor spraying  Defaults Standard Euses 2.1  Assessment type Biocides | |  |  |
| Name | Velue | Units | Statua |
| SEWAGE TREATMENT |  |  |  |
| GENERAL |  |  |  |
| Number of inhabitants feeding one STP | 1E+04 | [0q1 | D |
| Sewage flow | 200 | [Led-1.ri-1] | D |
| Effluent discharge rate of local STP | 2E+06 | [1.d-lj | O |
| Temperature correction for STP degractation | No |  | D |
| Temperature of air a bove aeration tank | 15 | [oC] | D |
| Temperature of water in aeration tank | 15 | roCI | D |
| Height of air column above STP | 10 | Eml | D |
| Number of inhabitants ef region | 2E+07 | [dg] | D |
| Number of inhabitants *e* continente system | 3.5E+08 | [ed] | O |
| Windspeed in the system | 3 | [m.s-11 | D |
| RAW SEWAGE |  |  |  |
| Mass of 02 binding material per person per day | 54 | [g.eq-1.d-1] | D |
| Dry weight solids produoed per person per dey | 0.09 | [kg.eg-1.d-1] | D |
| Density solids in raw sewage | 1.5 | [k01-1] | D |
| Fraction of organio carbon in raw sewage sludge | 0.3 | [kg,kg-1] | D |
| PRIMARY SETTLER |  |  |  |
| Depth cf primary settler | 4 | M | D |
| Hydraulic retention Erne of pernary settler | 2 | [hl | D |
| Density suspended and settled solids in primary sellier | 1.5 | [kg.1-1] | D |
| Fraction of organic carbon in settled sewage sludge | 0.3 | [kg .kg-1] | D |
| ACTIVATBD SLUDGE TANK |  |  |  |
| Depth of aeration tank | 3 | iml | D |
| Densify solids of activated sludge | 1.3 | [kg.I-1] | D |
| Concentration sakis of activated sludge | 4 | [kg.m-3] | D |
| Steady state 02 concentration in activated sludge | 2E-03 | [kg,m-3] | D |
| Mode of aeration | Surface |  | D |
| Aeraaon rate of bubble aeration | 1.31E-05 | [m3.s-1.eq-lj | D |
| Fraction of organic carbon in activated sewage sludge | 0.37 | [kg.kg-1] | D |
| Sludge foaffin9 rate | 0.15 | [kg.kg-l.d-1] | D |
| Hydraulic retention time in aerator (9-box STP) | 6.9 | [hrl | O |
| Hydraulic retention lime in aerotor (6-box STP) | 10.8 | [hr] | O |
| Sludge retention time of aeration tank | 9.2 | Pl | 0 |
| SOLIDS-LIQUIDS SEPARATOR |  |  |  |
| Depth of solids-iiquid separator | 3 | fml | D |
| Density suspended and settled solids in solids-liquid separator | 1.3 | [kg.1-1] | D |
| Concentration solids in effluent | 30 | [mg.I-1] | D |
| Hydraulic retention lime of solide-liquid separator | 6 | [hrj | D |
| Fraction of organic carbon in effluent sewage sludge | 0.37 | [kg.kg-1] | D |
| LOCAL DISTRIBUTION |  |  |  |
| AIR AND SURFACE WATER |  |  |  |
| Concentration in air e source strength 1 [kg.r1-1] | 2.78E-04 | [mg.m-31 | D |
| Standard deposition flux of aerosol-bound compounds | 0.01 | [mg.m-2.d-1] | D |
| Standard deposition flux of gaseous compounds | 4E-04 | [mg.m-2,d-1] | O |
| Suspended solids concentration in STP effluent mater | 15 | [m8.1-11 | n |
| Dettlon factor (rivera) | 10 | H | D |
| Flow rate of the river | 1.8E+04 | [rn3.d-t] | D |
| Calculate dilution from river flow rate | No |  | D |
| Dilution factor (comtal arecs) | 100 | H | D |

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| EUSES 2 Full report | Single substance |  |  |
| Printed on Study  Substance Defauits  Assessment type | 12-02-2016 17:05:28 Etofenprox  Appendix 2: RTU indoor spraying Standard Fuses 2.1 Biocides |  |  |
| Name | Value | Units | Status |
| SOI Io |  |  |  |
| Mixing depth of grassland soli | 0.1 | [ml | D |
| Dry sludge application rate on agrioultural soif | 5E+03 | [kg.ha-1.yr-1] | D |
| Dry sludge application rate on grassiand | 1000 | [kg.ha-1.yr-1] | D |
| Averaging lime soif (for terrestrial ecosystem) | 30 | [d] | D |
| Averaging tinte agriculture' soli | 180 | 'dl | D |
| Averaging borie grasstand | 180 | Idt | D |
| PMTC, air side of air-soif interface | 1 05E-03 | [m,s-1] | O |
| Stil-air PMTC (ainsoil interface) | 5,56E-06 | [m s-1.1 | D |
| Safi-water film PMTC (air-sali interface) | 5.56E-10 | [m ,s-1j | D |
| Mixing depth agricultural soli | 0,2 | Eml | D |
| Fraction of min water infiltrating soit | 0.25 | E-1 | D |
| Average annuel precipitation | 700 | [mm.yr-1] | o |
| REGIONAL AND CONTINENTAL DISTRIBUTION |  |  |  |
| CONFIGURATION |  |  |  |
| Fraction of direct regional emissions to seawater | 1 | E%1 | D |
| Fraction of direct continental ernissiona to seawater | 0 | [%) | D |
| Fraction of regional STP effluent to seawater | 0 | 1%] | D |
| Fraction of continental STP effluent Io seawater | 0 | 1%1 | D |
| Fraction of How from continental rivers to regional rivers | 0.034 | H | O |
| Fraction of How from continental rivers to regional sea | 0 | El | D |
| Fraction of flow from continental rivers to continental sea | 0.960 | iol | O |
| Nimbe of inhabitants of region | 2E+07 | [eg] | D |
| [Venter of inhabitants M the EU | 3.7E+08 | [eg] | D |
| Number of inhabitants of continental system | 3.5E+08 | [et11 | O |
| AREAS |  |  |  |
| REGÉONAL |  |  |  |
| Area (lando-rivers) of regional system | 4E+04 | [km2] | D |
| Area fraction of freshwater, region (excl. sea) | 0.03 | 1-1 | D |
| Area fraction of naturel sa, region (excl. sea) | 0.27 | Il | D |
| Area fraction of agriculture' soif, region (excl. ses) | 0,6 | H | D |
| Area fraction of industriatiurban soli, region (excl. sea) | al | [-] | D |
| Length of regional seawater | 40 | [km] | D |
| Width of regional seawater | 10 | [km] | D |
| Area of regional seawater | 400 | [km2] | O |
| Area (land+riversoisea) of regional system | 4.04E+04 | [km2] | O |
| Area fraction of freshwater, region (total) | 0,0297 | H | O |
| Area fraction of seawater, region (total) | 9.9E03 | [o] | O |
| Area fraction «naturel soit, region (total) | 0,267 | [-1 | 0 |
| Area fraction of agriculture' stil, region (total) | 0.594 | [-] | O |
| Area fraction of indestrialturban soli, region (total) | 0.099 | H | O |
| CONTINENTAL |  |  |  |
| Total ares of EU (continent+region, incl. sea) | 7.04E+06 | (km2] | D |
| Ares (landoriversosea) of continental system | 7E+06 | (km2] | O |
| Area (lendorivers) of continental system | 0.5E+06 | [km2] | O |
| Area fraction of freshwater, continent (excl. sea) | am | f-1 | D |
| Area fraction of naturei soit, continent (excl. sea) | 0.27 | 1-1 | D |
| Area fraction of agriculture' soli, continent (excl, sea) | 0.6 | H | D |
| Area fraction of industeatiurban soli, continent (excl. sea) | 0.1 | H | D |
| Area fraction of freshwateo, continent (total) | 0,015 | H | O |
| Ares fraction of seawater, continent (total) | 0.5 | Ï-1 | D |
| Area fraction of naturel sok, continent (total) | 0.135 | [-] | 0 |
| Area fraction of agriculture' soif, continent (total) | 0.3 | H | O |
| Area fraction of industrial/forban sou, continent (total} | 0.05 | H | 0 |
| MODERATE |  |  |  |
| Area of moderate system (incl.contlnent,regien) | 8.5E+07 | [km2] | D |
| Area of moderate system (exacontinent, region) | 7.8E+07 | [km2] | O |
| Area fraction of water, moderate system | 0.5 | H | D |
| ARCTIC |  |  |  |
| Area of arclic system | 4.25E+07 | [km2] |  |
| Area fraction of water, arctic system | 0.6 |  | D |

