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

PT18

Etofenprox

BC-QP065436-14

FR CA

Date: [12/01/2023]

Table of Contents

1 CONCLUSION

INTRODUCTION OF THE APPLICATION

France, as e-CA, received an application from LODI SA for a renewal of authorisation for the biocidal product DIGRAIN SPRAY.

The biocidal product DIGRAIN SPRAY containing 0.204% of etofenprox is a product type (PT) 18 uses against crawling insects including cockroaches (e.g. *Blattella germanica*, *Blatta orientalis*), garden ants (*Lasius niger*) and ticks (*Ixodes ricinus*). The biocide product DIGRAIN SPRAY is a RTU intended to be applied on indoors (in domestic houses) surfaces by non-professional/general public users.

SUMMARY AND OVERALL CONCLUSION OF THE ASSESSMENT

Physico-chemical properties and analytical methods
The physico-chemical properties of the product DIGRAIN SPRAY have been described and considered acceptable in the conditions of use detailed in the SPC.

The product DIGRAIN SPRAY is an emulsion oil in water (EW). All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.
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 7days at 0°C or 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed.
The long term stability studies performed in PET and HDPE packaging are acceptable. **Nevertheless, the final characteristics of trigger spray after long term storage that were required in post-authorization for the initial authorisation and then at renewal have only partly been submitted. As a result the shelf-life has been shortened to take into account the data submitted by the authorisation holder.**
Its technical characteristics are acceptable for an EW formulation.
The product is not classified for physical hazards.

The analytical methods are acceptable.

Efficacy
Efficacy of the product DIGRAIN SPRAY has been demonstrated against crawling insects including cockroaches (e.g. *Blattella germanica*, *Blatta orientalis*), garden ants (*Lasius niger*) and ticks (*Ixodes ricinus*), in the conditions of uses detailed in the SPC.

Resistance
Resistance to etofenprox is documented for several groups of insects including notably cockroaches and ticks.
A monitoring of scientific literature related to the resistance of the target organisms to the active substance etofenprox is requested at the next renewal.

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

Substances of concern (SoCs)

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

Risk for Human Health

The product is not classified for human health.

Primary exposure (industrial/professional users)

The risk is considered acceptable for non professional users during application by trigger spray.

Secondary exposure (general public)

The risk is considered unacceptable for infant crawling on treated surface. Therefore, a RMM is needed: **The product should not be applied in zone accessible to children.**
The risk for adult touching a treated surface or exposed to volatile residues is acceptable.

Risk for consumer under indirect exposure via food

No specific residue data was submitted in the context of this dossier. The intended indoor use in private homes by surface spraying is not expected to lead to contamination of food, feed or livestock considering the following precautionary statements:

- Remove all food, feed and drinks prior to treatment.
- Do not apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed and drinks.
- To avoid indirect contamination during nearby application, cover all surfaces and facilities likely to be in contact with food, feed, drinks and animals.

Risk for the environment

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

The estimated risks of the product DIGRAIN SPRAY for the non-target organisms are acceptable only with the specific instruction of use: "The product has to be applied only on restricted areas on surfaces not regularly cleaned, for example behind the fridge or under the oven" for treatments in domestic houses only.
The estimated concentrations in groundwater, related to the use of the product DIGRAIN, are below the threshold value defined by Directive 98/83/EC.

Overall conclusion

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

Uses	**Doses**	**Conditions of use**	**Conclusions**
Crawling insects including: - cockroaches, nymphs and adults (e.g. *Blattella germanica*, *Blatta orientalis*) - garden ants adults (*Lasius niger*) - ticks adults (*Ixodes ricinus*)	77 mL per sqm	Application by spraying on surfaces. Indoor use in domestic house Non-professionals	**Acceptable**

The following are to be given to the eCA as a post-authorisation requirement:

- Monitor the resistance of target organisms to the active substance and submit the results of this monitoring at next renewal of the authorisation

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier[1]	**Country (if relevant)**
DIGRAIN SPRAY	

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	**LODI SAS**
	Address	Parc d'Activités des Quatre Routes 35 390 Grand Fougeray France
Authorisation number	**FR-2017-0082**	
Date of the authorisation	**27/09/2017**	
Expiry date of the authorisation	**11/01/2028**	

2.1.1.3 Manufacturer(s) of the products

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

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

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*
Location of manufacturing sites	Omuta Works 30 Asamuta-cho, Omita Fukuoka 836-8610 Japan

** A letter was provided by MITSUI to declared that the manufacturer location has changed*

1 Please fill in here the identifying product name from R4BP.

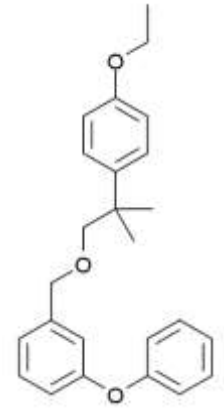
2.1.2 Product composition and formulation

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

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

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

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

2.1.2.2 Candidate(s) for substitution

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

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product[2]

Common name	IUPAC name	Function	CAS number	EC number	Content (% w/w)
Etofenprox technical	2-(4-ethoxyphenyl)-2-methylpropyl 3-phenoxybenzyl ether	Active substance	80844-07-1	407-980-2	0.204

2.1.2.4 Information on technical equivalence

Not relevant. There is no technical equivalence for this substance.

2.1.2.5 Information on the substance(s) of concern

Please see the confidential annex for further details.

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

Please see the confidential annex for further details.

2.1.2.7 Type of formulation

EW – Emulsion oil in water

2.1.3 Hazard and precautionary statements[3]

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

[It should also be stated if some P statements triggered by the criteria in CLP has been excluded due to the risk assessment.]

Classification	
Hazard category	Aquatic chronic 1
Hazard statement	H410: Very toxic to aquatic life with long lasting effects
Labelling	
Signal words	Warning GHS09
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.

2 Please delete as appropriate.

3 For micro-organisms based products: indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC (Biological Agents at Work).

Classification	
Note	EUH 208: Contains 2-methyl-2H-isothiazole-3-one and 1,2-benzisothiazol-2(2H)-one. May produce an allergic reaction.

2.1.4 Authorised use(s)

2.1.4.1 Use description[4]

Table 1. Use # 1 – name of the use

Product Type	18
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Crawling insects including - Cockroaches (*Blattella germanica, Blatta orientalis*) - Adults & nymphs - Ants *(Lasius niger*) – Adults Ticks (*Ixodes ricinus*) - Adults
Field of use	Indoor use in domestic house
Application method(s)	Surface spraying
Application rate(s) and frequency	Ready to use. 77 mL/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 (250 mL to 2L)

2.1.4.2 Use-specific instructions for use[5]

2.1.4.3 Use-specific risk mitigation measures

4 Copy this section as many times as necessary (one table per use, together with any instructions for use, risk mitigation measures and other directions for use that are use-specific. It has to be noted that in accordance with Document CA-May14-Doc.5.6 – Final, the SPC of a biocidal product presents the authorised uses as a number of pre-defined uses to which the product label shall have full correspondence.

5 Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance.

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

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

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

2.1.5 General directions for use

2.1.5.1 Instructions for use[6]

- Comply with the instructions of uses.
- 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.
- If the infestation persists contact a professional.
- Protection against tick bites is not demonstrated. The use of personal anti-vector protection in combination with a biocide repellent product is recommended.
- DIGRAIN SPRAY kills crawling insects (cockroaches, ants) and ticks within 24 hours.
- Apply a maximum of 20 pump strokes along a band of 1 m x 20 cm.

2.1.5.2 Risk mitigation m easures

- Remove all food, feed and drinks prior treatment.
- Do not apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed and drinks.
- To avoid indirect contamination during nearby application, cover all surfaces and facilities likely to be in contact with food, feed, drinks and animals.
- For use only in areas that are inaccessible to infants, children, pets and non-target animals.

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

- IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.
- IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.
- IF ON SKIN: Take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation or rash occurs: Get medical advice.
- IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor
- If medical advice is needed, have product container or label at hand

2.1.5.4 Instructions for safe disposal of the product and its packaging

Do not discharge unused product on the ground, 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

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

Shelf-life : 6 months

6 Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance.