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| EUSES 2 Full report | Single substance |  |  |
| Printed on Study  Substance Defaulls  Assessment type | 12-02-2016 17:05:28 Etofenprox  Appendix 2: RTU indoor spraying Standard Eoses 2.1 Diacides |  |  |
| Name | Value | Units States | |
| TROPIC |  |  | |
| Area of tropic system | 1.275E+08 | [km2j D | |
| Area fraction of water, tropic system | 0.7 |  | |
| TEMPERATURE |  |  | |
| Environmental temperature, regional scats | 12 | loC] D | |
| Environmental temperature, continental state | 12 | [oC] D | |
| Environmental temperature, ninderate state | 72 | foC1 D | |
| Environmental temperature, arct1c sosie | -10 | [oCI D | |
| Environmental temperature, tropic state | 25 | [oCl D | |
| Enthalpy of vaporisation | 50 | [iti,mol-1] D | |
| Enthalpy of solution | 10 | 11(J.mol-11 D | |
| MASS TRANSFER |  |  | |
| Air-film PMTC (air-water interface) | 3,25E-03 | [m.s-1] 0 | |
| Walenfilm PMTC (air-water interface) | 4.1E-06 | [rms-11 O | |
| PMTC, air &de of air-sait interface | 1.05E-D3 | [m.s-1] O | |
| PMTC, soli side of air-s&1 interface | 1,95E-09 | [m.s-1] o | |
| Soif-air PMTC (air-soli interface) | 5.56E-06 | [m.s-1] D | |
| Soit-water film PMTC (air-soit interface) | 566E-10 | [nts-1] D | |
| Water-film PMTC (sediment-water interface) | 2,78E-06 | [rn.s-1] D | |
| Pore water PMTC (sediment-water Interface) | 2,78E-08 | [ms-1] D | |
| AIR |  |  |  |
| GENERAL |  |  |  |
| Atmospheric mixing height | 1000 | 1m] | D |
| VVindspeed M the system | 3 | [m.s-1] | D |
| Aerosol deposition velocity | 1E-03 | fm.s-11 | D |
| Aerosol collection officiency | 2E+05 | ii | D |
| RAIN |  |  |  |
| Average precipitation, regional system | 740 | frnm.yr-11 D | |
| Average precipltation, continental system | 700 | [mm.yr-1] D | |
| Average precipitation, moderato system | 700 | [mrn.yr-1] D | |
| Average pmcipltation, aras system | 250 | [mm.yr-1] D | |
| Average precipltaticn, tropic system | 1.3E+03 | Imm.yr-11 D | |
| RESIDENCE TIMES |  |  |  |
| Residence time of air, regional | 0.687 | fdl | O |
| Residence time of air, continental | 9.05 | IdJ | O |
| Residence time of air. moderate | 30.2 | [d] | O |
| Residence time of air, arctic | 22.3 | Icll | O |
| Residence time of &r, tropic | 38.6 | [d] | O |
| WATER |  |  |  |
| DEPTH |  |  |  |
| Water depth of freshwater, regional system | 3 | [m] | D |
| Waterdepth of seawater, regional system | 10 | Iffil | D |
| Waterdepth of freshwater, continental system | 3 | ImJ | D |
| Waterdepth of seawater, continental system | 200 | tril | D |
| Waterdepth, moderate system | 1000 | [m] | D |
| Waterdepth, arctic system | 1000 | [m] | D |
| Waterdepth, tropic system | 1000 | [il] | D |
| SUSPENDED SOLIDS |  |  |  |
| Suspended solids conc. freshwater, regional | 15 | [mg.1-1 ❑ | |
| Suspended serfs cone. seawater, regional | 5 | [mg.1-1 D | |
| Suspended solids cone freshwater, continental | 15 | [mg.1-1 D | |
| Suspended solids conc. seawater, continental | 5 | [mg.1-1 D | |
| Suspended solids cone. seawater, moderato | 5 | [mg.1-1 D | |
| Suspended solide sono. seawater, arclic | 5 | [mg.1-1 D | |
| Suspended solids conc. seawater, tropic | 5 | jrng,1-1 D | |
| Concentration solids in effluent, regional | 30 | [mg.1-1 D | |
| Concentration solids in effluent, continental | 30 | [mg.1-1 D | |
| Concentration biota | 1 | Ungwwf1-11 D | |

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| EUSES 2 Full report | Single substance |  | |
| Printed on Study  Substance Defautts  Assessment type | 12-02-2016 17:05:28 Etofenprax  Appendix 2: RTU indoor spraying Standard Euses 2.1 Biocides |  | |
| Name | Value | Units States | |
| RESIDENCE TIMES |  |  | |
| Residence time of freshwater, regional | 43.3 |  | |
| Residence time of seawater, regional | 4.64 | [d] | |
| Residence time of freshwater, continental | 172 | [d] | |
| Residence time of seawater, continental | 365 | [d] | |
| Residence time of water, moderate | 2.69E+03 | [d] | |
| Residence time of water, arctic | 5.84E+03 | [d] | |
| Residence time of water, tropic | 1.09E+04 | [d] | |
| SEDIMENT |  |  | |
| DEPTH |  |  | |
| Sediment mixing depth | 0.03 | [m] | |
| SUSPENDED SOLIDS |  |  | |
| (Blogenic) prod. susp. solids in freshwater, reg | 10 | [g,m-2.yr-1] | |
| (Biogenic) prod. susp. solids in seawater, reg | 10 | [g m-2.yr-1] | |
| (Biegenic) prod. susp. solids in freshwater, cont | 10 | [g.m-2.yr-1] | |
| (Blogenic) prod, susp, solids M seawater, cent | 5 | [g.m-2.yr-1] | |
| (Blogenic) prod. susp. solids in water, moderate | 1 | [g na -2.yr-1] | |
| (Blogenic) prod, susp. solids in water. arche | 1 | [g,m-2,yr-1] | |
| (Blogenic) prod. susp. solids in water, tropic | 1 | [g,m-2.yel] | |
| SEGMENTATION RATES |  |  | |
| Settling yelocity of suspended solids | 2.5 | [IA-1] | |
| Net sedimentation rate, freshwater, regional | 2.8 | [rnm.yr-1 |  |
| Net sedirnentation rate, seawater, regional | 1.53 | [atm .yr-1 |  |
| Net seclimentation rate, freshwater, continental | 2.75 | [mm.yeet |  |
| Met sedimentation rate, seawater, continental | 6.89E-03 | [mm.yr-1 |  |
| Net sedimentation rate, moderate | 2.8E-03 | [mm.yr-1 |  |
| Net seclimentahon rate, arctic | 2E-03 | [mm,yr-1 |  |
| Net sedirnentation rate, tropic | 2E-93 | [mm.yr-1 |  |
| SOIL |  |  | |
| GEt4ERAL |  |  | |
| Fraction of rain water infitrating sol | 0.25 |  | |
| Fraction of rain water running off soli | 0.26 |  | |
| DEPTH |  |  | |
| Chernical-dependent soli depth | No |  | |
| Mixing depth naturel soif | 0.05 | [m] | |
| Mixing depth agricultural soif | 0.2 | [fft] | |
| Mixing depth industrialfurban soif | 0.05 | [m] | |
| Mixing depth of soli, moderate system | 0.05 | [m] | |
| Mixing depth of soit, arctic system | 0.05 | [nl] | |
| Mixing depth of soit, tropic system | 0.05 | [m] | |
| EROSION |  |  | |
| Soli erosion rate, regional system | 0.03 | [mm.yr-1] | |
| Soit erosion rate, continental system | 0.03 | [mm.yr-11 | |
| Soli erosion rate, moderate system | 0,03 | [mm.yr-1] | |
| Soit erosion rate, arctic system | 0.03 | [mm.yr-1] | |
| Soit erosion rate, tropic system | 0.03 | [mm.yr-1] | |
| CHARACTERISTICS OF PLANTS, WORMS AND CATTLE |  |  | |
| PLANTS |  |  | |
| Volume fraction of water in plant tissue | 0.65 | im3.m-31 | |
| Volume fraction of ilpids in plant tissue | 0.01 | [m3.m-3] | |
| Volume fraction of air in plant tissue | 0,3 | [m3.rn-3] | |
| Correction for differences between plant iipids and octanot | 0,95 | [-] | |
| Bull( density of plant tissue (wel. weight) | 07 | [kg.I-1] | |
| Rate constant for metabolism in plants | 0 | [d-1] | |
| Rate constant for photolysis in plants | 0 | [it1-1] | |
| Leal surface arec | 5 | [m2] | |
| Conductance | 1E-03 | [ms-1] | |
| Shoot volume | 2 | Ill | |
| Rate constant for dilution by growth | 0.035 | [dl] | |
| Transpiration stream | 1 | ELd-ii | |

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| RUSES 2 Full report | Single substance |  |  |
| Printed on Study  Substance Defaults  Assessment type | 12-02-2016 17:05:28 Etofenprox  Appendix 2: RTU lndoor spraying Standard Euses 2.1 Biocides |  |  |
| Name | Value | Units | Status |
| WORMS |  |  |  |
| Volume fraction of water Inside a worm | 0,84 | [m3.m-31 | D |
| Volume fraction of lipids Inside a worm | 0.012 | [m3.rri-3] | D |
| DensIty of earthworms | 1 | [kgivwt.1-1] | D |
| Fraction of gut loading in worm | 0,1 | [kg.kg-11 | D |
| CATTLE |  |  |  |
| Daily intake for calife of grass (dryweight) | 16,0 | [kg.d-l] | D |
| Conversion factor grass from dryweight to wetweight | 4 | [kg.kg-1] | D |
| Daily intake of soli (dryweight) | 0.41 | [kg.d-1] | D |
| Daily inhalation rate for cattle | 122 | [m3.d-1] | D |
| Daily intake of drinking water for cattle | 55 | [I.d-1] | D |

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| RUSES 2 Full report Single substance | |  |  |
| Printed on 12-02-2016 17:0628  Study Etofenprox  Substance Appendix 2: RTU indoor spraying  Defaults Standard aises 2.1  Assessment type Biocides | |  |  |
| Name | Value | Units | Status |
| SUBSTANCE |  |  |  |
| SUBSTANCE IDENTIFICATION |  |  |  |
| Generai rame | Etofenprox |  |  |
| Description |  |  |  |
| CAS-No |  |  | D |
| EC-notification no. |  |  | D |
| EiNECS no. |  |  | D |
| PHYSICO-CHEIVIICAL PROPERTIES |  |  |  |
| Moiecular weight | 376.5 | [g.moi-1] S | |
| Melting point | 37.4 | [CC] S | |
| Bolling point | 72 | [oC] D | |
| Vapour pressure at test temperature | 8.13E-07 | [Pa] S | |
| Temperature at which vapeur pressure was measured | 25 | [oC] D | |
| Vapour pressure at 25 [oC] | 8.13E-07 | [Pa] O | |
| Octanol-water partition coefficient | 6.9 | [log10] S | |
| Water solubility at test temperature | 0,0225 | 1ing.1-11 S | |
| Temperature e which solubility was measured | 20 | 100] S | |
| Watersoiubility at 25 [oC] | 0.0241 | [mg.1-1] O | |
| PARTITION COEFFICIENTS AND BIOCONCENTRATION FACTORS |  |  |  |
| ,SOLIDS-WATER |  |  |  |
| Chemical Bass for Koc-QSAR | Predorninantly hydrophobies | | S |
| Organic carbon-water partition coefficient | 2,8524E+04 | [1.kg-1 S | |
| Solies-water partition coefficient in soli | 570 | [l.kg-1 O | |
| Solids-water partition coefficient ln sediment | 1.43E+03 | [1.kg-1 O | |
| Solids-water partition coefficient suspended mener | 2.85E+03 | [1.kg-1 O | |
| Solids-water partition coefficient in raw sewage sludge | 8.56E+03 | [1.kg-1 O | |
| Solids-water partition coefficient in settled sewage sludge | 8.56E+03 | [1.kg-1 O | |
| Solids-water partition coefficient in actitiated sewage sludge | 1,06E+04 | [{\_kg-1 O | |
| Solids-water partition coefficient in effluent sewage sludge | 1.06E+04 | [1.kg-1 O | |
| Soif-water partition coeffielent | 856 | [m3.m-3] O | |
| Suspended matter-water partition coefficient | 714 | [m3.m-3] O | |
| Sedimenbwater partition coefficient | 714 | [m3.m-3] O | |
| AIR-WATER |  |  |  |
| Environmental temperature | 12 | [oC] D | |
| Water solubility at environmental temperature | 0.0201 | [ing.1-1] O | |
| Vapour pressure at enyironmental temperature | 3.24E-07 | [Pa] O | |
| Suldicooled liquid vapeur pressure | 693E-07 | [Paj O | |
| Fraction of cheinical associated with aerosol perfides | 0.994 | H 0 | |
| Henry's law constant at test temperature | 0.0136 | [Pa.m3.mo1-1] S | |
| Temperature at which Henrys law constant was measured | 25 | [CC] D | |
| Henrys law constant at 25 [oC] | 0.0136 | [Pairrt3,misl-1] O | |
| Henrys law constant at erwiromental temperature | 8.51E-03 | [Pa.m3.mo1-11 O | |
| Air-water partitioning coefficient | 2.75E-06 | [m3.m-3] O | |
| BIOCONCENTRATION FACTORS |  |  | |
| PREDATOR EXPOSURE |  |  | |
| Bioconcentration factor for earthwerms | 05281E+04 | [i.kgww41] | |
| HUMAN AND PREDATOR EXPOSURE |  |  | |
| Bioconcentration factor for fie | 2.565E+03 | [i.kgwwt.-1] | |
| QSAR valid for calculation of BCF-Fish | Yes |  | |
| Biomagnification factor in fiel | 2 |  | O |
| Biomagnification factor in predetor | 2 | [-] | O |
| HUMAN EXPOSURE |  |  |  |
| Partition coefficient betweenteayes and air | 1.31E+10 | [m3.m-3] O | |
| Partition coefficient between plant tissue and water | 3.59E+04 | [113.m-3] O | |
| Transpiration-stream concentration factor | 0.0378 | [-1 O | |
| Bioaccumulation factor for meat | 0.0794 | 1d.kg-1] O | |
| Bioaccomulation factor for rniik | 0.0251 | [d.kg-11 O | |
| Purification factor for surface water | 0.25 | [-] O | |
| DEGRADATION AND TRANSFORMATION RATES |  |  |  |
| CHARACTARIZATION |  |  |  |
| Characterizallon of biodegradability | Not biodegradable |  | D |

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| EUSES 2 Full report | Slngte substance |  | |  |
| Printed on Study Substance | 12-02-2016 17:05:28 Etofenprox  Appendix RTU incloor spraying | | |  |
| Defauits | Standard Euses 2.1 |  | |  |
| Assessment type | Biocides |  | |  |
| Name |  | Value Units | | Status |
| STP |  |  | |  |
| Degradation calculation methad in STP |  | First order, standard OECD/EU tests | | D |
| Rate constant for biodegradation in STP |  | 1.3 [d) (DT50) | | S |
| Total rate constant for degradation in STP |  | 0.533 [d-1] | | O |
| Maximum growth rate of opacifie mieroorganisms |  | 2 [d-1] | | D |
| Half saturation concentration |  | 0.5 18 .m-3] | | D |
| WATER/SEDIMENT |  |  | |  |
| WATER |  |  | |  |
| Rate constant for hydrolysis in surface water |  | 6,93E-07 [d-1] (12[oC]) | | 0 |
| Rale constant for phololysts in surface water |  | 47 [d] (DT50) | | S |
| Rate constant for biodegradation in surface water |  | 38.1 [cl] (DT50,12[oC]) | | S |
| Total rate constant for degradation tri bulk surface waler |  | 0.166 [d-11 (12[0C1) | | O |
| Rate constant for biodegradation in saltwaler |  | 0 [d-1] (12[oC]) | | O |
| Total rate constant for degradation tri bulk saltwater |  | 0.147 [d-11 (12[0C]) | | O |
| SEDIMENT |  |  | |  |
| Rate constant for biodegradation in aerated sediment |  | 61.1 [d] (DT50,12[oC1) | | S |
| Total rate constant for degradation in bulk sediment |  | 1.13E-03 [d-1] (12[oC]) | | 0 |
| AIR |  |  | |  |
| Specific degradation rate constant with OH-radicals |  | 0 [cm3.motecle-1] | | D |
| Rate constant for degradation in air |  | 6.2 [hr] (DT50) | |  |
| SOIL |  |  | |  |
| Rate constant for biodegradation in bulk soif |  | 22.8 [d] (DT50,12[toCI) | | S |
| Total rate constant for degradation in bulk soit |  | 0.0304 [d-11 (12[oC]) | |  |
| REMOVAL RATE CONSTANTS SOIL |  |  | |  |
| Total raie constant for degradation M bulk soft |  | 0.0304 [d-1 | (12[oC]) | O |
| Rate constant for volatilisation from agrleuttural oeil |  | 1.46E-06 [c1-1 |  | 0 |
| Rate constant far leaching from agriculture' soit |  | 2.8E-06 [(1-1 |  | O |
| Total rate constant for removal from agricultural top soif |  | 0.0304 [d-1 |  | O |
| Rale constant for volatilisation from grassland soli |  | 2.9E-06 [d-1 |  | 0 |
| Rate constant for leaching from grassland soif |  | 5,6E-06 [d-1 |  | O |
| Total rate constant for removal from grassland top soif |  | 0.0304 [d-1 |  | O |
| Rate constant for volatilisation from 4ndusirtal soit |  | 5.8E-06 [d-1 |  | 0 |
| Rate constant for leaching from industrial soil |  | 1.12E-05 [d-1 |  | 0 |
| Total rate constant for removal from industrial soit |  | 0.0304 [d-1 |  | 0 |

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Study Etofenprox

Substance Appendix RTU indoer spraying

Oefaults Standard Euses 2.1

Assessment type Biocides

Name Value Units Status

|  |  |
| --- | --- |
| RELEASE ESTIMATION  BIOCIDE SCENARIO INPUT DATA Usage/production tige  Scenario cholce for biocides Additionat scenario information | Non-professional use  (18) Insecticides  (18.2.1)Indoor, spray application |

PRIVATE USE

Emission scenario Local omissions (STP) S

INTERMEDIATE RESULTS

RELEASE FRACTIONS AND EIVIISSION DAYS

PRIVATE USE GENERAL

Fraction of active ingredient 0.2

Surface or air space treatment Surface treatment (nrea) S

Application soupe General surface treatment S

Troatment rate, amount of product per area 0.15

Arca of treated surface, house 388 [m2]