Keep out of reach of children and non-target animals/pets

2.1.6 Other information

2.1.7 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
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

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

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

2.1.8.2 Access to documentation

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

2.2 Assessment of the biocidal product

2.2.1 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 Formicinae: Garden ant - Adults Ixodidae: Ticks - 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

2.2.2 Physical, chemical and technical properties

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

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>Comment</th></tr>
<tr><td>Physical state at 20 °C and 101.3 kPa
Colour at 20 °C and 101.3 kPa
Odour at 20 °C and 101.3 kPa</td><td>visual method</td><td>Test item: Etofenprox 2g/L
Batch n°: RTU20141126Etof</td><td>A white, homogeneous emulsion The odour was found to be slightly more intense without altering the smell of the product.</td><td>[redacted], study LODI.05/2014</td><td>Acceptable</td></tr>
<tr><td>Acidity / alkalinity pH value</td><td>CIPAC MT 75.3</td><td>Test item: Etofenprox 2g/L
Batch n°: RTU20141126Etof</td><td>8.1 at 20.8ºC (neat).</td><td>[redacted], LODI.18/2014</td><td>Acceptable</td></tr>
<tr><td>Relative density / bulk density</td><td>oscillating densitometer</td><td>Test item: Etofenprox 2 g/L RTU
Batch n°: RTU20150122Etof</td><td>1.0023.</td><td>[redacted], LODI.20/2015</td><td>Acceptable</td></tr>
<tr><td>Storage stability test – accelerated storage</td><td>CIPAC MT 36.3</td><td>Test item: Etofenprox 2 g/L RTU
Batch n°: RTU20150122Etof</td><td>Appearance of commercial packaging:
<table>
<tr><th></th><th>Initial</th><th>After 14 days at 54°C</th><th>After 21 days at 54°C</th></tr>
<tr><td>HDPE bottle</td><td>White round bottle. No leak of the bottle or the cap. White liquid, no deposit</td><td>No change, no deformation</td><td>No change, no deformation</td></tr>
<tr><td>Weight in HDPE bottle</td><td>1057.93</td><td>1056.86</td><td>1056.27</td></tr>
<tr><td>% variation</td><td>-</td><td>-0.1%</td><td>-0.15%</td></tr>
</table></td><td>[redacted], report LODI.04/2013
[redacted], report LODI.03/2015</td><td>Acceptable, the packaging is stable after accelerating storage.</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>Comment</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td>PET bottle</td><td>White round bottle. Clean bottle</td><td>No change, no deformation</td><td>No change, no deformation</td></tr>
<tr><td>Weight in PET bottle</td><td>278.34</td><td>276.98</td><td>276.37</td></tr>
<tr><td>% variation</td><td>-</td><td>-0.5%</td><td>-0.7%</td></tr>
<tr><td>HDPE bottle with PP trigger</td><td>Bottle opaque, ergonomic and black. Clean bottle. White liquid</td><td>No change, no deformation, dry box</td><td>No change, no deformation, dry box</td></tr>
<tr><td>Weight in HDPE bottle with trigger</td><td>573.98</td><td>573.33</td><td>573.00</td></tr>
<tr><td>% variation</td><td>-</td><td>-0.2%</td><td>-0.2%</td></tr>
</table>
</td><td></td><td></td></tr>
<tr><td></td><td>Method for AS content validated in study LODI 04/2014

CIPAC MT 46.3

CIPAC MT 75.3

CIPAC MT 36.3</td><td>ETOFENPROX 2 g/L RTU Batch No RTU 20150122Etof

ETOFENPROX 2 g/L RTU Batch No RTU 20150122Etof

Etofenprox 2 g/L Batch IN0190216</td><td>
Storage in glass flask with PE cap
<table>
<tr><th></th><th>Initial</th><th>After 21 days at 54°C in bottle</th></tr>
<tr><td>SA content (g/L)</td><td>2.11</td><td>2.02</td></tr>
<tr><td>% variation content</td><td>/</td><td>-4.27</td></tr>
</table>
Storage in white opaque PET flask
<table>
<tr><th></th><th>Initial</th><th>After 14 days at 54°C</th><th>After 21 days at 54°C</th></tr>
<tr><td>Appearance</td><td>Homogeneous white opaque liquid</td><td>No change</td><td>No change</td></tr>
<tr><td>pH pure</td><td>7.90 at 21.3°C</td><td>7.36 at 21.0°C</td><td>7.15 at 20.8°C</td></tr>
</table>
Storage in glass flask with PE cap
<table>
<tr><th></th><th>Initial</th><th>After 14 days at 54°C</th><th>After 21 days at 54°C</th></tr>
<tr><td>Initial emulsification</td><td>Homogeneous white liquid</td><td>Homogeneous white liquid</td><td>Homogeneous white liquid</td></tr>
</table>
</td><td>[redacted], study No LODI.04/2015

[redacted] DEFITRACES report No. 15-912011-002

[redacted], study No LAB2016-</td><td>Acceptable, the product is considered stable after accelerated storage.</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>Comment</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td>Emulsion stability after 30 min, 2h, 24h</td><td>Homogeneous white liquid</td><td>Homogeneous white liquid</td><td>Homogeneous white opaque liqui</td></tr>
<tr><td>Re-emulsification after 30 sec</td><td>Homogeneous white liquid</td><td>Homogeneous white liquid</td><td>Homogeneous white liquid</td></tr>
<tr><td>Final emulsion stability after 30 min</td><td>Homogeneous white liquid</td><td>Homogeneous white liquid</td><td>Homogeneous white liquid</td></tr>
</table>
Emulsion characteristics of undiluted test item are stable.

Spray pattern for Etofenprox 2g/L RTU stored in HDPE bottle with trigger
<table>
<tr><th></th><th>Initial</th><th>After 7 days at 54°C</th><th>After 14 days at 54°C</th></tr>
<tr><td>Mean spray delivered amount for 10 sprays</td><td>6.36 g</td><td>6.39 g</td><td>6.42 g</td></tr>
<tr><td>Mean spray delivered amount</td><td>0.636 g</td><td>0.639 g</td><td>0.642 g</td></tr>
<tr><td>Variation</td><td>/</td><td>0.47%</td><td>0.94%</td></tr>
<tr><td>Nozzle observations</td><td>Presence of droplets around the nozzle</td><td>Presence of droplets around the nozzle</td><td>Presence of droplets around the nozzle</td></tr>
<tr><td rowspan="2">Mean Spray pattern</td><td>Outer diameter 18.7 cm</td><td>Outer diameter 20.2 cm</td><td>Outer diameter 20.1 cm</td></tr>
<tr><td>Internal diameter 10.7 cm</td><td>Internal diameter 10.2 cm</td><td>Internal diameter 10.2 cm</td></tr>
</table>
</td><td>04 (non GLP)

[redacted]
Study N° LAB2020-01</td><td></td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>Comment</th></tr>
<tr><td>Storage stability test – long term storage at ambient temperature</td><td>GIFAP Monograph n°17</td><td>Etofenprox 2 g/L
Batch RTU 20141126Etof</td><td><u>Packaging stability</u>
Storage in PET bottle
<table>
<tr><th></th><th>Initial</th><th>After 6 months at 20°C</th><th>After 12 months at 20°C</th></tr>
<tr><td>Aspect</td><td>White liquid without deposit</td><td>White liquid without visible deposit</td><td>White liquid without visible deposit</td></tr>
<tr><td>%variation</td><td>/</td><td>-0.44%</td><td>-0.84%</td></tr>
<tr><td>Packaging</td><td>Bottle round, white, opaque with a white cap. Bottle clean.</td><td>No leak or deformation</td><td>No leak or deformation</td></tr>
</table>
Storage in PEHD bottle
<table>
<tr><th></th><th>Initial</th><th>After 6 months at 20°C</th><th>After 12 months at 20°C</th></tr>
<tr><td>Aspect</td><td>White liquid without deposit</td><td>White liquid without visible deposit</td><td>White liquid without visible deposit</td></tr>
<tr><td>Packaging %variation</td><td>/</td><td>-0.02%</td><td>-0.05%</td></tr>
<tr><td>Packaging</td><td>Bottle round, white, opaque with a white cap. Bottle clean.</td><td>No leak or deformation</td><td>No leak or deformation</td></tr>
</table></td><td>[redacted], study No LODI.15/2014 (for packaging stability)
[redacted], study No LODI.08/2014 (for chemical stability)
[redacted], study No LAB2020-02</td><td rowspan="2">The product is chemically and physically 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.
Packaging integrity and spray characteristics are available only after 6 months storage at ambient temperature.
Overall, a shelf life of 6 months is therefore supported.</td></tr>
<tr><td></td><td></td><td></td><td>Storage in PEHD bottle with trigger
<table>
<tr><th></th><th>Initial</th><th>After 6 months at 20°C</th><th>After 12 months at 20°C</th></tr>
<tr><td>Aspect</td><td>White liquid without deposit</td><td>/</td><td>/</td></tr>
<tr><td>%variation</td><td>/</td><td>-0.01%</td><td>-0.05%</td></tr>
</table></td><td></td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>Comment</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td>Packaging</td><td>Bottle clean, ergonomic, oval, opaque and black with a black trigger.</td><td>No leak or deformation</td><td>No leak or deformation</td></tr>
</table>
<u>Chemical stability</u>
<table>
<tr><th></th><th>Initial</th><th>After 6 months at 20°C</th><th>After 12 months at 20°C</th></tr>
<tr><td>Chemical stability</td><td>2.03 g/L</td><td>1.97 g/L</td><td>1.98 g/L</td></tr>
<tr><td>%variation</td><td>/</td><td>-2.96%</td><td>-2.46%</td></tr>
</table>
Internal specific method (LAB_I_047)
The analytical method was validated in study LODI.04/2014
Packaging for storage is unknown.