TreatMent rate, amount of product per volume ?? [9.71-3] D

Volume of treated air, house 58 (m31

PRÉPARATION 112

Nurnbor of preparations per day, house 1 H 0

Quantity of product used per preparation, house 2.89E+03 [g] 0

Type of formulation Liquid S

Type of container 1 liter S

Fraction emitted to air during mixingiloading 0 H S

Fraction emitted to the applicator during mixingiroading 0 H S

Fraction emitted to the froor during mixingkading G H S

|  |  |
| --- | --- |
| PREPARATEON 212  HOUSES  Emission to air during mixing/loading Emission to applicator during mixingilooding Emission to four during mixing/loading | * [g.d-1] O * [g.c1-1] O * (g,d-l] 0 |

APPLICATION 112

Number of applications per day, house 1 [-] O

Ouantity of product used per application, house 2.89E+03 [g] O

Fraction emitted to air during application 0.02 H O

Fraction emitted to the applicator during application 0.02 H 0

Fraction emitted to the fluor during application 0.11 H 0

Fraction emitted to treated surfaces during apptication 0.85 H O

|  |  |
| --- | --- |
| APPLICATION 212  HOUSES  Emission to air during application  Emission to applicator during application  Emission to oor during application  Emission to treated surfaces during application | 0.118 [g .d-l] O  0.115 Igid-11 O  0.535 [g.d-1] O  4.1 [g dl] O |

CLEANING 1/2

VVashable or disposable applicators Washable S

Fraction emitted to Saki waste from appricator 0 H O

Fraction emitted to wastewater from applicator 1 H 0

Cfeaning method for treated surfaces Othe methods S

Fraction emitted to solid waste from cieaning treated surfaces 0 H O

Fraction emitted to wastewater frorn cleaning treated surfaces 1 FI o

Cieaning efficiency 50 Wol 0

CLEANING 2/2 HOUSES

Emission to air during cleaning 0 [g,d-11 O

Emission to soild waste from applicator G [g.d-13 O

Emission to solid waste from treated surfaces 0 (g.d-11 O

Emission to wastewater from applicator 0.115 [0.d-1] O

Emission to wastewater from treated surfaces 2.77 [g.d-11 O

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Study Etofenprox

Substance Appendtx 2: RTU indoor spraying

Defaults Standard Euses 2.1

Assessment type Biocides

Name Value Units Status

TOTAL

Total emission to air from one bouse 1.16E-04 1kg.d-11 O

'ratel emission to wastewater from one house 2.89E-03 [kg.d-1] O

Total emission ta solid waste from one bouse 0 [kg.d-1] O

Number of houses per STP 4E-1-03 (f] O

Simultansity factor 0.204 >1 S

Local emission to wastewater during episode 0.0236 [kg.d-1] O

Number of emission deys per year 1 H O

|  |  |
| --- | --- |
| REGIONAL AND CONTINENTAL RELEASES  PR1VATE USE  REG1ONAL  Regionai release to air  Regional release to wastewater  Regionai release to surface water  Regional release ta industrial son  Regional release to agrioultural soil  CONTINENTAL  Continental release to air  Continental release to wastewater Continental release to surface water Continental release to industriel soit Continental release to agriculture! soif  REGIONAL AND CONTINENTAL TOTAL MISSIONS Tata regional emission to air  Tata regional omission to wastewater Tata regionai emission to surface water Tota regionai emission to industrial soif Tata regional emission to agricultural soif Tota continental emission ta air  Tata continental emission to wastewater Tata continental emission to surface water Tata continental emission fo industrial soi! Teta continental emission to agriculture! soli | 0 [kg.d-1] O   * [kg.d-1] O * [kg.d-1] O * [kg.ci-1] O * [kg .d-1] O * kgid-11 O * kg.d-1] O   0 kgid-11 0   * kg.d-1} O * kg.d-11 O * kg.d-11 O * kg.d-11 O   0 kg.d-11 O  0 kg.d-11 O   * kg.d-11 O * kg.c1-11 O * kg.d-11 O * kg.d-11 O   lL kg.(1-13 O   * kg.d-11 O |

LOCAL IPRIVATE USE]

Local emission to air during episode 0 fkg.d-l] O

Emission to air calculated by special scenarii] Yes O

Local emission to wastewater during episode 0.0236 [kg.d-1] O

Emission to water calculated by special scenaria Yes O

Specific biocides scenado evellabie Yes D

Show this step in further calculations Yes O

Intermittent release No D

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| --- | --- | --- | --- |
| EUSES 2 Full report | Single substance |  |  |
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| Name | Value | Units | Status |
| DISTRIBUTION |  |  |  |
| SE1NAGE TREATMENT |  |  |  |
| CONTINENTAL |  |  |  |
| Frachon of omission directed to air | 0 | PA] | 0 |
| Fraction of omission directed to water | 0 | [U] | 0 |
| Fraction of emission directed to sludge | 0 | 1%1 | O |
| Fraction of the emission degraded | 0 | [%] | O |
| Total of fractions | 0 | [A] | 0 |
| Indirect emission to air | 0 | [kg.d-1) | 0 |
| Indirect emission to surface water | Ci | [kg.d-1] | 0 |
| Indirect emission to agricultural soif | 0 | [kg.d-1[ | O |
| RÉGIONAL |  |  |  |
| Fraction of omission directed to air | 0 | [iliA] | O |
| Fraction of emission directed M water | 0 | [A] | O |
| Fraction of omission directed M sludge | 0 | ['A] | 0 |
| Fraction of the emission degraded | 0 | [io] | 0 |
| Total of fractions | 0 | [%] | 0 |
| Indirect omission to air | 0 | [kg.d-1] | O |
| Indirect emission to surface water | 0 | [kg.d-1] | O |
| Indirect omission to agriculture! soif | 0 | [kg.d-1] | O |
| [PRIVATE USE] |  |  |  |
| INPUT AND CONFIGURATION [PRIVATE LISE] |  |  |  |
| INPUT |  |  |  |
| Use or bypass STP (local freshwater assessment) | Use STP |  | D |
| Use or bypass STP (local marine essesernent) | Use STP |  |  |
| Local omission M wastewater during eptsode | 0.0236 | [kg.d-1] | O |
| Concentration M untroatod wastewater | 0.0118 | [rng.t-1] | 0 |
| Local omission entering the STP | 0.0236 | [kg.c1-1] |  |
| CONFIGURATION |  |  |  |
| Type of local STP | With primary settier (9-box) D | |  |
| Numbor of inhabitants feeding this STP | 1E+04 | fecil | O |
| Effluent discharge rate of this STP | 2E+06 | [I.d-1[ | O |
| CalculaM dilution from river flow rate | No |  | O |
| Flow rate of the river | 1.8E+04 | [m3.f1-1] | O |
| Dilution factor (rivais) | 10 | tri | O |
| Dilution factor (coastal areas) | 100 | 1-1 | O |
| OUTPUT [PRIVATE USE] |  |  |  |
| Fraction of omission directed to air by STP | 2.5E-03 | [%] | 0 |
| Fraction of omission directed M water by STP | 0.21 | [%] | S |
| Fraction of omission directed to sludge by STP | 89.76 | rh] | S |
| Fraction of the emission degraded in STP | 9 | *Mi* | S |
| Total of fractions | 90 | Pifii | O |
| Local indirect emission to air from STP during episode | 5.9E-07 | [kg.ci-1] | O |
| Concentration in untreatod wastewater | 0.0118 | Img.1-11 | O |
| Concentration of chemical (total) in the STP-effluent | 2.47E-05 | [mg.1-1] | O |
| Concentration in effluent exceeds solubilify | No |  | O |
| Concentration in dry sewage sludge | 26.8 | [mg.kg-1] | O |
| PEC for rrilermorganisms in the STP | 2.47E05 | [mg.l-1] | O |

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| Printed on 12-02-2016 17:05:28  Study Etofenprox  Substance Appendix 2: RTU indoor spraying  Defaults Standard Euses 2.1  Assessment type Biocides | | |  |  |
| Name | | Value | Units | Status |
| REGIONAL, CONTINENTAL AND GLOBAL DISTRIBUTION | |  |  |  |
| PECS | |  |  |  |
| REGIONAL | |  |  |  |
| Regiona | PEC in surface water (total) | 0 | [mg,t-1] | O |
| Regiona | PEC in seawater (total) | 0 | [mg.I-1] | O |
| Regiona | PEC in surface water (dissolved) | 0 | [mg.I-1] | O |
| Qualitative | assessment met be needect (TGD Part II, 5\_6) | No |  | O |
| Regiona | PEC in seawater (dissolved) | 0 | [mg.1-1] | O |
| Qualitative | assessrnent might be needed (TOI) Part II, 5.6) | No |  | O |
| Regiona | PEC h air (total) | 0 | [rng.m-3] | O |
| Regiona | PEC h agricultural soit (total) | 0 | [mg.kgwwt-1] | O |
| Regiona | PEC h pore waler of agrieultural soifs | 0 | [mg.1-1] | O |
| Regiona | PEC in natural sait (total) | 0 | [mg.kgwwt-1] | O |
| Regiona | PEC in industrial soif (total) | 9 | [mg.kgwwt•1] | O |
| Regiona | PEC h sediment (total) | 0 | [mg.kgwwt-1] | O |
| Regiona | PEC h seawater sediment (total) | 0 | [mg.kgwwt-1] | O |
| CONTINENTAL | |  |  |  |
| Continental PEC In surface water (total) | | 0 | [mg.t-1] | O |
| Continental PEC h seawater (total) | | 0 | [mg.!-1] | O |
| Continental PEC in surface waler (dissolved) | | 0 | [mg.I-11 | O |
| Continental PEC h seawater (dissolved) | | 0 | [mg.I-1] | O |
| Continentaf PEC h air (total) | | 0 | [mg,m-3] | O |
| Continental PEC h agrlcultural soif (total) | | 0 | rmg.kgwwt-11 | O |
| Continentat PEC h pore water of agricuitural soifs | | 0 | [mg.I-1] | O |
| Continental PEC h natural soli (total) | | 0 | [mg.kgwyvt-1 ] | O |
| Continental PEC h industrial soit (total) | | 0 | [mg.kgwyvt-1I | O |
| Continental PEC h sediment (total) | | 9 | [mg.kgwwt-1] | O |
| Continental PEC in seawater sediment (total) | | 9 | [mg.kgwart-1] | O |
| GLOBAL: MODERATE | |  |  |  |
| Moderate PEC h water (total) | | 0 | [mg.1-1] | O |
| Moderate PEC in water (dissolved) | | 0 | [mg.1-1] | O |
| Moderate PEG in air (total) | | 0 | [mg.m-3] | O |
| Moderato PEC in soif (total) | | 0 | [mg.kgwart-1] | O |
| Moderate PEC in sediment (total) | | 0 | [mg.kgwwt-1] | O |
| GLOBAL: ARCTIC | |  |  |  |
| Arctic PEC in water (total) | | 0 | [mg.I-1] | O |
| Arctic PEC h water (dissolved) | | ❑ | [mg.1-1] | O |
| Arctic PEC h air (total) | | 0 | [mg.m-3] | O |
| Arctic PEC h soit (total) | | 0 | [mg:4:0mM ] | O |
| Arctic PEC h sediment (total) | | 0 | [mg.kgarwa-1] | O |
| GLOBAL: TROP1C | |  |  |  |
| Tropic PEC in water (total) | | 0 | [mg.1-11 | O |
| Tropic PEC in water (dissolved) | | 0 | [mg.1-1] | O |
| Tropic PEC in air (total) | | 0 | [mg.m-3] | O |
| Tropic PEG h soli (total) | | 0 | Img.kgwixib11 | O |
| Tropic PEC in sediment (total) | | 0 | [mg.kgwwt•1j | O |
| STEADY-STATE FRACTIONS | |  |  |  |
| REGIONAL | |  |  |  |
| Stearly-state mass fraction h regional froshwatar | | ?? | Pii, | O |
| Steady-state mass fraction h regional seawater | | ?? | t'Al | O |
| Steady-state mass fraction h regional air | | 7? | 1%1 | O |
| Steady-state mass fraction h regional agir:cultural soli | | ?? | 'Yr] | O |
| Steady-state mass fraction h regional natural soli | | ?? | i%1 | O |
| Steady-state mass fraction h regional industrial soif | | ?? | 1%1 | O |
| Steady-state mass fraction h regional freshwater sediment | | ?? | PM | O |
| Steady-state mass fraction h regional seawater sediment | | ?? | 1%] | 0 |

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Substance Appendix 2: RTU indoor spraying

Defaults Standard Euses 2.1

Assessment type Biocides

Name Value Units Slatus

|  |  |  |  |
| --- | --- | --- | --- |
| CONTINENTAL |  |  |  |
| Steady-state mass fraction In continental freshwater | ?? | [%] | O |
| Steady-state mass fraction in continental seawater | ?? | [%] | O |
| Steady-state mass fraction In continental air | 7? | [%] | 0 |
| Steady-state mass fraction In continental agricultural soit | ?? | [11%1 | O |
| Steady-state mass fraction In continental natural soit | ?? | [1%] | O |
| Steady-state mass fraction in continental industrial soit | ?? | [%] | o |
| Steady-state mass fraction in continental freshwater sediment | ?? | [%] | O |
| Steady-state mass fraction h continental seawater sediment | ?? | [%] | 0 |
| GLOBAL: MODERATE |  |  |  |
| Steady-state mass fraction in moderate water | ?? | rio) | o |
| Steady-state mass fraction in moderate air | ?? | [A) | 0. |
| Steady-state mass fraction h moderate soif | ?? | Cvo) | O |
| Steady-state mass fraction h moderate sediment | ?? | [%] | o |
| GLOBAL: ARCTIC |  |  |  |
| Steady-state mass fraction h arctic water | ?? | riol | 0 |
| Steady-state mass fraction h arctic air | ?? | [%] | O |
| Steady-state mass fraction h amtic soit | ?? | [h] | O |
| Steady-state mass fraction in arctic sedlment | ?? | [%] | 0 |
| GLOBAL: TROP1C |  |  |  |
| Steady-state mass fraction h tropic water | ?? | [%] | O |
| Steady-state mass fraction h tropic air | ?? | rAl | O |
| Steady-state mass fraction h tropic soit | ?? | M1 | O |
| Steady-state mass fraction in tropic sediment | ?? | (%) | O |
| STEADY-STATE MASSES |  |  |  |
| RÉGIONAL |  |  |  |
| Steady-state mass in regional freshwater | 0 | [kg] | O |
| Steady-state mass in regional seawater | 0 | [kg] | O |
| Steady-state mass in regional air | o | [kg) | O |
| Steady-state mass in regional agricultural soif | o | [kg] | O |
| Shady-state mass in regional neural sait | 0 | [kg] | O |
| Steady-state mass in regional industrial soi! | o | [kg) | O |
| Steady-state mass in regional freshwater sediment | 0 | [kg] | O |
| Steady-state mass in regional seawater sediment | 0 | [kg] | o |
| CONTINENTAL |  |  |  |
| Steady-state mass in continental freshwater | D | [kg] | O |
| Steady-istate mass in continental seawater | 0 | [kg] | O |
| Steady-state mass in continental air | 0 | [kg] | O |
| Steady-state mass in continental agricultural soli | 0 | [kg] | O |
| Steady-state mass in continental neural soi! | 0 | [11g] | O |
| Steady-state mass in continental industrial soif | 0 | [kg] | 0 |
| Steady-state mass in continental freshwater sediment | 0 | [kg] | O |
| Steady-state mass in continental seawater sediment | 0 | [kg] | 0 |
| GLOBAL: MODERATE |  |  |  |
| Steady-state mass in moderate water | ci | [kg] | O |
| Steady-state mass in moderate air | 0 | [kg] | 0 |
| Steady-state mass in moderate soli | 0 | [h£1] | O |
| Steady-state mass in moderate sediment | 0 | [kg] | O |
| GLOBAL: ARCTIC |  |  |  |
| Steady-state mass in arctie water | Cl | [kg] | 0 |
| Steady-state mass in arctie air | 0 | [kg] | O |
| Steady-state mass in arctie soit | 0 | [kg] | O |
| Steadyestate mass in arctie sediment | o | tkol | O |
| GLOBAL; TROPIC |  |  |  |
| Steady-state mass in tropic water | 0 | !kg} | O |
| Steady-state mass in tropic air | o | [kg] | O |
| Steady-state mass in tropic soi! | 0 | lkg] | 0 |
| Steady-state mass in tropic sediment | o | [kg] | O |

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Substance Appendix 2; RTU indoor spraying