Spray pattern for Etofenprox 2g/L RTU stored in HDPE bottle with trigger
<table>
<tr><th></th><th>Initial</th><th>After 6months in HDPE</th></tr>
<tr><td>Mean spray delivered amount for 10 sprays</td><td>6.26 g</td><td>6.19 g</td></tr>
<tr><td>Mean spray delivered amount</td><td>0.626 g</td><td>0.619 g</td></tr>
<tr><td>Variation</td><td>/</td><td>1.1%</td></tr>
<tr><td>Nozzle observations</td><td>Presence of droplets around the nozzle</td><td>Presence of droplets around the nozzle</td></tr>
<tr><td rowspan="2">Mean Spray pattern</td><td>Outer diameter
20.0 cm</td><td>Outer diameter
20.1 cm</td></tr>
<tr><td>Internal diameter
10.3 cm</td><td>Internal diameter
9.9 cm</td></tr>
</table>
</td><td></td><td></td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>Comment</th></tr>
<tr>
<td></td>
<td></td>
<td>Etofenprox 2 g/L
Batches
IN0190216 (pourability, persistent foaming, emulsion characteristics)
RTU20141126 Etof (compatibility between product and packaging, content of active substance)
RTU20150505 Etof (pH determination) .</td>
<td>
<u>Chemical stability</u> Packaging: PET
<table>
<tr><th></th><th>Initial</th><th>After 18 months at 20°C</th><th>After 24 months at 20°C</th></tr>
<tr><td>Chemical stability</td><td>2.03 g/L</td><td>1.83 g/L</td><td>1.91 g/L</td></tr>
<tr><td>%variation</td><td>/</td><td>-9.85%</td><td>-5.91%</td></tr>
</table>
Internal specific method (LAB_I_047_e)
The analytical method was validated in study LODI.04/2014
Packaging: PET
<table>
<tr><th></th><th>Initial</th><th>After 6 months at 20°C</th><th>After 12 months at 20°C</th><th>After 18 months at 20°C</th><th>After 24 months at 20°C</th><th>After 36 months at 20°C</th></tr>
<tr><td>pH (CIPAC MT 75.3)</td><td>8.16</td><td>7.78</td><td>7.47</td><td>7.43</td><td>7.23</td><td>7.37</td></tr>
</table>
Packaging : PET
CIPAC MT 36.3
<table>
<tr><th></th><th>Initial</th><th>After 6 months at 20°C</th><th>After 12 months at 20°C</th></tr>
<tr><td>Initial emulsification</td><td>Homogeneous white liquid</td><td>Homogeneous white liquid</td><td>Homogeneous white liquid</td></tr>
<tr><td>Emulsion stability
-30’
-2h</td><td>
- Homogeneous white liquid
- Homogeneous white liquid</td><td>
- Homogeneous white liquid
- Homogeneous white liquid</td><td>
- Homogeneous white liquid
- Homogeneous white liquid</td></tr>
<tr><td>After 24h</td><td>Homogeneous white liquid</td><td>Homogeneous white liquid</td><td>Homogeneous white liquid</td></tr>
</table>
</td>
<td>[redacted] study No LODI.09/2014 (for chemical stability of AS)

[redacted] study No LODI.23/2015 (for chemical stability of AS)

[redacted] study No LAB2016-05 (for chemical stability of AS)</td>
<td></td>
</tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>Comment</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td>Final emulsion stability</td><td>Homogeneous white liquid</td><td>Homogeneous white liquid</td><td>Homogeneous white liquid</td></tr>
</table>
Packaging for storage is unknown.
<table>
<tr><th></th><th>After 24 months at 20°C</th><th>After 36 months at 20°C</th></tr>
<tr><td>Initial emulsification</td><td>Homogeneous white liquid</td><td>Homogeneous white liquid</td></tr>
<tr><td>Emulsion stability
-30’
-2h</td><td>- Homogeneous white liquid
- Homogeneous white liquid</td><td>- Homogeneous white liquid
- Homogeneous white liquid</td></tr>
<tr><td>After 24h</td><td>Homogeneous white liquid</td><td>Homogeneous white liquid</td></tr>
<tr><td>Final emulsion stability</td><td>Homogeneous white liquid</td><td>Homogeneous white liquid</td></tr>
</table>
White opaque PET flask.
<table>
<tr><th></th><th>Initial</th><th>After 12 months</th><th>After 24 months</th><th>After 36 months</th></tr>
<tr><td>Aspect</td><td>Homogeneous white liquid</td><td>Homogeneous white liquid</td><td>Homogeneous white liquid</td><td>Homogeneous white liquid</td></tr>
<tr><td>Persistent foaming (CIPAC MT 47.2)
After 1’ for neat product</td><td>No foam</td><td>10 mL</td><td>5 mL</td><td>No foam</td></tr>
</table>
</td><td>[redacted] study No 16-912011-002 (for chemical stability of AS)</td><td></td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>Comment</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td>Pourability
CIPAC MT 148</td><td>Mean residue: R=0.16%
Mean rinsed residue: R'=0.15%</td><td>Mean residue: R=0.15%
Mean rinsed residue: R'=0.19%</td><td>Mean residue: R=0.14%
Mean rinsed residue: R'=0.18%</td><td>Mean residue: R=0.12%
Mean rinsed residue: R'=0.19%</td></tr>
</table>
Storage in HDPE bottle with trigger
<table>
<tr><th></th><th>Initial</th><th>After 18 months at 20°C</th><th>After 24 months at 20°C</th></tr>
<tr><td>Aspect</td><td>White liquid without deposit</td><td>/</td><td>/</td></tr>
<tr><td>Packaging</td><td>Bottle is ergonomic, black and opaque with a trigger. The bottle is clean.</td><td>No leak or deformation</td><td>No leak or deformation</td></tr>
</table>
Storage in HDPE bottle 1L
<table>
<tr><th></th><th>Initial</th><th>After 18 months at 20°C</th><th>After 24 months at 20°C</th></tr>
<tr><td>Aspect</td><td>White liquid without deposit</td><td>White liquid</td><td>White liquid</td></tr>
<tr><td>Packaging</td><td>Bottle round, white, opaque with a white cap. Bottle clean.</td><td>No leak or deformation</td><td>No leak or deformation</td></tr>
</table>
Storage in PET bottle 250mL
<table>
<tr><th></th><th>Initial</th><th>After 18 months at 20°C</th><th>After 24 months at 20°C</th></tr>
</table>
</td><td>[redacted] study No LODI.09/2014 (for packaging stability)</td><td></td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comment
			Aspect: White liquid without deposit / / Packaging: Bottle round, white, opaque with a white cap. Bottle clean. / No leak or deformation / No leak or deformation		
Storage stability test – **low temperature stability test for liquids**	CIPAC MT 75.3 CIPAC MT 36.3	ETOFENPROX 2 G/L RTU Batch RTU20141126Etof	**Initial**: Homogeneous white opaque liquid; pH 1% w/v in standard water D: 7.90 at 21.3°C **After 7days at 0°C in glass bottle**: No change; 6.84 at 19.8°C after 1'; 6.92 at 20.0°C after 2'	[redacted], report n° 14-912011-005	Acceptable The preparation is stable at low temperature.
Effects on content of the active substance and technical characteristics of the biocidal product - **light**			Packaging are opaque PET and HDPE and the active substance is not light sensitive.		Acceptable
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**			See accelerated storage The product is stable at temperature and is an oil in water emulsion, therefore no effect of humidity on the characteristics of the product is expected.		Acceptable
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**			See results of storages above. Packagings are stable and compatible with the product.		Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comment
Wettability	-	-	-	-	-
Suspensibility, spontaneity and dispersion stability	-	-	-	-	-
Wet sieve analysis and dry sieve test	-	-	-	-	-
Emulsifiability, re-emulsifiability and emulsion stability	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	[redacted] study No LAB2016-05 (non GLP)	Acceptable
Disintegration time	-	-	-	-	-
Particle size distribution, content of dust/fines, attrition, friability	-	-	-	-	-
Persistent foaming	CIPAC MT 47.2	Etofenprox 2 g/L Batch IN0190216	Concentration: pure Test temperature: 20 °C ± 2 °C Foam after 10”, 1’, 3’ and 12’: 0 mL (2 assays)	[redacted] study No 16-912011-002	Acceptable
Pourability	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%	[redacted] study No 16-912011-002	Acceptable
Burning rate — smoke generators	-	-	-	-	-

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>Comment</th></tr>
<tr><td>Burning completeness — smoke generators</td><td>-</td><td>-</td><td>-</td><td>-</td><td>-</td></tr>
<tr><td>Composition of smoke — smoke generators</td><td>-</td><td>-</td><td>-</td><td>-</td><td>-</td></tr>
<tr><td>Spraying pattern — aerosols and sprays</td><td>-</td><td>Etofenprox 2 g/L</td><td>Spray pattern for Etofenprox 2g/L RTU stored in HDPE bottle with trigger:
<table>
<tr><th></th><th>Initial</th></tr>
<tr><td>Mean spray delivered amount for 10 sprays</td><td>6.36 g</td></tr>
<tr><td>Mean spray delivered amount</td><td>0.636 g</td></tr>
<tr><td>Variation</td><td>/</td></tr>
<tr><td>Nozzle observations</td><td>Presence of droplets around the nozzle</td></tr>
<tr><td rowspan="2">Mean Spray pattern</td><td>Outer diameter
18.7 cm</td></tr>
<tr><td>Internal diameter
10.7 cm</td></tr>
</table></td><td>LAB 2020-01 [redacted]</td><td>Acceptable</td></tr>
<tr><td>Physical compatibility</td><td>-</td><td>-</td><td>-</td><td>-</td><td>-</td></tr>
<tr><td>Chemical compatibility</td><td>-</td><td>-</td><td>-</td><td>-</td><td>-</td></tr>
<tr><td>Degree of dissolution and dilution stability</td><td>-</td><td>-</td><td>-</td><td>-</td><td>-</td></tr>
<tr><td>Surface tension</td><td>EC A5 Method OECD Guideline 115</td><td>Test item: ETOFENPROX 2G/L RTU Batch: RTU20141126Etof</td><td>The surface tension was found to be 30.8 ± 0.4 mN/m at 20.1ºC ± 0.1ºC.</td><td>[redacted] report 13-912011-006</td><td>Acceptable The preparation is surface active.</td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comment
Viscosity	OECD Test Guideline 114 (Viscosity of Liquids)	Test item: ETOFENPROX 2G/L RTU Batch: EC20130114 Etof	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.	[redacted], report14-912011-006	The preparation is a non-Newtonian liquid.

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. 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. The long term stability studies performed in PET and HDPE packaging are acceptable **Nevertheless, the final characteristics of trigger spray after long term storage that were required in post-authorization for the initial authorisation and then at renewal have only partly been submitted. As a result the shelf-life has been shortened to take into account the data submitted by the authorisation holder. Only 6 months can be authorised.** Its technical characteristics are acceptable for an EW formulation.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comments
Explosives	Statement	-	The product Etofenprox 2g/L RTU is not explosive. An evaluation of the structural groups in the structural formula of each substance, including the oxygen balance,	[redacted] study	See below

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comments
			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.	LODI.09/2015	
	DSC screening	Test item: Etofenprox 2g/L *Batch n°: LAB0408202101*	The DSC screening test was performed from 25 to 600°C (5°C/min). No exothermic peak was observed.	[redacted] No. 21-912011-001	As no exothermic peak >300J/g was observed, the product is not explosive according to CLP regulation.
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 has no ingredient classified as flammable. Moreover, Etofenprox was found to possess a flash point > 110 ºC, while for the co-formulants the flash point is > 180 ºC according to their Safety Data Sheets. The product is not classified as flammable liquid under Regulation (EC) No 1272/2008 as the flash point is greater than 60 ºC.	-	The product is a water based product with no co-formulant classified as flammable (see confidential annex). The product is not classify as flammable.
Flammable solids	-	-	Not required as the product is a liquid product.	-	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comments
Self-reactive substances and mixtures	*DSC screening*	Test item: Etofenprox 2g/L Batch n°: *LAB0408202 101*	The DSC screening test was performed from 25 to 600°C (5°C/min). No exothermic peak was observed.	[redacted] *No. 21-912011-001*	As no exothermic peak >300J/g was observed, the product is not self-reactive according to CLP regulation.
Pyrophoric liquids	EU method A.13	Test item: Etofenprox 2g/L Batch n°: RTU201501 22Etof	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.	[redacted], study LODI.07/2015+ am n°1 LODI.07/2015	Acceptable
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 water based 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 exothermically with combustible materials and if it has oxidising properties. No component of Etofenprox 300 g/L EC is associated with oxidising	[redacted], study LODI.05/2013+am1 study	The product does not contains co-formulants classified Ox.1, Ox.2 or Ox.3, therefore, the

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comments
			properties therefore the formulation does not contain oxidising properties.	LODI.05/2013	product is not classified as oxidising liquid according to CLP regulation. It is noted that "no data available" is reported in the MSDS of some co-formulants for this hazard, therefore it is not clear if all of them have been tested. However, considering the high proportion of water in the product DIGRAIN SPRAY, it is not considered classified for oxidising properties
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.	[redacted]	See below

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>Comments</th></tr>
<tr><td></td><td></td><td></td><td>It has been shown that this co-formulant (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.</td><td>report 15 LKC 06</td><td></td></tr>
<tr><td></td><td>UN Test C.1</td><td>Test item: Etofenprox 2g/L
Batch n°: LAB0408202101</td><td>The test was performed at 55 °C ± 1 °C and maintained for 7 days.
<table>
<tr><th>Loss of mass (%)</th><th>Steel sample</th><th>Aluminium sample</th></tr>
<tr><td>Immersed plate</td><td>0.08</td><td>0.00</td></tr>
<tr><td>Partially immersed plate</td><td>0.23</td><td>0.00</td></tr>
<tr><td>Headspace plate</td><td>0.09</td><td>0.00</td></tr>
<tr><td colspan="3">Neither localised nor uniform corrosion was observed after the test.</td></tr>
</table></td><td>[redacted]
[redacted]
No. 21-912011-001</td><td>Acceptable
The product is not corrosive to metal according to CLP regulation.</td></tr>
<tr><td>Auto-ignition temperatures of products (liquids and gases)</td><td>Statement</td><td>-</td><td>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</td><td>[redacted], study LODI.08/2013</td><td>See below
.</td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comments
	EC A15	Test item: Etofenprox 2g/L Batch n°: RTU20141126Etof	No auto-ignition temperature was observed up to 599 °C (corrected temperature).	[redacted], report 14-912011-007	Acceptable The preparation does not auto-ignite up to 599 °C.
Relative self-ignition temperature for solids	-	-	Not required as the product is a liquid product.	-	
Dust explosion hazard	-	-	Not required as the product is a liquid product.	-	

Conclusion on the physical hazards and respective characteristics of the product
The formulation is not classified for physical hazards.

2.2.4 Methods for detection and identification

Principle of the analytical method:

Acidified test item (pH<5) is extract with a SPE extraction, active substance is quantified by a GC method using a FID detector. An internal standard method is used for this quantification.

Analytical methods for the analysis of the product as such including the active substance, impurities and residues								
Analyte (type of analyte e.g. active substance)	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)		Limit of quantification (LOQ) or other limits	Reference
					Mean	RSD		
Etofenprox	GC/FID	80% of ai content in product – 1.6 g/L (n=3)	N=5 (in triplicates) From 0.96 to 1.44 g/L	No interferences, chromatogra	104% at 1.6g/L 96% at 2.0g/L	At 1.18g/L (n=18), mean RSD=0.68 %	-	[redacted], final report n°

		100% of ai content in product – 2.0 g/L (n=3) 120% of ai content in product – 2.4 g/L (n=3)	Y=2.26456 x+0.00449 R^2=0.9996	ms were provided	104% at 2.4g/L			LODI.04/2014

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

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

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

Main Group 03: Pest Control

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

DIGRAIN SPRAY is a ready-to-use emulsion in water product and is intended to be used against cockroaches, ants and ticks indoor in private areas.
The product DIGRAIN SPRAY is intended to be used by non-professionals users

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

The product is intended to be used against the following target organisms:
- Cockroaches (*Blattella germanica* and *Blatta orientalis*), adults and nymphs;
- Garden Ants (*Lasius niger*), adults;
- Ticks (*Ixodes ricinus*), adults;

in order to control their infestation and protect humans and animals

The product is also claimed to be effective on "crawling insects".