Defaults Standard Euses 2,1

Assessment type Biocides

Name Value Units Stem

|  |  |  |  |
| --- | --- | --- | --- |
| LAPE CYCLE STEPS FRIVATE USE] LOCAL CONCENTRATIONS AND DEPOSITIONS [PRIVATE USE] AIR |  |  |  |
| Concentration h air during emission episode | 1.64E-10 | [rng.m-3] | O |
| Annuel average concentration hi air, 100 nt from point source | 4.49E-13 | ring.m-31 | O |
| Total deposition flux during mission episode | 5,56E-09 | [ing,m-2,r1-1( | O |
| Annuai average total deposition flux | 1.51E-11 | [mg.m-2.d-1] | O |
| WATER, SEDIMENT |  |  |  |
| Concentration in surface water during emission episode (dissoived) | 2.37E-06 | [mg,1-1] | O |
| Concentration in surface water exceeds solubility | No |  | O |
| Annuel average concentration h surface water (dissotved) | 6,5E-Og | [mg.1-1] | O |
| Concentration in seawater during emission episode (dissoived) | 2.37E-07 | [mg:1-1] | O |
| Annuel average concentration in seewater (dissolved) | 6.5E-10 | [ing.1-1] | O |
| BOIL, GROUNDWATER |  |  |  |
| Concentration in agric. soif averaged over 30 deys | 0.0258 | fmg.kgwwl-1) | O |
| Concentration in agric. soi! averaged over 180 deys | 7.16E-03 | [mg,kgww1-1] | Q |
| Concentration in grassland averaged over 180 days | 2.136E-03 | [ing,kgww1-1] | O |
| Fraction of sMady-state (agriculture! soif) | 1 | H | 0 |
| Fraction of steadystate (grassland soit) | 1 | H | O |
| LOCAL PECS (PRIVATE USE] |  |  |  |
| AIR |  |  |  |
| Animal average local PEC h air (total) | 4.49E-13 | [mg.rn-3] |  |
| WATER, SEDIMENT |  |  |  |
| Local PEC in surface water during mission episode (dissoived) | 2.37E-06 | trng,1-1] | O |
| Qualitative HSSAssment might be needed (TGD Part II, 5,6) | No |  | O |
| Annuel average local PEC in surface water (dissoived) | 6.5E-09 | [mg,i-1] | O |
| Local PEC in fresh-water sedirnent during mission episoda | 1.47E-03 | [mg.kgwvit-1] | O |
| Local PEC in seawater during emission episode (dissolved) | 2.37E-07 | img,i-11 | 0 |
| Qualitative assessmerit might be needed (TGD Part H, 6,6) | No |  | O |
| Annuel average local PEC in seawater (dissoived) | 8.5E-10 | [mg.I-1] | O |
| Local PEC h manne sediment during emission episode | 1.47E-04 | (mg.kgww1-1) | O |
| SOIL, GROUNDWATER |  |  |  |
| Local PEC h agric. sait (total) averaged over 30 deys | 0.0258 | img.kgww1-11 | O |
| Local PEC in agric. soil (total) averaged over 180 days | 7.16E-03 | jmg,kgwvit-11 | O |
| Local PEC in grassland (total) averaged over 180 clays | 2.86E-03 | [mg.kgwwt-1] | O |
| Local PEC in pare water of agriculture! soli | 1,42E-05 | [mg.l-1] | O |
| Local PEC in pore water of grassland | 5.69E-06 | [mg.1-1] | O |
| Local PEC in groundwater Linder agriculture! sois | 1.42E-05 | img.1-11 | O |

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Substance Appendix 2: RTU incicor spraying

Defaults Standard Euses 2.1

Assessment type Biocides

Name Value Units Statua

EXPOSURE

SECONDARY POISONING

SECONDARY POISONING [PRIVATE USE]

Concentration in fish far secondary palsoning (freshwater) 1.67E-05 [mg.kgwwt-1]

Concentration in earthworms from agricultural soil 0.809 Impikg-11

Concentration in fish for seconclary poisoning (marine) 1,67E-06 rrig.kgvewt-1]

Concentration in fish-eating marine top-predators 6.57E-07 [mg.kgwvid-1]

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| Name | Value | Units | Status |
| EFFECTS |  |  |  |
| INPUT OF EFFECTS DATA |  |  |  |
| MICRO-ORGANISMS |  |  |  |
| Test system | Activated sludge growth inhibition, IS0-15522 | |  |
| EC50 for micro-organisms in a STP | ?? | [mg.1-1] | D |
| EC10 for micro-organisms ln a STP | ?? | fmg.1-11 |  |
| NOEC for micro-organisms in a STP | ?? | Img.1-11 |  |
| AQUATIC ORGANISMS |  |  |  |
| FRESH WATER |  |  |  |
| 1..(E)C50 SHORT-TERNI TESTS |  |  |  |
| LC50 for fish | ?? | [mg.1-1( | D |
| L(E)C50 for Daphnie | 77 | [mg.1-11 | D |
| EC50 for alose | ?? | [mg.1-1] | D |
| LC50 for addilicnaltaxonomic croup | 7? | fmg.1-11 | D |
| Aguatic species | &ber |  | D |
| NOEC LONG-TERM TESTS |  |  |  |
| NOEC for fish | ?? | [mg.1-11 | D |
| NOEC for Daphnis | ?? | [mg.!-11 | D |
| NOEC for algae | ?? | ]mg.1-11 | D |
| NOEC for addition& taxonomic group | ?? | [mg.1-1] | D |
| NOEC for additions( taxonomic group | 7? | [mg.I-1] | D |
| NOEC for addition& taxonomic group | ?? | [mg.1-1] | D |
| NOEC for additions( taxonomie. group | ?? | [mg .1-1] | D |
| MARINE |  |  |  |
| L(E)C50 SHORT-TERM TESTS |  |  |  |
| LC50 for fish (marine) | ?? | frng.1-11 | D |
| L(E)C54 for crustaceans (marine) | ?? | [mg.1-1] | D |
| EC50 for algae (marine) | ?? | [rogE1] | D |
| LC50 for addition& taxonomie group (marine) | ?? | [egitl] | D |
| Marine species | other |  | D |
| LC50 for additional taxonomie group (marine) | ?? | [rrig.1-1] | D |
| Marine species | other |  | D |
| NOEC LONG-TERM TESTS |  |  |  |
| NOEC for ftsh (marine) | ?? | [mg.I-1] | D |
| NOEC for crustaceans (marine) | ?? | [eg.1-1] | D |
| NOEC for algae (manne) | ?? | leg.1-1] | ❑ |
| NOEC for additions] taxonomie group (marine) | ?? | [mg.1-1] | D |
| NOEC for addition& taxonomie group (marine) | ?? | Img.1-1j | D |
| FRESH WATER SEDIMENT |  |  |  |
| L(E)C50 SHORT-TERM TESTS |  |  |  |
| LC50 for fresh-wator sedlment organism | 7? | [mg.kgwwt-1] |  |
| Weight fraction C organic carbet:, in tested sediment | 4.05 | fkg.kg-1] | D |
| EC101NOEC LONG-TERM TESTS |  |  |  |
| EC10 for fresh-water sediment organism | ?? | [mg.kgwwt-1] | D |
| Weight fraction of organic carbon in tested sediment | 0.05 | fkg.kg-11 | D |
| EC10 for fresh-water sediment organism | ?? | fmg.kgwwt-11 | D |
| Weight fraction of organic carbon in tested sediment | 0.05 | [kg.kg-1] | 0 |
| EC10 for fresh-water sediment organism | ?? | [rrig.kgwwt-1] | D |
| Weight fraction of organic carbon in tested sediment | 0.05 | [kg.kg-1] | 0 |
| NOEC for fresh-water sediment organism | ?? | [mg.kgwwt-1] | D |
| Weight fraction of organic carbon M tested sediment | 0.05 | [k04-1] | O |
| NOEC for fresh-wster sediment organism | ?? | [mg.kgwwt-11 | D |
| Weight fraction of argente carbon in tested sediment | 0.05 | fkg.kg-11 | D |
| NOEC for fresh-water sediment organism | ?? | fmg.kgwwt-11 | D |
| Weight fraction of organic carbon M tested sediment | 0.05 | [kg.kg-1] | D |
| MARINE SEDIMENT |  |  |  |
| L(E)C50 SHORT-TERNI TESTS |  |  |  |
| LC50 for marine sediment organise | ?? | [mg.kgwwt-1] | D |
| Weight fraction of organic carbon in tested sediment | 0.05 | pcg.kg-1 I | D |