Application rate:
Spray application to be applied at a rate of 77 mL product / m².

2.2.5.3 Effects on target organisms, including unacceptable suffering

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

2.2.5.4 Mode of action, including time delay

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

2.2.5.5 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.

2.2.5.6 Efficacy data

The following table summarises the efficacy studies submitted with the product DIGRAIN SPRAY by the applicant.

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Direct spray Surface treatment Residual efficacy	Indoor Crawling insects	DIGRAIN SPRAY Etofenprox 2 g/L	*Blattella germanica* (adults, nymphs) *Blatta orientalis* (adults, nymphs) *Lasius niger* (adults) *Ixodes ricinus* (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 m^3 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: 1m^3/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); 100% mortality within 24h. SURFACE TREATMENT / RESIDUAL SPRAY TRIAL: KT100 (D0)= 1h for all modalities. KT100 (D0 + 8 weeks) = 1 to 4h, except for adult cockroaches on porous 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**	[redacted] 6.7_01_Lab crawling insects, mites, spider, flying insects RI=1

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Surface treatment Residual efficacy	Indoor Crawling insects	DIGRAIN SPRAY etofenprox 2 g/L	*B. germanica* (adults, nymphs) *B. orientalis* (adults, nymphs) *L. niger* (adults) *I. ricinus* (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 m^3 (6 m^2) 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 / m^2	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 m^2**	[redacted] 6.7_02_Simulated use crawling insects, mites, spider, flying insects RI=2

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

Submitted efficacy data are compliant with the requirements and criteria of the efficacy guidance part B/C for the following claimed uses:

- Use against cockroaches (including *B. germanica, B. orientalis*), adult and nymphs;
- Use against garden ants (*Lasius niger*), workers.

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

Regarding the data provided to support the use against ticks, the Guidance on the Biocidal Products Regulation, Volume II Efficacy- Assessment and Evaluation (Parts B+C), (Version 3.0; 2018; chapter: 5.6.4.7.2.2) requires that "For products that knockdown and kill ticks a simulated-use tests should be performed in which the product is applied according to the instruction for use and then tested in the presence of a person or an arm or foot or animal." However, there is no host in the simulated-use test by Serrano (2016), thus it is not proven that the DIGRAIN SPRAY kills before ticks start feeding. But, as there no claim to protect human against tick bites, submitted data are considered sufficient to support a surface treatment intended to kill ticks within 24 hours. Following sentences will be added in the SPC:

- Protection against tick bites is not demonstrated. The use of personal anti-vector protection in combination with a biocide repellent product is recommended.
- DIGRAIN SPRAY kills crawling insects (cockroaches, ants) and ticks within 24 hours.

Conclusion on the efficacy of the product
The product DIGRAIN SPRAY has shown a sufficient efficacy against crawling insects including cockroaches (e.g. *B. germanica*, *B. orientalis*; adults and nymphs), garden ants (*L. niger*; workers) and ticks (*I. ricinus*; adults), when applied by spraying at the application rate of 75 ml/m² of treated area (porous and non-porous surfaces), with a residual activity of 8 weeks.Thus, the claim application rate of 77 mL / m² is validated.

2.2.5.7 Occurrence of resistance and resistance management

As described in the Assessment Report (Sept. 2013), etofenprox is an IRAC[7] Mode of Action group 3A insecticide. Resistance to etofenprox and other pyrethroids is documented for several groups of insects.
B. germanica belongs to those insect species with the highest numbers of observed resistance cases against pyrethroids worldwide. Resistance cases occurred on all continents under highly diverse climatic conditions. Specifically for *B. germanica*, a resistance mechanism against etofenprox (and other pyrethroids) has been described in the literature[8]. No resistance to etofenprox is reported in the scientific literature for ants.
Regarding ticks, populations of *Rhipicephalus sanguineus* s.l. have been reported to exhibit sodium channel target site insensitivity to permethrin and etofenprox, which is likely due to the prolonged use of pyrethroids against many pests in and around the home[9]. Resistance

[7] IRAC: Insecticide Resistance Action Committee. http://www.irac-online.org/
[8] Gliniewicz A, *et al*. [Susceptibility of cockroaches *Blattella germanica* L. collected from hospitals to selected pyrethroid and carbamate insecticides]. Rocz Panstw Zakl Hig. 1996;47(3):333-41. Polish. PMID: 9026900.
[9] Tucker NSG *et al*. Prevalence and distribution of pathogen infection and permethrin resistance in tropical and temperate populations of *Rhipicephalus sanguineus* s.l. collected worldwide. Med Vet Entomol. 2021 Jun;35(2):147-157. doi: 10.1111/mve.12479.

is also reported for bed bugs[1011] and mosquitoes belonging to *Aedes* spp. *Anopheles* spp. and *Culex* spp.[12131415161718192020].

Resistance against one chemical belonging to a specific group of chemicals is known to confer cross-resistance against other compounds belonging to the same group. The use of etofenprox will therefore have an impact on the resistance development against other pyrethroid insecticides and *vice versa*. If these insecticides are used repeatedly, the resistant individuals may eventually dominate the pest insect population. These resistant insects may not be controlled by etofenprox or by other group 3A insecticides.

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

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

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

2.2.5.8 Known limitations

None

2.2.5.9 Evaluation of the label claims

See Efficacy conclusion above.

[10] Tawatsin A, *et al*. Insecticide resistance in bedbugs in Thailand and laboratory evaluation of insecticides for the control of *Cimex hemipterus* and *Cimex lectularius* (Hemiptera: Cimicidae). J Med Entomol. 2011 Sep;48(5):1023-30. doi: 10.1603/me11003.

[11] Dang K. *et al*. Insecticide resistance and resistance mechanisms in bed bugs, *Cimex* spp. (Hemiptera: Cimicidae). Parasit Vectors. 2017 Jun 29;10(1):318. doi: 10.1186/s13071-017-2232-3.

[12] Fonseca-González I. *et al*. Insecticide resistance status of *Aedes aegypti* (L.) from Colombia. Pest Manag Sci. 2011 Apr;67(4):430-7. doi: 10.1002/ps.2081.

[13] Koou SY. *et al*. Pyrethroid resistance in *Aedes aegypti* larvae (Diptera: Culicidae) from Singapore. J Med Entomol. 2014 Jan;51(1):170-81. doi: 10.1603/me13113.

[14] Francis S. *et al*. Screening of insecticide resistance in *Aedes aegypti* populations collected from parishes in Eastern Jamaica. PLoS Negl Trop Dis. 2020 Jul 27;14(7):e0008490. doi: 10.1371/journal.pntd.0008490.

[15] Koffi AA. *et al*. Insecticide resistance status of *Anopheles gambiae* s.s population from M'Bé: a WHOPES-labelled experimental hut station, 10 years after the political crisis in Côte d'Ivoire. Malar J. 2013 May 4;12:151. doi: 10.1186/1475-2875-12-151.

[16] Menze B.D. et al. Multiple Insecticide Resistance in the Malaria Vector *Anopheles funestus* from Northern Cameroon Is Mediated by Metabolic Resistance alongside Potential Target Site Insensitivity Mutations. PLoS One. 2016 Oct 10;11(10):e0163261. doi: 10.1371/journal.pone.0163261.

[17] Richards S.L. *et al*. Insecticide Susceptibility Screening against Culex and Aedes (Diptera: Culicidae) Mosquitoes From the United States. J Med Entomol. 2018 Feb 28;55(2):398-407. doi: 10.1093/jme/tjx198.

[18] Ghorbani F. *et al*. High Resistance of Vector of West Nile Virus, *Culex pipiens* Linnaeus (Diptera: Culicidae) to Different Insecticides Recommended by WHO in Northern Iran. J Arthropod Borne Dis. 2018 Mar 18;12(1):24-30. PMID: 30018991.

[19] Richards S.L. *et al*. Baseline Insecticide Susceptibility Screening against Six Active Ingredients for Culex and Aedes (Diptera: Culicidae) Mosquitoes in the United States. J Med Entomol. 2017 May 1;54(3):682-695. doi: 10.1093/jme/tjw231.

[20] Rahimi S. *et al*. Resistant status of *Culex pipiens* complex species to different imagicides in Tehran, Iran. J Vector Borne Dis. 2020 Jan-Mar;57(1):47-51. doi: 10.4103/0972-9062.308800.

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

DIGRAIN SPRAY is not intended to be used with other biocidal products.

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

Summary table of animal studies on skin corrosion /irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Duration of exposure**	**Results** *Average score (24, 48, 72h)/ observations and time point of onset, reversibility; other adverse local / systemic effects, histopathological findings*	**Remarks** *(e.g. major deviations)*	**Reference**
OECD guideline 404 Reliability 1	New Zealand rabbits 3	Digrain spray 0.5 ml Semi occlusive dressing during 4 hours on an undamaged skin area	Skin reaction appreciated 1 hour, 24, 48 and 72 hours after removal of the patch. Mean score 24-48 and72h: Erythema and eschar: Animal 1: 0 Animal 2: 0.67 Animal 3: 1 reaction was totally reversible between days 1 and 3 Oedema formation: Animal 1: 0 Animal 2: 0 Animal 3: 0.33	Dryness of the skin was noted in one animal on day 3 and in a second animal on days 3 and 7	[redacted]

			reaction was totally reversible on day 2.		

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

Eye irritation

Summary table of animal studies on serious eye damage and eye irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance ,Dose levels, Duration of exposure**	**Results** *Average score (24, 48, 72h)/ observations and time point of onset, reversibility*	**Remarks** *(e.g. major deviations)*	**Reference**
OECD guideline 405 Reliability 1	New Zealand rabbits 3	0.1 mL in one eye.	Ocular examinations were performed on both right and left eyes 1 hour, 24, 48 and 72 hours following treatment. Light effects on conjunctivae are observed and are reversible on day 1: Redness in 2 animals, associated with chemosis in 1 animal, 1 hour after instillation. Mean score= 0 for all animals for conjunctivae chemosis and redness, iris lesion and cornea opacity	The other eye remains untreated and serves as control.	[redacted]

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

Respiratory tract irritation

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

Skin sensitization

Summary table of animal studies on skin sensitisation					
Method, Guideline, GLP status, . Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle,** **Dose levels, duration of exposure Route of exposure** *(topical/intradermal, if relevant)*	**Results** *(EC3-value or amount of sensitised animals at induction dose); evidence for local or systemic toxicity (time course of onset)*	**Remarks** *(e.g. major deviations)*	**Reference**
OECD guideline 406 Reliability 1	Guinea pigs 20/group	Digrain spray Induction: Intradermic injection = 5% Topical application = 100% 10-day rest Challenge: topical application under occlusive dressing for 24h with test item at 100% and diluted at 50% in water	No cutaneous reaction attributable to allergy in treated group and no cutaneous intolerance reaction in negative control group	Before the main assay, a preliminary assay was realized in order to determine the tested concentration.	[redacted]

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not classified
Justification for the value/conclusion	Reaction and observed effects are compared to CLP regulation criteria.
Classification of the product according to CLP	Not classified. 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.

Respiratory sensitization (ADS)

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

Acute toxicity

Acute toxicity by oral route

Summary table of animal studies on acute oral toxicity						
Method Guideline GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance Dose levelsType of administration** *(gavage, in diet, other)*	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**Value LD50**	**Remarks** *(e.g. major deviations)*	**Reference**
OECD guideline 423	6 females Sprague Dawley rats	Digrain spray 2000 mg/kg bw	No mortality No clinical sign Body weight evolution is normal Not change in macroscopical examination	>2000 mg/kg bw		[redacted]

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

Acute toxicity by inhalation

Summary table of animal studies on acute inhalation toxicity						
Method, Guideline, GLP status , Reliability	**Species, Strain, Sex, No/group**	**Test substance, form** *(gas, vapour, dust, mist)* **and particle size (MMAD) Actual and nominal concentration, Type of administration** *(nose only / whole body/ head only)*	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**LC50**	**Remarks** *(e.g. major deviations)*	**Reference**
OECD guideline	Three males and three females RccHan : WIST strain rats	Exposure to aerosol atmosphere of digrain spray by nose only during **4** hours 14 days of observation Mean achieved atmosphere concentration: 5.59 mg/L with with mean MMAD of 1.99 µm and an inhalable fraction (< 4µm) of 82.4%.	No mortality Increase respiratory rate, hunched posture, piloerection and wet fur. Animals recovered to appear normal on day 3 post-exposure. 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	>5.59 mg/L		[redacted]

			animals at necropsy			

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

Acute toxicity by dermal route

Summary table of animal studies on acute dermal toxicity						
Method, Guideline, GLP status, Reliability	**Species, strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Surface area**	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**LD50**	**Remarks** *(e.g. major deviations)*	**Reference**
OECD guideline 402	10 Sprague Dawley rats (5 males and 5 females)	Digrain spray 2000 mg/kg bw	No mortality No clinical sign neither cutaneous reactions Body weight evolution is normal Not change in macroscopical examination	>2000 mg/kg bw		[redacted]

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not classified
Justification for the selected value	Compared to the criteria for classification of CLP regulation

Classification of the product according to CLP and DSD	Not classified

Information on dermal absorption

Summary table of in vitro studies on dermal absorption					
Method, Guideline, GLP status, Reliability	**Species, Number of skin samples tested per dose, Other relevant information about the study**	**Test substance, Doses**	**Absorption data for each compartment and final absorption value**	**Remarks** *(e.g. major deviations)*	**Reference**

Summary table of in vitro studies on dermal absorption					
OECD 428	Human skin 8 skin samples Analysis of receptor fluid at 0, 0.5, 1, 2, 4, 6, 8, 10, 12 and 24 hours after application. At 8h, dose formulation is removed from the skin by washing Following the 24h sampling time-point, system is dismantled and skin is analysed. The remaining Franz cells donor and receptor chambers were washed and the washings retained for analysis of radioactivity	Digrain spray	Less than 75 % of the total absorption in receptor fluid occurred within the first 12 hours of the experiment. Therefore, the amount of active substance in stratum corneum is considered as absorbed. Low recovery for several replicats. Therefore, a normalisation correction is performed. 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. Absorbed dose = 12%	Integrity of the human skin is confirmed by assessing the permeability of tritiated water.	[redacted]

Value(s) used in the Risk Assessment – Dermal absorption			
Substance	Etofenptox		
Value(s)*	12%		
Justification for the selected value(s)	EFSA guidance on dermal absorption 2012*		

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

In the context of this renewal, it may be reviewed with the EFSA guidance on dermal absorption of 2017. Applying this guidance 2017, a dermal absorption of 11% is obtained. This difference of absorption will not have an impact on conclusion. Therefore, the initial dermal absorption value of 12% is maintained to determine exposure.
This approach is in line with the approach proposed for product using a dermal absorption study assessed during the assessment of an active substance (see note of the coordination group for biocides: dermal absorption value for the authorisation of biocidal products).

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

No SOC is identified.

Available toxicological data relating to a mixture

Not available

Other

Etofenprox is classified for lactation H362. However, considering its concentration in the product, no classification of the product is needed.

2.2.6.2 Exposure assessment

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

Summary table: relevant paths of human exposure							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Industrial use	**Professional use**	**Non-professional use**	**Industrial use**	**Professional use**	**General public**	**Via food**
Inhalation	Not relevant	Not relevant	Yes	Not relevant	Not relevant	Yes	

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

List of scenarios

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.

Summary of use:

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 m^2	0.15 g/m^2	0.2 %

Exposure can occur during:
- Spraying
- Volatilisation of residue
- Contact with treated surface:
    - an infant who crawls on treated surface with a hand to mouth transfer (wet and dry surface)
    - an adult who touchs a treated surface with its hands (wet and dry surface)

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
1.	Spraying	Primary exposure Product is applied via a trigger spray	Non professional
2.	Volatilisation of residue	Secondary exposure	General public
3.	Infant crawling on treated surface	Secondary exposure Dermal exposure and oral exposure via a hand to mouth transfer Exposure is determined for contact with wet and dry surface	General public
4.	Adult who touch a treated surface	Secondary exposure Dermal exposure Exposure is determined for contact with wet and dry surface	General public

Industrial exposure

Not relevant

Professional exposure

Not relevant

Non-professional exposure

Scenario [1]

Description of Scenario [1]			
Exposure during spraying is determined using the Consumer Spraying and Dusting Model 2 of BHHEM.			
	Parameters	Value	Source
Tier 1	Dermal absorption	12%	See above
	Inhalation absorption	100%	Default value
	Body weight	60 kg	Recommendation 14 of the ad hoc WG on human exposure
	Concentration of active substance	0.2 %	Applicant data
	Hands/forearms exposure	36.1 mg product/minute	BHHEM[21]
	Legs feet face exposure	9.7 mg product/minute	
	Inhalation	10.5 mg product/m^3	
	Duration of exposure	10 minutes	BHHEM

Calculations for Scenario [1]

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake mg ai/kg/d**	**Estimated dermal uptake mg ai/kg/d**	**Estimated oral uptake mg ai/kg/d**	**Estimated total uptake mg ai/kg/d**
Scenario [1]	1	7.29E-05	1.83E-03	Not relevant	1.9E-03

Exposure of the general public

Scenario [2]

Description of Scenario [2]
Exposure to volatile residue is determined according to the HEEG opinion 13 “Assessment of inhalation exposure of volatilised biocides active substance”.