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| Printed on  Study Substance Defaults Assessment type | 12-02-2016 17:05:28 Etofenprox  Appendix 2: RTU indoor spraying Standard Euses 2.1 Biocides |  |  |
| Name | Vaine | Units | Stalus |
| EC10/NOEC LONG-TERM TESTS |  |  |  |
| EC10 for marine sediment organism | ?? | [mg.kgwwt-1] | D |
| Weight fraction of organic carbon in tested sediment | 0.05 | [kg.kg-11 | D |
| EC10 for marine sediment organism | ?? | [mg.kgwwl-1j | D |
| Weight fraction of organic carbon in tested sediment | 0.05 | [kg.kg-1] | D |
| EC10 for marine sediment organism | ?? | [mg.kgerwt-1[ | D |
| Weight fraction 0f organic carbon in tested sediment | 0.05 | [kg.kg-1j | D |
| NOEC for marine sediment organism | ?? | [mg.kgwwt-1] | D |
| Might fraction of organic carbon in tested sediment | 0.05 | [kg.kg-1] | D |
| NOEC for marine sediment organism | ?? | [mg.kgwwt-1[ | D |
| Weight fraction of organic carbon in tested sediment | 0.05 | [kg.k9-1] | D |
| NOEC for marine sediment organism | ?? | [mg.kgwwt-1j | D |
| Weight fraction of organic carbon in tested sediment | 0.05 | [kg.kg-1I | D |
| TERRESTRIAL ORGANISMS |  |  |  |
| L(E)C50 SHORT-TERM TESTS |  |  |  |
| LC50 for plants | 0.234 | [mg.kgdwit-1] | S |
| Weight fraction of organic carbon in tested sok | 0.02 | [kg.kg-11 | D |
| LC50 for earthworms | 16.1 | [Mg.kgdwt-1] | S |
| Weight fraction of organic carbon in tested soil | 0.02 | [kg.kg-1] | D |
| EC50 for microorganisms | ?? | [mg.kgwiert-1j | D |
| Weight fraction of organic carbon in tested soli | D.02 | [kg.kg-1] | D |
| L050 for other terrestrial species | ?? | [mg.kgww1-1] | D |
| Weight fraction of organic carbon in tested soli | 0.02 | [kg.kg-1] | D |
| NOEC LONG.TERM TESTS |  |  |  |
| NOEC for plants | ?? | [mg.kgwyeli | D |
| Weight fraction of organic carbon in tested soif | 0.02 | Iit94-11 | D |
| NOEC for earthworms | 62.5 | [mg.itgdwt-1] | S |
| Weight fraction of organic carbon in tested soif | 0.0588 | [kg.kg-1] | S |
| NOEC for rn icroorganisms | 0.5 | [mg.kgdwit-11 | S |
| Weight fraction of organic carbon in testes' soli | 8.3E-03 | [kg.kg-1] | S |
| NOEC for additional taxonomie group | 1.06 | [mg.kgdwd-1] | S |
| Terrestrial species | other |  | D |
| Weight fraction of organic carbon in tested soli | 0.0294 | [kg.kg-1] | S |
| NOEC for additionsl taxonomie group | 83 | [mg.kgdwil-lj | S |
| Terrestrial species | other |  | D |
| Weight fraction of organic carbon in tested soil | 0.0294 | [kg.kg-1] | S |
| BIRDS |  |  |  |
| LC50 in avion dietary study (5 days) | 7? | [mg.kg-1] | D |
| NOEC via food (hirds) | ?? | [m91(9-1] | D |
| NOAEL (birds) | ?? | [mg.kg-1 d-11 | D |
| Conversion factor NOAEL to NOEC (birds) | 8 | [kg.d.kg-11 | D |
| MAMMALS |  |  |  |
| REPEATED DOSE |  |  |  |
| ORAL |  |  |  |
| Oral NOAEL (repdose) | ?? | [mg.kg-td-l] | D |
| Oral LOAEL (t'enclose) | ?? | [mg.kg-l.c1-1) | D |
| Omt CED (repdose) | ?? | [mg.kg-].d-11 | D |
| species for conversion of NOAEL to NOEC | Rattus norvegious (>6 weeks) | | S |
| Conversion factor NOAEL M NOEC | 20 | 1kg.d.kg-11 | 0 |
| NOEC via food (repdose) | 7? | [mg.kg-1) | D |
| LOEC via food (repdose) | 7? | [mg.kg-1] | D |
| CED via food (repdose) | 77 | [mg.kgfood-1] | D |
| INHALATORY |  |  |  |
| Inhalatory NOAEL (repdose) | ?? | jimg.m-3[ | D |
| Inhalatory LOAEL (repdose) | ?? | [mg.m-3[ | D |
| Inhalatory GED (repdose) | ?? | frng.m-31 | D |
| Correction factor for allometrio soaling | 1 | FI | 0 |
| DERMAL |  |  |  |
| Dormi NOAEL (repdose) | ?? | [rog.kg-1.d-1] | D |
| Germai LOAEL (repdose) | ?7 | [mg.kg-1.d-1] | D |
| Dermal CED (repdose) | ?? | [ing.kg-1A-1] | D |

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Study Etofenprox

Substance Appendix 2: RTU indoor spraying

Defaults Standard Buses 2.1

Assessment type Biocides

Name Value Units Status

FERTILITY ORAL

Oral NOAEL (fent) ?? fmg.kg-1A-11 D

Oral LOAEL (fort) ?? jrng.kg-1A-1] D

Oral CED (fed) ?? jrng.kg-1A-1] D

Species for conversion of NOAEL to NOEC Battus norvegicus (<,,-6 weeks) D

Conversion factor NOAEL to NOEC 10 jkg.d.kg-1] 0

NOEC via food (fert) ?? tfn61(6-11 D

LOEC via food (fera) ?? 1c10.kg-1 I D

CED via food (fert) ?? [mg:kg food-1] D

kNHALATORY

Inhalatory NOAEL (fort) ?? Img.m-21 D

Inhalai:or:y LOAEL (fers) ?? [mg.m-3j D

Inhalalory CED (fert) ?? [mg.m-3) D

Correction factor for allometric scaling I [-] D

DERMAL

Derme/ NOAEL (fert) ?? [mg.kg-1A-1] D

Derme/ LOAEL (fert) ?? [mg.kg-1A-1] D

Derme/ CED (fort) ?? [mg.kg-1.d-1] D

MATERNAL-TOX ORAL

Oral NOAEL (mattox) [mg.kg-1A-1] D

Oral LOAEL (mattox) ?? [mg.kg-1 .d-1] D

Oral CED (mattox) ?? tmg.ltgl.d-1] D

Species for conversion of NOAEL to NOEC Pattus norvegicus (ks--6 weeks) D

Conversion factor NOAEL to NOEC 10 [kg.cl.kg-11 O

NOEC via food (mattax) ?? jnig.kg-11 D

LOEC via food (radas) ?? [m94-11 D

CED via food (mattox) ?? jmegfood-1 j D

1NHALATORY

Inhalatory NOAEL (mattox) ?? [mg.m-3] D

Inhalatory LOAEL (mattox) ?? [mg:m-3] D

Inhalatory CED (mattox) ?? [reg.m-0] D

Correction factor for ailometric soaling I H D

DERMAL

Derme) NOAEL (mattox) ?? [mg.kg-1A-1] O

Dermai LOAEL (mattox) ?? [mg.kg-1.d-1] D

Derme! CED (mattox) ?? [mg.kg-1.d-11 D

DEVELOPMENT-TOX ORAL

Oral NOAEL (devtox) 37 S

Oral LOAEL (devtox) ?? r[mmg':k'gg.1:oldl D

Oral CED (devtox) ?? [mg:kg-IA-1] D

Species for conversion of NOAEL to NOEC Rattus norvegicus (>6 weeks) S

Conversion factor NOAEL ta NOEC 20 [kg.d.kg-1] 0

NOEC via food (devtox) 740 [mg-kg-1] O

LOEC via food (devtox) ?? [17104-1] D

CED via food (devtox) ?? [mg.kgfood-1] D

INHALATORY

Inhalatory NOAEL (devtox) 84.8 [rng.m-3] O

inhalatory LOAEL (devtox) ?? [mg.m-3] D

Inhalatory CED (devtox) ?? jmg.m-3] D

Correction factor for altometric sceling 1 [-] D

DERMAL

Dermal NOAEL (devtox) 370 [rng.kg-l.d-1] O

Dermal LOAEL (devtox) ?? [rog.kg-1.d-1] D

Dermal CED (devtox) ?? Img.kg-l.d-1j D

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| Printed on Study  Substance Defaults  Assessment type | 12-02-2016 17.05:28 Etefenprox  Appendix 2: MI indoor spraying Standard Euses 2.1 Biocides |

Name Value Units Statue

|  |  |
| --- | --- |
| CARC (THRESHOLD)  ORAL  Oral NOAEL (eue)  Oral LOAEL (carc)  Oral CED (carc)  Species for conversion of NOAEL to NOEC  Conversion factor NOAEL to NOEC  NOEC via food (carc)  LOEC via food (carc)  CED via food (cars)  INHALATORY  Inhalatory NOAEL (carc)  Inhalatory LOAEL (carc)  Inhalatory CED (carc)  Correction factor for ailometric scaling  DERMAL  Dermal NOAEL (carc) Damai LOAEL (core) Dermal CED (carc)  CARC (NON•THRESHOLD)  ORAL  Oral T25 for non-threshold affects Oral GED for non-threshold affects Species for conversion of NOAEL to NOEC Conversion factor NOAEL to NOEC T25 via food for non-threshold affects CEC via food for non-threshold affects  INHALATORY  Inhalatory T25 for non-threshold affects Inhalatory CED for non-threshold affecta Correction factor for allometnc scaling  DERMAL  Dermal T25 for non-threshold affects Dermal CED for non-threshold affects  AGATE  Oral LD50  Oral Discriminatory Dose  Inhalatory LC50 Dermal L050  PREDATOR  Duration of (sub-)chronic oral test NOEC via food for secondary poisoning Source for NOEC-via-food data | ?? [mg.kg-l.d-11  ?? [mg.kg-1A-1)  ?? [mg.kg-1.d-1]  Ranus norvegicus (<,.6 weeks)  10 [kg cl.kg-1]  ?? [mg.kg-11  ?? (t80-If0-11  ?? [mg.kgfood-1]  [mg.m-3]  7? [mg.rn-3]  ?? [mg.m-3]  [mg.kg-1.d-1] [ing.kg-1.d-1] [rog.kg-1.d-1]  ?? [rng.kg-1.d-1]  ?? [mg.kg-1.d-1]  Ratios norvegicus (<=6 weeks)  10 [kg.d.kg-1]  ?? img.kgfocid-11  ?? [mg kgfood-1]  [mg.m-3] [mg.m-3]  [mg.kg-1A-1] [mg.kg-1A-1]  mg.kg-1] Img.kg-1] [ing,m-3] irrig.kg-11  28 days  ?? [mg.kg-1]  No data available, enter manually |

BIO-AVAILIBILITY

Bioavailability for oral uptake (oral to inhalation) 0.5

Bioavailability for oral uptake (oral to dermal) 1 Fl

Bloavallability for oral uptake (route to oral) 1   
Bioavailability for inhalation (route from inhalation)

Bioavailability for Inhalation (route M inhalation) E-]