[21] Biocides human health exposure methodology

Description of Scenario [2]			
	Parameters[1]	Value	Source
Tier 1	Vapor pressure	8.13E-07 Pa	CAR
	Molecular weight	376.47 g/mol	CAR
	Adult body weight	60 kg	Recommendation 14 of the ad hoc WG on human exposure
	Child body weight	23.9 kg	
	Toddler body weight	10 kg	

Calculations for Scenario [2]

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

Scenario [3]

Description of Scenario [3]			
Exposure is determined for infant crawling on treated surface. Exposure via hand to mouth contact is also determined. This exposure is estimated based on the approach proposed in Consexpo fact sheet "Cleaning products". ConsExpo software is not used for the calculation. Dermal exposure of infants can take place on any uncovered skin, that is the head, the arms and hands, and on the legs and feet. According to the Recommendation 12 of the ad hoc WG on human exposure, a transfer coefficient of 0.2 m2/h and 1h of exposure are used. Oral exposure is determined considering that the hands form about 20 % of the total uncovered skin. It is assumed that 50 % of the product that ends up on the hands is taken in orally (ConsExpo: Pest control Fact Sheet). This means that via hand-mouth contact 10 % of the calculated external dermal exposure is ingested and that the internal dermal exposure is 90 % of the calculated external dermal exposure.			
	Parameters1	Value	Source
Common parameters	Application rate	0.15 g as/m2	Applicant data
	Dermal absorption	12%	See above
	Oral absorption	30%	CAR

Description of Scenario [3]			
	Body weight	8 kg	Recommendation 14 of the ad hoc WG on human exposure
Tier 1 wet surface	Fraction of active substance dislodgeable	100%	Default value
Tier 1 dried surface		30%	BHHEM
Tier 2 dried surface after 4 hours for carpet		11%	Study of CAR
Tier 2 dried surface after 7 days for carpet		4%	Study of CAR

Calculations for Scenario [3]

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Infant crawling	Tier 1	Not relevant	4.05E-01	1.13E-01	5.18E-01
	Tier 2 (30%)	Not relevant	1.22E-01	3.38E-02	1.55E-01
	Tier 2 - 4h (11%)	Not relevant	4.46E-02	1.24E-02	5.69E-02
	Tier 2 – 7 days (4%)	Not relevant	1.62E-02	4.50E-03	2.07E-02

Scenario [4]

Description of Scenario [4]			
An adult can be exposed touching a treated surface (wet and dried) with its hands (palm of both hands).			
	Parameters[1]	Value	Source
Parameters	Application rate	0.15 g as/m2	Applicant data
	Dermal absorption	12%	See above
	Body weight	60 kg	Recommendation 14 of the ad hoc WG on human exposure
	Fraction of active substance dislodgeable from wet surface	100%	Default value
	Fraction of active substance dislodgeable from dried surface	30%	BHHEM

Description of Scenario [4]			
	Hands area	410 cm2	Recommendation 14 of the ad hoc WG on human exposure

Calculations for Scenario [4]

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [4]	Wet surface	Not relevant	1.26E-02	Not relevant	1.26E-02
Scenario [4]	Dried surface	Not relevant	3.78E-03	Not relevant	3.78E-03

Combined scenarios

A non-professional who treats his house can also be exposed to volatile residues and when he touches a treated surface. As a worst case, only assessment of a non-professional who touchs a wet surface is presented.

Scenarios combined	Estimated total uptake mg/kg/d
Scenarios [1+2+4]	1.46E-02

Monitoring data

Not relevant

Dietary exposure

No specific residue data was submitted in the context of this dossier. The intended indoor use in private homes by surface spraying is not expected to lead to contamination of food, feed or livestock considering the following precautionary statements:

- Remove all food, feed and drinks prior to treatment.
- Do not apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed and drinks.
- To avoid indirect contamination during nearby application, cover all surfaces and facilities likely to be in contact with food, feed, drinks and animals.

Information of non-biocidal use of the active substance

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

[1] Reg. (EU) No 540/2011

Estimating Livestock Exposure to Active Substances used in Biocidal Products

Not relevant

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

Not relevant

Aggregated exposure

Not relevant

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation

Reference	Study	NOAEL (LOAEL)	AF[1]	Correction for oral absorption	Value
AELshort-term	Rat developmental neurotoxicity feeding study	28.4 mg/kg bw/d	100	30% oral absorption	0.085
AELmedium-term	Rat subchronic feeding study	20 mg/kd bw/d	100	30% oral absorption	0.06
AELlong-term	Rat 2-year feeding study	3.7 mg/kg bw/d	100	30% oral absorption	0.011
ARfD	Not determined				
ADI					

Maximum residue limits or equivalent

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

Specific reference value for groundwater
[If it is proposed to derive a value according to BPR Annex VI point 68, other than the maximum permissible concentration laid down by Directive 98/83/EC, please include the argumentation and the calculations here. Otherwise, please delete this chapter.]

Risk for industrial users

Not relevant

Risk for professional users

Not relevant

Risk for non-professional users

Systemic effects

As the product is applied at maximum 2 times/year, the short term AEL is used.

Task/ Scenario	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario [1]	1	8.5E-02	1.9E-03	2%	Yes

The risk is considered acceptable for non-professional.

Local effects

The product is not classified.

Risk for the general public

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

A delayed effect until 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.

Task/ Scenario	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario [2] adult	1	6.0E-02	3.35E-05	0.06%	Yes
Scenario [2] child	1	6.0E-02	6.31E-05	0.11%	Yes
Scenario [2] toddler	1	6.0E-02	6.79E-05	0.11%	Yes
Scenario [3] wet	1	8.5E-02	5.18E-01	609%	No
Scenario [3] dried	1	6.0E-02	1.55E-01	259%	No
Scenario [3] dried 4h	2	8.5E-02	5.69E-02	67%	Yes
Scenario [3] dried 7 days	2	6.0E-02	2.07E-02	35%	Yes
Scenario [4] wet	1	8.5E-02	1.26E-02	15%	Yes
Scenario [4] dried	1	6.0E-02	3.78E-03	6%	Yes

Estimated exposure to volatile residues is inferior to AEL.
Estimated secondary exposures of an adult touching a treated surface are inferior to AELs.
Estimated secondary exposures of infant crawling in treated surface are superior to AEL for the generic scenarios. It is inferior to AEL for carpet. However, 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: **For use only in areas that are inaccessible to infants, children, pets and non-target animals.**

Combined scenarios

The scenario is considered as an acute exposure, therefore short term AEL is used.

Scenarios combined	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario [1+2+4 wet]	1	8.5E-0	1.46E-02	17%	Yes

Estimated combined exposure is inferior to AEL.

Local effects

The product is not classified.

Conclusion

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: **For use only in areas that are inaccessible to infants, children, pets and non-target animals.**
- the risk linked to the exposure to volatile residues is considered acceptable.
- the risks for adult touching treated surface are acceptable.

Risk for consumers via residues in food

Based on the proposed measures, the intended indoor use in private home 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:

- Remove all food, feed and drinks prior to treatment.
- Do not apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed and drinks.
- To avoid indirect contamination during nearby application, cover all surfaces and facilities likely to be in contact with food, feed, drinks and animals.

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

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

2.2.7 Risk assessment for animal health

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

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

2.2.8 Risk assessment for the environment

2.2.8.1 Effects assessment on the environment

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

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

With regard to the formation of metabolites in aquatic systems, two major metabolites – α–CO and 4'-OH– were detected in the CAR at significant concentrations (i.e. >10 %) in the aqueous photolysis study and water-sediment degradation study, respectively. The maximum percentages analysed in these studies are 63.5% for the α–CO in water and did not exceed 21.4% for the 4'OH in sediment.

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

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

Classification and labelling of the Product DIGRAIN SPRAY	
Value/conclusion	**Aquatic Chronic 1 ; H410**

Further Ecotoxicological studies

No new data is available.

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

No new data is available.

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

No new data is available.

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

No new data is available.

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

No new data is available.

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

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

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

No new data is available.

Leaching behaviour (ADS)

No new data is available.

Testing for distribution and dissipation in soil (ADS)

No new data is available.

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

No new data is available.

Testing for distribution and dissipation in air (ADS)

No new data is available.

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

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

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

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

2.2.8.2 Exposure assessment

General information

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

Emission estimation

For the first authorisation, the product has been authorized for a domestic use at the application rate of 77 mL product/m^2 when the treated area was restricted to a medium scale surface (corresponding to the area of a barrier treatment) for only two applications per year. For efficacy reasons, the product cannot be applied on surfaces frequently cleaned and the following risk mitigation measure was applied: Do not clean the treated area until the treatment is finished (up to 8 weeks). Moreover the applicant has restricted the intended use to applications *'… only on restricted areas on surfaces not regularly cleaned, for example behind the fridge or under the oven'.* These indications are sufficient to justify the application of the 'barrier' scenario.

The product is a ready to use and should not be diluted. No release during the preparation is relevant.

Scenario [1] – Indoor, spray application

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 1 – Indoor, spray application. Barrier treatment			
Application rate of biocidal product	0.077	$L.m^{-2}$	S
Density of the product	1.0023	$kg.L^{-1}$	S
Fraction of active substance in the product	2.04E-03	-	S
Treatment rate of etofenprox	1.57E-01	$g_{as}.m^{-2}$	O
Area treated	20	m^2	Barrier treatment for a domestic house – TAB ENV 204 (02/2021)
Area wet cleaned per house	5.9	m^2	Barrier treatment for a domestic house – TAB ENV 204 (02/2021)
Number of applications per day, house	1	-	D
Fraction emitted to air	0.020	-	D
Fraction emitted to applicator	0.020	-	D
Fraction emitted to floor and treated surfaces	0.960	-	D
Emission to applicator during application	6.29E-05	$kg.d^{-1}$	O
Emission to floor and treated surfaces during application (from the wet cleaned area before cleaning)	8.91E-04	$kg.d^{-1}$	O

Cleaning efficiency surface	0.5	-	D - Surface
Cleaning efficiency applicator	1	-	D
Number of houses connected to the STP	4000	-	D
Simultaneity factor	0.204	%	2 applications per year

Calculations for Scenario [*1*]

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	4.15E-03	

Fate and distribution in exposed environmental compartments

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

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	Value	Unit	Remarks
Etofenprox			
Molecular weight	376.47	$g.mol^{-1}$	
Water solubility (at 20°C)	0.0225	$mg.L^{-1}$	
Log Octanol/water partition coefficient	6.9	Log 10	
Organic carbon/water partition coefficient (Koc)	28 524	$L.kg^{-1}$	
Henry's Law Constant (at 25°C)	0.0136	Pa/m3/mol	
Biodegradability	Not readily biodegradable		
DT_{50} for degradation in soil	22.8	d (at 12ºC)	
BCF fish	2565	$L.kg^{-1}$	
BCF earthworm	95281	$L.kg^{-1}$	
BMF	2	-	
αCO			
Molecular weight	299	$g.mol^{-1}$	
Highest percentage of α–CO in aqueous photolysis study (	63.5	%	
4'-OH			
Molecular weight	393	$g.mol^{-1}$	

Highest percentage of 4'-OH in aqueous water-sediment study	21.4	%	

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

PEC metabolite = PEC parent x highest percentage of the metabolite relatively to etofenprox x (molar weight metabolite / molar weight parent)

Calculated fate and distribution in the STP		
Compartment	Percentage [%]	Remarks
	Scenario 1	
Air	0%	Agreed at WGIV 2016 (post approval)
Water	1.5%	
Sludge	92.6%	
Degraded in STP	5.9%	

Calculated PEC values

Summary table on calculated PEC values					
Scenario 1	**PEC_{STP}**	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{GW}**
	[mg/L]	[mg/L]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[mg/l]
Etofenprox	3.11E-05	2.98E-06	1.85E-03	4.69E-03	2.58E-06
αCO	n.c.	1.51E-06	n.c.	n.c.	n.c.
4'-OH	n.c.	n.c.	4.14E-04	n.c.	n.c.

n.c.: not concerned

Primary and secondary poisoning

Primary poisoning

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

Secondary poisoning

Summary table on calculated PEC values		
	$PEC_{oral\ predator\ (fish)}$	**$PEC_{oral\ predator\ (earthworm)}$**
	[mg/$kg_{wet\ fish}$]	[mg/$kg_{wet\ earthworm}$]
Scenario 1	7.65E-03	1.11E-01

2.2.8.3 Risk characterisation

Atmosphere

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

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

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values	
Scenario 1	**$PEC/PNEC_{STP}$**
Etofenprox	1.38E-03
αCO	n.c.
4'-OH	n.c.

n.c.: not concerned

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

Aquatic compartment

Summary table on calculated PEC/PNEC values		
Scenario 1	**$PEC/PNEC_{water}$**	**$PEC/PNEC_{sed}$**
Etofenprox	5.52E-01	2.94E-01
αCO	3.42E-02	n.c.
4'-OH	n.c.	3.45E-02

n.c.: not concerned

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

Terrestrial compartment

Calculated PEC/PNEC values	
Scenario 1	**$PEC/PNEC_{soil}$**
Etofenprox	7.41E-01
αCO	n.c.

4'-OH	n.c.

n.c.: not concerned

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

Groundwater

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

Primary and secondary poisoning

Primary poisoning

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

Secondary poisoning

Summary table on secondary poisoning				
Scenario	**$PEC_{fish}/PNEC_{birds}$**	**$PEC_{fish}/PNEC_{mammals}$**	**$PEC_{earthworm}/PNEC_{birds}$**	**$PEC_{earthworms}/PNEC_{mammals}$**
Scenario 1	2.30E-04	3.10E-04	3.33E-03	4.49E-03

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

Mixture toxicity

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

Aggregated exposure (combined for relevant emission sources)

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

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

The environmental risk assessment of the product DIGRAIN SPRAY is based on the active substance and two environmentally relevant metabolites, αCO and 4'OH.
The product DIGRAIN SPRAY will not pose risk to the environmental compartments for an application of the product in restricted areas (covered by the barrier treatment scenario). Therefore, the specific instruction of use is applied as intended by the applicant:
"The product has to be applied only on restricted areas on surfaces not regularly cleaned for example behind the fridge or under the oven."

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

Summary table for the risk assessment of the product DIGRAIN SPRAY					
	PEC/PNEC$_{STP}$	PEC/PNEC$_{water}$	PEC/PNEC$_{sed}$	PEC/PNEC$_{soil}$	PEC/PNEC$_{GW}$
Scenario 1	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable

2.2.9 Measures to protect man, animals and the environment

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

2.2.10 Assessment of a combination of biocidal products

For biocidal products that are intended to be authorised for the use with other biocidal products.
[Please, refer to Guidance for Human Health Risk Assessement, Volume III, Part B - to characterise the risk in case of exposure to several products]

2.2.11 Comparative assessment

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

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

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

Since etofenprox does not meet the exclusion criteria as outlined in Article 5(1), no further assessment is needed at this point.

The product DIGRAIN SPRAY can be authorised for a period not exceeding 5 years in accordance with Article 23(6) of BPR.

COMPARATIVE ASSESSMENT REPOF

3 ANNEXES[22]

3.1 List of studies for the biocidal product

Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner (PUB / ORG)
[redacted]	[redacted]	Etofenprox 30CE: Acute oral toxicity in the rat, Acute toxic class method	Yes	ORG
[redacted]	[redacted]	Etofenprox 300 g/L EC: Acute inhalation toxicity (nose only) study in the rat	Yes	ORG
[redacted]	[redacted]	Etofenprox 2 g/L RTU: Evaluation of acute dermal toxicity in rats	Yes	ORG
[redacted]	[redacted]	Etofenprox 2 g/L RTU: Assessment of acute dermal irritation	Yes	ORG
[redacted]	[redacted]	Etofenprox 2 g/L RTU: Assessment of acute eye irritation	Yes	ORG
[redacted]	[redacted]	Etofenprox 2 g/L RTU: Assessment of sensitising properties on albino guinea pigs: Maximisation test according to Magnusson and Kligman	Yes	ORG
[redacted]	[redacted]	The in vitro dermal absorption of radiolabelled etofenprox in two formulated products for biocidal use	Yes	ORG
[redacted]	[redacted]	Report amendment: The in vitro dermal absorption of radiolabelled etofenprox in two formulated products for biocidal use	Yes	ORG

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

3.2 Output tables from exposure assessment tools

expo digrain.xlsx

3.3 New information on the active substance

3.4 Residue behaviour

3.5 Summaries of the efficacy studies (B.5.10.1-xx)[23]

3.6 Confidential annex

3.7 Other

23 If an IUCLID file is not available, please indicate here the summaries of the efficacy studies.