Bioavailability for dermal uptake (route from dermal) 0.1 1-7

Bioavailability for dermal uptake (route to dermal) 0.1

ENVIRONMENTAL EFFECTS ASSESSMENT ENVIRONMENTAL PNECS

FRESH WATER

Same taxonomie group for LC60 and NOEC No

Toxicological data used for extrapolation M PNEC Aqua 5.4E-05

Assessment factor applied in extrapolation to PNEC Aqua 10

PNEC for aquatic organisme 5.4E-06

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|  |  |  |  |
| --- | --- | --- | --- |
| EUSES 2 Pull report Single substance | |  |  |
| Printed ion 12-02-2016 17:05:28  Study Etofenprox  Substance Appendix 2: RTU indoor sproying  Defaults Standard Euses 2.1  Assessrnent type Biocides | |  |  |
| Name | Value | Units  Status |  |
| INTERMITTENT RELEASES |  |  |  |
| Toxicological data used for extrapolation ta PNEC Agua | 5.4E-05 | Ung,1-1} | S |
| Assessment Factor applied M extrapolation to PNEC Aqua | 10 | H | S |
| PNEC for agualic organisms, intermittent releases | 5.4E-06 | [mg.1-1j | 0 |
| STATISTICAL |  |  |  |
| PNEC for aqualic organisms with statisiical method | ?? | [mg.1-1] |  |
| MARINE |  |  |  |
| Same taxonomie group for marine LC50 and NOEC | No |  | O |
| Toxicotogical data used for extrapolation to PNEC Marine | ?? | [mg.1-1] | 0 |
| Assessment factor applied in extrapolation M PNEC Marine | ?? | E-I | O |
| PNEC for marine organisms | ?? | img.1-1l | 0 |
| STATISTICAL |  |  |  |
| PNEC for marine organisms with statisticol method | ?? |  | D |
| FRESH WATER SEDIMENT |  |  |  |
| Toxicological data used for extrapolation to PNEC sediment (free) | 0.63 | Img.kgwwl-1] | S |
| Assessment factor applied M extrapolation fo PNEC sediment (fresh) | 100 | H | S |
| PNEC for fresn-water sediment organisms (from toxicologicar data) | 6.3E-03 | frng.kgwvit-1] | o |
| PNEC for fresh-water sediment urgoniens (eguilibrium partitioning) | 3,35E-03 | fmg.kgww1-1] | o |
| Eguiiibrium partitioning used for PNEC in fresh-water sedirnent? | No |  | S |
| PNEC for fresh-water sediment, normalised to 10% ia.c. (local) | 6.3E-03 | fmg.kgwint-1) | S |
| PNEC for fresh-water sediment, normalised to 5% ac. (regional) | 6.3E-03 | fmg.kgwwt-lj | O |
| MARINE SEOIMENT |  |  |  |
| Toxicological data used for extrapolation to PNEC sediment (marine) | ?? | [mg.kgwwt-1] | o |
| Assessment factor applied in extrapolation ta PNEC sediment (marine) | ?? | [-] | 0 |
| PNEC for marine sediment organisms (from toxicological data) | ?? | Img.kgww1-1 | o |
| PNEC for marine sediment organisms (eguilibrium partitioning) | ?? | img.kgww1-1i | O |
| Eguilibrium partitioning used for PNEC in marine sediment? | Yes |  | O |
| PNEC for marine sediment, normarised to 10% o.c. (local) | ?? | [mg.kgww1-1] | 0 |
| PNEC for marine sediment, norrnalised to 5% oc. (regional) | ?? | (mg.koww1-1) | O |
| TERRESTRIAL |  |  |  |
| Same taxonomie group for LC50 and NOEC | No |  | O |
| ToxicologIcal data used for extrapolation to PNEC Terr | 0.636 | hing.kgwwt-1] | O |
| Assessment factor applied in extrapolation to PNEC Terr | 10 | f-1 | O |
| PNEC for terrestital organisms (from toxicological data) | 0.0635 | [mg.kgwert.-1 ] | O |
| PNEC For terrestrial organisms (eguilibriurn partitioning) | 2.72E-03 | [mg.lqww1-1] | o |
| Eguilibrium partitioning used for PNEC in sais? | No |  | 0 |
| PNEC for terrestrial organisms | 0,0636 | tmg.kgwviet-1) | O |
| STATISTICAL |  |  |  |
| PNEC for terrestrial organisms with statistical method |  | tmg.kgwwt-i] | D |
| SECONDARY POISONING |  |  |  |
| Toxicological data used for extrapolation to PNEC oral | 740 | [mg.kg-1] |  |
| Assessment factor applied in extrapolation to PNEC oral | 30 | 1-1 |  |
| PNEC for secondary poisoning of birds and mammors | 24.7 | [mg.kg-1] |  |
| STP |  |  |  |
| Toxicological data used for extrapolation to PNEC micro | 0.0225 | Cmg.1-11 | S |
| Assassinent factor applied in extrapolation to PNEC micro | 1 | H | S |
| PNEC for micra-organisms in a STP | 0.0225 | [mg.1-1] | O |

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Study Etofenprex

Substance Appendlx 2: RTU indoor spraying

Defaults Standard Euses 2.1

Assessment type Biocides

Name Value Units Stalus

|  |  |  |  |
| --- | --- | --- | --- |
| RISK CHARACTERIZATION ENVIRONMENTAL EXPOSURE LOCAL  RISK CHARACTERIZATION OF [PRIVATE USE] WATER |  |  |  |
| RCR for the local fresh-water compartment | 0.439 | H | 0 |
| Intermittent release | No |  | D |
| RCR for the local marine compartment | ?? | H | O |
| RCR for the local fiesh-waler compartment, stalistical method | ?? | H | 0 |
| RCR for Me local marine compartment, statistical method | ?? | H | O |
| SEDINIENT |  |  |  |
| RCR for the local fresh-water sediment campement | 0.234 | 1-1 | O |
| Extra factor 10 applied to PEC/PNEC | No |  | O |
| RCR for the local marine seenent compartment | ?? | H | 0 |
| Extra factor 10 applied to PEC/PNEC | Yes |  | O |
| S011. |  |  |  |
| RCR for the local soi! compartment | 0.406 | H | O |
| Extra factor 10 applied to PEC/PNEC | No |  | O |
| RCR for the local soit compartment, statistical method | ?? | H | 0 |
| STP |  |  |  |
| RCR for the sewage treatment plant | 1.1E-03 | H | 0 |
| PREDATORS |  |  |  |
| RCR for fish-eating birds and mammals (fresh-water) | 6.76E-07 | H | O |
| RCR for fish-eating lairds and mentais (marine) | 6.76E-08 | H | O |
| RCR for top predators (marine) | 2.7E-08 | [-] | O |
| RCR for worrn-catins birds and marnmale | 0.0247 | H | 0 |
| REGIONAL |  |  |  |
| WATER |  |  |  |
| RCR for the regional fresh-water compartment | 0 | H | O |
| RCR for the regional marine compartment | ?? | [-] | 0 |
| RCR for the regional fresh-water compartment, elatistical method | ?? | H | 0 |
| RCR for the regional merle compartment, statistical method | ?? | 1-1 | 0 |
| SEDIMENT |  |  |  |
| RCR far the regicnal fresh-water sediment compartment | o | fi | 0 |
| Extra factor 10 applied to PEC/PNEC | No |  | O |
| RCR for *the* regional marine sediment compartment | ?? | H | 0 |
| Extra factor 10 applied to PECiPNEC | Yes |  | O |
| SOIL |  |  |  |
| RCR for the regional soif compartment | 0 | Il | O |
| Extra factor 10 applied to PECiPNEC | No |  | O |
| RCR for the regional soi! compartment, stattstical method | ?? | [-] | O |

1. Please fill in here the identifying product name from R4BP. [↑](#footnote-ref-2)
2. IRAC: Insecticide Resistance Action Committee. http://www.irac-online.org/ [↑](#footnote-ref-3)
3. Guidance on Dermal Absorption. EFSA journal 2012 ;10(4) :2665 [↑](#footnote-ref-4)
4. This scenario is considered more relevant for a child of approximately one year and more (toddler) than for an infant. [↑](#footnote-ref-5)
5. Assessment report Etofenprox - Product-type 18 (Insecticide) - September 2013 - Austria [↑](#footnote-ref-6)
6. Guidance on the Biocidal Product Regulation – Volume IV Environnement- Part B Risk Assessment (active substance). Version 1.0- April 2015. [↑](#footnote-ref-7)
7. According to the conclusions at WG-Meeting IV/2016 the fraction of emission directed to sludge should be 92.8 [↑](#footnote-ref-8)
8. Völkel, W. (2014), 14C-Etofenprox - biodegradation in a sewer system, Innovative Environmental Services (IES) Ltd, report no. 20130056, GLP, unpublished, OECD 314A [↑](#footnote-ref-9)
9. Emission Scenario Document OECD ‘ESD for insecticides, acaricides and products to control other arthropods (PT18) for household and professional uses’ ENV/JM/MONO(2008)14 (ESD 2008) [↑](#footnote-ref-10)
10. Data which have not been already submitted for the purpose of the Annex I inclusion. [↑](#footnote-ref-11)